Methodology Note

Supporting The

Disclosure Of Transfers Of Value

of

Plusultra pharma

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CONTENT

1. PURPOSE OF THIS METHODOLOGY NOTE

Plusultra pharma GmbH and Plusultra pharma UK Ltd. (herein after "Plusultra pharma", "we" or "us") believe that cooperation with healthcare professionals, healthcare organizations and patient organizations is a vital component in the commercialization of medicinal products and medical devices. We value and pursue regular interactions with professionals, e.g. in relation to the commercialization of medicinal products or medical devices, consultancy engagements or the support of medical education.

It is our policy to conduct our business in an honest and ethical manner. Simultaneously, we acknowledge and believe in transparency as an essential element for encouraging und maintaining confidence in our company and our products. It is our mission to promote transparency and build confidence in our relations with HCPs, HCOs and POs.

Therefore, Plusultra pharma has decided to voluntarily disclose the transfers of value (ToVs) to or for the benefit of HCPs, HCOs and POs per year in Europe and the UK. We will publish our Disclosure Reports on ToVs as of Reporting Period 2022, following the general principles set forth in the EFPIA Code of Practice. For consistency purposes the Disclosure Reports will be made using the standardized Disclosure Report Template attached in the Appendix.

This Methodology Note is aimed at supporting the annual Disclosure Reports and to facilitate the understanding of the disclosed ToVs.

The rules set forth in this Methodology Note apply to the disclosure of ToVs of our European operations as specified therein without prejudice to the applicability of our Data Protection Policy and Anti-Bribery and Corruption Policy.

2. GENERAL TERMS OF DISCLOSURE

The disclosure of ToVs on an individual or aggregate basis and its amount follows the general principles set forth in the EFPIA Code of Practice.

2.1 Covered interactions

Following the EFPIA Code of Practice, only certain categories of benefits are covered by the obligation to disclose. Accordingly, benefits of monetary value must be documented and disclosed in connection with

- Donations and grants (cash and in-kind)
- Training events
- Service and consulting fees
- Research and Development by mother company Nobelpharma Co. Ltd.

The following areas are not covered by the transparency obligations:

- over-the-counter drugs
- distribution of medical samples and sales of medicinal products by Plusultra pharma to HCPs and/or HCO
- information and educational materials, items of medical value
- meals and beverages

Training courses to which Plusultra pharma invites HCPs will not be disclosed, provided that no additional costs (e.g. travel and accommodation costs) beyond the internal costs of holding the event and, if applicable, meals and beverages, are borne or reimbursed by Plusultra pharma.

Cancellation fees are neither documented nor reported. In case of a No-show (e.g. in relation to Events) the expenses (e.g. hotel booking) are not reported. Since no payment or reimbursement of expenses is made to the HCPs, these costs are not disclosed.

2.2 Individual and Aggregate disclosure

2.2.1 Individual disclosure

The Disclosure Report normally includes the name of the Recipient of the ToV. For each HCP and HCO all ToVs during the Reporting Period are allocated into one of the categories and reported in total per (sub)category disclosing the name and address of principal practice or business of the HCP/HCO.

Each ToV made to a PO during the Reporting Period is listed separately in the name of the PO and is assigned to one of the categories. The disclosure shall include a short description of the nature of the support/service provided (as clear and comprehensible as possible without revealing confidential information).

Plusultra pharma is committed to disclose ToVs individually wherever possible. If a ToV cannot be disclosed on an individual basis for legal reasons (data protection, see Section 2.3) or the ToV relates to Research and Development an aggregate disclosure is made.

2.2.2 Aggregate disclosure

Whenever the individual Recipient cannot be disclosed for legal reasons or ToVs that relate to Research and Development, such ToVs are disclosed on an aggregate basis.

The name and address of the Recipient is withheld. Plusultra pharma reports aggregate disclosures separately and identifies for each category:

- the number of Recipients concerned by aggregate disclosure on an absolute basis and as percentage of all Recipients and
- the entire amount attributable to ToVs to these Recipients.

2.2.3 Disclosure of ToVs directly / indirectly benefiting Recipients

ToVs are only disclosed once. In general, a ToV made to one Recipient (e.g. HCO) that also indirectly benefits another person/entity (e.g. HCP) is disclosed as ToV to Recipient (HCO) at the first level.

However, if Plusultra pharma provides benefits through intermediaries (e.g. PCO) to specific HCPs/HCOs/POs, ToVs are disclosed on the subcontracted HCP/HCO/PO level wherever possible.

2.3 Data protection and consent

The collection, processing and disclosing of personal data is subject to data protection and the applicable data protection laws and regulations (generally, throughout the European Union the General Data Protection Regulation GDPR and the local laws in the UK).

