

Novartis: Methodological note for HCP/ORDM/HCO disclosure 2025

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Novartis Pharmaceuticals UK Limited (“Novartis”) supports the promotion of transparency around relationships with Healthcare Professionals (HCPs), Other Relevant Decision Makers (ORDMs), and Healthcare Organisations (HCOs) associated with Transfers of Value (ToV) related to prescription only medicines by establishing a single, consistent transparency standard in Europe for disclosing ToVs across its affiliates and European countries, by following the EFPIA transparency requirements and local requirements.

The objective of this methodological note is to explain Novartis’ approach to disclosure, to include key definitions, the scope of disclosed activities and key elements of the process followed to capture and report data.

Reports pertaining to Members of the Public and Patient Organisations which are distinct from HCOs are published independently on the Novartis website.

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1 Definitions

1.1 Recipients

Definition of a Health 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 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 practicing HCP, but excludes (x) all other employees of a Member Company and (y) a wholesaler or distributor of medicinal products.

Definition of Other Relevant Decision Maker (ORDM) 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 article 21 of the EFPIA 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.

Definition of a HealthCare 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 article 21 of the EFPIA 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.

1.2 Kind of ToVs

Examples of types of ToV in scope of disclosure include:

- Collaborative Working
- Donations and Grants
- Event Sponsorship
- Event Registration Fees
- Event Travel and Accommodation
- Contracted Services – Fees
- Contracted Services – Expenses
- Research and Development (R&D)

Collaborative Working

These arrangements are instruments that allow Novartis to collaborate with one or more reputable organisations, including pharmaceutical companies, healthcare organisations, patient organisations, and / or public / private organisations, for a shared purpose to improve or, at a minimum, maintain patient care and in addition can enhance patient experience, improve disease management and/or address barriers to ensure patients have access to the most appropriate and effective treatment or strengthen healthcare system overall. Areas of collaboration could include, but are not limited to, implementation / improvement science, healthcare disparity, medical education, healthcare service improvement and disease awareness.

Donations and Grants

Funding is a monetary or in-kind contribution provided by Novartis to drive Novartis' mission, advance scientific knowledge, or support communities.

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 organisations.

ToVs disclosed under this category included but is not limited to:

- ToVs to a charitable organisation in the name of the benefitting HCO if the charitable organisation falls under the EFPIA definition of a benefitting HCO.
- Charitable product donations made to HCOs in the context of humanitarian aid
- Grant requests from HCOs that include explicit support for publication.

Event Sponsorship

Sponsorship agreements with HCOs / third party organisations appointed by HCOs to manage an Event/Activity are contributions provided by or on behalf of Novartis to third parties for activities and events with an affinity to healthcare and/or aligned with our strategic objectives under which the sponsored party provides a benefit to Novartis in return for the payment. Benefits obtained by Novartis in exchange of sponsorship may include having a satellite meeting, exhibit booth space, providing promotional and/or scientific presentations, visual advertising at the meeting, symposia slots, the right to distribute promotional materials in welcome packages.

Indirect sponsorship of an HCP through an HCO is disclosed under this category as payment to the HCO as first level Recipient of the ToV. This applies to the following categories:

- ToV related to intermediaries selecting the faculty who acted as speakers or faculty at an event;
- ToV related to advertising space, sponsoring of speakers/faculty, satellite symposia at congresses, courses provided by HCOs.

ToV made through a Professional Conference Organiser (PCO) as intermediary e.g. for the hire of booths or stand space on behalf of an HCO, are disclosed as ToV in the name of the sponsored HCO as benefitting Recipient.

If an intermediary organised an event with sponsorship of Novartis 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 ToV to each HCO involved in the event, it was assumed that all HCOs had similar levels of involvement. Consequently, the ToV was divided by the number of HCOs, which would each be reported as having received their equal share of the ToV.

Novartis discloses ToV related to preceptorships considering that such non-promotional independent “practical” training offered to HCPs by other HCPs or HCOs – typically in a specific disease area at a reputed teaching institution (faculty of medicine, university, university hospital) – falls under the definition of “Events” and is disclosed in the name of that contracting entity.

Event - Registration Fees

Where registration passes are purchased directly by Novartis, from an HCO (for example a learned society), on behalf of an HCP/ORDM, costs will be disclosed against the recipient HCP/ORDM.

