

## **Methodological Note**

### **Introduction**

Britannia Pharmaceuticals Ltd (BPL) is a part of STADA Arzneimittel AG, specialising in neurological pharmaceuticals. BPL believes transparency and honesty are essential in maintaining and upholding confidence in our products and the pharmaceutical industry. BPL regularly collaborates with various Healthcare Professionals (HCPs), Other Relevant Decision Makers (ORDMs) and Healthcare Organisations (HCOs) in the interests of patients. These collaborations are essential for the continuous improvement of patient care and the sharing of knowledge which may be relevant to clinical decision making.

BPL are committed to ensuring transparency is respected at all times. Acting with integrity is one of STADA's core business values, ensuring the way BPL conducts business with openness and to the highest ethical standards, in caring for people's health as a trusted partner.

### **General considerations**

This methodological note details the approach taken by BPL with regards to the collection and submission of all Transfers of Value (ToVs) to HCPs, ORDMs and HCOs, and research and development, as mandated in the Association of the British Pharmaceutical Industry (ABPI) Code of Practice.

All ToVs disclosed relate to UK HCPs, ORDMs and HCOs. This report includes ToVs made by other European STADA affiliates made to HCPs, ORDMs and HCOs who are based in the United Kingdom.

ToVs made to Patient Organisations, journalists, and members of public, including patients, are disclosed separately on the Disclosure UK Gateway portal website.

### **Consent**

HCP consent to disclose ToVs against them is requested for each activity; it is requested using an electronic consent preference form. The consent form is stored electronically on the HCPs record in a password protected internal system, designed to manage, and record ToVs. The HCPs consent preference is recorded within the electronic system and the consent preference form is uploaded as evidence of consent.

If an HCP provides consent to disclose ToVs associated with each activity against them, this will be disclosed against the individual.

If an HCP declines to provide consent to disclose, any ToVs made to that HCP will be disclosed within the aggregate.

ToVs made to self-incorporated HCPs and ORDMs, where the individuals are the sole owner of the company, will be disclosed against the individual, if consent has been provided.

### **Data Privacy**

A statement around consent is included within our standard contracts and payment request forms, our consent form. Should the HCP wish to discuss BPL's data privacy policy further, BPL has provided an email address to raise any questions.

### **Reporting period and dates**

ToVs disclosed are those that have a reporting date between 1<sup>st</sup> January 2023 and 31<sup>st</sup> December 2023. Disclosed ToVs also include some activities conducted in 2022 where payment was made in 2023.

The reporting date for monetary ToVs is the date in which the payment was made, irrespective of when the activity/event occurred.

BPL has not provided any benefits in kind and non-monetary ToVs in 2023.

### **Currency**

All payments disclosed are in Great British Pounds (GBP).

### **Reporting categories**

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

<b>Reporting category</b>	<b>Examples of specific activities</b>
Collaborative Working	Note: BPL did not participate in any Collaborative Working in 2023.
Donations and grants to HCOs	<ul style="list-style-type: none"> <li>- Charitable contributions</li> <li>- Grants and donations (in cash or in kind) for the purpose of supporting healthcare, scientific research or education</li> </ul>
Contribution to costs of Events: Sponsorship agreements with HCOs / third party organisations appointed by HCOs to manage an Event	<p>ToVs provided to HCOs or to a third-party agency on behalf of an HCO with regards to the cost of events</p> <p>For example:</p> <ul style="list-style-type: none"> <li>- Funding an event in return for a display booth or Stand area at the event</li> <li>- Satellite symposia at a congress</li> <li>- Nurse Service (package deal)</li> </ul> <p>Note: the nurse service cannot be disclosed elsewhere on the template as it is not considered a grant, donation, collaborative working or a contracted service (as per note M)</p>
Contribution to costs of Events: Registration Fees	<ul style="list-style-type: none"> <li>- Registration fees paid for HCPs/HCOs to attend third-party educational events</li> </ul>

