Santen Oy Methodology Note

on Disclosure of Payments and other Transfers of Values to Healthcare Professionals and Healthcare Organizations following the EFPIA Code of Practice

Czech Republic / Santen Oy

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1. Introduction - Santen's Commitment to Transparency Reporting

As part of the effort to achieve greater transparency in the financial relationships between manufacturers and HCPs/HCOs, Santen is committed and responsible for the accurate and timely recording and reporting of Transfers of Value (ToV) and/or payments to HCPs and HCOs in the country of residence and registration, respectively, in accordance with applicable local laws/regulations and industry standards. We believe that transparency is essential to building and maintaining confidence in us and in our medicines and strongly support the work being done by The European Federation of Pharmaceutical Industries and Associations (EFPIA) to improve transparency across the pharmaceutical industry. This methodological note presents how the ToVs are categorized and in what format they are disclosed.

2. Definitions

2.1 Healthcare Professional (HCP)

Santen is fully aligned with and follows the EFPIA Code definition

EFPIA Code definition: 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/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. The definition of HCPs 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, recommend or administer Medicinal Products and (ii) any employee of Santen whose primary occupation is that of a practicing HCP, but excludes (x) all other employees of Santen and (y) a wholesaler or distributor of Medicinal Products.

2.2 Healthcare Organization (HCO)

Santen is fully aligned with and follows the EFPIA Code definition

EFPIA Code definition: any legal person/entity (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 POs within the scope of article 21) whose business address, place of incorporation or primary place of operation is in Europe or (ii) through which one or more HCPs provide services.

2.3 Patient Organization (PO)

Santen is fully aligned with and follows the EFPIA Code definition

EFPIA Code definition: non-for-profit legal person/entity (including the umbrella organization to which it belongs), mainly composed of patients and/or caregivers, that represents and/or supports the needs of patients and/or caregivers and which business address, place of incorporation or primary place of operation is in Europe.

2.4 Transfers of Value (ToV)

Santen is fully aligned with and follows the EFPIA Code definition

EFPIA Code definition: Direct and indirect ToV, whether in cash, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development and sale of POM exclusively for human use.

- Direct ToVs are those made directly by Santen for the benefit of a Recipient.
- Indirect ToVs are those made on behalf of Santen for the benefit of a Recipient, or those made through a Third Party and where Santen knows or can identify the Recipient that will benefit from the Transfer of Value.

2.4 Prescription-only Medicines (POM)

Santen is fully aligned with and follows the EFPIA Code definition

EFPIA Code definition: is a Medicinal Product that requires a medical prescription issued by a professional person qualified to prescribe.

2.5 Recipient

Any HCP or HCO/PO as applicable, in each case, whose primary practice, principal professional address or place of incorporation is in Europe.

3. Transfer of Value Categories according to EFPIA Code

The following defines what Transfers of Value are reported in which EFPIA category.

3.1 For ToVs to a HCO, an amount related to any of the categories set forth below:

Donations and Grants. Donations and Grants to HCOs that support healthcare, including donations and grants (either cash or benefits in kind) to institutions, organizations or associations that are comprised of HCPs and/or that provide healthcare.

Contribution to costs related to Events. Contribution to costs related to Events, through HCOs or Third Parties, including support to HCPs to attend Events, such as:

- ✓ Registration fees
- ✓ Sponsorship agreements with HCOs or with Third Parties appointed by an HCO to manage an Event
- ✓ Travel and accommodation

Fees for Service and Consultancy. ToVs resulting from or related to contracts between Santen and HCOs under which such HCOs provide any type of services to Santen, or any other type of funding not covered in the previous categories. Fees, on the one hand, and on the other hand ToVs relating to expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts.

3.2 For ToVs to a HCP:

Contribution to costs related to Events. Contribution to costs related to Events, such as:

- ✓ Registration fees
- ✓ Travel and accommodation

Fees for Service and Consultancy. ToVs resulting from or related to contracts between Santen and HCPs under which such HCPs provide any type of services to Santen, or any other type of funding not covered in the previous categories. Fees, on the one hand, and on the other hand ToVs relating to expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts.

3.3 Research and Development (R&D) ToV.

Research and Development ToVs in each Reporting Period must be disclosed by Santen on an aggregate basis. Costs related to Events that are clearly related to activities covered in this section can be included in the aggregate amount under the "Research and Development Transfers of Value" category.

For sake of clarity, activities not falling within the definition of R&D ToVs, that are not conducted to maintain a marketing authorization (in application and following definitions of

the “Clinical Trials” Regulation 536/2014), will be disclosed under “consultancy/fee-for-service”.

