

Methodology Statement - Organon Luxembourg

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1. Introduction

This Methodology note summarizes the methodology used in preparing Organon's disclosure according to the EFPIA Disclosure Code and identifying transfers of value, made directly or indirectly to or for the benefit of a Recipient.

2. Definitions

Recipients

Any HCP or HCO, whose primary practice, principal professional address or place of incorporation is in Luxembourg.

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 EFPIA 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.

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.

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For the avoidance of doubt, the definition of HCP 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.

Kind of ToVs

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 prescription-only Medicinal Products exclusively for human use.

- Direct ToVs

Transfers of value made directly by Organon for the benefit of a Recipient.

- Indirect ToVs

Transfers of value made on behalf of Organon for the benefit of a Recipient, or transfers of value made through an intermediate and where Organon knows or can identify the HCP/HCO that will benefit from the Transfer of Value.

- Aggregate ToVs

For Transfers of Values, which cannot be disclosed on an individual basis for legal reasons, the amounts attributable to such ToVs will be disclosed on an aggregate basis. The aggregate disclosure identifies (i) the number of Recipients covered by such disclosure, and (ii) the aggregate amount attributable to Transfers of Value to such Recipients.

- 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)
- (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 15.01 of the HCP Code)

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3. Disclosure's scope

Products concerned

Prescription-only medicine.

Excluded transfers of value

- a. solely related to over-the-counter medicines (except in some countries in which over-the-counter-medicines are required to be included in the disclosure);
- b. provision of materials and objects of informative or educational character;
- c. meals and drinks);
- d. samples;
- e. fees charged by logistics agencies assisting in organizing travels and meetings;
- f. discounts, price reductions and other trading devices commonly used in the sale of medicinal products;
- g. related to anonymous marketing research

Transfer of value date

- a. Date of Transfer of Value is the date of the effective payment to the recipient.
- b. If the payment is executed at several different dates (e.g. for one and the same assignment fees are paid at another date than travel costs) the date of the largest amount of payment effected is taken as payment date.
- c. In case of sponsorship of HCP/HCO to attend medical/scientific meetings/events managed by third party incl. payment by third party, the event date is taken as transfer of value date if the effective payment date of registration fees to event organizer, accommodation costs to hotels etc. significantly differ from the transfer of value date (= receipt of the congress batch, date of accommodation etc.) of the recipient.

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Direct transfer of value

- a. Transfers of value are represented as the cost amount for Organon and not the recipient's revenue.
- b. Non-financial transfers of value are disclosed based on the financial valuation of the non-financial spend (goods / service time spend etc.).

Indirect transfer of value

- a. Transfers of value provided to HCOs by a third party company, e.g. through an organizer of medical events are reported with the HCO as recipient.
- b. Transfers of value to individual HCPs executed by a third party company are reported with the individual HCP as recipient.
- c. Transfers of value to individual HCPs (e.g. invitations, covering travel or accommodation costs) executed by a HCO are reported as transfer of value to the HCO.

Transfer of value in case of partial attendances or cancellation

- a. In case of partial attendance or cancellation, or services not delivered, but value was transferred anyway e.g. according to contract clause, the transferred value is disclosed.
- b. If no value was transferred, the information on the transfer of value is not part of disclosure.

Cross-border activities

- a. Cases of cross-border transfers of value to HCPs/HCOs, falling in the scope of the Transparency Code, are disclosed in accordance with the recipient's country of practice (HCP) or country of registration (HCO).
- b. If one HCP/HCO has several countries of practices / registration the country in which context the assignment took place discloses the transfers of value.

Disclosure Type

a. Disclosure of individual data:

- If the signed consent declaration, with disclosure explicitly consented in a given validity period, is obtained the individual data and transfer of value in the reporting period are disclosed as required by the Efpia disclosure template.

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- If in the closed contract, the disclosure consent has been explicitly granted by signature, and consent has not been denied (non-consented) or withdrawn in at least one assignment by signature the individual data and transfer of value in the reporting period are disclosed as required by the Efpia disclosure template. This is applied for countries with individual consent declaration required by local law or codices.

b. Disclosure of aggregated data:

- Signed consent declarations with disclosure explicitly non-consented in the given validity period lead to disclosure of aggregated data of transfer of value in the reporting period as required by the Efpia disclosure template.

- Transfers of value to recipients from which consent declaration could not be obtained are disclosed on an aggregated basis.

- If in any (at least one) contract closed, with transfer of value in the reporting period, the disclosure consent has explicitly not been granted by signature all transfers of value in the reporting period to the recipient are disclosed on an aggregated basis as required by the Efpia disclosure template. This is applied for countries with individual consent declaration required by local law or codices.

4. Specific considerations

Country unique identifier

As guidance on the professional code in the EFPIA country, the unique identifiers include

- the Full Name
- for a HCP: the City of Principle Practice
- for a HCO: the City where Registered
- the Country of Principal Practice
- the physical address of the Principal Practice, and
- where applicable: the Unique Country Local Identifier (e.g. a professional code).

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Whether such full details can be publically disclosed depends on local applicable personal data protection laws and regulations

Self-incorporated HCP

A self-incorporate HCP constitutes a HCO (see above section 'Definition of HCO')

Multiannual agreements and transfers of value in different calendar years

In case of multiannual agreements or other agreements based on which the transfers of value are provided in different calendar years, the information is included in the report about those which were effectively paid to the recipient in a given calendar year / reporting period.

