

Blue Earth Group Methodological Note

(1st January 2024 to 31st December 2024)

This Methodological Note describes the methods used by Blue Earth Group (BEG) to meet its obligations and the requirements for disclosing payments and Transfers of Value (TOV) to Healthcare Professionals (HCPs), Other Relevant Decision Makers (ORDMs) and Healthcare Organisations (HCOs) and Patient Organisations or the Public, Including Patients and Journalists as outlined in the ABPI Code of Practice for the Pharmaceutical Industry.

Country:	United Kingdom
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1 Introduction

Interactions between pharmaceutical companies and healthcare professionals (HCPs) and healthcare organisations (HCOs) are indispensable for the exchange of knowledge and the improvement of patient care. BEG is fully committed to ensuring that these interactions meet the high standards of integrity and transparency expected by patients, governments, society and other stakeholders.

Up to 17 October 2024, Blue Earth Therapeutics Ltd (BET) and Blue Earth Diagnostics Ltd (BED) were wholly-owned subsidiaries of the same parent, Bracco Horizons. Whilst still majority-owned by Bracco Horizons, BET is no longer a wholly-owned subsidiary. While the 2024 disclosure still includes Transfers of Value (ToVs) from both BED and BET, from 2025 onwards, BED will no longer disclose under BEG but will report its ToVs independently as Blue Earth Diagnostics Ltd (BED).

BEG complies with the obligation to identify, collate and disclose transfers of value to healthcare professionals and healthcare organisations in accordance with the: ABPI Code of Practice on disclosure of transfers of value to HCPs and HCOs and incorporates the requirements of the EFPIA Disclosure Code. For more information on the above-mentioned codes please visit <http://transparency.efpia.eu> or <https://www.abpi.org.uk>

2 Document Purpose and Scope

This Methodological Note summarises the methodologies and business decisions as well as country specific considerations applied by Blue Earth Group when preparing its disclosure report. The report includes transfers of value by all Blue Earth Group companies (Blue Earth Diagnostics Ltd and Blue Earth Therapeutics Ltd) to healthcare professionals and healthcare organisations based in the United Kingdom.

3 Definitions

TRANSFER OF VALUE (TOV)

Direct and indirect Transfers of Value (TOVs), whether for promotional purposes or otherwise, in connection with the development and sale of prescription-only medicinal products exclusively for human use.

RECIPIENTS

Any healthcare professional and healthcare organisation whose primary practice, principal professional address or place of incorporation is in the United Kingdom.

- **Healthcare Professional** (HCP) is defined as includes 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 transfers of value (Clause 28), the term also includes any employee of a pharmaceutical company whose primary occupation is that of a practising health professional.
- **Healthcare Organisation** (HCO) is 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 Europe or an organisation through which one or more healthcare professionals or other relevant decision makers

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provide services.

REPORTING CATEGORIES

BEG follows the ABPI Code of Practice's definition of the reporting categories. The following table provides examples (list not exhaustive) of the specific activities reported under each category.

Collaborative Working (which includes Joint Working)	<ul style="list-style-type: none"> - BEG did not participate in any Collaborative Working in 2024.
Donations and grants to HCOs	<ul style="list-style-type: none"> - BEG did not provide any Charitable Donations or Grants to HCOs - BEG provided financial ToVs to UK HCOs in the form of R&D
Contribution to costs of events – sponsorship agreements with HCOs or with third parties appointed by a HCO to manage an Event	<ul style="list-style-type: none"> - Funding an event in exchange for the placement of a brand logo in a conference program or invitation communication - Funding an event in return for a display booth or projection area at the event - Satellite symposia at a congress - Funding or support of HCO website in return for space to publish educational or promotional content or link to any BEG website - Other advertisement space (in paper, electronic or another format) <p>Note: Catering costs are only included in the disclosed TOV if they form part of the sponsorship package.</p>
Contribution to costs of events – registration fees	<ul style="list-style-type: none"> - Registration fees paid for HCPs/HCOs to attend third-party educational events <p>Note: BEG does not charge registration fees for its own events. Logistical costs e.g., hire of facilities associated with BEG stand-alone events are not disclosed.</p>
Contribution to costs of events – travel and accommodation	<ul style="list-style-type: none"> - Travel (e.g., flight, train, taxi, mileage reimbursement, parking) - Accommodation <p>Note: Travel and accommodation costs related to services or research & development activities are not covered in this category.</p>
Contracted Services - Fees	<ul style="list-style-type: none"> - Speaker engagements - Advisory boards and other consulting engagements - Data analysis, medical writing and development of educational materials - Other research-related services (if not falling under the definition of Research and Development*)
Contracted Services - expenses	<ul style="list-style-type: none"> - Travel (e.g. flight, train, taxi, mileage reimbursement and parking) - Accommodation

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	Note: Where expenses are immaterial or cannot be disaggregated from the service fee without unreasonable effort they are disclosed under “Fees for Services and Consultancy” category.
Research and development	<ul style="list-style-type: none"> - Fee for investigator activities related to research and development - Funding of investigator-initiated research - Activities contracted to CROs, where indirect TOVs are made to HCPs/HCOs <p>Note: TOVs related to research activities which do not fall under the definition of Research and Development* (e.g. retrospective non-interventional studies) are not covered in this category. TOVs related to research & development are disclosed in aggregate form.</p> <p><i>*Research and Development TOVs: TOVs to HCPs/HCOs related to the planning and conduct of (i) non-clinical studies (as defined in the OECD Principles of GLP), (ii) clinical trials (as defined in Regulation 536/2014), or (iii) non-interventional studies that are <u>prospective</u> in nature and that involve the collection of patient data from or on behalf of individual, or groups of HCPs specifically for the study (Clause 24.6 SI of the ABPI Code).</i></p>

4 Disclosure Scope

EXCLUDED TRANSFER OF VALUE

The following TOVs are not included in BEG’s disclosure report:

- TOVs excluded from the scope of the ABPI’s Disclosure Requirements, such as informational and educational materials, items of medical utility, food and beverage, medical samples,
- Fees charged by logistics agencies assisting in organising travel and meetings,
- TOVs which are part of the ordinary course of purchase and sale of medicinal products, such as discounts, price reductions and other trading devices.

