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1 Introduction

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

A glossary has been included at the end of this methodological note containing an alphabetical list of the main terms (highlighted in bold) which are used within this note and their definitions.

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

Santhera UK Ltd will start to report formerly for the UK from 2019 and Ireland from 2020 which will help supplement the ToV reporting that has been ongoing in the Netherlands, Belgium, France and Iberia (Spain and Portugal).

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](#)

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.

2 Definition of Transfers of Value

ToVs may arise from the following broad types of activity (there are others):

- a. Advisory Boards** - HCPs give Santhera advice on particular 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.
- b. Speaker meetings** - HCPs may be engaged to train others on specific disease areas or on the use of Santhera's medicines. Santhera may pay an honorarium to each speaker and may pay travelling expenses to the speaker(s).
- c. Sponsorship** – Santhera may sponsor one or more HCOs for arranging educational events or sponsor HCP/ORDM (individual/s) to attend or participate in such events.
- d. Clinical trials prior to approval** - Santhera pays HCOs to participate in clinical trials 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 trials to travel to meetings with other HCPs involved in the same clinical trials. Note that clinical trial ToVs are reported as an aggregated (single) figure under **research and development activities** within each country provided the ToVs fall within the scope of the original agreed trial protocol; any ToVs outside of that scope are reported as fees for services and associated travelling expenses.
- e. Market research** - small ToVs might be made to HCPs/ORDMs in return for answering questions about Santhera products and / or a therapeutic area. Santhera only participates in “blind” market research where it does not know the identities of the participants. Santhera has therefore not reported any ToVs for market research activities.
- f. 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.
- g. Grants and Donations** – Santhera may make grants or donations to HCOs for the purpose of supporting research.
- h. Food and Drink** - not reportable under the EFPIA nor ABPI Disclosure Code.

3 Definition and Management of Cross-Border Spend

Some ToVs to UK and Ireland HCPs/ORDMs/HCOs are made by Santhera Pharmaceuticals Switzerland (The Head Office), or by a Santhera Affiliate which is not the UK nor Ireland country of principal practice of the HCP/ORDM or HCO receiving the ToVs.

For example, Santhera's Head Office or an events agency working for Santhera's Head Office might make ToVs to several HCPs from different countries which may include the UK and Ireland. This is called **Cross-Border Spend**.

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Any ToVs made by, or on behalf of the UK/Ireland Affiliate to UK and/or Ireland 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’** as defined under the ABPI Disclosure Code within its internal systems to aid extraction of relevant ToVs. The Reportable Recipients are defined in the Glossary.

Where an HCP 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 an HCO, that ToV is disclosed under the name of the HCO, not the department. The local reporting template used is the Excel Spreadsheet provided by Disclosure UK.

From 1st October 2019, Chiesi Farmaceutici S.p.A. took over distribution of Raxone® (idebenone) for all ophthalmological indications. Any UK & Ireland associated ToV initiated and processed by Santhera will continue to be reported by Santhera UK Ltd.

5 How Transfers of Value are captured and recorded 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 for speakers, and may also include honoraria payments.

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

Research and Development Transfers of Value

For the purpose of disclosure, research and development ToVs are transfers of value to HCPs or HCOs related to the planning or conduct of:

- non-clinical studies
- 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.

Costs that are subsidiary to these activities can be included in the aggregate amount.

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Santhera will only publicly disclose details of payments made to HCPs/ORDMs in relation to market research or similar projects e.g. surveys etc., if Santhera is made aware of the identities of those participating in such projects. Usually the identity of participants in market research sponsored by Santhera is 'blinded' to Santhera employees so ToV reporting in these cases will not be possible. This is because the focus of the requirements concerning transparency is on areas where there are direct relationships between the parties and that is not so where the company does not know the identity of the participants. [ABPI Code of Practice 2019, the Use of Consultants, Clause 23.2 and 23.3]

So in summary, the types of spend reported will include contracts and transactions related to:

- Speaking at and chairing meetings
- Training services
- Advisory board meetings
- Fees and expenses paid to HCPs/ORDMs
- **Sponsorship** of attendance at meetings, which includes registration fees and the costs of accommodation and travel, both inside and outside the UK
- Donations, grants and benefits in kind provided to HCOs
- Joint working with PAGs/NHS

Patient Organisation Transfers of Value

Santhera will make publicly available at a national level, a list of **patient organisations** to which it provides financial support and/or significant indirect/non-financial support, which will include a description of the nature of the support that is sufficiently complete to enable the average reader to form an understanding of the significance of the support.

