

Santhera UK Ltd: Methodological note for HCP/ORDM/HCO disclosure 2025

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1 Definitions

1.1 Recipients

Healthcare Organisation (HCO) - either a healthcare, medical or scientific association or organisation such as a hospital, clinic, foundation, university or other teaching institution or learned society whose business address, place of incorporation or primary place of operation is in the United Kingdom or an organisation through which one or more health professionals or other relevant decision makers provide services.

Health Professional (HCP) - any member of the medical, dental, pharmacy or nursing profession and any other person who in the course of their professional activities may administer, prescribe, purchase, recommend or supply a medicine. In relation to the annual disclosure of Transfer of Value, the term also includes any employee of a pharmaceutical company whose primary occupation is that of a practising healthcare professional.

Other Relevant Decision Maker (ORDM) - particularly includes someone with an NHS role who could influence in any way the administration, consumption, prescription, purchase, recommendation, sale, supply or use of any medicine but who is not a health professional.

Patient Organisation (PO) - means an organisation mainly comprised of patients and/or caregivers or any user organisation such as a disability organisation, carer or relative organisation and consumer organisation that represents and/or supports the needs of patients and/or caregivers.

Reportable Recipient (or Recipient) - Means any HCP/ORDM/HCO/POs in relation to whom Santhera is required to disclose the Transfers of Value that it makes.

1.2 Kind of ToVs

Advisory Boards and consultancy services – Reportable Recipients may give Santhera advice on aspects of its strategy or the use of its medicines. Santhera may pay an honorarium to each participant and/or pay their travelling expenses to the place where the meeting is being held. In addition, POs may from time to time provide consultancy services to Santhera to support clinical and educational development.

Meetings - Reportable Recipients may be engaged for their knowledge and expertise on various topics to educate others on specific therapeutic areas or on the use of Santhera's medicines. Santhera may pay an honorarium to such Recipients for providing services, and may also pay travelling expenses.

Sponsorship - Santhera may provide sponsorship to Reportable Recipients towards an activity. In such cases where it is an event/meeting and subsistence is provided, secondary to the educational nature, the subsistence will be included in the ToV disclosure.

Support to attend events/meetings - Santhera may support attendance by Reportable Recipients to attend or participate in educational or scientific events. 'Support' in this context is the provision of a financial contribution, in whole or in part, whether paid directly or indirectly.

This could include costs towards travel, accommodation and/or registration fees to support the attendance of the individual to an event organised or created by a Third Party Vendor and/or independent organisation.

Third Party Vendor means any agency (e.g. medical education agency, events agency, Contract Research Organisation) which makes payments to Reportable Recipients on Santhera's behalf.

Clinical research - Santhera may provide funds, benefits-in-kind or services to HCOs to participate in clinical research which are an essential part of ensuring that medicines are effective and have an appropriate safety profile. Santhera may also pay travelling expenses for HCPs involved in clinical research to travel to meetings with other HCPs involved in the same clinical research.

Note that clinical research ToVs are reported as an aggregated (single) figure under **research and development activities** provided the ToVs fall within the scope of the original agreed research protocol; any ToVs outside of that scope are reported as fees for services and associated travelling expenses.

Market research - ToVs might be made to HCPs/ORDMs in return for answering questions about Santhera products and/or a therapeutic area. Santhera generally participates in "blind" market research where it does not know the identities of the participants. Santhera therefore does not generally report any ToVs for market research activities.

Investigator Sponsored Research - Research may be undertaken by individual HCPs and/or HCOs where they would like to investigate a particular aspect of a Santhera medicine. This type of research, where supported by paying a grant to the relevant HCO, is reported as a ToV under the appropriate heading.

Grants and Donations - Santhera may provide grants or donations to HCOs or POs, for the purpose of supporting healthcare, scientific research or education, with no consequent obligation on the recipient organisation, institution and the like to provide goods or services to the benefit of the pharmaceutical company in return.

Collaborative working - Santhera may work with NHS to enhance patient care, benefit patients and/or benefit to the NHS and at a minimum to maintain patient care, with a shared commitment to delivery of the activity successfully.

Note: Generally, contributions towards subsistence (food and drinks) are not included in the disclosure, as not reportable under the ABPI Code. It is different – and a disclosure must be made – if subsistence cost is included in a broader sponsorship package, e.g. where drinks are served at a congress and included in the congress price.

