Methodology of CHIESI BULGARIA Ltd

This methodology is prepared pursuant to the provision of section 5 of EFPIA Code (EFPIA Code of Practice) and section 5 "Disclosure of transfers of value from pharmaceutical companies" of Code of Ethics of the Research-based Pharmaceutical Industry in Bulgaria (effective as of 01.04.2023) for ddisclosure of transfers of value from pharmaceutical companies to healthcare professionals (HCP), healthcare organizations (HCO) and Patient organizations (PO).

The purpose of this document is to explain and summarize the methodology used by Chiesi Bulgaria in preparing the disclosures and identifying Transfers of Value to healthcare professionals and healthcare organisations, namely:

- methodologies applied to identify both the categories of Recipients, and the transfer of value and its subsequent disclosure;
- general information and country specific considerations;
- treatment of multi-year contracts, VAT and other tax aspects;
- currency aspects and other issues related to the timing and amount of Transfers of Value.

Chiesi Bulgaria Ltd is part of Chiesi Group, in this capacity is a full member of ARPharM (Association of the Research – Based Pharmaceutical Industry in Bulgaria). Its activity is entirely subject to the principles and requirements laid down in the Code of Conduct of Chiesi Group.

Further information on this Code may be found on the company website https://www.chiesi.bg/en/sustainability/ethics-and-transparency/

In our capacity as member of EFPIA (European Federation of Pharmaceutical Industries and Associations), ARPharM respectively, we encourage the transparency of relationships between the pharmaceutical industry and the healthcare professionals and organisations in line with EFPIA rules and all national legal regulations as we are convinced that we should be independent partners with a common goal, i.e. cooperation and exchange of knowledge and research and development activities, without any intervention or influence in violation of the law.

Our main priority, as a member of EFPIA, ARPharM respectively, is to contribute to the protection and enhancement of human health and human life,

ensuring the access of Bulgarian patients to high quality, safe and effective medicinal products for the purpose of prevention, diagnosis, and treatment of diseases.

As much as the interactions between the industry and healthcare professionals can create the potential for conflict of interests, we fully share all EFPIA, respectively ARPharM criteria and requirements laid down in their codes and principles to ensure that these interactions meet the high standards of integrity that patients, governments, and all other stakeholders expect.

In relation to the above, this Methodology determines the respective types of transfers of value that must be disclosed, which of them should be excluded, along with the respective other information that will help its users to be clear about the method we use to collect, organise, and report the disclosed data.

DEFINITIONS

Company

Company for the purpose of this Code is any company, member of ARPharM, and any company manufacturing or holding a Marketing Authorisation for medicinal products in human medicine in Europe which is committed to comply with the Code of Ethics of the Research-based Pharmaceutical Industry in Bulgaria. Separate legal entities belonging to the same multinational company, whether this multinational company is the parent company, a subsidiary company or any other form of enterprise or organisation – shall be deemed to constitute a single company, and as such committed to compliance with the Code.

Recipient

Recipient is any healthcare professional or healthcare organisation or patient organization, as applicable in each case that can be clearly identified and whose main practice, principal professional address or place of registration is in Bulgaria.

Unique identifier

For HCP: Unique Identification Number (UIN): Any medical doctor practising on the territory of Republic of Bulgaria, provided he/she meets the requirements of the Health Act and is registered in the National register of the Bulgarian Medical Association, respectively in the district register of doctors, on the territory of practice.

For HCO: Unique Identification Code, BULSTAT (UIC) – unique identification code obligatory for the companies registered in the commercial register of Republic of Bulgaria.

Healthcare Professional (HCP)

A healthcare professional is any of the following: medical doctors, Doctor of Dental Medicine, pharmacists, nurses, midwives, medical laboratory technicians, paramedics, assistant pharmacists, or any other person who, in the course of his or her professional activities, may prescribe, purchase, supply, recommend or administer medicinal products and whose primary practice, principal professional address or place of registration is in Europe.

The definition of health professional includes:

1. any official or employee of a government agency or other organisation (whether in the public or private sector) that may prescribe, purchase, supply, recommend or administer medicinal products and
2. any employee of a company whose primary occupation is that of a practising healthcare professional.

This definition excludes:

1. all other employees of a specific company and
2. a wholesaler or distributor of medicinal products.

