



NOVAVAX

# Methodology notes for the EFPIA/ABPI Disclosure Report of Transfers of Value

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## 1. Introduction

Novavax is a member of the European Federation of Pharmaceutical Industries and Associations' (EFPIA) Vaccines Europe. Through its direct membership of 37 national associations, 39 leading pharmaceutical companies and a growing number of small and medium-sized enterprises (SMEs), EFPIA's mission is to create a collaborative environment that enables its members to innovate, discover, develop, and deliver new therapies and vaccines for people across Europe, as well as contribute to the European economy. Vaccines Europe (VE) is the specialized vaccine industry group within EFPIA. It represents major innovative research-based global vaccine companies as well as small and medium sized enterprises operating in Europe.

Novavax's success depends on positive and regular collaboration with the healthcare industry. This includes frequent interactions with healthcare professionals (HCPs) and healthcare organizations (HCOs). The value of these interactions is essential to improving the quality of treatments to patients and gaining real-world insights to deliver better healthcare.

We recognize that these interactions can present conflicts of interest and to preserve the integrity of the clinical decision-making processes, Novavax is committed to transparency about how we operate as a business and about the relationships we have with HCPs and HCOs. We hope sharing information about these relationships in a transparent way will help preserve the critical value these relationships bring to patient management.

We believe that transparency is essential to building and maintaining confidence in us and in our medicines and strongly support the work being done by EFPIA to improve transparency across the pharmaceutical industry.

This methodological note presents how the transfers of value are categorized and in what format they are disclosed.

## 2. Transfer of Value Categories

The following table defines what transfers of value are reported in which EFPIA category and subcategory for either HCO or HCP recipients.

| Category                                | Sub-category           | Description and Types of Transfers of Value Included  |
|---|------------------------|---|
| Donations and Grants to HCO's           |                        | Donations and Grants to HCO's that support healthcare including donations, grants and benefits in kind to institutions, organizations or associations that are comprised of HCPs and/or that provide healthcare.  |
| Research & Development                  |                        | Research and Development transfer of values to HCPs/HCOs associated with: <ul style="list-style-type: none"> <li>• Non-clinical</li> <li>• Clinical trials in Phase I to Phase IV</li> <li>• Investigator sponsored studies</li> <li>• Non-interventional studies</li> </ul>  |
| Contribution to costs related to Events |                        | Events include all scientific professional meetings, congresses, conferences, symposia and other similar events.  |
|   | Sponsorship agreements | Sponsorships with HCOs/third party appointed by an HCO to manage an Event. <p>Examples:</p> <ul style="list-style-type: none"> <li>• Rent of booths at an event</li> <li>• Advertisement space (in paper, electronic or other format)</li> <li>• Satellite symposia at a Congress</li> <li>• Sponsoring of speakers/faculty</li> <li>• Drinks or meals provided by the organizers (included in the "Sponsorship Agreement")</li> <li>• Courses provided by an HCO (where the</li> </ul> |

|                                 |                        |   |
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|                                 |                        | Member Company does not select the individual HCPs participating  |
|                                 | Registration Fees      | Registrations fees related to attending a Congress or Symposia.   |
|                                 | Travel & Accommodation | <p>Travel and Accommodation in relation to attending a Congress or Symposia.</p> <p><u>Example:</u></p> <ul style="list-style-type: none"> <li>• Fees for airfare, train, etc.</li> <li>• Car rental, car services, taxi transfers</li> <li>• Parking fees</li> <li>• Petrol</li> <li>• Tolls</li> <li>• Etc.</li> </ul> <p>Note: Meals that are part of a reimbursement to an HCP may be included in the Travel &amp; Accommodation amount</p>   |
| Fee for service and consultancy |                        | <p>Transfers of value resulting from or related to contracts between Member Companies and institutions, organizations, associations, or HCPs under which such institutions, organizations, associations, or HCPs provide any type of services to a Member Company, or any other type of funding not covered in the previous categories. Fees, on the one hand, and on the other hand ToVs relating to expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts.</p> |
|                                 | Fees                   | <p><u>Examples:</u></p> <ul style="list-style-type: none"> <li>• Speaker fees</li> <li>• Speaker training</li> <li>• Medical writing</li> </ul>   |