The following rules apply to the disclosure of ToVs to specified Recipients without prejudice to our Data Protection Policy the European Union and UK and subject to stricter data protection rules established by applicable local legislation, where the Recipient is situated:

- In principle, the voluntary disclosure of ToVs including personal data of a natural person (e.g. name and address of a HCP) depends on his/her prior consent. Individual disclosure of ToVs is only carried out with consent of the concerned HCP. The requirements for valid consent are high. Consent must be voluntary, informed, unambiguous and specific. In a contract requiring consent to data processing and disclosure this section must be highlighted and stated in clear and transparent language to constitute a valid declaration of consent.

- The voluntary disclosure of ToVs including personal data of a legal person/entity generally does not depend on its consent. Exceptionally, Plusultra pharma requests consent from legal persons/entities (i) if an individual is contracted or (ii) if the legal person/entity consists of less than six individuals, easily allowing an identification of or allocation of data to each individual and thus establishing a personal reference.

To allow for individual disclosure of ToVs, Plusultra pharma requests and accurately documents consent from Recipients prior to providing benefits. If consent is not given, is not sufficiently documented and secured or is withdrawn, ToVs for that Recipient are disclosed on an aggregate basis. The Disclosure Report will be updated in the event of a withdrawal of an informed consent.

2.4 Cross Border Reporting

The Disclosure Report covers ToVs made to HCPs, HCOs and POs who primarily practice in Europe and the UK. Generally, these ToVs are made either by Plusultra pharma GmbH or the UK subsidiary Plusultra pharma UK Ltd..

Besides, the responsible Plusultra pharma subsidiary will make its best effort to document and disclose ToVs made by non-European Plusultra pharma companies, i.e. Nobelpharma Co., Ltd. Japan, Nobepharma America, LLC. and Jiangsu Nobelpharma Co., Ltd, to HCPs, HCOs and POs who practice in Europe.

3. CATEGORIES OF TOVS

3.1 Overview and Examples

The following table explains the categories used in the annual Disclosure Report.

If not indicated otherwise, each (sub)category may relate to HCPs, HCOs and POs. The material requirements of the individual interactions with HCPs, HCOs as well as POs are specified in the Anti-Bribery and Corruption Policy.

CATEGORY[1]	SUBCATEGORY	EXAMPLE
Donations and Grants (to HCOs/POs)	/	▪ Charitable contributions (monetary or in-kind) ▪ Educational grants (e.g. courses performed by a HCO where Plusultra pharma does not choose the participating HCPs individually)

[1] The categories follow the EFPIA-Guideline.

CATEGORY[1]	SUBCATEGORY	EXAMPLE
Contribution to costs related to Events	Sponsorship agreements (with HCOs/POs or with third parties (e.g. PCOs) managing an event appointed by HCOs)	▪ Compensation in exchange for advertising space (e.g. brand logo in invitation or program, banner at congress premises etc.) ▪ Compensation in exchange for a display booth at a congress ▪ Sponsoring training courses of a HCO
	Registration Fees	▪ Fees for registration of HCP/HCO/PO attending an Event (e.g. congress)
	Travel and Accommodation	▪ Train, flight, taxi, public transport or parking ▪ Hotel expenses
Fees for service	Fees	▪ Speaker engagement ▪ General consulting services ▪ Services related to congresses organized by third parties ▪ Data analysis services ▪ Medical writing (unless related to Research and Development) ▪ Developing educational / information materials
	Related Expenses (as agreed in the contract)	▪ Train, flight, taxi, public transport or parking ▪ Hotel expenses
Research and Development by mother company Nobelpharma	/	▪ Clinical and research collaboration ▪ Clinical trials, clinical investigations

CATEGORY[1]	SUBCATEGORY	EXAMPLE
Co. Ltd.		▪ Non-interventional studies ▪ Committees on data monitoring in relation to studies ▪ Investigator initiated trials, investigator sponsored trials

3.2 Details on the recognition methodology

In this Section, further details are provided regarding the recognition methodology for each relevant category and subcategory of any ToV.

3.2.1 ToV related to Donations and Grants

Grants to a hospital/university department or teaching institution are disclosed in the name of the legal entity that is the Recipient of the ToV (e.g. the hospital, university or an independent department within these HCOs).

ToVs to a charitable organization falling under the definition of a HCO/PO are disclosed in the category "Donations and Grants" in the name of the benefitting HCO/PO wherever possible.

Charitable donations in kind (e.g. product donations) to HCOs/POs as humanitarian aid are also disclosed under the category "Donations and Grants" indicating the net market value of such donation in kind.

