

Novo Nordisk Pharma AG Methodology Note - reporting year 2015 ("Methodology")

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Preamble

Novo Nordisk Pharma AG (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 AG 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 Art. 28 of the Pharma Cooperation Code (Code of conduct of the pharmaceutical industry in Switzerland on cooperation with healthcare professional circles and patient organizations), 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 Pharma Cooperation Code. The 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 Pharma AG 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 Pharma AG HCP/HCO ToV reporting obligation in June 2016 for the reporting year 2015 and can be found here: www.novonordisk.ch

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 Pharma Cooperation 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. 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 Pharma AG discloses all Novo Nordisk group's ToV to HCPs/HCOs having their Principal Practice in Switzerland.

b) Data Protection

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 Pharma Cooperation Code, the following items Novo Nordisk does **not** disclose:

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

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 (laboratory) 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.

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
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 and related taxes
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'.

Terminology	Novo Nordisk approach
Aggregate	<p>There are three levels of aggregation:</p> <ol style="list-style-type: none"> 1. R&D aggregate 2. Aggregate HCP ToV <ol style="list-style-type: none"> a. If HCP consent to disclose individual data has not been obtained or has been revoked 3. Aggregate HCO ToV <ol style="list-style-type: none"> a. If HCO consent to disclose individual data has not been obtained or has been revoked
CME – Continued Medical Education	<p>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'.</p>
CRO (Clinical Research Organisation)	<p>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.</p> <p>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.</p> <p>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 individual as the case may be)</p> <p>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.</p>
Devices	<p>Pure devices (items of medical utility) without active ingredients are not part of the EFPIA Disclosure Code and are therefore not disclosed.</p> <p>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.</p>
Disclosure Currency	<p>Disclosure currency is the local currency of the Novo Nordisk EFPIA Affiliate.</p> <p>Novo Nordisk's financial systems automatically calculate currency postings based on <u>payment date</u> and daily exchange rate.</p>

Terminology	Novo Nordisk approach
Donations and Grants	<p>Donations and Grants cannot be provided to an HCP but only to an HCO in EFPIA countries.</p> <p>Covering the costs for an individual HCP to attend an event as delegate will be disclosed as a 'Contribution to costs of Events'.</p>
Events	<p>Event activities where a delegate participates in congresses, conferences, symposia and similar external events will be disclosed as a 'Contribution to costs of Events' towards the individual delegate.</p> <p>Delegate participants have to pay a self-contribution of at least 33% (or 20% if in education). The disclosed ToV is reduced by the self-contribution.</p> <p>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.</p>
Fees for Service and Consultancy	<p>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'.</p> <p>Any additional compensation (e.g. travel time compensation or similar) provided to an HCP is disclosed as a 'Fee for Service and Consultancy'.</p>
Foundations	<p>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.</p> <p>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 Nordisk 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.</p> <p>Only if a foundation fulfils the HCO definition, the ToV will be published accordingly HCO disclosure requirements.</p>

Terminology	Novo Nordisk approach
HCO (Health Care Organisation)	<p>Legal persons that are institutions, organisations, associations or other groups of healthcare professionals which provide healthcare services or consultancy tasks or other services in healthcare (e.g. hospitals, clinics, foundations, universities or other educational establishments, scientific societies or professional associations, community practices or networks, but not patient organisations).</p> <p>One-person HCOs (consisting of only one HCP) are defined as an HCO.</p> <p>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.</p>
HCP (Health Care Professional)	<p>Natural persons that are physicians, dentists and pharmacists who are working in particular in a practice or hospital, together with pharmacists active in retail businesses, and persons who are authorised by Swiss law on therapeutic products, to prescribe, deliver or use prescription-only medicinal products for humans.</p>
Investigator Meetings	<p>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.</p> <p>Per this definition, a ToV related to an Investigator Meeting will always fall under R&D ToV.</p>
Investigator-Sponsored Study	<p>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.</p> <p>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, it will be disclosed as an individual ToV to the Recipient (either HCP or HCO).</p>
Market Research Programmes (MRP)	<p>Any 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.</p>
Meals and Drinks	<p>Meals and drinks are not covered by the EFPIA disclosure requirements and therefore not disclosed.</p>

Terminology	Novo Nordisk approach
PO (Patient Organisation)	<p>Not-for-profit organisations (including the organisations to which they are affiliated) based or active in Switzerland, which consist primarily of patients or their carers and which represent or support the needs of patients or their carers.</p> <p>In terms of disclosure, POs are handled as HCOs.</p>
Recipient	<p>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.</p> <p>Wholesalers, distributors or retailers of medical products are not Recipients.</p> <p>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</p>
Registration Fee	<p>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.</p> <p>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).</p>
Related Expenses for 'Fees for service and consultancy'	<p>Any ToV related to 'Fees for service and consultancy', e.g. accommodation, travel, etc. Excluding meals and drinks.</p>
Report Corrections	<p>Corrections of the ToV report will be managed by Novo Nordisk on a case-by-case basis.</p>
Reporting Period	<p>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.</p> <p>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.</p> <p>ToVs made under multi-year contracts will also follow the payment date of each individual payment.</p>

Terminology	Novo Nordisk approach
<p>Research and Development Transfers of Value (R&D ToV)</p>	<p>All ToVs to HCPs or HCOs related to the below will be disclosed as R&D ToV (aggregated):</p> <ul style="list-style-type: none"> • Non-clinical research activities (incl. service/consultancy, and/or research collaborations) with or without connection to any Project or Study ID. • 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). <p>Excluded from the R&D are:</p> <ul style="list-style-type: none"> • ToV related to retrospective non-interventional studies • ToV related to epidemiological studies based on external databases and registries. • ToV related to activities not covered by the R&D definition above. <p>These types of ToV will be disclosed under the relevant HCP/HCO category.</p> <p>*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.</p>
<p>Sponsorship Agreement</p>	<p>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.</p> <p>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'.</p> <p>Sponsorship Agreements are formalised in contracts that describe the purpose of the sponsorship and the related ToV, e.g.:</p> <ul style="list-style-type: none"> • 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).

Terminology	Novo Nordisk approach
Transfers of Value (ToV)	<p>Disclosure of a ToV follows the Recipient and not the ultimate beneficiary of the ToV.</p> <p>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.</p> <p>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, etc. will not be split on the participating individuals and will, therefore, not be disclosed.</p> <p>Transfers of Value related to medical samples, investigational compounds and biological samples are excluded from disclosure obligations.</p> <p>'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.</p>
Travel	Costs of flights, trains, taxi, etc.
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:	Comment
1.0	31. May 2016	27. Jun. 2016	New document	Same document is translated to german and french