Methodology for R&D spend documentation

Research and Development Transfers of Value will be disclosed in aggregate.

In scope are ToV to HCPs/HCOs related to the planning and conduct of:

- a. Non-clinical studies (as defined in the OECD Principles of GLP)
- b. Clinical trials (as defined in Directive 2001/20/EC)
- c. 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 (cfr Section 15.02 of the EFPIA HCP Code)

Non-interventional studies that are retrospective in nature will be disclosed under the individual HCO spend category.

The determination of R+D spend according to EFPIA regulations is based on Organon Healthcare's regular internal expense reporting and allocations.

5. Consent management

Consent collection

- a. The process of obtaining consent will usually be managed through a clause in the contract between the healthcare professional and Organon.

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b. Disclosure consent declaration is obtained with each assignment according as to the local law or codices in the country of practice / registration of the recipient.

Management of recipient consent withdrawal

- a. If the consent to disclose individual data and transfer of value is withdrawn the individual data will be removed from the disclosed form within a period of 14 days after submitting written withdrawal.
- b. Consent may not be partially withdrawn or granted for selected assignments. Withdrawal of a disclosure consent for selected assignments leads to revocation of disclosing any individual data in the reporting period.

Management of recipient's request

Requests and/or complaints by Recipients shall be lodged with the local Organon Legal Entity and Organon contact person as stated in the contract.

Partial consent

No partial consent is granted. The Recipient only may give full consent to any aspect of disclosure or may decline consent in full.

6. Disclosure Form

Date of Publication

Disclosure will be made within six months after the end of the reporting period. The exact date of publication for Luxembourg this is June 30st.

Disclosure platform

Disclosure reports are published on the Company's own website. And will be disclosed in english, using the EFPIA disclosure template.

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7. Disclosure of financial data and calculation rules

Currency (local or if not, specify the exchange rate)

- Total value of the transfers of value is disclosed in local currency after conversion from foreign currencies per the exchange rates adopted on the day of documenting the effective payments in the electronic system.
- Reference point of conversion is EUR.
- Basis of the calculation of transfer rates is the company-internal exchange rate table which is updated monthly.

VAT included or excluded

Transfers of value are disclosed with VAT excluded, with the exempt for travel, accommodation, and registration amounts, which will be reported including VAT.

Calculation rules

- Transfers of value effected in the reporting period are summed up (for individuals or aggregated) according to the segmentation of the Efpia disclosure template requirements.
- Only amounts of payments effected within the given calendar year (= reporting period) are considered with the calculation (see also note re ToV date and ToV in different calendar years).
- Calculation is executed with amounts of harmonized (same) currency (see also note to Currency).

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8. Approval Information

Prepared / Reviewed / Approved	Signature
Business Practices Manager, prepared Marian van de Burgt	
Legal & Compliance Director, approver Arber Gjunksi	
Finance Lead, approver Isabel Vandenberk	
Managing Director, approver Petra Willems	

Organon Luxembourg Disclosure Report													
Date of publication: 31/05/2023													
	Full Name	HCPs: City of Principal Practice HCOs: city where registered	Country of Principal Practice	Principal Practice Address	Unique country identifier <i>OPTIONAL</i>	Donations and Grants to HCOs and POs	Contribution to costs of Events			Fee for service and consultancy		Total	
							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		
<i>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 appropriate)</i>													
HCPs	Villemont, Patrice	Differdange	Luxembourg	Rue Theis 12						300		300	
	Bill, Stéphanie	Esch-sur-Alzette	Luxembourg	Rue Emile Mayrisch 75				129	315			444	
	Bonmariage, Martine	Lintgen	Luxembourg	Rue de Diekirch 8A				129	315			444	
	Delvigne, Serge	Bertrange	Luxembourg	Beim Schlass 3				129	315			444	
	Girs, Noella	Bavigne	Luxembourg	Bockslay 4				129	315			444	
	Gruber, Alain	Larochette	Luxembourg	Rue de Medernach 16				129	315			444	
	Kalengayi, Serge	Dudelange	Luxembourg	Av. Grande-duchesse Charlotte 94				129	315			444	
	Labranche, Virginie	Lintgen	Luxembourg	Rue de Diekirch 8A				129	315			444	
	Loor, Michel	Bavigne	Luxembourg	Bockslay 4				129	315			444	
	Matos, Pedro	Luxembourg	Luxembourg	Rue Glesener 19				129	315			444	
	Rischette, René	Larochette	Luxembourg	Rue de Medernach 16				129	315			444	
	Soares Marques, Ana	Remich	Luxembourg	Rue Enz 1				129	315			444	
	Waldbillig, Marc	Dudelange	Luxembourg	Rue de la Libération 48A				129	315			444	
	<i>OTHER, NOT INCLUDED ABOVE - where information cannot be disclosed on an individual basis for legal reasons</i>												
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						
<i>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)</i>													
HCOs	SOCIÉTÉ LUXEMBOURGEOISE DE CARDIOLOGIE ASBL									3500		3500	
	<i>OTHER, NOT INCLUDED ABOVE - where information cannot be disclosed on an individual basis for legal reasons</i>												
	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						
<i>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)</i>													
POs	Name						Description of the transfer of value						
	<i>OTHER, NOT INCLUDED ABOVE - where information cannot be disclosed on an individual basis for legal reasons</i>												
	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		