



## **Methodological Note**

Methodological Note on Disclosure of Payments and other Transfers of Values to Health Care Professionals and Health Care Organisations in accordance with the Association of the Pharmaceutical Industry in Norway (LMI) 'Industry Rules'

**2024**

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## Reference to Transparency Laws and Regulations

BioCryst supports laws and regulations that promote transparency around relationships between life science companies, Healthcare Professionals (HCPs) and Healthcare Organisations (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. BioCryst follows the European Federation of Pharmaceutical Industries and Associations (EFPIA) transparency requirements, and the requirements set forth in local laws and codes.

BioCryst is not a member of the Association of the Pharmaceutical Industry in Norway (LMI) within EFPIA, however BioCryst complies voluntarily with the obligation to collect, disclose and report ToVs from member companies to HCPs and HCOs in accordance with the Industry Rules.

## Purpose of Methodological Note

The purpose of this Methodological Note is to summarise the business decisions, methodologies and any country specific considerations applied by BioCryst in order to collect and report ToVs for each disclosure category as more particularly described in the Industry Rules for the Association of the Pharmaceutical Industry in Norway.

## Definitions

**Contribution of 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 organised or created by BioCryst and/or a Third Party.

**Donations and Grants:** collectively, mean providing funds, benefits-in-kind or services freely given for the purpose of supporting medical research and development or improved patient treatment with no consequent obligation on the recipient to provide goods or services to the benefit of BioCryst 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) organised or sponsored by or on behalf of BioCryst.

**Healthcare Organisation (HCO):** means legal entities which perform healthcare services or research or educational services, or an organisation with a medical or scientific purpose, with the exception of patient associations.

**Healthcare Professional (HCP):** means a physician, dentists, pharmacist, nurse or any other natural person within healthcare who has a right to prescribe, purchase, supply, recommend or administer a medicinal product, including employees of BioCryst whose primary occupation is that of a practicing healthcare personnel. All other employees of BioCryst are excluded from the definition of healthcare personnel.

**Medicine:** means any branded or unbranded medicine intended for use in humans which requires a marketing authorisation.

**Research and Development Transfers of Value:** means transfers of value to recipients related to the planning or conduct of (i) non-clinical studies (as defined in OECD's Principles for Good Laboratory Practice); (ii) clinical trials (as defined in Directive 2001/20/EC); or (iii) prospective non-interventional studies which include the collection of patient data from or on behalf of healthcare personnel.

**Sponsorship:** is a support provided by or on behalf of BioCryst, when permitted by law, as a contribution to support an activity (including an Event) performed, organised or created by a HCO, a PO or a Third Party.

**Third Party:** Third parties working for and on behalf of BioCryst where such parties exist and have provided a ToV on BioCryst's behalf have been reported to BioCryst 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 BioCryst for the benefit of a Recipient. Indirect ToVs are those made on behalf of BioCryst for the benefit of a Recipient, or those made through a Third Party and where BioCryst 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 category of the Ethical Rules for the Pharmaceutical Industry.

<b>ToVs to an HCO</b>	Donations and Grants	Donations and Grants to HCOs that support healthcare, scientific research and development.
	Contribution to Cost of Events	Contribution to costs related to Events, through HCOs or third parties, such as:  i. Sponsorship agreement with HCOs or with third parties appointed by an HCO to manage an Event;
	Fees for Service and Consultancy	Transfers of Value resulting from or related to contracts between BioCryst and HCOs under which such institutions, organisations or associations provide any type of services to BioCryst. 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.
<b>ToVs to an HCP</b>		Contribution to costs related to Services and Consultancy, such as: i. Registration fees; and ii. Travel and accommodation
	Fees for Services and Consultancy	Fees for Service and Consultancy. ToVs resulting from or related to contracts between BioCryst and HCPs under which such HCPs provide any type of services to BioCryst, including non-interventional

		studies that are retrospective in nature <sup>1</sup> . 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.
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## Business Decisions

The purpose of this Methodological Note is to provide guidance on the specific business decisions made by BioCryst 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 NOK. If a ToV is captured in another currency, it is converted into NOK based on the date on which the ToV occurred utilising the corresponding daily exchange rate.
Disclosure of cross-border ToVs	ToVs to an 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
Local identifiers	BioCryst will disclose the country unique identifier for HCPs and/or HCOs where the national code mandates the inclusion of this data element.
ToV dates	<p>BioCryst discloses payments and ToVs based on the date the payment or ToV occurred as follows:</p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• 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 BioCryst.</li> </ul>
Events that are cancelled or HCP does not participate	BioCryst 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 spans 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 categorised 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 categorised 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 Medicines	BioCryst does not disclose a ToV for any Medicine provided to an HCO which represents an in-kind charitable contribution.
Consent	<p>BioCryst collects consent as of the first engagement for a 1 year period with all HCPs and HCOs based on local requirements:</p> <ul style="list-style-type: none"> <li>• If consent is given for all engagements, BioCryst discloses transfers of value to the HCP under the individual section of the applicable Disclosure Report.</li> <li>• If BioCryst does not receive consent for all engagements, BioCryst reports all TOVs in the aggregate section of the applicable Disclosure Report.</li> <li>• If the consent form is not returned to BioCryst, BioCryst reports all ToVs in the aggregate section of the Applicable Disclosure Report.</li> </ul>
ToV corrections	HCPs and HCOs may request the correction of published ToVs that are found to be incorrect. In these circumstances, BioCryst will correct and re-publish these ToVs.
BioCryst employees who practice as HCPs	BioCryst does not disclose salaries paid to HCPs employed by BioCryst. BioCryst does not disclose any support provided by BioCryst to a BioCryst employee who is an HCP to attend a third-party meeting, as it is deemed that the BioCryst employee attended the meeting for professional reasons related to their employment.

## Disclosure Requirements

Disclosure Period	Each reporting period covers an entire calendar year.
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