2 Disclosure's Scope

2.1 Products concerned

As Santhera has no "over-the-counter" medicines and no medical devices, all ToVs to be reported relate to prescription-only medicines, i.e., those medicines that must be prescribed by a suitably qualified HCP.

2.2 Company concerned

Some ToVs to Reportable Recipients (HCPs/ORDMs/HCOs/POs whose principal professional address or place of incorporation is in the UK) are made by Santhera Pharmaceuticals (Switzerland) Ltd (Head Office), or by a Santhera affiliate which is not Santhera (UK) Ltd, or a third-party vendor. This is called Cross-Border Spend and is included in the disclosure.

2.3 Excluded ToVs

The ToVs corresponding to the following categories or provided in relation with the following activities, are not included in the disclosure information:

- payments to healthcare professionals for orders and deliveries of medicinal products
- the delivery of free of charge samples of medicinal products to healthcare professionals
- objects intended for healthcare professionals, information and training materials of moderate value which are intended exclusively for the medical or pharmaceutical activity or used for advanced or further medical or pharmaceutical training and which, in both cases, are also of benefit to patients
- writing implements and pads of modest value, made available to participants at events by pharmaceutical companies; these writing implements and pads may not bear any references to the pharmaceutical company or to particular medicinal products
- payment for meals (including beverages) of appropriate and reasonable prices according to the threshold applicable to each country.

See also note at the end of clause 1.2 (Kind of ToVs).

2.4 ToVs date

The date recorded against each ToV determines the ToV reporting period. The ToV date recorded by Santhera is the payment date for all direct ToVs. For indirect ToV, the relevant date is the last day of the respective event, the date when the ToV took place, or the date reported by a Third Party Vendor.

2.5 Direct ToVs

Direct spend means all ToVs to a Reportable Recipient made directly by Santhera, irrespective of activity type. Direct ToVs may occur in any of the categories of activities undertaken by Santhera mentioned in clause 1.2 (Kind of ToVs), including but not limited to consultancy/fees-for-service.

2.6 Indirect ToVs

All ToVs to a Reportable Recipient which are made by a Third Party Vendor on Santhera's behalf and where Santhera knows or can identify the recipient that will benefit from the transfer of value.

Indirect ToVs occurs where Santhera engages a Third Party Vendor, such as an event organiser, medical education agency, Contract Research Organisation (CRO), consultancy agency or other service providers to organise activities for which payments or benefits are provided to Reportable Recipients.

2.7 Non-monetary ToVs

Any non-monetary ToVs and benefits-in-kind will be reported on a fair market basis, meaning that Santhera will disclose them based on the value or the amount the receiving party would have paid for an equivalent service/benefit. For any non-financial support where a meaningful monetary value cannot be assigned, Santhera will disclose a descriptive note instead of a quantified amount.

2.8 ToVs in case of partial attendances or cancellation and refund

In case of partial attendances or cancellation, Santhera will disclose only those ToVs that were actually received or retained by the Reportable Recipient. ToVs that were refunded will not be disclosed. Where a ToV cannot be refunded (e.g. due to non-refundable registration fees), it will be disclosed even if the intended participation did not occur.

2.9 Cross-border activities

Cross-border ToVs occurs where a payment is made by a Santhera affiliate which is not Santhera (UK) Ltd to a Reportable Recipient, and payments to a non-UK Reportable Recipient by the UK affiliate. All cross-border ToVs are disclosed in the Recipient's home country. Home country refers to the country where the recipient has their primary place of practice or registration.

Affiliates are responsible for ensuring the ToVs it initiates are accurately and completely captured and validated. Santhera has implemented a group-wide process that consolidates the ToVs initiated across all affiliates and jurisdictions. This shall ensure that ToVs initiated by any Santhera entity which include cross-border payments are captured and made available for disclosure in the correct jurisdiction.

2.10 R&D

Santhera may provide funds, benefits-in-kind or services to certain Reportable Recipients to participate in clinical research which are an essential part of ensuring that medicines are effective and have an appropriate safety profile. Santhera may also pay travelling expenses for such Reportable Recipients involved in clinical research to travel to meetings with other Reportable Recipients involved in the same clinical research.

Note that clinical research ToVs are reported as an aggregated (single) figure under research and development activities provided the ToVs fall within the scope of the original agreed research protocol; any ToVs outside of that scope are reported as fees for services and associated travelling expenses.

2.11 Voluntary disclosure

Not applicable

3 Specific considerations

3.1 Country unique identifier

Santhera remains responsible for ensuring that all payments to Reportable Recipients are captured and are reported only once.

