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# Novo Nordisk LLC  Methodology Note - reporting year 2015 (”Methodology”)

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## Preamble

Novo Nordisk LLC (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 LLC is committed to transparency which  requires public disclosure of certain 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 first disclosure based on full year 2015 data.

According to Section 3.05 of the EFPIA Disclosure Code and Chapter 7  of the Association of International Pharmaceutical Manufacturers (AIPM) Code of Practice, 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 and the Association of International Pharmaceutical Manufacturers (AIPM) Code of PracticeThe Methodology note, including a general summary and/or country-specific considerations, describes the methodologies applied along with any other principles applied in the identification of ToV and subsequent disclosure.

Therefore, the aim of this Methodology is to provide a clear and simple explanation of how Novo Nordisk LLC fulfils its reporting obligation and it provides a basic framework for interpretation. This Methodology is structured as follows:

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

This Methodology is part of the Novo Nordisk LLC HCP/HCO ToV reporting obligation in June 2016 for the reporting year 2015 and can be found here: http://www.novonordisk.ru/about-company/changing_diabetes/scientific_and_information_activities.html

# 1. General Summary

Novo Nordisk fully supports the disclosure initiative and puts forth its best effort to i) implement the transparency initiative, ii) interpret the EFPIA Disclosure Code and Association of International Pharmaceutical Manufacturers (AIPM) Code of Practice, 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. If more than one country is covered by one Novo Nordisk Affiliate, the Novo Nordisk EFPIA Affiliate will submit as many reports as it covers countries (disclosed for each country in their respective language). Where Novo Nordisk has more than one Novo Nordisk organisation within the same country, the disclosure will be made via the respective Novo Nordisk EFPIA Affiliate office.
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 LLC discloses all Novo Nordisk group's ToV to HCPs/HCOs having their Principal Practice in Russia.

### b) Data Protection

Novo Nordisk works with HCP and HCO in full compliance with all applicable rules and regulations, including, but not limited to, limitations imposed by Russian legislation on interaction with healthcare professionals.

Novo Nordisk accepts existing legal rights (e.g. applicable data protection rights) which may impose certain limitations to disclosure on an individual named basis. Novo Nordisk has approached all HCPs (and HCOs – if applicable) in order for them to provide their consent to Novo Nordisk publishing on an individual named basis details of any ToV they receive from Novo Nordisk. Where consent is not provided (or subsequently revoked), all ToVs made to such recipient has been anonymised and aggregated. Novo Nordisk does not disclose any ToVs to an HCP on an individual named basis if only partial consent has been given.

**c) Items excluded from Disclosure**

In accordance with the EFPIA Disclosure Code and Association of International Pharmaceutical Manufacturers (AIPM) Code of Practicethe 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

iii) Transfers of Value (ToV) related to investigational compounds and biological samples

iv) transfers of value that are part of ordinary course purchases and sales of pharmaceutical products by and between a pharmaceutical company and an healthcare professional or a healthcare organization, as relevantv) expenses on HCO services incurred by Novo Nordisk Production site for production purposes maintenance.

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

Where Novo Nordisk provides a benefit in kind to an HCO but the benefit in kind does not result in a permanent enrichment of the HCO, e.g. loan of (laboraty) equipment to a hospital in connection with and for the purpose of the HCOs conduct of a clinical trial, such benefit in kind is not disclosed.

However, value added tax and pass-through costs paid by Novo Nordisk to or via an HCO are disclosed although there is no enrichment of/monetary benefit to the receiving HCO. For instance, if Novo Nordisk compensates an HCO conducting a clinical study for costs towards patients' transport, and these costs are paid out to the HCO (to cover the taxi costs paid by the HCO), these pass-through costs are disclosed. Amounts of ToV to HCO include Value Added Tax and all other relevant taxes.

Amounts of ToV to HCP include personal income taxes.

## 2. Terminology and Definitions

The terminologies below reflect Novo Nordisk's approach and explanation of how the disclosure requirements have been interpreted in a Novo Nordisk context.

| Terminology | Novo Nordisk approach |
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| **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.:<br>• room rate<br>• fees for additional services (Wi-Fi, late check-out, etc.)<br>• hotel gratuity (for housekeeping, bellman, etc.)<br>• related taxes<br><br>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:<br><br>1. R&D aggregate<br>2. Aggregate HCP ToV<br>a. If HCP consent to disclose individual data has not been obtained<br>b. Data privacy limitations (if required by local regulations)<br>3. Aggregate HCO ToV<br>a. In case in the event when in accordance with conditions of the contract there are limitations and/or prohibition to disclose information on transfers of value to or for the benefit of healthcare organizations and the attempt to renegotiate the contract provisions was not successful or<br>b. to the extent otherwise provided by local legislation. |
| **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'. |

