

PharmaSwiss Bulgaria EOOD

Busch Health

Methodology

For disclosure of payments and other Transfers of Value to Healthcare Professionals and Healthcare Organizations in compliance with the BGPharma requirement for disclosure of Transfers of Value

June 2020

1. General information

PharmaSwiss publishes this Transfer of Value report to comply with applicable transparency obligations according to the relevant laws and requirements.

2. Applicable code

The Transfer of Value report was prepared according to the applicable requirements of BGPharmA for disclosure of transfers of value to Healthcare Professionals and Healthcare Organizations, following the Code of Conduct on Interactions with the Healthcare Community (Medicines for Europe Code of Conduct).

3. Transfer of Value

A Transfer of Value can include everything of value that is provided (or “transferred”) by PharmaSwiss (directly or indirectly via a third party acting on PharmaSwiss direction) to a recipient, including monetary payments or material benefits, such as meals, travel, accommodation, etc.

Transfers of value from third parties acting on behalf of PharmaSwiss to recipients, in which cases PharmaSwiss is aware or informed of the identity of the recipient, are also included in this report.

- The Direct Transfer of Value is the one directly transferred from PharmaSwiss to the recipient
- The Indirect Transfer of Value is the one transferred from a third party acting on behalf of PharmaSwiss, in which cases PharmaSwiss is aware of or is able to identify the Healthcare Professional that is the recipient of the transfer of value.

4. Organization of the disclosure

Data was collected, processed and reported through a company-developed system according to organizational needs and requirements.

Transfers of value were registered directly in the system for all direct payments. Transfers of value for indirect payments were recorded outside the system and then uploaded into the system.

All financial transfers of value were reconciled with our financial system.

5. Recipients of Transfers of Value

- Healthcare Professional (HCP) is any individual who is a doctor, a member of medical, dental, pharmaceutical or nursing profession, or any other person who, in the course of his or her professional activities, may prescribe, purchase, supply, recommend or administer a medicinal product.

For avoidance of doubt, the definition of Healthcare Professional includes:

- (1) any official or employee of a government agency or other organization (whether in the public or private sector) that may prescribe, dispense, purchase or administer medicinal products, and
- (2) any employee of a pharmaceutical company whose primary occupation is that of a practicing Healthcare Professional,

But excludes

- (a) all other employees of a pharmaceutical company, and
- (b) a wholesaler or distributor of medicinal products.

- Healthcare Organization (HCO) is any entity,
 - (1) 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 scientific society, or
 - (2) through which one or more Healthcare Professionals provide healthcare services.

For the avoidance of doubt, wholesalers, distributors, and similar commercial intermediaries are not considered HCOs.

6. Scope of the Transfer of Value report

- Fee for Service and Consultancy

The expert advice and support by HCPs and HCOs are important to help PharmaSwiss in making decisions and taking actions that benefit the patients and Healthcare Communities.

PharmaSwiss may engage HCPs and HCOs to provide the necessary services, such as lecturing or providing expertise, product training and knowledge.

- Meetings and Hospitality

Meetings between PharmaSwiss and HCPs and HCOs facilitate the beneficial and important interactions amongst them. Meetings may be held for educational, scientific or research purposes, and for promotional purposes as well. Reasonable hospitality may be provided in connection with such meetings.

Depending on the nature of the meeting, hospitality may include hotel accommodation, meals and drinks, and must always be necessary, reasonable, and secondary to the main purpose of the meeting. Stand-alone hospitality or entertainment, not connected to any work-related meeting, is prohibited.

- Educational Support for HCPs

PharmaSwiss may support scientific, medical, pharmaceutical and professional education in the communities it serves. By inviting and funding HCPs to meetings and conferences, PharmaSwiss contributes to the advancement of scientific knowledge and the improvement of patient care.

PharmaSwiss may provide educational support by paying registration costs, travel and accommodation, and reasonable hospitality to individual HCPs to attend events with educational purposes in areas relevant to their professional fields. Educational support may be provided for company-organized events or for congresses and conferences organized by third parties.