ToVs made to a PO are disclosed in the category "Donations and Grants" in the name of the benefitting PO wherever possible.

3.2.2 ToV related to Events

ToVs related to Events are allocated into one of the subcategories "Sponsorship agreements", "Registration Fees" and "Travel and Accommodation" and disclosed therein in the name of the Recipient, as far as possible.

(a) Sponsorship agreements

Sponsorship agreements are written contracts which describe the purpose of the sponsorship, the counter performance and the related (direct/indirect) ToV.

A general rule, if a sponsorship made to an HCO indirectly benefits individual HCPs, the sponsorship is nevertheless disclosed in the subcategory

“Sponsorship agreements” as ToV to the HCO as the relevant Recipient (see also Section 2.2.3). This applies, e.g. to ToVs related to intermediaries selecting the speaker or to HCPs attending an Event as well as to all ToVs related to advertising opportunities, satellite symposia at congresses, courses provided by HCOs.

The following exceptional case are to be considered:

- If Plusultra pharma can decide that the HCO shall use a particular part of the agreed sponsoring amount to invite or engage one or more HCPs selected by Plusultra pharma, the ToV is split: the specific part allocated to each HCP is disclosed in the appropriate subcategory with the name of the HCP.

- ToVs made through a third party (e.g. a PCO) are reported in the subcategory “Sponsorship agreements” or in the category “Fees for service” depending on the nature of the spend and are disclosed in the name of the benefitting Recipient (HCO/PO).

(b) Registration Fees

ToVs related to fees for the registration of a HCP/HCO/PO attending an Event are disclosed in the subcategory “Registration Fees” on an individual basis in the name of the benefitting HCP/HCO/PO, as far as possible.

This applies whenever Plusultra pharma bears the Registration Fees for Events organized by third parties as well as in the event Plusultra pharma waives the Registration Fee for the benefitting HCP/HCO/PO for an Event which has been organized by or on behalf of Plusultra pharma.

Costs incurred by Plusultra pharma in connection with the organization of its own training events for HCPs are not allocated to the individual participants (e.g. the costs of renting premises). Exceptions to this are Travel and Accommodation costs that are directly attributable to the participating HCP. These are recorded and disclosed as "Travel and Accommodation” to Events.

(c) Travel and Accommodation

Plusultra pharma discloses ToVs attributable to Travel and Accommodation related to Events on an individual basis in the subcategory “Travel and Accommodation” in the name of the benefitting HCP/HCO/PO.

In principle, the ToVs are disclosed to the Recipient at the first level (see Section 2.2.3). If ToVs are made through a HCO or third party on behalf of

Plusultra pharma to or for the benefit of the travelling Recipient, they are disclosed on an individual basis in the name of the travelling Recipient.

Travel and Accommodation costs for a group of Recipients (e.g. transportation of a group by bus) which cannot be allocated to an individual HCP or HCO are not disclosed.

3.2.3 ToV related to Fees for service

ToVs related to Fees for service are laid down in a written contract that specifies the purpose of the ToV.

Plusultra pharma allocates ToVs related to Fees for service into one of the subcategories “Fees” and “Related Expenses”. In principle, the ToVs are disclosed in the applicable subcategory on an individual basis in the name of the Recipient.

For multi-year contracts, please also see Section 4.1.

(a) Fees

Fees that Plusultra pharma pays a contract partner in exchange for his/her services are disclosed as ToVs in the subcategory “Fees”.

This category includes fees for services rendered by HCPs, such as speaker services, medical consulting services and participation in advisory board meetings (unless they fall under "Research and Development").

Expenses for meals and beverages in connection with such activities are generally not recognized and disclosed (see also Section 2.1). If, in individual cases, these costs cannot be separated from the expenses for service and consulting fees (or for Research and Development), they are included and disclosed under the respective category.

(b) Related Expenses

The subcategory “Related Expenses” covers costs borne by Plusultra pharma as contractually agreed and which relate to services of the contract partner (see specified activities under (a) subcategory “Fees”) but which are not part of the actual fee, e.g. costs for necessary Travel and Accommodation. These costs are disclosed as ToVs in the subcategory “Related Expenses” with the name of the Recipient.

In case such costs could not be precisely distinguished from the fees, such ToVs are disclosed as part of the total amount of fees under the category “Fees for service”, wherever possible in the name of the Recipient.

3.2.4 ToV related to Research and Development

Plusultra pharma itself does not have research and development but discloses ToVs related to Research and Development activities by its mother company Nobelpharma Co. Ltd. in EU under the category “Research and Development” on an aggregate basis.

