

## Organon LLC Methodology Statement

### **Disclosure of ToV to Healthcare Professionals, Healthcare Organizations and Patient Organizations.**

Organon LLC believes that interactions between pharmaceutical companies and Healthcare Professionals for the purpose of provision of information about new methods and ways of treatment as well as innovational medicines have a profound and positive influence on the quality of patient treatment in the world and the value of future research of medicines.

We're confident that such interactions require compliance with high ethical standards, including assurance of transparency of such interactions.

As such, being the member of the Association of International Pharmaceuticals Manufacturers (AIPM), Organon LLC committed to disclose pre-defined types of transfers of value to Healthcare Professionals, Healthcare Organizations and Patient Organizations on an annual basis.

The methodology described below identifies the main approaches used by Organon LLC in disclosing information about ToV. This information will help you to understand how data is collected, organized, and categorized for future disclosure on our website.

### **Terms and definitions**

**Events** - all promotional, scientific or professional meetings, congresses, conferences, symposia, and other similar events (including, but not limited to, advisory board meetings, visits to research or manufacturing facilities, and planning, training or investigator meetings for clinical trials and noninterventional studies) organized or sponsored by or on behalf of Organon LLC;

**Healthcare Organization (HCO)** – any legal entity (i) that is a healthcare, medical, pharmaceutical or scientific association or organization (irrespective of the legal or organizational form) such as a hospital, clinic, foundation, university or other teaching institution, patient organizations, whose business address, place of incorporation or primary place of operation is in Russia or (ii) which provides services through one or more healthcare professionals.

**Healthcare Professional (HCP)** - doctors and other medical professionals, heads of medical organizations, pharmaceutical professionals (including pharmacists), heads of pharmacy organizations, and other specialists the professional activity of which is concerned with pharmaceutical products and who in the process of their professional activity have the right to prescribe, recommend, purchase, supply, or administer pharmaceutical products.

**Patient organization** - a non-commercial organization representing the interests and needs of patients, their families, and/or persons taking care of patients and/or disabled persons.

**Recipients** – any HCO, HCP or Patient organization whose primary practice, main professional address or place of incorporation is Russia.

**Transfers of Value (ToV's)** – direct and indirect transfers of value, whether in cash, in kind or otherwise, made for the purposes allowed by the applicable legislation in connection with the development and sale of prescription-only pharmaceutical products exclusively for human use. Direct transfers of value are those made directly by Organon LLC for the benefit of a Recipient. Indirect transfers of value are those made on behalf of Organon LLC for the benefit of a Recipient, or transfers of value made through an intermediate and where Organon LLC knows or can identify the healthcare professional/healthcare organization/ Patient organization that will benefit from the transfer of value.

**Research and Development TOV's** - transfers of value to healthcare professionals or healthcare organizations related to the planning or conduct of (i) pre-clinical studies; (ii) clinical trials; or (iii) post-registration observation (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.

**General information about transferred values**

**Excluded ToV's.** Without limitation, transfers of value that (i) are solely related to over-the-counter pharmaceutical products; (ii) are related to items of medical utility, meals and drinks, samples to the extent they are not restricted by applicable legislation; (iii) are part of ordinary course purchases and sales of pharmaceutical products by and between Organon LLC and HCP or HCO, as relevant, do not fall within the scope of the disclosure obligation; (iv) medical samples, investigational compounds and biological samples for study; (v) informational or educational materials and items of medical utility; (vi) meals and drinks; and (vi) group transfers, do not fall within the scope of the disclosure.

**ToV Recognition Date.** Information about ToV is based on the accruals made by Organon LLC to certain Recipients, which is reflected in the corresponding reporting periods.

**HCO ToV's.** Categories for ToV's to HCOs include contributions to costs related to Events, including sponsorship of HCP's directly or indirectly through HCO's to attend Events, such as:

- a. registration fees if a part of an inclusive package,
- b. sponsorship agreements with HCO's or with third parties appointed by an HCO to manage an Event (examples include hiring a booth or stand space, acquiring advertising space (in paper, electronic or other format), arranging a satellite symposia at a congress, sponsoring of speakers or faculty, the costs of drinks or meals provided by the HCO if part of an inclusive package, and courses provided by a HCO where Organon LLC does not select the individual HCPs that participate), and
- c. travel and accommodations if a part of an inclusive package.

