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1 Introduction

This methodological note (**Note**) is intended to help readers understand how the Transfers of Value (**ToVs**) to Healthcare Professionals (**HCPs**), Other Relevant Decision Makers (**ORDMs**) Healthcare Organisations (**HCOs**), Patient Organisations (**POs**) and **Public** (Patients and Journalists) within the UK have been collated and reported by Santhera Pharmaceuticals and its affiliate Santhera (UK) Ltd (collectively, **Santhera**).

A glossary (**Glossary**) has been included at the end of this Note containing an alphabetical list of the main terms which are used within this Note and their definitions.

Santhera (UK) Ltd will start to report for the UK from 2025 (for 2024 activity).

The information disclosed will remain in the public domain for at least three years from the time of disclosure via the Disclosure UK database at [Disclosure UK \(abpi.org.uk\)](https://disclosure.uk).

Santhera will document all disclosures and retain the records for at least five years after the end of the calendar year to which they relate.

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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 Scope of Transfers of Value

Santhera will disclose on ToVs in relation to the following types of activity:

a. Advisory Boards and consultancy services

Health Care Professionals (**HCPs**), Other Relevant Decision Makers (**ORDMs**) 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, Patient Organisations (**POs**) may from time to time provide consultancy services to Santhera to support clinical and educational development.

b. Meetings

HCPs and ORDMs 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 speakers, chairpersons and any other HCPs providing services, and may also pay travelling expenses.

c. Sponsorship

Santhera may provide sponsorship to one or more HCOs or POs 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.

d. Support to attend events/meetings

Santhera may support attendance by HCPs/ORDMs (individual/s) 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 to individual HCPs/ORDMs to attend events/ meetings.

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.

e. 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.

f. 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.

g. 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.

h. 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.

i. 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: Subsistence is not included, as not reportable under the ABPI Code, unless it has been provided as part of sponsorship of an HCO/PO in relation to their own event as described above.

3 Definition and Management of Cross-Border Spend

Some ToVs to UK HCPs/ORDMs/HCOs/POs 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.

Any ToVs made to UK HCPs/ORDMs/HCOs, including Cross-Border Spend, are described under the section *“How Transfers of Value are captured and recorded by Santhera”*.

4 Which Recipients of Transfers of Value are reported by Santhera

Santhera has and will continue to flag all **Reportable Recipients** based on primarily practicing in the UK (as such term is defined under the ABPI Disclosure Code; see Glossary) within its internal systems to aid tracking and reporting of relevant ToVs.

Where an HCP/ORDM has set up a separate legal entity through which to deliver his/her services, Santhera will aim to disclose the ToV under the name of the HCP once consent has been obtained.

Where Santhera has made a ToV to a department within a HCO, that ToV is disclosed under the name of the HCO, not the department. The local reporting template used is in the format as required by Disclosure UK.

5 How Transfers of Value are disclosed by Santhera

5.1. Types of Spend

Santhera makes some ToVs directly or indirectly to HCPs, ORDMs and HCOs:

Direct Spend typically covers items such as fees for services and associated travelling expenses, plus any non-monetary ToVs made to HCPs via Santhera employee out-of-pocket expenses.

ToVs made to HCPs and HCOs by **Third Party Vendors** on behalf of Santhera are called **Indirect Spend**. Indirect Spend typically covers travel and accommodation at meetings and conferences and may also include honoraria payments.

Fees, expenses and the like due to consultants will be disclosed whether paid directly to them, to their employers, to HCOs, or to companies or charities, etc.

5.2. ToV Dates

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.

5.3. Treatment of Tax

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.

5.4. Currency Management

UK HCP/ORDMs/HCOs are normally paid in GBP, and these payments will be reported as such.

If payments are made in a different currency, Santhera will convert these to GBP before reporting, using the exchange rate it uses in its financial reports.

5.5 Non-financial benefits

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 fair market 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.

5.6 Data validation

Once the report has been put together, Santhera's Data Steward will check it for accuracy.

6 Legal basis for processing and disclosure of ToV data

Santhera previously relied on written consent from HCPs/ORDMs to process lawfully personal data. As from the reporting period 2024, 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, as supplemented in the UK by the UK Data Protection Act 2018).

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 HCP and HCO 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 the applicable industry code of practice, such as 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 HCP, Santhera provides individual HCP 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 an HCP 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 HCP will be disclosed on the mandatory template as published by the Prescription Medicines Code of Practice Authority (PMCPA) with the name identified. If HCP decides to opt 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.

7 How Santhera avoids reporting duplicate transactions

Santhera remains responsible for ensuring that all payments to UK HCP/ORDMs/HCOs 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.