|  |  |   |
|--|--|---|
|  |  | <ul style="list-style-type: none"> <li>• Data analysis</li> <li>• Development of education materials</li> <li>• General Consulting/Advising</li> </ul>  |
|  | Related expenses agreed in the fee for service or consultancy contract | <p>Related expenses agreed in the fee for service or consultancy contract:</p> <p>Example:</p> <ul style="list-style-type: none"> <li>• Fees for airfare, train, boat or ferry (incl. booking fees)</li> <li>• Car rental, car services, taxi transfers</li> <li>• Parking fees</li> <li>• Petrol</li> <li>• Tolls</li> </ul> <p>Note: Meals that are part of a reimbursement to an HCP will be included in the Travel &amp; Accommodation amount</p> |

### 3. Decisions

This section highlights the decisions that drive our collection, aggregation, and reporting process. The specific individual country information, whenever appropriate, is included in the section on Scope of Disclosures.

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|-----------|---|
| Tax & VAT | All payments and transfers of value to be disclosed exclusive of taxes such as VAT where possible. In instances where VAT was not separated it will be included. Exceptions include when Novavax has paid a withholding tax as part of the transfer of value.   |
| Consent   | <p>Novavax is collecting consent at the first point of first engagement with all HCPs and HCOs based on local requirements. This language is contained in all consulting agreements:</p> <ul style="list-style-type: none"> <li>• If consent is given for all engagements, Novavax will disclose transfers of value to the HCP under the individual section of the applicable disclosure report ('Disclosure Report').</li> </ul> |

|                               |   |
|-------------------------------|---|
|                               | <ul style="list-style-type: none"> <li>• If Novavax does not receive consent for all engagements, Novavax will default all transfers of value to the aggregate section of the applicable Disclosure Report.</li> </ul> <p>Revoking of individual consent:</p> <ul style="list-style-type: none"> <li>• If an HCP or HCO revokes consent prior to publication of the data, Novavax will update the data and include the transfers of values for the corresponding HCP or HCO, yet without identifying them, in the aggregate section of the applicable Disclosure Report.</li> <li>• If an HCP or HCO revokes consent after publication of the data, Novavax will remove personal data about transfers of value to the corresponding HCP or HCO from the Disclosure Report at the latest by the end of the month following the month in which Novavax received notice of withdrawal of consent, and will update the transfers of values for the corresponding HCP or HCO, yet without identifying them, in the aggregate section of applicable Disclosure Report.</li> </ul> |
| Currency                      | All payments and transfers of value will be disclosed in local currency. If a payment is captured in another currency, it will be converted into local country currency based on the date at which the transfer of value occurred and corresponding daily exchange rate.  |
| Transfer of values correction | HCPs or HCOs may request to review published transfers of values. If the transfer of value is found to be incorrect, we will correct and re-publish these transfers of values.  |
| Transfer of Value Dates       | <p>Novavax will disclose payments and transfers of value based on the date the payment or transfers of value occurred as follows:</p> <ul style="list-style-type: none"> <li>• For direct payments (all fees to HCPs and HCOs, Sponsorships,</li> </ul>   |

|   |   |
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|   | <p>Grants &amp; Donations): the transfer of value date is the date of the wire transfer to the recipient</p> <ul style="list-style-type: none"> <li>• For other types of transfers of value such as travel &amp; accommodation: the transfer of value date is the start date of the travel, event, or the date the transfer of value took place</li> </ul>  |
| Events that are cancelled or HCP does not participate | In circumstances when a flight or accommodation is booked but the event is cancelled or HCP does not attend, no transfer of value will be attributed to that HCP.   |
| Disclosure of cross-border Transfers of Value         | Where a TOV is made outside of the recipient's country the TOV will be reported within the country where the recipient has its principal practice.  |
| Local Identifiers                                     | Novavax will disclose the "Country Unique Identifier" for HCPs and/or HCOs where the local code has mandated this data point and where consent has been provided.   |
| Disclosure of Recipient                               | <p>Novavax will disclose the legal entity or name of the person to whom we transferred the item of value.</p> <p>In circumstances when a transfer of value is made to a HCO for a registration fee or travel expenses related to attending a congress or symposia, if known, we will report the name of the HCP whom we consider the beneficiary of the transfer of value.</p> <p>When consent is not provided by that HCP, the item will be reported in aggregate against the HCO.</p> |



## 4. Publication of Disclosures

### *Publication*

Novavax will follow local country trade association procedures and legislation for publishing disclosure reports.

