

Theratechnologies UK Disclosure Methodology Note

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1. Introduction

Theratechnologies was founded in 1993. Headquartered in Montreal, Quebec, Canada, it employs approximately 200 people in Canada, the United States and in Europe. Theratechnologies commercializes two medicines in HIV and has research programs in NASH, Oncology and HIV. Theratechnologies conducts clinical research, educational and pre-launch activities for various medicinal products in the United Kingdom.

2. Purpose

Theratechnologies engages Healthcare Professionals (HCPs) and Healthcare Organisations (HCOs) to provide valuable, independent advice, guidance and expertise to support clinical development and commercialisation of drug therapies that meet unmet medical needs. The ABPI (Association of the British Pharmaceutical Industry) code requires member companies to publish a note summarising the method used by the company in preparing its Disclosure Report and identifying transfers of value for each category of spend relating to HCPs and HCOs.

Theratechnologies is committed to ensure that the nature and scope of transfers of value (ToV) with healthcare professionals (HCPs) and healthcare organisations (HCOs) are clear and transparent. Therefore, Theratechnologies has published applicable ToV provided directly or indirectly to HCPs or HCOs for the 2021 calendar year on the ABPI's central platform. This Methodological Note provides guidance on how Theratechnologies has recorded and publicly reported this information in accordance with the current requirements of the ABPI Transparency Code. This document represents the Methodology Note for the reporting period 1st January 2021 to 31st December 2021.

3. Definitions

Definitions used within the Disclosure Report and Methodology Note are consistent with ABPI terminology:

Event

All promotional, scientific or professional meetings, congresses, conferences, symposia, and other similar events, including advisory board meetings and training or investigator meetings for clinical trials.

Healthcare Professional (HCP) Anyone that is a member of the medical, dental, pharmacy or nursing professions and any other persons in the course of their professional activities that may administer, prescribe, purchase, recommend or supply a medicine.

Healthcare Organisation (HCO)

A healthcare organisation (HCO) is a healthcare, medical or scientific association or organisation such as a hospital, clinic, foundation, university or other institutions in which one or more healthcare professionals or other relevant decision makers provide a service.

Transfer of Value (ToV)

The term 'transfer of value' (TOV) means a direct or indirect transfer of value, whether in cash, in kind or otherwise, in connection with the development or sale of medicines. A direct transfer of value is one made directly by a company for the benefit of a recipient. An indirect transfer of value is one made by a third party on behalf of a company for the benefit of a recipient where the identity of the company is known to, or can be identified by, the recipient.

4. Transfer of value categories for disclosure

Fee for service and consultancy

This category will include the fees and any related expenses covered by a consultancy agreement with an HCP. The fee will be reported under the 'Fees' sub-category and any related expenses, such as travel, accommodation or registration fees, will be reported under the 'Related expenses agreed in the fee for service or consultancy contract. The fees will be related to expenses related to:

- Speaker fee (including associated preparation work)
- Advisory Boards and other consultancy engagements (including associated preparation work)
- Educational/Scientific Events
- Training

Contribution to costs of Events

This category includes fees related to:

- Sponsorship agreements with HCOs/ third parties appointed by HCO to manage an Event
- Registration Fees
- Travel and Accommodation
- Internal costs for internal events

Donations and grants to HCOs

Donations and Grants to HCOs that support healthcare, including donations and grants to institutions, organisations or associations that are comprised of HCPs and/or that provide healthcare. These transfers of value are altruistic in nature.

Research and Development (R&D) transfers of value

The EFPIA Disclosure Code and the ABPI Code defines these activities as transfers of value to HCPs or HCOs related to the planning or conduct of:

- non-clinical studies (as defined in OECD Principles on Good Laboratory Practice)
- Phase I to IV clinical trials (as defined in Directive 2001/20/EC)
- Non-interventional studies that are prospective in nature and that involve the collection of patient data from or on behalf of individual, or groups of, HCPs specifically for the study

5. Data Privacy

Agreements between Theratechnologies and HCPs/HCOs relating to ToV have included a Transparency section where HCPs and HCOs were notified of Theratechnologies Transparency disclosure obligations. In accordance with applicable laws, rules, regulations and requirements relating to the privacy and security of personal data (as defined by the UK Data Protection Act 2018 (DPA ACT)), the Company shall obtain permission from the individual prior to disclosing personal data such as individual Transfers of Value. The company has made every effort to secure the necessary permissions. Where permission has not been obtained or where the individual HCP has refused permission, the Company has declared the total spend as an aggregate figure as a separate line entry within the relevant disclosure category.

6. Accounting

Currency and Tax

The Disclosure Report will show transfers of value made in the currency in which payment was made. Where amount is requested is not in GBP, this will be calculated on the day of approval using a currency converter tool from a recognised commercial bank website.

Theratechnologies will only publish the transfer of value to an HCP/HCO in the Disclosure Report for the country where the HCP/HCO has their primary practice.

Value Added Tax (VAT): Where applicable, disclosure of payments does not include VAT. Cross border ToV may or may not include VAT depending on the submitting source.

Indirect Payments (Payments made to HCPs/ HCOs through Agency) Theratechnologies may contract with agencies (such as an advertising, marketing or medical education agency) that go on to make transfers of value to HCPs/HCOs. Theratechnologies makes the best effort to ensure that these transfers of value made on its behalf are captured and reported but the end recipient (HCPs/HCOs) may not appear within Theratechnologies accounting tool.

Research and Development: Research and development, and in particular clinical trials, are subject to transparency legislation under the EU Clinical Trial Regulation (2001/20) and the European Medicines Agency Transparency Policy (Policy 0070). The names of investigators working on industry-sponsored trials will be disclosed publicly in the Clinical Study Reports published by the European Medicines Agency. For the purpose of disclosure, Research and Development (R&D) ToV are ToV to HCPs or HCOs related to the planning or conduct of:

- non-clinical research studies
- Phase I to IV clinical trials
- non-interventional studies

The total aggregate disclosure includes ToV made by Theratechnologies to HCPs/HCOs. Biological samples and investigational compounds will be excluded from R&D disclosures. Lending of laboratory equipment that is used exclusively for conducting a study will be returned at the end of the study will not be disclosed in the R&D aggregate amount.

Out of Scope: Meals, drinks, promotional aids, and patient support items are out of scope.

7. Date Methodology

Theratechnologies has endeavoured to disclose to the ABPI for publication on its central platform all direct and indirect ToVs made between 1 January 2021 and 31 December 2021 inclusively that fall within its disclosure obligations as set out in Clauses 19 – 24 of the Code, applying the relevant definitions contained

therein. Please note that the process of compiling and synthesizing such information is a time-consuming and complex undertaking. In the event that we learn of other direct and indirect ToV disclosures during the reference period that should have been reported, Theratechnologies will provide the UK ABPI with an updated Disclosure Report.