Event - Travel and Accommodation

As part of its support for continuous medical education, Novartis may cover travel and accommodation costs for HCPs/ORDMs attending educational events or meetings organised by independent bodies, as well as educational events or meetings organised by Novartis.

These costs may include flights, ground transportation, hotel accommodation and other related travel expenses. Expenses related to subsistence (food and drink) are not disclosed, in line with the ABPI 2024 Code of Practice and EFPIA disclosure guidance.

Ground transportation costs (e.g., bus or taxi arranged for group travel and not attributable to specific HCPs/ORDMs) are reported in aggregate. Where the identities of the HCPs/ORDMs are known, the cost is disclosed per individual HCP/ORDM.

Contracted Services - Fees

Novartis engages HCPs/ORDMs/HCOs to provide services when there is a genuine and legitimate business need and where the HCP/ORDM/HCO is qualified and appropriate to provide the services.

These services can include but are not limited to speaking at and chairing meetings, advising, providing training and consultancy services.

When Novartis arranges for a contracted service with a HCP/ORDM via the HCPs/ORDMs employer (an HCO), ToV will be disclosed against the HCO.

Contracted Services - Expenses

As part of contracted services, related expenses can be paid for and can include costs associated with travel, hotel accommodation, registration fees, subsistence and any visa costs. Such costs may be paid directly by Novartis to travel and/or accommodation providers or meeting organisers (where relevant) or reimbursed directly to the individual when supported by appropriate receipts.

Research and Development

All ToV related to R&D activities performed by Novartis (including services performed by contractors not fulfilling a permanent role) or by Clinical Research Organisations on Novartis' behalf will be disclosed on an aggregate basis.

2 Disclosure's Scope

2.1 Products concerned

Prescription-only medicines (e.g. combination products/diagnostics and medicinal products).

2.2 Company concerned

[Novartis Pharmaceuticals UK Limited.]

2.3 Excluded ToVs

Examples include but is not limited to, the following:

- ToVs that are solely related to over the counter (OTC) medicines
- ordinary course purchases and sales of medicines by and between Novartis and an HCP or an HCO
- samples of medicines
- provision of pens, pencils and notebooks to meeting delegates
- provision to HCPs/ORDMs of materials and items for patient support which are to be passed onto patients
- subsistence (food and drink) provided to attendees during a meeting/event organised by Novartis.

2.4 ToVs date

[Data coverage from January 1 2025 to December 31 2025. Disclosure is performed for the full calendar year.]

2.5 Direct ToVs

Direct ToVs are defined as those ToVs, payments or in kind, made directly by the Novartis affiliate to the benefitting HCPs/HCOs.]

These ToVs are disclosed based on the date the payment has been cleared via banking system.]

2.6 Indirect ToVs

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. Examples include but is not limited to, the following:

- Congress travel and accommodation
- Collaborative Working payment to 3rd party supplier
- Goods and Services Grant]

Indirect ToVs related to events for example attendance to scientific 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 day of the event.

2.7 Non-monetary ToVs

[These include items or benefits that are not direct monetary payments but still represent value provided by Company to HCPs or HCOs. Examples include In-kind ToVs, for example, project management on a Collaborative Working Project, staff time, delivery of training and education, home delivery services and virtual congress passes.]

2.8 ToVs in case of partial attendances or cancellation and refund

Refunds for partial attendance or cancellations are typically handled within the broader framework of how ToVs are defined based on payment date, FMV on actual participation accounted for, and disclosed. Cancellation Fees are not reported. No-shows are not reported if Novartis is unable to confirm the benefit was received. Partial attendance and refunds will only be adjusted in exceptional circumstances and assessed on a case by case basis.

If Novartis has processed a refund (full or partial) equivalent to the initial payment, neither transaction will be recorded since no actual value was transferred.

If a refund (full or partial) has been issued for a payment made in a year already published, the refunded amount will be subtracted from the total disclosed transfer value in the upcoming year. The amount disclosed will be the net difference. If the individual received no payment the succeeding year, the disclosure report will display a negative value.

