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Moderna: Methodological note for HCP/ORDM/HCO disclosure [2025]

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Moderna supports laws and regulations that promote transparency around relationships between life science companies, Healthcare Professionals (HCPs), Other Relevant Decision Makers (ORDMs) and Healthcare Organizations (HCOs) associated with Transfers of Value (ToVs) related to medicinal products. Moderna seeks to apply a single, consistent transparency standard in Europe for disclosing ToVs across its affiliates and European countries, following the European Federation of Pharmaceutical Industries and Associations (EFPIA) transparency requirements and the requirements set forth in local laws and codes.

As a member of Vaccines Europe, a specialized vaccine group within EFPIA, and the Association of the British Pharmaceutical Industry (ABPI), Moderna complies with the obligation to collect, disclose and report ToVs from member companies to HCPs and HCOs in accordance with Clauses 28 to 31 of the 2024 ABPI Code of Practice.

The purpose of this methodological note is to summarize the business decisions, methodologies and United Kingdom-specific considerations applied by Moderna to collect and report ToVs for each relevant disclosure category described in the ABPI 2024 Code of Practice

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1 Definitions

1.1 Recipients

Healthcare Professional (HCP): Any natural person that is a member of the medical, dental, pharmacy or nursing professions and any other person who, in the course of their professional activities, may prescribe, purchase, supply, recommend or administer a Medicine and whose primary practice, principal professional address or place of incorporation is in Europe. For the avoidance of doubt, the definition of HCPs 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, recommend or administer Medicinal Products; and (ii) any employee of Moderna whose primary occupation is that of a practicing HCP.

Other Relevant Decision Maker (ORDM): Someone with an NHS role who could influence in any way the administration, consumption, prescription, purchase, recommendation, sale, supply, or use of any medicine but is not a health professional.

Healthcare Organization (HCO): Any legal person or entity (i) that is a healthcare, medical or scientific association or organization, irrespective of legal or organizational form, such as a hospital, clinic, foundation, university, other teaching institution or learned society, except for Patient Organizations 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 HCPs provide services.

Third Party: Third parties working for and on behalf of Moderna where such parties exist and have provided a ToV on Moderna's behalf have been reported to Moderna and are disclosed as required.

1.2 Kind of ToVs

Transfers of Value (ToV): Direct and indirect transfers of value, whether in cash, in kind or otherwise, made for promotional purposes or otherwise in connection with the development and sale of medicines. Direct ToVs are made directly by Moderna for the benefit of a recipient. Indirect ToVs are made on behalf of Moderna for the benefit of a recipient, or through a Third Party where Moderna knows or can identify the recipient that will benefit from the ToV.

Contribution to costs related to Events (HCO): Contribution to costs related to Events, through HCOs or third parties, including sponsorship to HCPs to attend Events, such as:

- Registration fees
- Sponsorship agreement with HCOs or with third parties appointed by an HCO to manage an Event; and
- Travel and accommodation

Donations and Grants (HCO): Donations and Grants to HCOs that support healthcare, scientific research, or education

Fees for Service and Consultancy (HCO): Transfers of Value resulting from or related to contracts between Moderna and HCOs under which such institutions, organizations or associations provide any type of services to Moderna. 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.

Contribution to costs related to Events (HCP): Contribution to costs related to Events, such as:

- Registration fees; and
- Travel and accommodation

Research and Development Transfers of Value: ToVs 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 Regulation 536/2014; 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.

2 Disclosure's Scope

2.1 Products concerned

This methodological note concerns ToVs made in connection with the development and sale of medicines. For this purpose, Medicine means any branded or unbranded medicine intended for use in humans which requires a marketing authorization.

2.2 Company concerned

This methodological note applies to Moderna's collection, aggregation and reporting of ToVs in the United Kingdom..

2.3 Excluded ToVs

Moderna does not disclose salaries paid to HCPs employed by Moderna. Moderna also does not disclose support provided by Moderna to a Moderna employee who is an HCP to attend a third-party meeting, as it is deemed that the Moderna employee attended the meeting for professional reasons related to their employment.

Moderna does not disclose food and beverage expenses paid to HCPs related to Services and Consultancy contracts.

Where a flight or accommodation is booked but the event is cancelled or the HCP does not attend, no ToV will be attributed to the HCP.

2.4 ToVs date

Moderna discloses payments and ToVs based on the date the payment or ToV occurred as follows:

- For direct payments, including all fees to HCPs and HCOs, sponsorships, grants and donations, the ToV date is the date on which the check is processed, or the wire transfer is made to the recipient, rather than the date of the event or service.
- For other ToVs, including travel and accommodation, the ToV date is the start date of the event, the date the ToV took place, or the date reported by the intermediary that provided the data to Moderna.

2.5 Direct ToVs

Direct ToVs are those made directly by Moderna for the benefit of a recipient.