| Terminology | Novo Nordisk approach |
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| **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.<br><br>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.<br><br>In case the CRO acts as a Third Party Representative (TPR) and provides a ToV to an identifiable HCP/HCO on behalf of Novo Nordisk (pass-through costs for the TPR), such ToV needs to be tracked as all other ToV and will be disclosed in the relevant disclosure category (aggregated or indiviual as the case may be)<br><br>A ”TPR” is a third party who in performing activities under a contract with Novo Nordisk is acting towards public officials and/or Healthcare Professionals (HCP) on behalf of Novo Nordisk or as a representative in furthering Novo Nordisk’s interests. |
| **Devices** | Pure devices (items of medical utility) without active ingredients are not part of the EFPIA Disclosure Code and are therefore not disclosed.<br><br>In cases where Novo Nordisk cannot split ToV related to durable devices from the devices with active ingredients, the ToV will be disclosed in the relevant EFPIA Disclosure Categories. |
| **Disclosure Currency** | Disclosure currency is the local currency of the Novo Nordisk EFPIA Affiliate.<br><br>Novo Nordisk’s financial systems automatically calculate currency postings based on payment date and daily exchange rate. |
| **Donations and Grants** | Donations and Grants cannot be provided to an HCP but only to an HCO in EFPIA countries.<br><br>Covering the costs for an individual HCP to attend an event as delegate will be disclosed as a ‘Contribution to costs of Events’. |
| **Events** | Event activities where a delegate participates in congresses, conferences, symposia and similar external events will be disclosed in two ways:<br><br>a. as a ‘Contribution to costs of Events’ towards the individual delegate;<br>b. to follow Russian local legislation on some restrictions in interaction between pharmaceutical companies and HCPs, invitation of HCPs to events (followed with expenses in regard of HCP) requires establishment of relationship with the employer of the HCP (HCO as usual) via exchange of invitation-acceptance letters or entering into a service/consultancy contract with HCP in a direct connection with a participation in |

| Terminology | Novo Nordisk approach |
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| | event.<br><br>From legal and finance perspectives and following provisions provided in article 7.3.5. section VII of AIPM Code, it is presumed that in case of exchange of invitation-acceptance letters ToV is made to HCPs indirectly via HCO (HCP's employer) and such ToV is to be disclosed once on an individual HCO level (if documental evidence will be obtained).<br><br>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 will be disclosed as a 'Contribution to costs of Events' towards the individual delegate. |
| **Fees for Service and Consultancy** | Fees include any remuneration for services provided, e.g. speaker engagements, provision of consultancy services and participation in advisory board meetings (if not covered under R&D ToVs). ToV related to meals and drinks is not disclosed unless Novo Nordisk is unable to split such meals and drinks from the fees, in which case the full amount will be allocated as 'Fees for Service and Consultancy'.<br><br>Any additional compensation (e.g. travel time compensation or similar) provided to an HCP is disclosed as a 'Fee for Service and Consultantcy'. |
| **Foundations** | In Novo Nordisk a foundation is considered 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 organisation.<br>In Novo Nordisk, we consider foundations (including those related to Novo Nordisk, e.g. Novo Nordisk Haemophilia Foundation, World Diabetes Foundation) 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 therefore not subject to the EFPIA Disclosure code.<br><br>Only if a foundation fulfils the HCO definition, the ToV will be published accordingly HCO disclosure requirements. |
| **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. |

| Terminology | Novo Nordisk approach |
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| | Laboratories are not considered HCOs. However, if the ”laboratory test” are part of an activity within the scope of the Code, the related ToV will be reported in line with the Code provision.<br><br>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’.<br><br>Govermental bodies (e.g. Ministry of Healthcare) are not HCO. |
| **HCP (Health Care Professional)** | Doctors and other medical professionals, heads of medical organizations, pharmaceutical professionals (including pharmacists), heads of pharmacy organizations, and other specialists the professional activity of which is concerned with pharmaceutical products and who in the process of their professional activity have the right to prescribe, recommend, purchase, supply, or administer pharmaceutical products. |
| **Investigator Meetings** | An Investigator Meeting is an event organised 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.<br><br>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.<br><br>If an ISS falls within the definition of R&D, it will be disclosed as R&D ToV (aggregated). However, if the ISS does not fall within the R&D definition (e.g. if it is a non-interventional retrospective study), it will be disclosed as an individual ToV to the Recipient (either HCP or HCO). |
| **Market Research Programmes (MRP)** | Ano ToV in connection with 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 is not disclosed. ”Blinded” means Novo Nordisk does not know what concrete HCP is participating in the MRP. ”Double blinded” means neither HCP nor Novo Nordisk have concrete knowledge about the other but it is anonymised on both sides. |
| **Meals and Drinks** | Meals and drinks are not covered by the EFPIA disclosure requirements and therefore not disclosed. |