Where a ToV is made to an individual HCP/ORDM indirectly via an HCO, such a transfer will be disclosed once only, preferably as a transfer to the HCP/ORDM.

For jointly organised events and partner organisations, the participating companies agree in advance which ToVs will be reported by each company. This mechanism avoids duplicate reporting for joint activities.

We use unique identifiers to categorize countries and types of Reportable Recipients to support accurate reporting of ToVs and take reasonable steps to identify and resolve any potential duplicates.

3.2 Self-incorporated HCP

Where a self-employed HCP is incorporated in a legal entity that consists of only that one HCP, this is considered as an HCP.

If an HCP is “self-employed” but has not set up a legal entity, they are treated as an individual HCP.

Where an HCP provides services through an HCO, and the contract and payment are made to that HCO, the ToV is disclosed against the HCO as the recipient, where applicable.

Santhera uses a consistent approach using its finance systems and supporting documentation to determine classification and disclosure.

3.3 Multi-year agreements

ToVs arising from agreements that span more than one calendar year are disclosed in the reporting year in which the ToV is considered to have been made. For direct ToVs this is generally the payment date, for indirect ToVs this is generally the date of the event/the date the ToV occurred or the date reported by the Third Party Vendor, as applicable.

3.4 Country specificities

Not applicable

3.5 Quality Checks

Santhera performs internal pre-disclosure quality checks prior to submission. Reportable Recipients are flagged in finance tools used for expenses and invoices, and flagged transactions are consolidated in a tool which is used to generate country reporting extracts.

The consolidated list of ToVs against the Reporting Recipient attributes/identifiers is reviewed for completeness, appropriate categorisation and consistency prior to disclosure.

4 Data protection legal basis

4.1 Consent collection

Not applicable

4.2 Legitimate interests

Santhera applies legitimate interests as the legal basis of processing and disclosing ToV data under the applicable data protection legislation (the EU General Data Protection Regulation, the UK Data Protection Act 2018 (DPA 2018), and the UK GDPR).

Consistent with the established principles set out in the applicable pharmaceutical industry code of practice, publication of ToV data serves important legitimate interests because it instils public confidence in the integrity of the relationship between the pharmaceutical industry and Reportable Recipients by demonstrating transparently that these interactions are legitimate and with the purposes of advancing medical sciences and most importantly improving patient outcomes. Santhera is required to fully comply with its disclosure obligations consistent with those developed by the Association of the British Pharmaceutical Industry (ABPI).

In order to balance the legitimate interests to comply with disclosure requirements against the individual interests, rights and freedoms of the Reportable Recipients, Santhera provides individual Reportable Recipients with information about how and why their personal data will be processed and disclosed, with specific instructions for them to contact Santhera if they wish to exercise their right to opt out of disclosure on an identifiable basis.

Provided a Reportable Recipient raised no objection to Santhera's processing and disclosing personal data in the way as described, the total sum of all transfers of value made by Santhera to the respective Reportable Recipient will be disclosed on the template as published by the Prescription Medicines Code of Practice Authority (PMCPA) with the name identified. If the respective Reportable Recipient decides to opt out of public disclosure in an identified manner, the transfer of value data will be aggregated without reference to any personal information.

A dispute or discrepancy, or a request to withdraw consent for future individual disclosure may be directed to Santhera by emailing privacy@santhera.com.

5 Form of disclosure

5.1 Date of publication

The date of publication is latest 30 June in line with the ABPI's Disclosure UK timeline.

5.2 Disclosure platform

www.disclosureuk.org.uk

5.3 Disclosure language

English

6 Disclosure financial data

6.1 Currency

All disclosed ToVs are reported in British Pounds (GBP).

Where a payment is invoiced or made in a currency other than GBP, the amount is converted to GBP using the exchange rate applied in Santhera's financial reports.

6.2 VAT included or excluded

ToV will be calculated based on the actual amount received by the Recipient either in cash or in kind.

The general approach is as follows:

- Including VAT for expenses such as travel, accommodation, congress registration fees if applicable.
- Excluding VAT for fees, or contract based ToVs.

6.3 Calculation rules

Any non-monetary ToVs and benefits-in-kind will be reported on a fair market basis, meaning that Santhera will disclose them based on the value or the amount the receiving party would have paid for an equivalent service/benefit. For any non-financial support where a meaningful monetary value cannot be assigned, Santhera will disclose a descriptive note instead of a quantified amount.

7 Additional Information

not applicable