Activities under the definition of Research and Development may relate to

- the planning and conduct of clinical trials,
- clinical investigations etc. or related to post marketing trials and
- investigator meetings (in which case the total amount of ToVs is disclosed).

ToV in relation to IIS: ToVs related to investigator initiated and investigator sponsored (IIS) clinical or non-interventional study are generally reported in the category “Research and Development” (aggregated). In such IIS, Nobelpharma is not the initiator (sponsor) but provides financial support and/or products. If the IIS does not fall under the definition of "Research and Development" (especially if it is a non-interventional retrospective study), it is reported as an individual ToV to the respective Recipient (HCP or HCO).

ToV in relation to consultancy services: ToVs related to consultancy services which fall under the definition of Research and Development are reported in the category “Research and Development”, e.g. consultancy or advisory board activities related to the planning/conducting of clinical trials/investigations etc., ethics/steering/ committees, scientific meetings or speaker programs.

ToVs in relation to CROs: Services to a contract research organization (CRO) are disclosed on an aggregated basis under "Research and Development". When a contract research organization provides monetary benefits to HCPs or HCOs on behalf of Nobelpharma Co. Ltd. (e.g. fees to third-party physicians), these monetary benefits are recorded and disclosed with the ultimate Recipient of the benefit, if known to Plusultra pharma and Nobelpharma Co. Ltd.

The category "Research and Development" does not include:

- Services related to epidemiological studies based on external databases and registries.
- Services related to retrospective non-interventional studies.
- Services for activities not covered by the Research and Development definition.

Such services not counted as Research and Development are published under the other categories.

4. SCOPE OF DISCLOSURE

The Disclosure Report covers ToVs with a reporting date falling within the relevant Reporting Period. The first Reporting Period is 2022.

4.1 Reporting Date of ToVs

For assigning the correct reporting date the ToVs must be separated into Monetary ToVs and Non-Monetary ToVs:

- A Monetary ToV consists of a payment made by Plusultra pharma to the Recipient directly or through an intermediary (e.g. Fees for service). The Reporting Date is the day of the actual payment.

- A Non-Monetary ToV is a benefit other than a (monetary) payment provided by Plusultra pharma directly or through an intermediary (e.g. paying travel expenses directly to the travel agent) to a Recipient. The Reporting Date for these ToVs is when the event (e.g. travel or congress) took place.

ToVs under multi-year contracts are also recognized accordingly with the date of the individual payment.

4.2 Currency

ToVs are disclosed in Euros or Pound sterling. If a ToV was not made in Euro or Pound sterling, it is converted into Euro or Pound sterling according to the average value of the exchange rate applicable at the time of the transaction.

4.3 Value added tax

The ToVs are disclosed with net amounts only. In the event VAT cannot accurately be excluded, the gross ToV amount is disclosed.

5. PUBLICATION

Plusultra pharma will collect and report ToVs to HCPs, HCOs and POs for each calendar year. The Disclosure Reports are published annually by the end of June for the preceding year.

- Disclosure Reports of Plusultra Pharma GmbH will be made available on the website https://plusultra-pharma.de.

- Disclosure Reports of Plusultra Pharma UK Ltd. are available on the ABPI Disclosure UK website.

The Disclosure Reports are based on the standardized Disclosure Report Template attached in the Appendix.

Each Disclosure Report remains accessible for a minimum of 3 years after its first disclosure unless a shorter period is required under national legislation (e.g. because the legal basis for disclosure no longer applies).

Corrections and republication of the Disclosure Report are carried out as needed on a case-by-case basis.

The Disclosure Reports are published in English.

APPENDIX

I. DEFINITIONS

Term	Definition
Donations and Grants	The support of healthcare, scientific research, education or development by providing funding, services or assets for free without obligation on the Recipient for services in exchange to the benefit of the donor.
Events	Any professional, scientific, promotional or educational conference, congress or meeting and similar events (e.g. visiting facilities for manufacturing or research) that is organized or sponsored by Plusultra pharma.
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 POs) 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)	A natural person whose primary practice, principal professional address or place of incorporation is in Europe and (i) who is a member of the medical, dental, pharmacy or nursing profession or (ii) who can purchase, supply, prescribe, recommend or administer a medicinal product or medical device during professional activities. This includes (i) officials or employees of a government, agency or other organization (public or private) who can purchase, supply, prescribe, recommend or administer medicinal products or medical devices and (ii) employees of Plusultra pharma whose primary occupation is that of a practicing HCP, but excludes all other employees of Plusultra pharma, a wholesaler or distributor of medicinal products or medical devices.
Patient Organization (PO)	A voluntary, non-profit organization of patients and/or their families, whose activities involve group support in coping with diseases, disseminating information about diseases and therapy options, lobbying in healthcare and social policy, publishing of media to inform and support patients and/or providing advisory services.
Professional Conference Organizer (PCO)	A company that specializes in the organization and management of events such as congresses, seminars, conferences etc.
Promotion	Any activity performed, sponsored or organized by Plusultra pharma (or with its approval) that supports and promotes the sale, supply,

