

Novo Nordisk s.r.o., Czech Republic, Methodology Note - reporting year 2019 ("Methodology")

Table of contents

Preamble	0
1. General Summary	1
2. Terminology and Definitions.....	2
3. Change log of Methodology:	9

Preamble

Novo Nordisk s.r.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 s.r.o., Czech Republic 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. In 2020, the disclosure is based on full year 2019 data.

According to Section 3.05 of the EFPIA Disclosure Code and of the "AIFP kodex upravující zveřejňování plateb a jiných plnění farmaceutických společností zdravotnickým odborníkům a zdravotnickým zařízením ", 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 "AIFP kodex upravující zveřejňování plateb a jiných plnění farmaceutických společností zdravotnickým odborníkům a zdravotnickým zařízením ". The Methodology note, including a general summary and/or country-specific considerations, describes the methodologies applied, along with any other principles, in the identification of ToVs and subsequent disclosure.

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

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

This Methodology is part of the Novo Nordisk s.r.o. HCP/HCO ToV reporting obligation in June 2020 for the reporting year 2019 and can be found here: AIFP web pages: www.transparentnispoluprace.cz

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 "AIFP kodex upravující zveřejňování plateb a jiných plnění farmaceutických společností zdravotnickým odborníkům a zdravotnickým zařízením", according to their 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 s.r.o. discloses all Novo Nordisk group's ToV to HCPs/HCOs having their Principal Practice in Czech Republic.

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 “AIFP kodex upravující zveřejňování plateb a jiných plnění farmaceutických společností zdravotnickým odborníkům a zdravotnickým zařízením”, Novo Nordisk does **not** disclose the following items:

- 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

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.

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	<p>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.:</p> <ul style="list-style-type: none"> • room rate • fees for additional services (Wi-Fi, late check-out, etc.) • related taxes <p>Meals and drinks do not have to be disclosed under the EFPIA disclosure code and therefore are separated/reduced from the accommodation invoice.</p>
Advisory Board	<p>ToV related to Advisory Board activity will be disclosed as 'Fee for service and consultancy', unless it falls into the Novo Nordisk definition of R&D in which case it will be disclosed aggregated as ToV related to R&D.</p>
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 b. Data privacy limitations (if required by local regulation) c. Other legal reasons to not report at individual levels (if required by local regulation) 3. Aggregate HCO ToV <ol style="list-style-type: none"> a. Data privacy limitations (if required by local regulations) b. Other legal reasons to not report at individual levels (if required by local regulations)
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), these expenses will be disclosed in the relevant disclosure category, e.g. individually as 'Fees for Service and Consultancy' or aggregated as R&D ToV, as the</p>

Terminology	Novo Nordisk approach
	<p>case may be.</p> <p>A "TPR" is a business partner that interacts with Public Officials and/or Healthcare Professionals/Healthcare Organisations on behalf of or in the interest of Novo Nordisk.</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>
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 related to delegate participation in congresses, conferences, symposia and similar external events will be disclosed as a 'Contribution to costs of Events' towards the individual delegate.</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</p>

Terminology	Novo Nordisk approach
	<p>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, will the ToV be published according to HCO disclosure requirements.</p>
HCO (Health Care Organisation)	<p><u>Any legal person</u> (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.</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" is part of an activity within the scope of the Code e.g. R&D, the related ToV will be reported in line with the Code provision.</p> <p>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'.</p>
HCP (Health Care Professional)	<p>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.</p> <p>In Czech Republic according to AIFP decision we use an exception for the nursing professions, who may not prescribe, therefore will not be disclosed.</p> <p>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.</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</p>

Terminology	Novo Nordisk approach
	<p>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 (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).</p> <p>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.</p>
Market Research Programmes (MRP)	<p>Anyo 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>
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> <p>"Registration Fees" (and related travel and accommodation) will be disclosed as a ToV to HCP delegates (when engaged/paid via an HCO or any other 3rd Party) provided Novo Nordisk is aware of the individual HCP beneficiary (the delegate).</p>

Terminology	Novo Nordisk approach
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'	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	<p>Disclosure is made on an annual basis, and each reporting period covers a full calendar year (the "Reporting Period"). The Reporting Period is the calendar year 2018 and disclosure is made no later than 30 June 2019.</p> <p>Tracking of ToVs will follow the payment date and not the date of event. E.g.: An event takes place in November 2017 and the ToV is paid in February 2018. This ToV will be tracked in 2017 and disclosed in 2018.</p> <p>ToVs made under multi-year contracts will also follow the payment date of each individual payment.</p>
Research and Development Transfers of Value (R&D ToV)	<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, grant/donation 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 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. <p>These four types of ToV will be disclosed under the relevant HCP/HCO category.</p>

Terminology	Novo Nordisk approach
	<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>**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.</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>Sponsorships can only be provided to an HCO.</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"> • Hire/rental for booths in country where HCOs has its principal establishment (even if third party is appointed by HCOs to manage the event). • 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"). <p>Courses provided by an HCO (where the Member Company does not select the individual HCPs participating).</p>
<p>Transfers of Value (ToV)</p>	<p>Disclosure of a ToV follows the Recipient and not the ultimate beneficiary of the ToV.</p> <p>All ToVs to the Recipient HCPs and HCOs will be stated in gross amounts, however excluding VAT and as reported in Novo Nordisk's financial systems. This means that any non-VAT related taxes, social security expenses etc. will be included in the disclosed amounts while VAT will be excluded where possible.</p> <p>ToV related to Novo Nordisk company organised events will only be disclosed if these are related to individual travel and accommodation. All other internal or external costs e.g. facilities, conference rooms, joint bus transportation etc. will not be split on the participating individuals and will, therefore, not be disclosed.</p> <p>ToVs related to medical samples, investigational compounds and biological samples are excluded from disclosure</p>

Terminology	Novo Nordisk approach
	<p>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	<p>Costs of flights, trains, baggage handling, car hire, tolls, parking fees, taxi, etc.</p> <p>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.</p>
Unique Identifier	<p>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. AIFP in Czech Republic decided to use as a unique identifier the registration number of ČLK/ČLnK and in case of HCO the company registration number (IČO).</p>

3. Change log of Methodology:

Edition no.	Effective date:	Disclosed on:	Changes to document:
1.0	1.2.2016	30.06.2017	New document
2.0	1.2.2017	30.06.2017	<p>Updated document to align with reporting year dates and updates to the corresponding Internal Methodology for 2016.</p> <ul style="list-style-type: none"> - "Investigator-Sponsored Study" "blinded" and "double blinded" studies clarified - "Recipient" clarified in case of delegate support (registration fees, travel and accommodation) <p>"Reporting Period" updated</p>
3.0	1.2.2018	30.6.2018	"Reporting Period" updated
4.0	1.2.2019	30.6.2019	"Reporting Period" updated
5.0	1.2.2020	30.6.2020	"Reporting Period" updated