

Methodological Note on Disclosure of Payments and other Transfers of Values to Health Care Professionals and Health Care Organizations following the 'ABPI 2021 Code of Practice'

Reference to Transparency Laws and Regulations	. 2
Purpose of Methodological Note	. 2
Definitions	. 2
Categories for Disclosure	. 3
Business Decisions	. 4
Disclosure Requirements	. 6

Reference to Transparency Laws and Regulations

Moderna supports laws and regulations that promote transparency around relationships between life science companies, Healthcare Professionals (HCPs) and Healthcare Organizations (HCOs) associated with Transfers of Value (ToVs) related to medicinal products by establishing a single, consistent transparency standard in Europe for disclosing ToVs across its affiliates and European countries. Moderna follows 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, Moderna complies with the obligation to collect, disclose and report ToVs from member companies to HCPs and HCOs in accordance with the ABPI 2021 Code of Practice requirements.

Purpose of Methodological Note

The purpose of this Methodological Note is to summarize the business decisions, methodologies and any country specific considerations applied by Moderna in order to collect and report ToVs for each disclosure category as more particularly described in the ABPI 2021 Code of Practice.

Definitions

- Contribution to Costs related to Events: is support provided or covering the costs of travel, accommodation and/or registration fees to support the attendance of an individual HCP to an Event organized or created by Moderna and/or a Third Party.
- Donations and Grants: collectively, mean providing funds, benefits-in-kind or services freely given for the purpose of supporting healthcare, scientific research or education, with no consequent obligation on the recipient to provide goods or services to the benefit of the Moderna in return.
- Events: All professional, promotional, scientific, educational 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) organized or sponsored by or on behalf of Moderna.
- Healthcare Organization (HCO): any legal person/entity (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 article 21) whose business address, place of incorporation or primary place of operation is in Europe or (ii) through which one or more HCPs provide services.
- 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 his/her 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 purpose of this Code, 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.

- Medicine: means any branded or unbranded medicine intended for use in humans which requires a marketing authorization.
- Other Relevant Decision Maker: Includes 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.
- 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 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.
- **Sponsorship**: is a support provided by or on behalf of Moderna, when permitted by law, as a contribution to support an activity (including an Event) performed, organized or created by a HCO, a PO or a Third Party.
- **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.
- Transfers of Value (ToV): Direct and indirect ToV, whether in cash, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development and sale of medicines. Direct ToVs are those made directly by Moderna for the benefit of a Recipient. Indirect ToVs are those made on behalf of Moderna for the benefit of a Recipient, or those made through a Third Party and where Moderna knows or can identify the Recipient that will benefit from the Transfer of Value.

Categories for Disclosure

The following table defines what activities are reported in which ABPI category.

	Donations and Grants	Donations and Grants to HCOs that support healthcare, scientific research or education
ToVs to an HCO	Contribution to Cost of Events	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

	Fees for Service and Consultancy	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.
ToVs to an HCP	Contribution to costs related to Events	Contribution to costs related to Events, such as: Registration fees; and Travel and accommodation
	Fees for Services and Consultancy	Fees for Service and Consultancy. ToVs resulting from or related to contracts between Moderna and HCPs under which such HCPs provide any type of services to Moderna, including non-interventional studies that are retrospective in nature ¹ . 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.

Business Decisions

The purpose of this Methodological Note is to provide guidance on the specific business decisions made by Moderna that drive the collection, aggregation and reporting of our TOVs.

Tax & VAT	Payments and ToVs are disclosed as the gross value and exclude taxes such as VAT and income tax.
Currency	All payments and ToVs are disclosed in the Pound sterling (GBP). If a ToV is captured in another currency, it is converted into the Pound Sterling based on the date on which the ToV occurred utilizing the corresponding daily exchange rate.
Disclosure of cross-border ToVs	ToVs to a HCP/HCO whose practice, professional address or place of incorporation is in Europe, are disclosed in the country where the recipient has its principal practice.
Language	Disclosure is made in English.

_

¹ Non-interventional studies that are retrospective in nature 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.

Local identifiers	Moderna will disclose the country unique identifier for HCPs and/or HCOs where the national code mandates the inclusion of this data element.
	Moderna discloses payments and ToVs based on the date the payment or ToV occurred as follows:
ToV dates	 For direct payments (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 as opposed to the date of the event or service. For other ToVs (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.
Events that are cancelled or HCP does not participate	Moderna will attribute the 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 will be attributed to the HCP.
Multi-year contracts	Where contracts are valid for more than one year, each individual ToV is captured and disclosed in the corresponding reporting period.
Benefit in Kind ToV	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 span over two calendar years, the ToV is reported in the calendar year in which the ToV was actually delivered.
Self-incorporated HCP	A ToV to a sole proprietor or to an individual HCPs 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 HCPs legal entity is reported to the HCO if the ToV is categorized as "Donations and Grants," "Joint Working", or "Sponsorship Agreements."
Indirect ToV to HCP via a third-party	Where an HCP has requested that their 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.
In-kind contributions of vaccines	Moderna does not disclose a ToV for any vaccine provided to an HCO which represents an in-kind charitable contribution.
Consent	Moderna collects consent per engagement with all HCPs based on local requirements:

ToV corrections	 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 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. HCPs and HCOs may request the correction of published ToVs that are found to be incorrect. In these circumstances, Moderna will correct and re-publish these ToVs. 	
Moderna employees who practice as HCPs	Moderna does not disclose salaries paid to HCPs employed by Moderna. Moderna does not disclose any 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.	

Disclosure Requirements