	prescription, recommendation, administration or consumption of its medicinal products or medical devices.
Recipient	The economic beneficiary HCP, HCO or PO whose primary practice, principal professional address or place of incorporation is in Europe.
Reporting Period	The disclosure cycle covers a full calendar year.
Research and Development:	In the context of medicinal products the planning or conducting of (i) clinical trials (definition in Regulation (EU) Nr. 536/2014), (ii) non-clinical studies (definition as in OECD Principles of Good Laboratory Practice), (iii) non-interventional studies (definition in Directive 2001/20/EC) which are prospective in nature and involve the collection of patient data by or on behalf of HCPs (individually or as a group) specifically for the study. In the context of medical devices the planning or conducting of clinical investigations (definition in Regulation (EU) 2017/745).
Transfer of Value (ToV):	A direct or indirect transfer of some form of value or benefit by Plusultra pharma in favor of a natural or legal person/entity whether in cash, or in kind or otherwise for Promotion or other purposes in relation with the development and sale of medical devices and prescription-only medicinal products, each exclusively for human use. • A <u>direct</u> ToV is carried out directly by Plusultra pharma itself for the benefit of the Recipient. • An <u>indirect</u> ToV is carried out on behalf of Plusultra pharma for the benefit of the Recipient or is made through a third party (e.g. a PCO) and Plusultra pharma knows or can identify the Recipient.

II. STANDARDIZED DISCLOSURE REPORT TEMPLATE

2021 EFPIA DISCLOSURE (inc. Vaccines Europe)												
Date of publication:												
	Full Name	**HCPs:** City of Principal Practice **HCOs:** city where registered	Country of Principal Practice	Principal Practice Address	Unique country identifier *OPTIONAL*	Donations and Grants to HCOs and POs	Contribution to costs of Events			Fee for service and consultancy		
							Sponsorship agreements with HCOs POs / third parties appointed by HCOs to manage an Event	Registration Fees	Travel & Accommodation	Fees	Related expenses agreed in the fee for service or consultancy contract, including travel & accommodation relevant to the contract	
HCPs	***INDIVIDUAL NAMED DISCLOSURE - one line per HCP (i.e. all transfers of value during a year for an individual HCP will be summed up; itemization should be available for the individual Recipient or public authorities' consultation only, as***											
						N/A	N/A					
						N/A	N/A					
						N/A	N/A					
						N/A	N/A					
						N/A	N/A					
						N/A	N/A					
	OTHER, NOT INCLUDED ABOVE - where information cannot be disclosed on an individual basis for legal reasons											
	Aggregate amount attributable to transfers of value to such Recipients					N/A	N/A					
	Number of Recipients in aggregate disclosure					N/A	N/A					
	% of the number of Recipients included in the aggregate disclosure in the total number, by category, of Recipients disclosed					N/A	N/A					
HCOs	***INDIVIDUAL NAMED DISCLOSURE - one line per HCO (i.e. all transfers of value during a year for an individual HCO will be summed up; itemization should be available for the individual Recipient or public authorities' consultation only, as appropriate)***											
	OTHER, NOT INCLUDED ABOVE - where information cannot be disclosed on an individual basis for legal reasons											
	Aggregate amount attributable to transfers of value to such Recipients					N/A	N/A					
	Number of Recipients in aggregate disclosure					N/A	N/A					
	% of the number of Recipients included in the aggregate disclosure in the total number, by category, of Recipients disclosed					N/A	N/A					
	Name	**Description of the transfer of value**										
POs	***INDIVIDUAL NAMED DISCLOSURE - one line per PO (i.e. all transfers of value during a year for an individual PO will be summed up; itemization should be available for the individual Recipient or public authorities' consultation only, as appropriate)***											
	OTHER, NOT INCLUDED ABOVE - where information cannot be disclosed on an individual basis for legal reasons											
	Aggregate amount attributable to transfers of value to such Recipients					N/A	N/A					
	Number of Recipients in aggregate disclosure					N/A	N/A					
	% of the number of Recipients included in the aggregate disclosure in the total number, by category, of Recipients disclosed					N/A	N/A					
	AGGREGATE DISCLOSURE											
	Transfers of Value re Research & Development as defined											N/A