

Disclosure Methodological Note for *Amicus Pharma d.o.o.e.l.*

	Approach
Background	Interactions between pharmaceutical companies and healthcare professionals and health care organizations are indispensable for the exchange of knowledge and the improvement of patient care. Amicus Pharma d.o.o.e.l. is fully committed to ensuring that these interactions meet the high standards of integrity and transparency expected by patients, governments, society and other stakeholders. Amicus Pharma d.o.o.e.l. as Responsible Citizen and committed organization in the Healthcare Sector is publishing a Transfers of Value report in order to meet transparency obligation and to demonstrate the Company's values.
Applicable Code	Amicus Pharma d.o.o.e.l. complies with the obligation to identify, collate and disclose transfers of value to healthcare professionals and health care organizations in accordance with Pharmabrend Nova Code of Conduct promotion of prescription drugs and communication with healthcare workers, Farmabrend Nova, Асоцијација на претставниците на странски производители на иновативни лекови (Association of foreign Innovative Pharmaceuticals Manufactures in Macedonia) Macedonian version: Microsoft Word - Kodeks Farmabrend Nova_HCP ДоѢДl.лект.16.5.2019 (fbn.mk) Кодекс за објавување на преноси на вредности
Transfers of Value	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 transfers of value are those made directly by Amicus Pharma d.o.o.e.l. for the benefit of a Recipient. Indirect transfers of value are those made on behalf of Amicus Pharma d.o.o.e.l. for the benefit of a Recipient, or those made through a Third Party and where Amicus Pharma d.o.o.e.l. knows or can identify the Recipient that will benefit from the Transfer of Value.
Recipient of Transfer of Value	Healthcare organization means any legal person/entity(ies) that is a health, medical or scientific association or organization (regardless of legal or organizational form) such as a hospital, clinic, foundation, university or other educational institution, or a scientific society whose business address, place of establishment or primary place of business is in Europe, or (ii) through which one or more HCPs provide services. Patient Organizations are not considered as Healthcare Organizations. Healthcare professional means any natural person who is a member of the medical, dental, pharmaceutical or nursing/technician professions or any other person who, in the course of his or her professional activities, may prescribe, purchase, supply, recommend or administer the Medicines and whose primary practice, main professional address or place of establishment is in Europe. The term "healthcare professional" also covers: (i) Any official or employee of a government, government agency or other organization (whether in the public or private sector) who may prescribe, purchase, supply, recommend or administer Medicines; and (ii) any employee of a Member Company whose primary occupation is an HCP, but excludes (x) all other employees of the member company and (y) wholesalers or distributors of Medicines

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. - 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.
Disclosure of aggregated data:	For Transfers of Values, which cannot be disclosed on an individual basis for legal reasons or because of shared cost allocation, 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. - Signed consent declarations with disclosure explicitly non-consented in the given validity period led 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.
Recipient's home country principle	Transfers of Value report includes not only Transfers of Value made to Recipients by Amicus Pharma d.o.o.e.l., but also Transfers of Value made to Recipients by foreign Swixx Biopharma affiliates.
Cross-border activities	Cases of cross-border transfers of value to HCPs/HCOs, falling in the scope of the EFPIA Code, are disclosed in accordance with the recipient's country of practice (HCP) or country of registration (HCO). If one HCP/HCO has several countries of practices / registration the country in which context the assignment took place discloses the transfers of value.
Self-incorporated HCP	If the contracting party is a company owned by an HCP, the amount is disclosed as Transfer of Value to the HCO (the company).
Excluded Transfers of Value	Without limitation, Transfers of Value that (i) are solely related to over-the-counter medicines; (ii) items of medical utility, meals, medical samples; or (iii) are part of ordinary course purchases and sales of Medicinal Products by and between Amicus Pharma d.o.o.e.l and an HCP (such as a pharmacist) or an HCO do not fall within the scope of the disclosure obligation; (iv) fees charged by logistic agencies assisting in organizing travel and meetings;
Date of Transfer of Value	• Donations and grants: ○ Monetary donation/grant: date of payment ○ In-kind donation/grant: date of the in-kind donation/grant provision • Contributions to costs of events: ○ Sponsorships agreements with HCOs: start date of event ○ Registration fees, travel, accommodation: start date of event • Fee for service and consultancy: ○ Fees: date of payment ○ Travel, accommodation: start date of event
Meals	• Meals disclosure is not required but these Transfers of Value may be included in the Travel & Accommodation amounts.
Transfer of Value in the case HCP finally does not participate at event	• In the case registration fee is paid and travel and/or accommodation is booked but the HCP does not attend an event, Transfer of Value is disclosed to that HCP in the amount of costs that Amicus Pharma d.o.o.e.l did not reimburse.

Transfer of Value provided to agency to support HCO's event	Transfer of Value is reported for that HCO even if the Transfer of Value is actually provided only to an agency which organizes an event for the HCO.
Transfer of Value provided to HCO but ultimate recipients are HCPs	Transfers of Value are reported for those HCPs if Amicus Pharma d.o.o.e.l knows or can identify HCPs that benefit from the Transfer of Value.
Multi-Year Contracts	Transfers of Value are reported on the relevant date of payment or start date of event (see above), irrespective of the duration of the contract.
Value Added Tax (VAT)	Transfers of Value are reported gross (cost + VAT) wherever possible. If a gross value is not available, then the net value is reported.
Currency Conversions	- All Transfers of Value are disclosed in local currency MKD. - If a payment is captured in another currency, it is converted into local currency by applying the exchange rate for the month that is deemed to be the Date of Transfer of Value using official exchange rate on the date when cost occurs.
Disclosure Period	- Each reporting period covers a full calendar year. - Transfers of Value are reported for all activities that take place in a given calendar year and for which an affiliate receives an invoice and makes a payment before the end of January next year.
Consent	- Amicus Pharma d.o.o.e.l collects consents for each relevant HCP/HCO interaction that should be disclosed individually by means of the contract or by means of a separate document, based on the local requirements. - Amicus Pharma d.o.o.e.l documents any consent revocation or opt-out. - If HCP's consent is not given or is withdrawn, Transfer of Value for that HCP is disclosed in aggregate and the Recipient's identity is therefore not publicly available. - If HCP revokes consent with any single Transfer of Value, all Transfers of Value provided to this HCP are included in the aggregate disclosure.
Disclosure Language	Disclosures are made in Macedonian and/or English language
Complaints or request for further information	- All complaints or requests for further information can be submitted locally to our email: northmacedonia.info@swixxbiopharma.com, which is supervised by office administrator. Office administrators then would record the report in One Trust system and additionally will ask responsible people for support (employee who is submitting the reports, lawyer and (or) compliance manager). - In case of general data protection questions or requests, the contact person – Data Protection Officer, which can be contacted by email: data@swixxbiopharma.com
Media Contact	All questions can be submitted locally to our email: northmacedonia.info@swixxbiopharma.com, which is supervised by office administrator.
Patient organizations	The methodology set out above applies also to Transfers of Value to Patient Organizations, which are published separately on www.swixxbiopharmapharm.com and available via a link on our affiliate website.