Healthcare Organisation (HCO)

A healthcare organisation is any legal person that is a healthcare, medical or scientific organisation or association (irrespective of the legal or organisational form) such as a hospital in the meaning of the Medical Treatment Facilities Act, foundation, university or other teaching institution, professional or scientific society (except for patient organisations within the scope of the EFPIA Patient Organisations (PO) Code) whose business address, place of incorporation or primary place of operation is in Europe or through which one or more HCPs provide services.

Transfers of Value (ToV)

Transfers of value are the direct and indirect transfers of value, whether in cash, in kind or otherwise, made for promotional purposes or otherwise, in connection with the development (research and development activity) and sale of prescription-only medicinal products for human use. Direct transfers of value are those made directly by a Company for the benefit of a Recipient. Indirect transfers of value are those made on behalf of a Company for the benefit of a Recipient, or those made through a Third Party and where the Company knows or can identify the Recipient that will benefit from the Transfer of value.

Research and Development Transfers of Value

Research and development transfers of value are transfers of value to HCPs or HCOs related to the planning or conduct of:

1. Medical research studies in the meaning of the Health Act.
2. Clinical trials (as defined in in Regulation 536/2014 and in the Medicinal Products in Human Medicine Act), or
3. 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 purposes of the study.

The transfer of value for the specific calendar year is subject to disclosure in the reporting year.

Territorial applicability of disclosure

Chiesi Bulgaria shall disclose transfers of value to HCPs and HCOs whose principal operations are in Republic of Bulgaria.

Consent

According to the General Data Protection Regulation (EU) 679/2016 and the local legislation, a preliminary consent is required for personal data disclosure in transfers of value.

For this purpose, any written contract with HCP/HCO should include a provision to that effect, and an Informed Consent should be signed to use the HCP personal data, as well as a Declaration of consent for the disclosure of transfers of value.

The consent may be withdrawn at any time. In such case, if the consent is withdrawn before the transfer of value is reported, then the transfer of value for the specific

person shall be presented in the part on aggregate disclosure without providing personal data for this person.

DATA DISCLOSURE:

Individual Disclosure:

Transfers of value to an HCP shall be disclosed on an individual basis, as follows:

- Fees for service and consultancy: as (but not limited to) preparing and delivering of presentations, lectures, scientific and review articles for specialised medical journals. The Company signs a Contract for consultancy Services with the healthcare professional. The disclosure is based on the gross amount fixed into the contract. In case of any expenses separate from the fees but related to them, these shall be disclosed separately, i.e., respectively under "fees" and "Ancillary expenses for the service agreed in the consultancy contract".
- Contribution to costs related to events (congress, conference, symposium, and other scientific events) in the home country or abroad: costs related to registration fees, travel and accommodation (for events abroad) during the event. The Company makes the expenses for the healthcare professional indirectly and signs a sponsorship contract with the HCP. The costs for the specific event may cover partly or in full the expenses for the HCP attendance at the scientific event. The amount agreed in the contract is disclosed in the respective columns of the disclosure format, i.e., "registration fee" and "travel and accommodation" (includes expenses for travel and accommodation). The transfer of value is disclosed excluding VAT where applicable.
- In case of non-attendance of an HCP at an event, and ToV that can be attributed to the specific HCP, these costs are disclosed individually.

During a scientific event, Chiesi Bulgaria does not cover HCP personal expenses, sports or entertainment costs during the event, or any HCP accompanying persons expenses.

Chiesi Bulgaria does not cover HCP expenses for membership in local scientific medical or international organisations/societies.

In view of the indirect transfers of value to HCP for attendance at a scientific event, Chiesi Bulgaria complies with the requirements of the EFPIA Code, ARPharM Code, the Chiesi Group Code of Conduct, and the national regulations on business trips in the home country and abroad.

When a transfer of value is intended for an individual HCP but is made indirectly through an HCO or third parties appointed by an HCO to manage an event, such transfer of value is disclosed only once, the ToV itself being made for the HCP on individual basis in line with the above disclosure rules.

Chiesi Bulgaria does not provide donations and grants (either in cash or in kind) to HCPs.

