



## **ABPI Disclosure Methodological Note**

**March 2023**

This note describes the methods used by Veriton Pharma Limited in the UK to meet its obligations and the requirements for disclosing payments and Transfers of Value (ToV) to Healthcare Professionals (HCPs), Other Relevant Decision Makers (ORDMs) Healthcare Organisations (HCOs) and patient organisations as outlined in the ABPI Code of Practice for the Pharmaceutical Industry.

Veriton Pharma Ltd, BTG Specialty Pharmaceuticals (Protherics Medical Development Ltd) and SERB Specialty Pharmaceuticals are three separate companies and financial entities in the SERB Pharmaceuticals group corporate umbrella. As the deadline for setting up separate accounts for BTG and SERB Specialty Pharmaceuticals has passed, the 2022 UK disclosures for these three companies are being disclosed under the current existing disclosure portal for Veriton Pharma Ltd, for transparency to ensure all data is easily accessible and displayed clearly in one place.

**Date of Preparation: March 2022**

## **Definitions**

### **Transfer of Value (ToV)**

The term transfer of value means a direct or indirect ToV, whether in cash, in kind or otherwise, made for promotional purposes or otherwise, in connection with the sale or development of licensed medicines.

### **Healthcare Professional (HCP)**

HCP's include members of the medical, dental, pharmacy and nursing professions and any other persons who in the course of their activities may administer, prescribe, purchase, recommend or supply a medicine.

### **Healthcare Organisation (HCO)**

HCO means 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 Europe or an organisation through which one or more HCPs or other relevant decision makers provide services.

### **Other Relevant Decision Maker (ORDM)**

ORDMs particularly include 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 HCPs.

## Research and Development

1. Outline Research and Development Transfers of Value to HCPs or HCOs related to the planning or conduct of

- (i) non-clinical studies (as defined in OECD Principles on Good Laboratory Practice);
- (ii) clinical trials (as defined in Directive 2001/20/EC); or
- (iii) non-interventional studies (NIS) 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.

Non-interventional studies retrospective in nature follow the same disclosure process as HCP honoraria/service fees. The disclosure of such transfers of value on an individual HCP basis is subject to obtaining HCP's informed consent as per country specific local requirements. In case the transfers of value for prospective and retrospective NIS cannot be distinguished, the disclosure of transfers of value will be made on an individual HCP basis (HCP's consent required) and therefore follows the same process as for retrospective NIS.

There are no retrospective NIS studies to report for Veriton, BTG or SERB for 2022

## 2. Composition of R&D Transfer of Value

The aggregate R&D Transfer of Value includes:

- Contribution to costs of Investigator Meetings and Committees
- Investigator fees for patient visits paid directly to clinical trial site staff or to CROs as an intermediary. Delayed or preliminary payments by CROs to clinical trial site staff are not considered

Other points to note:

- The aggregate R&D Transfer of Value does not include fees paid to Clinical Research Organisations (CROs).

## Transfers of Value

Categories disclosed against individual HCPs or ORDMs for ToV made in 2022

- 1) Fees for service and consultancy and associated related expenses agreed in the fee for service/consultancy contract

Veriton Pharma pays fair market value fees for the provision of services provided by HCPs/ORDMs. These services include chairing or speaking at meetings arranged by the company. This service provision is documented and agreed via a consultancy/speaker agreement and the fees/associated expenses are disclosed.

2) Associated expenses

These may include: travel expenses, accommodation rates (which may include dinner, bed and breakfast, or room only rates) and other associated expenses claimed by the service provider (e.g. parking, any additional appropriate subsistence).

3) Payments made to consultants in relation to market research where the identity of the participants is known to Veriton Pharma

Veriton did not make any such ToVs for market research in 2022

4) Sponsorship of HCPs/ORDMs for attendance at meetings (including registration fees and associated expenses in the form of travel and accommodation)

This service provision is documented and agreed via a consultancy/speaker agreement and the fees/associated expenses are disclosed.

5) Grants and donations made to Patient Advisory Groups can be found in the following locations:

- For Veriton Pharma Ltd: <https://www.veritonpharma.com/about-us/disclosures/>
- For BTG Speciality Pharmaceuticals: <https://btgsp.com/en-gb/special-pages/uk-disclosures>
- For SERB Speciality Pharmaceuticals: no payments have been made to date

## Categories disclosed against individual HCOs for ToV made in 2022

1) Fees for service

Fees paid to HCOs for the provision of a service (e.g. consultancy or speaker fees) are reported as fee for service against the relevant HCO for 2022

## **Management of consent disclosure for HCPs/ORDMs**

In line with the requirements of the Data Protection Act and the rights of data subject thereunder, Veriton Pharma will only make disclosure of an individual HCP's or ORDMD's personal data to the ABPI with the prior written consent of the HCP/ORDMD concerned.

Veriton Pharma records consent by asking those HCPs and ORDMDs engaged or sponsored by the company to consider signing and returning an agreement which includes a section for public disclosure. Once returned to Veriton Pharma the agreement is held electronically for at least 3 calendar years unless such HCP/ORDMD notifies the company of their wish to subsequently withdraw their consent during this time.

Each HCP/ORDMD is entitled to withdraw their consent to disclosure at any time. In such cases, HCPs and ORDMDs are asked to send an email to [info@veritonpharma.com](mailto:info@veritonpharma.com), notifying the company that they wish to withdraw their consent for the current calendar reporting period. Following publication of Veriton's ToV data, HCPs and ORDMDs are also able to contact the ABPI to withdraw their consent.

## **Financial Considerations**

### **Institutions and Private Companies**

Where an organisation is principally made up of a group of HCPs, but where ToV cannot be reasonably ascribed to an individual HCP within the organisation, this organisation has been designated an HCO and the ToV disclosed accordingly.

Where an HCP or ORDMD runs a private company, Veriton will treat this as if it were an individual HCP/ORDMD and will disclose against the individual.

## **Handling of VAT**

In general, Veriton Pharma defines ToV as a cost to the company and hence VAT is excluded from the reported ToVs.

### **Transactions and currency conversions**

All ToVs are disclosed in GBP. Any ToV made in foreign currency is converted using the daily exchange rates in the Veriton Pharma accounting system at the time ToV is applied.

## **Timing**

Veriton Pharma discloses to the ABPI all ToV made between January 1<sup>st</sup> and December 31<sup>st</sup> of one year, by the date specified by the ABPI in the following year.