2.6 Indirect ToVs

Indirect ToVs are those made on behalf of Moderna for the benefit of a recipient, or those made through a Third Party where Moderna knows or can identify the recipient that will benefit from the ToV.

Where an HCP has requested that payment is made to a third party, such as their employer, the ToV is reported in the name of the HCP who directed the payment.

For sponsorships, transfers of value made through a Professional Conference Organizer (PCO) are published in the name of the HCO. In the case of sponsorship agreements where different HCOs have participated, it is assumed that each HCO received an equal share and the ToV is published for each HCO.

2.7 Non-monetary ToVs

A ToV that consists of a benefit provided in kind is reported in the calendar year that the benefit was provided. If the benefit in kind provided to an HCO spans more than one calendar year, the ToV is reported in the calendar year in which the ToV was actually delivered.

2.8 ToVs in case of partial attendances or cancellation and refund

Moderna attributes ToVs that are incurred and can be reasonably associated to the HCP. In circumstances where a flight or accommodation is booked but the event is cancelled or the HCP does not attend, no ToV is attributed to the HCP.

2.9 Cross-border activities

ToVs to an HCP or HCO whose practice, professional address or place of incorporation is in Europe are disclosed in the country where the recipient has their or its principal practice.

2.10 R&D

Research and Development ToVs are ToVs to HCPs or HCOs related to the planning or conduct of non-clinical studies, clinical trials or prospective non-interventional studies that involve the collection of patient data from or on behalf of individual, or groups of, HCPs specifically for the study.

Non-interventional studies that are retrospective in nature are disclosed under Fees for Service and Consultancy. These include: (i) purely observational database review and/or research; (ii) retrospective review of records where all the events of interest have already happened; and (iii) studies in which the prescriber later becomes an investigator, but prescribing has already occurred.

2.11 Voluntary disclosure

Moderna discloses individually those contracts signed without remuneration, meaning zero-fee contracts, where the disclosed amount is 0 GBP or no ToV was received by the HCP or HCO.

3 Specific considerations

3.1 Country unique identifier

Moderna will disclose the country unique identifier for HCPs and/or HCOs where the national code mandates the inclusion of this data element.

3.2 Self-incorporated HCP

A ToV to a sole proprietor or to an individual HCP's legal entity is reported at an individual HCP level if the ToV is categorized as fees for service or consultancy and/or related expense, registration fees, and/or travel and accommodation.

A ToV to a sole proprietor or to an individual HCP's legal entity is reported to the HCO if the ToV is categorized as Donations and Grants, Joint Working, or Sponsorship Agreements.

3.3 Multi-year agreements

Where contracts are valid for more than one year, each individual ToV is captured and disclosed in the corresponding reporting period.

3.4 Country specificities

Disclosure is made in English and all payments and ToVs are disclosed in Pound Sterling (GBP). Moderna's United Kingdom disclosure follows Clauses 28 to 31 of the 2024 ABPI Code of Practice.

3.5 Quality Checks

HCPs and HCOs may request the correction of published ToVs that are found to be incorrect. In these circumstances, Moderna will correct and republish these ToVs.

Moderna may update previous data submissions based on the outcome of periodic internal monitoring and reviews in order to provide the most accurate data possible.

4 Data protection legal basis

4.1 Consent collection

Moderna collects consent per engagement with all HCPs based on local requirements:

- If consent is given for an engagement, Moderna discloses transfers of value to the HCP under the individual section of the applicable Disclosure Report.
- If Moderna does not receive consent, or consent cannot be successfully validated for an engagement, Moderna reports all ToVs in the aggregate section of the applicable Disclosure Report.
- If the consent form is not returned to Moderna, Moderna reports all ToVs in the aggregate section of the applicable Disclosure Report

4.2 Legitimate interests

Not Applicable

5 Form of disclosure

5.1 Date of publication

[DD/MM/YYYY

5.2 Disclosure platform

Disclosure UK – www.Disclosureuk.org.uk

5.3 Disclosure language

English

6 Disclosure financial data

6.1 Currency

All payments and ToVs are disclosed in Pound Sterling (GBP). If a ToV is captured in another currency, it is converted into Pound Sterling based on the date on which the ToV occurred utilizing the corresponding daily exchange rate.

6.2 VAT included or excluded

Moderna discloses the amount before VAT and taxes, unless VAT cannot be accurately excluded due to the complexity of VAT regimes around Europe and the inconsistency of whether VAT may or may not be reimbursable depending on where the transaction took place and the country of residency of the HCP or HCO.

Where income tax or equivalent is withheld by Moderna on amounts earned by the HCP, the ToV includes these amounts

6.3 Calculation rules

Not Applicable

7 Additional Information

For questions on the data contained in the Transparency reports, please contact Moderna's Compliance Team at: TransparencyReporting@modernatx.com

To exercise data privacy rights, please contact Moderna's Privacy Team at: Privacy@modernatx.com