The list of organisations being given support will be disclosed annually in respect of each calendar year.

The published information will include the monetary value of financial support and of invoiced costs. For significant non-financial support that cannot be assigned a meaningful monetary value, the published information will describe clearly the non-monetary value that the organisation receives.

[ABPI Code of Practice 2019, Relationship with Patient Organisations, Clauses 27.7 and 27.8.]

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 except for the following instances:

- a. Air / Rail Travel: The ToV date is the date the travel ticket is issued (i.e. the date on which Santhera has committed to the travel);
- b. Travel Transfers: The ToV date is the date the transfer was provided; and
- c. Accommodation: The ToV date is the latest date on which the accommodation was provided (i.e. the last day of the hotel stay).

ToV 'in kind' is reported as the event date and ToV 'in cash' is reported as the payment date.

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 pounds sterling and these payments will be reported as such.

Ireland HCP/ORDMs/HCOs are normally paid in Euros and these payments will be reported as such.

In the rare circumstance that payments are made in a different currency, Santhera will convert it to the HCP/HCO local currency before reporting.

6 How Santhera manages Consent

From October 2019, Santhera will seek **Consent** from Reportable Recipients as required by local **Data Privacy** legislation for individual disclosure of their ToVs. Such Consent will be obtained on an engagement-by-engagement basis and HCPs/ORDMs are given the choice to opt in. Please see template consent wording below. Any ToV taking place prior to October 2019 will be reported in aggregated form.

Dear.....

According to the EU and UK ABPI requirements, kindly be informed that Santhera must document and publicly disclose any benefits and certain transfers of value made directly or indirectly to health care professionals. Under these regulations, Santhera would automatically aggregate these for public disclosure.

However as part of our drive to increase transparency and improve trust in the Industry, the ABPI and Santhera UK are keen to encourage named disclosures in accordance with the GDPR legislation.

Opting into this process means that any public disclosure of benefits or transfers of value related to this advisory board will appear under your name. To opt in, please tick below.

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- I have read and understood the above information.*
- I would like to opt into the named disclosure process for this event.*

HCP Signature

Date

Yours faithfully

Santhera (UK) Ltd

.....

7 How Santhera avoids reporting duplicate transactions

Santhera UK Ltd remains responsible for ensuring that all payments to UK and/or Ireland HCP/ORDMs/HCOs are captured by Santhera UK Ltd and are reported only once.

Where a ToV is made to a single HCP indirectly via a HCO, such a transfer will be disclosed once only, preferably as a transfer to the health professional.

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

For jointly organised events, 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/IE Data Steward via email to Bettina.bergman@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 Data Privacy 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/Ireland) to a UK/Ireland payee (Reportable Recipient).
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.
Data Steward	The Data Steward is the individual at Santhera UK (Ltd) who is responsible for: <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	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.
Grant	Funding given to independent organisations, such as HCOs, for particular projects.
Healthcare Organisation (HCO)	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/Ireland or an organisation through which one or more health professionals or other relevant decision makers provide services.
Healthcare Professional (HCP)	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> . 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.

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Indirect Spend	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.
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's medicine. Santhera may choose to support this research by paying a Grant to the relevant HCO.
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 in relation to whom Santhera is required to disclose the Transfers of Value that it makes.
Sponsorship	Financial support to HCPs, HCOs or third party companies for the participation in, or delivery of certain activities which ultimately support patient care.
Third Party Company/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.