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Where Santhera works with other pharmaceutical companies, each company reports the ToVs relating to the activities that they organised.

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

The **Data Steward** is responsible for reviewing Reportable Recipient ToVs and taking reasonable steps to identify and resolve any potential duplicates.

As a minimum, Reportable Recipients who consent to individual disclosure will have their name, and institution details published; therefore, Santhera will have the opportunity to identify any duplications or other errors.

8 Publication of reports

The Data Steward is responsible for producing the local report required under the ABPI (and EFPIA) Disclosure Code, implementation and publishing it appropriately. The UK local report will be published via the UK Disclosure platform at [Disclosure UK](#).

Reportable Recipients may notify Santhera of any errors in reporting or withdraw their consent for up to 3 years following publication.

Santhera will retain the records for at least five years after the end of the calendar year to which they relate.

Any queries regarding Santhera's reporting methodology or content should be made to the UK Data Steward (privacy@santhera.com).

9 Glossary

This glossary includes the technical definitions of all terms used within this methodological note, including relevant abbreviations.

TERM	MEANING
Consent	Consent refers to the Reportable Recipient agreeing to Santhera's use and disclosure of that Reportable Recipient's personal data for transparency reporting purposes. To be valid, Consent must be given freely and must be informed.
Cross-border Spend	Any payment made by a Santhera affiliate or Headquarters (outside of the UK) to a UK payee (Reportable Recipient), and payments of a non-UK reportable recipient by the UK affiliate, where this payment is not reported in the Recipient's country.
Data Privacy/Data Protection	The laws relating to processing of personal data (information relating to an identifiable person), including Directive 95/46/EC (the Data Protection Directive) and national legislation implementing the same.

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Data Steward	<p>The Data Steward is the individual at Santhera UK (Ltd) who is responsible for:</p> <ul style="list-style-type: none"> • generating, maintaining and publishing the ABPI Disclosure Report • co-ordinating communications with Reportable Recipients and taking appropriate action to resolve any identified issues.
Direct Spend	<p>Direct spend means all Transfers of Value to a Reportable Recipient made directly by Santhera. In other words, all sums paid by Santhera directly to a Reportable Recipient. See also Indirect Spend.</p>
Grant and donations	<p>Collectively mean providing funds, benefits-in-kind or services freely given 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. Donations and grants to individuals are prohibited.</p> <p>In general, donations are physical items, services or benefits-in-kind which may be offered or requested. Grants are the provision of funds.</p>
Healthcare Organisation (HCO)	<p>The term means either a healthcare, medical or scientific association or organisation such as a <u>hospital, clinic, foundation, university or other teaching institution or learned society</u> whose business address, place of incorporation or primary place of operation is in Europe including UK or an organisation through which one or more health professionals or other relevant decision makers provide services.</p> <p>If a healthcare organisation consists of only one health professional or other relevant decision maker, then it would be subject to the requirements in the Code regarding individual health professionals.</p>
Healthcare Professional (HCP)	<p>The term includes members of the medical, dental, pharmacy and nursing professions and any other persons who in the course of their professional activities may <u>administer, prescribe, purchase, recommend or supply a medicine</u>.</p> <p>In relation to disclosure of transfers of value this term also includes any employee of a pharmaceutical company whose <u>primary</u> occupation is that of a practising health professional.</p>
Indirect Spend	<p>All Transfers of Value 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.</p>
Investigator Sponsored Research	<p>Research may be undertaken by individual HCPs and/or HCOs where they would like to investigate a particular aspect of a Santhera's medicine. Santhera may choose to support this research by paying a Grant to the relevant HCO.</p>

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Other Relevant Decision Makers (ORDM)	The term particularly includes those 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 are not health professionals.
Patient Organisations	Not-for-profit organisations (including the umbrella organisations to which they belong), mainly composed of patients and/or caregivers, that represent and/or support the needs of patients and/or caregivers.
Reportable Recipient	Means any HCPs/ORDMs/HCOs/POs/Public in relation to whom Santhera is required to disclose the Transfers of Value that it makes.
Sponsorship	A contribution, financial or otherwise, in whole or in part provided by or on behalf of a company, towards an activity (including an event/meeting or material) performed, organised, created, etc. by an HCO, PO or other independent organisation.
Third Party Vendor	Any agency (e.g. medical education agency, events agency, Contract Research Organisation) which makes payments to Reportable Recipients on Santhera's behalf.
Transfer of Value (ToV)	The term means a direct or indirect transfer of value, whether in cash, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development or sale of medicines.