

## EFPIA Disclosure Methodology

This methodological note is intended to help readers understand the disclosure of data regarding Transfers of Value (TOV) to Healthcare Professionals (HCPs) and Healthcare Organisations (HCOs) in Ireland during the calendar year 2021 made by Santen UK Limited (Santen). We have summarised below the methodologies used by Santen in preparing our disclosures and identifying each category of TOV.

Santen engaged with the ophthalmology community through supporting educational meetings, which involved TOVs for speakers. We also provided sponsorship for a small number of meetings organised by HCOs in 2021.

Santen did not make any TOVs to patient organisations in Ireland during 2021.

We marketed prescription-only medicines and one device in 2021. Santen did not make any TOVs related to devices in 2021.

Santen UK uses a management tool (CRM) through which all contacts and meetings with HCPs are reported.

Using this tool, we have captured and categorised all TOV agreements made in Ireland during 2021, including the following details:

- The HCP or HCO who received the TOV
- Period covered by the TOV
- Type of TOV, for example, consultancy, speaker fees, sponsorship and expenses incurred
- Value of the TOV, for example for fees and expenses incurred
- Currency in which the TOV was made
- Date TOV was made
- Whether consent to disclose individual data was gained, not given, or withdrawn

The data collected in the CRM have been electronically transferred into a transparency and disclosure tool called ITR (IQVIA Transparency Tool). ITR produces disclosure reports by country of HCP/HCO residence.

Where a HCP has given consent to disclose some parts of their TOV individually but consent is either not given or is missing and/or unknown for other parts, Santen has disclosed all TOV in aggregate. This does not apply to any HCPs in 2021.

Please find below some more information to support the understanding of our disclosure:

Contracts with HCPs/HCOs	Contracts in 2021 were signed for each specific service provided, for example for each speaker engagement. There are no multi-year contracts between Santen and HCPs. Transfers of value from 2021 onwards are disclosed according to the date of payment from Santen. Where a multi-year contract is in place, the TOV is disclosed based on the payment dates of the TOV.
'Donations', 'Grants' and 'Sponsorship'	<p>Santen defines these as "one-way" TOVs: for Donations there is no specific purpose defined for the TOV but for Grants there is a specified purpose; in both cases the company would not expect to receive a service in return.</p> <p>Santen donated a very small number of items to a HCO to benefit and maintain patient care during the COVID-19 Pandemic. Due to the small monetary value of these, only where a quantity greater than 5 have been provided have they been disclosed as Donations.</p> <p>Santen provided support to HCPs and HCOs during 2021, and defines 'Contracted Services' and 'Sponsorship' as a "two-way" TOV: in return for the TOV Santen received defined service, such as a space at a congress for an exhibition stand, consultancy or speaking engagement. There is an exception of the "two-way rule" for sponsorship to attend scientific congresses, for which there is no expected service in return.</p>
Obtaining disclosure consent	Santen requested all HCPs who received TOVs to give us their consent to disclose their individual details at the time of the specific TOV, using separate disclosure agreements. This was recorded in our CRM system.
Tax considerations	We do not deduct any taxes from our TOVs, but we make it clear in our HCP contracts that taxes where applicable must be paid by the HCP.
Payments	<p>Disclosure has been made based on the payment date of the TOV. This means that TOV for certain engagements may be disclosed in two different disclosure periods. For example, any deposits paid in 2021 for events in the next calendar year will appear in the 2021 disclosure, with the balance payable being disclosed in 2022.</p> <p>Where payments have been made by a third party for travel expenses on behalf of Santen, these are disclosed based on the date of travel.</p>
VAT	VAT is not paid on fees to HCPs, but is included in the payment of expenses. Where VAT has been included in payments to HCOs, we have disclosed the VAT as part of the Transfer of Value.
Currency	The great majority of our TOVs were paid in Euros, but where TOVs were made in different currencies, these were converted to Euros at the prevailing exchange rate.
Cross-border payments	There was one cross-border engagement in 2021.
Non-monetary transfers of value	Disclosure of non-monetary transfers of value is made at the equivalent value in monetary terms.
Research and Development	For the purpose of disclosure, R&D TOVs are transfers of value to a HCP or HCO related to the planning or conduct of: - non-clinical studies (as defined in the OECD Principles of Good Laboratory Practice) - clinical trials (as defined in Directive 2001/20/EC) - non-interventional studies that are prospective in nature and involve the collection of data from, or on behalf of, individual or groups of health professionals specifically for the study. There are no TOVs related to Research and Development activities in 2021.