- Transfer of value to a HCO when the final recipients are HCPs – such transfers of value are disclosed for each HCP, in the situation when PharmaSwiss is aware of and is able to identify the HCP that is the final recipient of such transfer of value.
- In the situation when registration fee has been paid, and travel and accommodation reservations have been made, but the HCP did not participate in the event, no disclosure is made for this particular transfer of value.

- **Sponsorship of Events**

Subject to the applicable rules and requirements, PharmaSwiss may provide financial sponsorship to third-party organizations for meetings, events or projects directed at HCPs, if the events are relevant to the company’s therapeutic areas or business interests. In recognition of this support, PharmaSwiss can receive commercial advertising opportunities, booth or exhibit space, distribution of promotional materials, company branding of banners and materials, and similar acknowledgements.

- Transfer of value to third party, which represents or acts on behalf of a HCO such transfer of value is a subject of disclosure even in the situation when the direct transfer of value is only performed to a third party, that organizes an event on behalf of a HCO.

7. Fair Market Value

If HCPs are engaged to perform a service, and if sponsorship or contributions are provided, the remuneration and payments must be at fair market value.

This is the value that would be paid as a result of the bona-fide bargaining between well-informed parties in an arm’s-length transaction for the goods or services to be provided. The value shall capture the nature and quality of the goods or services to be provided, the qualifications and experience of the goods or service provider, the geographic location where the goods or services are to be provided, the nature of the market for the goods or services to be provided, and the prevailing rates for similar goods or services.

8. Additional information regarding the methodology that was used in the preparation of the Transfer of Value report

- Direct payments – all transfers of value were registered and reconciled with the financial system of PharmaSwiss.
- Payments for meals – disclosure of payments for meals is not required, but in some occasions, such transfers of value may be included in the amount for reported travel and accommodation.
- Identification of HCPs and HCOs

For the avoidance of any doubt regarding the identity of HCP or HCO that is a recipient of a Transfer of Value, PharmaSwiss identified HCPs through their Unique Identification Number (UIN), and HCOs through Unified Identification Code (UIC).

- Currency and Exchange Rates
 - Locally provided Transfers of Value were collected and reported in Bulgarian leva (BGN).
 - In the situation when a Bulgarian HCP has received (directly or indirectly) Transfer of Value in another currency, payments were converted to Bulgarian leva based on the official exchange rate of the Bulgarian National Bank at the date the payment was executed.
- Treatment of VAT and other financial aspects - all payments, disclosed as transfers of value through direct and indirect payments are gross and/or include all applicable taxes (VAT, income tax, etc.) except for the honoraria paid to healthcare professionals, which are declared at net value.
- Other considerations
 - All payments reported as transfers of value through direct and indirect payments were disclosed as documented in the written agreement (contract) concluded between the parties.
 - Only transfers of value, related to prescription medicines were included in this report.

9. Informed consent

- **HCP**

PharmaSwiss respects the applicable data privacy laws and regulations for personal data protection, which imposes the need to obtain written informed consent from HCPs for individual disclosure of data for transfer of value that they receive from PharmaSwiss. In the situation

where such consent has not been provided or has been recalled, transfers of value to such recipients were aggregated and disclosed anonymously. PharmaSwiss did not disclose any transfers of value to HCPs who only gave their partial consent.

- **HCO**

Obtaining informed consent from HCOs for disclosure of transfers of value is not a legal requirement of the data protection law in Bulgaria.

10. Personal Data Protection

All applicable laws for personal data protection were adhered to while working with personal data that was obtained or collected from HCPs, HCOs, patients and patient organizations, or related to them.

Each disclosure of personal data is permitted and according to the applicable data protection laws.

11. Platform, Frequency and Period for disclosure

This PharmaSwiss EOOD disclosure report for 2019 was officially published in Bulgarian and English language at <http://www.pharmaswiss.bg/>.

The report will remain published for 3 years from the date of publication.

12. Contacts

Collection and disclosure of this information is controlled by PharmaSwiss EOOD, UIC 175426246, located in Sofia, zh.k. Lagera № 16 Troyanski prohod str., fl. 3 ap. 8 & 10, tel: +359 2 89 52 110, fax: +359 2 89 52 119, email: <http://www.pharmaswiss.bg/>.

If at any moment you have any questions or concerns regarding this methodological note or any other questions, please contact us at the above-mentioned contact details.