3.4 Examples of activities associated with ToVs (the list does not exhaustive):

Donations and Grants:

- Charitable contributions
- Business Donations
- Educational grants (e.g. fellowships, courses provided by an HCO where Santen does not select the individual HCPs participating)
- Sponsoring of speakers/faculty which by nature of purpose and funding are classified under educational grants

Contribution to costs related to Events

- Contribution to Cost of Events Sponsorship agreements (HCOs only)
- Placement of a brand logo in a conference program or invitation communication in exchange for supporting the program
- Funding an event in return for a display booth
- Funding an event in exchange for advertising space
- Other advertisement space (in paper, electronic or another format)
- Satellite symposia at a congress
- Registration fees paid for the HCP/HCO to attend events
- Travel (e.g. flight, train, taxi, car hires, tolls, mileage reimbursement, parking, shared ground transportation)
- Accommodation
- Travel Visa

Fees for Service and Consultancy

- Speaker engagements
- Advisory Boards
- Study-related engagements
- Preceptorships
- Post-marketing surveillance studies
- Non-Interventional Studies that are Retrospective in nature
- Medical writing
- Data analysis
- Development of education materials

- General consulting / advising
- Speaker training if linked to a speaker engagement

Research and Development

- Clinical Trials
- Data Monitoring Committees related to studies
- Non-Interventional Studies that are Prospective in nature
- Investigators Initiated Research (IIR)
- Investigator Sponsored Research (ISR)
- Clinical & Research Collaboration

3.5 ToVs excluded from the Scope

Santen is fully aligned with and follows the EFPIA Code definition

EFPIA Code definition: Without limitation, ToVs that (i) are solely related to over-the-counter medicines; (ii) are not listed in Section 23.05 of this article, such as Items of Medical Utility 29 (governed by Article 17), meals (governed by Article 10, especially Section 10.05), Medical Samples (governed by Article 19); or (iii) are part of ordinary course purchases and sales of Medicinal Products by and between a Member Company and a HCP (such as a pharmacist) or a HCO do not fall within the scope of the disclosure obligation described above in "General Obligation". Meals and drinks are not disclosed, but a threshold has been applied in each country, limiting hospitality under a certain value. The Code does not require to be disclosed: inexpensive items of medical value; information and educational materials designed for patients; samples; and activities solely relating to over-the-counter medicines. [Q&A – Q7]

4. Scope of Disclosure

This report includes ToVs processed by Santen during the reporting period for 2024.

Timing of TOV: The disclosure report includes transactions which have a reportable date within the reporting period being disclosed.

Reportable date: the dates to be considered for disclosure reports are as follows:

- ✓ In Cash ToVs – the clearing date is within the reporting period
- ✓ In Kind ToVs – meeting or event end date is within the reporting period

ToV in case of No-Shows or cancellation:

- ✓ Cancellation Fees are not reported
- ✓ No-shows are not reported if Santen Oy cannot confirm the in-kind benefit was received

Multi-year contracts: Where contracts are valid for more than one year, each individual ToV is captured and disclosed in the reportable disclosure period.

Consent management:
Consent is collected in accordance with the European Data Protection Regulation GDPR from each recipient, along with their signature on the written document covering the operation (contract or letter of agreement), or before publication upon presentation of the information to be published. Santen commits to make its best efforts to obtain the consent to publish in individual.

Santen does not accept partial consent or split disclosure.

In case consent was either not given by the Recipient or not documented sufficiently to prove the existence of consent, ToVs are disclosed on aggregate level only.

In the event of death of an HCP by the time of disclosure (by the publication date) the ToV is reported in aggregate.

HCP has a right to withdraw the consent. Consent withdrawal has been assessed according to the relevant local data privacy laws.

Any alternative way to manage individual publication of ToV (for example based on a different legal ground than consent like legitimate interest) is discussed with and assessed by Santen Data Privacy team.

Cross Border Reporting:
Where a ToV is made outside of the recipient's country those ToVs are reported within the disclosure report country based on the recipient's principal practice address. The cross-border disclosures are made on the Santen Corporate Website or locally either on each affiliate website, or in the separate disclosure platform in accordance with local requirements.

Currency and VAT:
ToVs are reported in local currency on the disclosure report. ToVs made in a non-local currency are converted to local currency prior to publication. Daily exchange rates for the ToV day of payment are applied. All reported ToV values include VAT.

Disclosure language:
Disclosure reports will be published using the language as defined by the local trade association code/law.

5. Publication

Publication: transparency disclosure reports to be published in line with country timelines as defined by the local trade association or government.

Disclosure platform: transparency disclosure reports to be published on the platform, defined by the local trade association or government.