If the individual has exercised their right to object within the limits of the law, the refund will subtract from the aggregate category totals. |

2.9 Cross-border activities

A cross-border ToV is one made to a recipient for an activity 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). Cross borders ToVs are disclosed in the country where the Recipient has its principal practice, principal professional address or place of incorporation. Delayed cross border payments may require to be disclosed in the next financial year until a system integration is complete. |

2.10 R&D

ToVs related to R&D activities are disclosed in aggregate form. Examples include, but is not limited to, the following:

- Activities related to the planning or conduct of non-clinical studies, clinical trials prospective non- interventional studies and that involve the collection of patient data from or on behalf of individual, or groups of HCPs specially for the study.
- Investigator-initiated trials and investigator-sponsored trials – since, although not initiated by Novartis, they may benefit from Novartis.
- 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 cost per meeting (incl. infrastructure, travel, logistic, and with exclusion of meals whenever possible) divided by the number of participants per country of practice
- Activities contracted to Contract Research Organisations (“CROs”) where Novartis makes indirect ToVs to HCPs/ HCOs falling under the definition of R&D
- ToVs related to early-stage research if it is under the definition of R&D in the European Federation of Pharmaceutical Industries & Associations (“EFPIA”) Disclosure Code.

2.11 Voluntary disclosure

N/A

3 Specific considerations

3.1 Country unique identifier

Novartis has developed HCP/HCO unique identifiers to ensure that the identity of the recipient benefitting from the ToV is clearly distinguishable for each Novartis affiliate.

3.2 Self-incorporated HCP

[This term refers to a HCP who is the sole shareholder of their own Limited company. When a HCP contracts with Novartis UK via a limited company, we are responsible for confirming that the HCP is connected to the company by either employment or ownership and the number of HCPs providing services / employed by the limited company. If more than one HCP provides services to the limited company then it is disclosed as a HCO. If only one HCP provides services then the ToV will be disclosed against the HCP as an individual.]

3.3 Multi-year agreements

[In case of multi-year contracts, ToVs are recognised based on the date the payment has been cleared via the banking system.]

3.4 Country specificities

[Where more than one pharmaceutical company is involved in a Collaborative Working project, Novartis will only be responsible for disclosure of financial or non-financial ToV that has been made by Novartis.

The executive summaries of each Collaborative Working project can be accessed via the links provided in the Report. These executive summaries are also available on Novartis' UK website www.novartis.co.uk]

3.5 Quality Checks

[Novartis has robust internal processes in place regarding the collection and reconciliation of transfers of value to recipients. Additional data and process monitoring takes place for quality assurance prior to reporting.]

4 Data protection legal basis

4.1 Consent collection

Novartis does not require freely given consent from recipients for individual disclosure of their information; the default position is public disclosure based on Legitimate Interests.

4.2 Legitimate interests

[Legitimate interest is used lawfully to meet the requirements of the EFPIA Disclosure Code while respecting data protection laws.]

Novartis maintains a completed a legitimate interest assessment, which concluded that in connection with the disclosure of ToVs on a publicly named basis, the benefits override the Recipients' interests.

Recipients maintain the right to request to object to public disclosure. This is not an automatic right.

There are two circumstances where Novartis would disclose on an aggregate (non-named) basis:

- i. where an HCP dies by the time of disclosure (by the publication date); or
- ii. where an HCP exercises their right to object, and such objection overrides Novartis' legitimate interests in disclosure.

Where an HCP exercises their right to object and such objection overrides Novartis' legitimate interest in disclosure, this may have retroactive effect on disclosures in the past and have impact on future disclosures.

5 Form of disclosure

5.1 Date of publication

30/06/25

5.2 Disclosure platform

Disclosure UK – www.disclosureuk.org.uk |

5.3 Disclosure language

English |

6 Disclosure financial data

6.1 Currency

Great British Pounds (GBP). If payments were made in another currency, these are converted to GBP (calculation of currency postings are based on payment date and daily exchange rate).

6.2 VAT included or excluded

Novartis discloses ToVs net amount only. If VAT (or similar tax) cannot accurately be excluded (such as, due to other customs or practices in cross-border transfers, the full ToV amount is disclosed. Where income tax or equivalent is withheld by Novartis on amounts earned by the HCP then the ToV will include these amounts. |

6.3 Calculation rules

Not applicable. |

7 Additional Information

7.1 Retention of data

Novartis will fulfil the obligation of the EFPIA and ABPI 2024 Code of Practice to be able to demonstrate that its disclosures were accurate at the time they were made in the event of a complaint, and be able to respond to requests from the Recipient or relevant authorities.

Declarations are:

- declared within six months of the end of the calendar year when payments were made
- publicly available for three years from when they were first disclosed
- kept for company records for a minimum of five years after the end of the relevant Reporting Period. |