Transfers of value to an HCO subject to individual disclosure, are set forth below:

- Fees for service and consultancy: The Company signs a Consultancy Contract with an HCO. The amount under the contract will be disclosed including/excluding VAT depending on the VAT registration of the company. In case of any expenses separate from the fees but related to them, these shall be disclosed separately, resp. under "fees" and "Ancillary expenses for the service agreed in the consultancy contract".
- Sponsorship for a scientific event in the home country – to an HCO or to third parties (appointed by an HCO to manage an event). Any sponsorship is secured/ensured by a contract between Chiesi Bulgaria and HCO or third party appointed to organize the event. Any contract decscribes the purpose of the sponsorship, the benefits to the company and related transfer of value. In case the sponsorship includes registration fees and travel and accommodation costs, and the recipient (HCP) can be identified, and the company has his/her consent, the ToV is subject to individual disclosure. In case the recipient cannot be identified, the disclosure shall be made in the name of the Health or Patient Organization

- Donations, either in cash or in kind, to HCOs: The Company concludes donation contracts and discloses transfers of value incl. VAT for the donations in kind.

Chiesi Bulgaria makes donations in cash to HCOs that support and organise an event by or under the auspices of the respective HCO.

The donations in kind provided by Chiesi Bulgaria to an HCO include medical equipment promoting the enhanced level of healthcare for the patients in the process of diagnosis and treatment by the HCPs in the HCO.

Aggregate Disclosure:

The following are subject to aggregate disclosure:

- Aggregate disclosure of research and development transfers of value (in accordance with Annex B of ARPharM Code of Ethics)
- Aggregate disclosure of transfers of value to HCPs where the consent for personal data disclosure was withdrawn
- Transfers of value which cannot be disclosed on an individual basis for legal reasons.

Disclosure of ToVs related to Events that have been cancelled

If an event is cancelled and if the ToV related to the event can be attributed to a recipient, it must be disclosed. Planned ToV for educational support to events should only be disclosed if a recipient received the benefit e.g., if event was cancelled and no ToV occurred to an individual then no disclosure is required, if an event was converted from face to face to virtual and recipient will receive ToV via virtual registration then this ToV must be disclosed.

Disclosure of registration fees for recorded events

The registration fee for an event, live and/or recorded is a ToV and must be disclosed.

Form of Disclosure

Reporting Period

Disclosures shall be made on an annual basis and each reporting period shall cover a full calendar year.

The reporting period shall be the calendar 2023 and the disclosure shall be made not later than on 30 June 2024.

Time of Disclosure

Disclosures shall be made within 6 months after the end of the relevant reporting period. For example: information on the transfers of value for the relevant year shall be disclosed not later than 30 June of the following year.

The disclosure date for transfers of value shall be the date of transfer of value by Chiesi Bulgaria Ltd; in case of transfer of value for travel and accommodation, the disclosure date refers to the starting date of the scientific event.

The information disclosed shall remain in the public domain for a minimum of 3 years after the time such information is first disclosed, unless in each case:

1. a shorter period is required under applicable Bulgarian data privacy or other laws or regulations, or

2. the relevant data protection legal basis (e.g. the Recipient's consent relating to a specific disclosure, if required by law) is revoked.

Currency

All disclosures of transfers of value are published in the local currency - BGN.

Format

For consistency purposes, disclosures will be made using a structure set forth in Annex A, reflecting the requirements of ARPharM Code of Ethics.

Platform

Disclosures shall be made on the website of the company https://www.chiesi.bg/en/.

Language of disclosure

Disclosures shall be made in Bulgarian.

Documentation and retention of records

All Transfers of value required to be disclosed shall be documented and the relevant records of the disclosures shall be maintained for a minimum of 5 years after the end of the relevant reporting period, unless the consent of the recipient for the disclosure of the transfer of value, including disclosure of their personal data, is revoked.

The contracts between the Company and the Recipient including Transfer of value subject to disclosure, contains clauses stipulating the consent of the recipient to be disclosed for transfer of value.

The contracts shall be retained in accordance with the applicable legal regulations.

Data excluded from disclosure

In compliance with EFPIA Code and ARPharM Code, Chiesi Bulgaria shall not disclose transfers of value if they refer to:

- Transfers of value relating to non-prescription medicinal products, informational and educational material, items for medical use only;

- Samples of medicinal products;
- Meals (governed by Article 10.6 in ARPharM Code of ethics)

Miscellaneous

In case of Transfers of value due under a long-term contract with an HCP or HCO, the disclosure shall be published based on the transferred value for the relevant reporting period, and not based on the entire ToV amount as per the signed contract.

In case of any shortages or deficiencies in this Methodology of Chiesi Bulgaria Ltd, the rules and regulations of ARPharM Code of Ethics of the Research-Based Pharmaceutical Industry in Bulgariais accessible on ARPharm website https://www.arpharm.org/en/consolidated-codeof-ethics, shall be applied, along with the applicable legal regulations of Republic of Bulgaria.