### *Date of publication*

Each country's disclosure report will be disclosed by the deadline as specified by the country's national trade association code or regulation.

### *Disclosure platform*

For countries with an external central platform: Novavax will publish the disclosure report on the specified central platform. Where possible this methodology report will accompany the disclosure report.

For markets with no external central platform: Novavax will publish the disclosure report on the transparency section of Novavax's global corporate website.

### *Language of Disclosure Reports*

Disclosure will be made in the language prescribed in the country's national association code and it will be available in English where required.

## 5. Definitions

### *HCO*

Any legal person (i) that is a healthcare, medical or scientific association or organization (irrespective of the legal or organizational form) such as a hospital, clinic, foundation, university or other teaching institution or learned society (except for patient organizations within the scope of the PO Code) whose business address, place of incorporation or primary place of operation is in Europe or (ii) through which one or more HCPs provide services. Per guidance from local Associations in some countries, if the personal name of the HCP is contained in the name of the legal entity, namely "self-

incorporated HCP", then the HCO will be considered a HCP for consent and disclosure purposes.

#### *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 per the EFPIA Code includes: (i) any official or employee of a government agency or other organization (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, and subject to local requirements.

#### *PO (Patient Organization)*

Not-for-profit legal person/entity (including the umbrella organization to which it belongs), mainly composed of patients and/or caregivers, that represents and/or supports the needs of patients and/or caregivers and which business address, place of incorporation or primary place of operation is in Europe.

#### *Donations and Grants*

Collectively, means those donations and grants (either cash or benefits in kind) within the scope of Article 11 of the HCP Code.

#### *Events*

All promotional, scientific or professional meetings, congresses, conferences, symposia, and other similar events (including, but not limited to, advisory board meetings, visits to research or manufacturing facilities, and planning, training or investigator meetings for clinical trials and non-interventional studies) (each, an "Event") organized or sponsored by or on behalf of a company (Article 10 of the HCP Code).

### *HCP Code*

EFPIA Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals, adopted by the EFPIA Board on 5 July 2007 and ratified by the EFPIA Statutory General Assembly on 19 June 2008, amended on 14 June 2011, and as further amended on 24 June 2013, and as may be amended, supplemented or modified from time to time.

### *Medicinal Products*

(a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or (b) any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis. (Article 1 of Council Directive 2001/83/EC, as amended)

### *Member Associations*

Collectively, the national member associations or their constituent members, as the context may require, are members of EFPIA and bound by the EFPIA codes of practice.

### *Member Companies*

Collectively, "corporate members" (as defined in the HCP Code) of EFPIA, their respective parent companies, if different, subsidiary companies (irrespective of whether a subsidiary is a company or such other form of enterprise or organization) and any companies affiliated with corporate members or their subsidiaries if such affiliated companies have agreed to be bound by this Code.

### *Recipient*

Any HCP or HCO or PO applicable as per local requirements, in each case, whose primary practice, principal professional address or place of incorporation is in Europe.

### *Research and Development Transfers of Value*

Transfers of Value to HCPs or HCOs related to the planning or conduct of (i) non-clinical studies (as defined in OECD Principles on Good Laboratory Practice); (ii) clinical trials (as defined in Directive 2001/20/EC); or (iii) non-interventional studies that are prospective

in nature and that involve the collection of patient data from or on behalf of individual, or groups of, HCPs specifically for the study (Section 15.02 of the HCP Code).

### *Transfers of Value*

Direct and indirect transfers of value, whether in cash, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development and sale of generic or branded prescription-only Medicinal Products exclusively for human use. Direct transfers of value are those made directly by a Member Company for the benefit of a Recipient. Indirect transfers of value are those made on behalf of a Member Company for the benefit of a Recipient, where the identity of such Member Company is known to or can be identified by the Recipient.