| Terminology | Novo Nordisk approach |
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| **Recipient** | Any HCP or HCO as applicable, in each case, whose primary practice, principal professional address or place of incorporation is in an EFPIA member country.<br><br>Wholesalers, distributors of medical products are not Recipients.<br><br>Disclosure of a ToV follows the Recipient and not the ultimate beneficiary of the ToV. This means that Novo Nordisk discloses a ToV towards the HCP/HCO with whom we have a contract and to whom Novo Nordisk directly transfers the value |
| **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 a ToV to an HCP/HCO and not as R&D ToV.<br><br>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 Novo Nordisk on a case-by-case basis. |
| **Reporting Period** | Disclosure 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 2015 and disclosure is made no later than 30 June 2016.<br><br>Tracking of ToVs will follow the payment date and not the date of event. E.g.: An event takes place in November 2014 and the ToV is paid in February 2015. This ToV will be tracked in 2015 and disclosed in 2016.<br><br>ToVs made under multi-year contracts will also follow the payment date of each individual payment. |
| **Research and Development Transfers of Value (R&D ToV)** | All ToVs to HCPs or HCOs related to the below will be disclosed as R&D ToV (aggregated):<br><br>• Non-clinical research activities (incl. service/consultancy, grant/donation and/or research collaborations) with or without connection to any Project or Study ID.<br>• Service/consultancy or grant/donation associated with clinical development and connected* to a Project ID or Trial ID.<br>• Service/consultancy or grant/donation associated with prospective non-interventional studies and |

| Terminology | Novo Nordisk approach |
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| | connected* to a Project ID or Study ID (except epidemiological studies based on external databases and registries).<br><br>Excluded from the R&D are:<br><br>• ToV related to epidemiological studies based on external databases and registries.<br>• ToV related to retrospective non-interventional studies.<br>• 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).<br>• ToV related to activities not covered by the R&D definition above.<br><br>These four types of ToV will be disclosed under the relevant HCP/HCO category.<br><br>*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.<br>**Any externally organised event or Novo Nordisk event, where the 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 established with an expectation of a 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. Donations and grants are offered without such expectation.<br><br>Sponsorships can only be provided to an HCO.<br><br>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'.<br><br>Sponsorship Agreements are formalised in contracts that describe the purpose of the sponsorship and the related ToV, e.g.:<br>• Hire/rental for booths in country where HCOs has its principal establishment (even if third party is appointed by HCOs to manage the event).<br>• Advertisement space (in paper, electronic or other format).<br>• Satellite symposia at a congress.<br>• Sponsorship of speakers. |

| Terminology | Novo Nordisk approach |
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| | • If part of a package, drinks or meals provided by the organisers (included in the ”Sponsorship Agreement”).<br>• Courses provided by an HCO (where the Member Company does not select the individual HCPs participating). |
| **Transfers of Value (ToV)** | Disclosure of a ToV follows the Recipient and not the ultimate beneficiary of the ToV.<br><br>All ToVs to HCPs and HCOs will be stated in gross amounts and as reported in Novo Nordisk’s financial systems. This means that any VAT, taxes, social security expenses etc. will be included in the disclosed amounts.<br><br>ToV related to Novo Nordisk organised events will only be disclosed if these are related to individual travel and accommodation. All other internal or external costs to e.g. facilities, conference rooms, joint bus transportation etc. will not be split on the participating individuals and will, therefore, not be disclosed.<br><br>Transfers of Value related to medical samples for clinical trials, investigational compounds and biological samples are excluded from disclosure obligations.<br><br>‘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 itself considered a ToV. “No Shows” means that Novo Nordisk made the arrangement for an HCP/HCO (e.g. booked and payed a hotel or flight) but the HCP/HCO did not use the arrangement.<br><br>Under sub-clause 7.3.2 of the AIPM Code of Practice categories for transfers of value to HCO among others include contribution to costs related to events though HCO or third parties, including sponsorship agreements with third parties appointed by HCO to manage an event. The definition of the Transfers of Value provided by the AIPM Code apart from direct payment to HCO includes also transfers (whether in cash or in kind) to third parties, where company member could identify HCO that benefit from the transfer of value being a beneficiary. When HCO appoints the technical organizer of the event, such technical organizer organizes an event using transfers of value received from sponsors for and under control of the HCO. Sponsorship fee paid to the technical organizer in this case shall be disclosed as transfer of value to the HCO, which appointed the technical organizer. As Transfers of value includes benefits in kind, disclosure does not necessarily means that HCO received money through the technical organizer; values in kind could be provided to HCO by technical organizer by means of renting the event facilities and financing other costs related to the event in HCO’s interests. |
| **Travel** | Costs of flights, trains, baggage handling, car hire, tolls, parking fees, taxi, etc. |

| Terminology | Novo Nordisk approach |
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| | 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. |

## 3. Change log of Methodology:

| Edition no. | Effective date: | Disclosed on: | Changes to document: |
|---|---|---|---|
| 1.0 | | | New document |