

ABPI Disclosure Methodology

This methodological note is intended to help readers understand the disclosure of data regarding Transfers of Value (TOV) to Healthcare Professionals (HCPs), Other Relevant Decision Makers (ORDMs) and Healthcare Organisations (HCOs) in the UK during the calendar year 2022 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 is a global pharmaceutical company focussed on ophthalmology and the UK subsidiary was set up at the end of 2014. We have contracted the services of a variety of HCPs to provide us with advice. We have also engaged with the ophthalmology community through supporting educational meetings and congresses that have involved TOVs for speakers, for sponsorship of HCPs to attend such meetings and congresses, and for sponsorship of meetings organised by a number of HCOs. TOVs made by other parts of Santen during 2022 have been reported as part of the UK disclosure.

Santen made TOVs to three patient organisations in the UK during 2022 and details about this activity is published on the Santen UK website. Santen UK had no active Joint Working Agreements in 2022, and one active collaborative working agreement.

We marketed prescription-only medicines and two ophthalmology medical devices in 2022. One of these medical device products can be sold directly to patients. A small number of TOVs related to these medical devices have been included in our disclosure.

We are a member of the ABPI and have closely adhered to the letter and the spirit of the ABPI Code of Practice in all of our activities including transfers of value during 2022.

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 the UK during 2022, including the following details:

- The HCP, ORDM 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- Whether consent to disclose individual data was gained, not given, or withdrawn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 in the required ABPI format for the UK.

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. The number of HCPs that this applies to in 2022 is 4.

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

Contracts with HCPs/HCOs	<p>Contracts are in place for all projects and services provided.</p> <p>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.</p> <p>TOV has not been reported where travel arrangements were cancelled and not used due to circumstances beyond the intended recipient's control.</p> <p>Collaborative Working Agreements are disclosed based on the date of the Transfer of Value.</p>
'Donations', 'Grants' and 'Sponsorship'	<p>Santen UK made a number of 'Donations' in 2022 and a small number of 'Grants'. Santen defines these as "one-way" TOVs: Donations have been classified as the provision of physical items, services or in-kind support and Grants as funding; in both cases the company would not expect to receive a service in return.</p> <p>Santen donated a small number of items to HCOs to benefit the NHS and maintain patient care. 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 2022, and defines 'Service contracts' 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. In line with the ABPI definition of "Sponsorship of Attendance" (Clause 10.10), 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	<p>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.</p>
Tax considerations	<p>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.</p>
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 2022 for events in the next calendar year will appear in the 2022 disclosure, with the balance payable being disclosed in 2023.</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	<p>VAT is not paid on fees to HCPs, except upon receipt of a VAT invoice, but is included in the payment of expenses. Where VAT has been included in payments to HCOs or HCPs, we have disclosed the VAT as part of the Transfer of Value.</p>
Currency	<p>The great majority of our TOVs were paid in sterling, but where TOVs were made in different currencies, these were converted to sterling at the prevailing exchange rate.</p>
Cross-border payments	<p>Other Santen affiliates engaged UK HCPs and HCOs and these TOVs are included in the report. Santen UK engaged a small number of HCPs from countries other than the UK and these payments will be reported by Santen affiliates in these countries, in accordance with the legislation or industry code in the country of residence. The payments were made in the currency of the country of residence.</p>
Non-monetary transfers of value	<p>Disclosure of non-monetary transfers of value is made at the equivalent value in monetary terms.</p>

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. ToVs related to Research and Development activities are disclosed under the “Research and Development” category in aggregate, based on the date of payment.
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