DIRECT AND INDIRECT TRANSFER OF VALUE

BEG discloses direct and indirect TOVs.

Direct TOVs are defined as those made directly by BEG to the benefitting Recipient.

Indirect TOVs are defined as those made on behalf of BEG for the benefit of a Recipient or made through an intermediary (e.g., meeting organiser) and where BEG knows or can identify the benefitting Recipient.

In general, TOVs are reported at the level of the first identifiable Recipient which falls under the definition of an HCP/HCO. Each TOV is only disclosed once to avoid duplication.

- TOVs to HCOs through a third party are disclosed under the HCO (e.g., sponsorship provided to a medical association through an event organiser),
- TOVs to individual HCPs through a third party are disclosed under the HCP (e.g., travel arrangements made through a travel agency),
- TOVs to self-incorporated HCPs are disclosed under the individual HCP,
- TOVs to individual HCPs/HCOs through a third party, for the purpose of R&D, are disclosed as an aggregate as part of R&D disclosure.

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NON-MONETARY TRANSFER OF VALUE

BEG discloses non-monetary Transfers of Value.

Where a benefit has been provided to a recipient in the form of services rendered by in-house expertise, to ensure full transparency, the disclosed value includes the total hourly rate, along with pro-rated pension and National Insurance contributions.

Where a benefit has been provided in the form of doses or precursor materials of our products for R&D purposes, the value is calculated using the projected commercial price. Considering the nature and the constraints of supply, valuating the doses using the value of the raw material or cost of goods was not only unfeasible due to manufacturing variations but would also undervalue the actual cost of the ToV. The calculation of the total ToV was attained by multiplying the projected commercial value of each dose by the number of doses used by each study.

BEG did not provide non-monetary ToV to UK recipients.

TRANSFER OF VALUE DATE

This disclosure report includes all TOVs disclosed had a payment made between 1st January 2024 and 31st December 2024. These payments can include some activities conducted in 2023 where payment was made in 2024.

CROSS-BORDER ACTIVITIES

TOVs are disclosed in the country where the Recipient has their primary practice, principal professional address or its place of incorporation.

The disclosure report includes all TOVs to Recipients based in the United Kingdom, including TOVs made by foreign affiliates and TOVs related to events taking place outside the United Kingdom.

FURTHER CONSIDERATIONS

TOVs to Contract Research Organisations/Clinical Research Organisations (CRO), are not included in the disclosure report unless (i) the CRO is comprised of HCPs or linked to a HCO and therefore falls under the definition of an HCO, or (ii) the TOV constitutes an indirect TOV through the CRO to the benefit of the HCP/HCO.

5 Consent Management

In compliance with applicable data privacy regulations, the disclosure of personal data is dependent on the explicit consent of the HCP concerned.

CONSENT COLLECTION

BEG advocates transparency and encourages Recipients to grant consent to full disclosure. BEG requests consent for each activity and for HCPs this has been given at the same time as contracts signed for each activity undertaken with BEG.

BEG discloses the TOV in the aggregate section of the disclosure report if:

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- the Recipient dissents to the disclosure of the data,
- the Recipient only grants partial consent,
- no response from the Recipient is received on time,
- the Recipient withdraws consent at any point during the year.
- all HCPs have consented to disclosure of their respective ToVs in this period. [in UK]

MANAGEMENT OF REQUESTS AND CONSENT WITHDRAWALS

Consent is voluntary and can be withdrawn at any time in writing to Medical@blueearthdx.com.

Recipients may also contact BEG at Medical@blueearthdx.com to request further information about, or corrections to, the published data.

6 Disclosure Form

TIME OF PUBLICATION

TOVs are disclosed on an annual basis and within six months after the end of the calendar year. The disclosure report remains in the public domain for a minimum of three years, unless required otherwise for legal reasons.

PLATFORM

The disclosure report is published on the ABPI central platform <https://search.disclosureuk.org.uk/>.

7 Financial Consideration

TAX ASPECTS

ToVs disclosed include VAT where a HCO/HCP or Company charges BEG VAT.

CURRENCY ASPECTS

TOVs are disclosed in the local currency, GBP. If a foreign currency needs conversion to local currency (GBP) the Bloomberg exchange conversion rate is used on the day of the transaction

CALCULATION RULES

TOVs are valued at the cost amount for BEG and not the Recipient's revenue.

For the calculation of non-monetary ToV, please see *Disclosure Scope > Non-monetary Transfer of Value* above.

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8 R&D Transfer of Value

The ToV for R&D conducted by BEG to the UK entities in 2024 is declared as an aggregate.

9 Multi-year Contracts

All contracts with HCPs run on an annual basis. In the UK, no multi-year contracts are in place.