**HCP ToV's.** Categories for ToV's to HCPs include:

- i) contributions to costs related to Events such as:
  - a. registration fees
  - b. travel and accommodations (such as costs of flights, trains, parking fees, taxis and hotel accommodation);
- ii) fees for service and consultancy (examples include ToV's resulting from or related to contracts between Organon LLC and HCPs under which, for example, Organon LLC pays for speakers' services, speaker training, medical writing, data analysis, development of educational materials, general consulting and advising via advisory boards/expert input forums). Fees, on the one hand, and on the other hand ToV relating to expenses agreed in the written agreement covering the activity (e.g., travel and accommodation) will be disclosed by Organon LLC as two separate amounts.

**Patient organizations ToV's.** When providing support to Patient organization, including financial support, Organon LLC explicitly discloses the fact, nature, value of its support of Patient organization on company's website.

**Aggregate Disclosure.** For ToV where certain information, which can be otherwise reasonably allocated to one of the categories (HCP, HCO or Patient organization), cannot be disclosed on an individual basis for legal reasons, Organon LLC will disclose the amounts attributable to such ToV in each reporting period on an aggregate basis. Such aggregate disclosure shall identify, for each category, (i) the number of Recipients

covered by such disclosure, on an absolute basis and as a percentage of all Recipients, and (ii) the aggregate amount attributable to ToV to such Recipients.

**Research and Development ToV.** Research and Development Transfers of Value in each Reporting period shall be disclosed by Organon LLC on an aggregate basis. Costs related to events that are clearly related to activities covered in this paragraph can be included in the aggregate amount under respective category.

**ToVs in case of partial attendances or cancellation.** ToV's are reported on the basis of what Organon LLC paid, and not what the Recipient received. In case of non- Organon LLC-initiated cancellation of a third party organized event, or if the HCPs invited to attend cancel their participation in the event at the last moment directly prior to the start of the event, the corresponding ToV is disclosed as the total actual costs incurred by Organon LLC.

**Cross-border activities.** Regardless of which Organon LLC entity contracts with and pays a Recipient, all HCOs, HCPs or Patient organizations, whose primary practice, main professional address or place of incorporation is in Russia, are reported by Organon LLC.

**Multi-year agreements.** Disclosure is made on the basis of the year the actual ToV's was provided and not on the basis of a pro rata amount of the intended total ToV under the agreement.

### **Consent management**

**Consent collection.** Data Protection legislation in Russia requires Organon LLC to obtain the consent of each Recipient to disclose their personal information. Organon LLC has made its best effort to obtain such consent so as to be as transparent as possible about the nature and scale of its interactions with HCPs, HCOs and Patient organizations. The means by which Organon LLC has obtained consent in Russia is by a separate consent in each contract covering all interactions with the HCP for an entire year / and separate consent letter for each HCO and Patient organization for unlimited period.

**Management of Recipient consent withdrawal.** A Recipient has the right to withdraw their consent at any time. If this occurs prior to Organon LLC's publication of the ToV, then the Recipient's ToV's shall be reported on an aggregate basis only with no disclosure of the Recipient's name. If consent is withdrawn by a Recipient after the publication of the relevant year's ToV's, then the Recipient's name and ToV's shall be removed and the corresponding amount to ToV's will be added to the aggregate reporting. In case of incidents, such as death of the Recipient – HCP, Organon LLC reserves the right to report all ToV's for that Recipient on the aggregated basis only.

### **Miscellaneous**

**Date of publication.** Organon LLC publishes the ToV for the preceding calendar year no later than 6 months after the end of the relevant reporting period. The information disclosed shall remain available for three (3) years thereafter, subject to individual disclosures being shifted to aggregate disclosure in the event of after-the-fact revocation of consent by the Recipient.

**Disclosure platform.** Organon LLC provides its annual disclosure via its web-site.

**Disclosure language.** Organon LLC provides its annual disclosure in Russian and English languages.

**Disclosure currency and taxes.** All disclosed ToV's are reported in local currency and exclude of VAT. Direct TOV of HCP's includes Personal Income Tax in the amount according to applicable legislation. Insurance premiums in connection with agreements concluded with HCPs are not taken into account in the disclosure of information.