

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 2020 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 and congresses, which involved TOVs for speakers and congress delegates. We did not provide sponsorship for any meetings organised by HCOs in 2020.

Santen did not make any TOVs to patient organisations in Ireland during 2020.

We marketed prescription-only medicines and one device in 2020. Santen did not make any TOVs related to devices in 2020.

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 2020, 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- Whether consent to disclose individual data was gained, not given, or withdrawn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 2020.

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

Contracts with HCPs/HCOs	Contracts in 2020 were signed for each specific service provided, for example attendance at an advisory group meeting or a speaker engagement. There are no multi-year contracts between Santen and HCPs. Transfers of value are disclosed according to the date of service from Santen.
'Donations', 'Grants' and 'Sponsorship'	<p>Santen UK made a small number of 'Grants' in 2020 and did not make any 'Donations'. 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 made a number of MEGS to HCOs during the COVID-19 Pandemic. Due to the small monetary value of these, only where a quantity greater than 5 have been provided to benefit and maintain patient care have they been disclosed as Grants.</p> <p>Santen defines 'Service contracts' and 'Sponsorship' as a "two-way" TOV: in return for a TOV Santen received defined service, such as a space at a congress for an exhibition stand, consultancy or lecturing. In line with the ABPI definition of "Sponsorship of Attendance" (Clause 22.5), there is an exception of the "two-way rule" for sponsorship to attend scientific congresses, for which there is no expected service in return. Santen provided support to HCPs during 2020. It did not provide support to HCOs.</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 contracts database and 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	Disclosure has been made based on the activity date of the TOV or, in the case of grants, the start date of the agreement. The Disclosure for 2020 includes TOV relating to activities undertaken or contracted in 2020 only.
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 were no cross-border engagements in 2020.
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 2020.