<p>Contribution to costs of Events: Travel and accommodation</p>	<ul style="list-style-type: none"> <li>- Travel (e.g., flight, train, taxi, mileage reimbursement, parking)</li> <li>- Accommodation</li> <li>- Travel and accommodation expenses associated with supporting HCPs to attend 3<sup>rd</sup> party conferences/company funded meetings</li> </ul> <p>Note:</p> <ul style="list-style-type: none"> <li>- Where group accommodation and transport has been provided as a ToV, the total cost has been divided by the number of attendees and this amount has been disclosed</li> <li>- Travel and accommodation costs related to services or research &amp; development activities are not covered in this category</li> </ul>
<p>Contracted Services: Fees</p>	<ul style="list-style-type: none"> <li>- Speaker engagements</li> <li>- Advisory boards and other consulting engagements</li> <li>- Data analysis, medical writing and development of educational materials</li> </ul>
<p>Contracted Services: Expenses</p>	<ul style="list-style-type: none"> <li>- Travel (e.g. flight, train, taxi, mileage reimbursement and parking)</li> <li>- Accommodation</li> </ul> <p>Note: Where BPL have been unable to separate expenses from the fee for service, these amounts have been disclosed together as a total fee</p>
<p>Research &amp; Development</p>	<ul style="list-style-type: none"> <li>- Fee for investigator activities related to research and development</li> <li>- Activities contracted to CROs, where indirect ToVs are made to HCPs/HCOs</li> </ul> <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 &amp; development are disclosed in aggregate form.</p> <p>*Research and Development ToVs: ToVs to HCPs/HCOs related to the planning and conduct of:</p> <ol style="list-style-type: none"> <li>i. non-clinical studies (as defined in the OECD Principles on Good Laboratory Practice)</li> <li>ii. clinical trials (as defined in Regulation 536/2014)</li> <li>iii. 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 health professionals specifically for the study</li> </ol>

### Data Collection

An internal electronic system is used to track consent and transfers of value made to HCPs, ORDMs and HCOs. Consent preference and details of payments are recorded against the HCP record card, within the electronic system. HCPs that decline to provide consent are automatically added to the aggregate. For those that consent, the consent preference form is uploaded as evidence of consent.

HCO payments are recorded within the electronic system against the HCO.

Finance provides a record of all payments made to HCPs/ORDMs and HCOs, this data is used to check the electronic system and highlight any discrepancies.

The commercial team provide a record of ToVs they have captured for 2023 which is used to reconcile against the payments recorded by the finance team and the internal electronic system.

### **Britannia Nurse Service**

BPL provides a nurse service as a package deal to HCOs. This service is covered under an honorary contract which is a legal agreement between BPL and an HCO, that allows a BPL's Specialist Nurse to work directly with patients for HCOs, providing therapy support. The Specialist Nurses is clinically responsible to, and accountable to, the HCOs' prescribing physician (and Specialist Nurse, where applicable) in the relevant service for Parkinson's Disease. BPL's Specialist Nurses work alongside HCPs to provide on-going support to Parkinson's patients once they have been prescribed BPL device aided products.

For employment and administrative matters, the Specialist Nurse reports to BPL, but BPL does not direct or control the clinical services provided by the Specialist Nurses to the HCOs' patients. The service employs nurses internally and via an external agency, and is led by an International Nurse Manager, who reports to the Medical Director. This is a package deal is independent of the Sales team and the commercial functions of the business.

The total cost of providing this service to the HCOs has been calculated using the total salaries from all nurses (internal and external agency) divided by the number of HCOs who have a honorary contract in place with BPL in 2023. This provides an average cost per HCO.

The cost is then disclosed against each HCO as a 'sponsorship agreement with HCOs/Third party organisations appointed by HCOs to manage an event' as this ToV cannot be disclosed elsewhere on the template as it is not considered a grant, donation, collaborative working, or a contracted service (as per note M).

### **Exclusions**

ToVs excluding from the scope of disclosure include:

- Medical items and ancillaries that are provided to patient free of charge that are required for the administration of BPL medicines are exclude from our disclosure.
- ToVs which are part of the ordinary course of purchase and sale of medicinal products, such as discounts and price reductions
- Subsistence is not within the scope of the ABPI disclosure obligations and as such no costs associated purely with subsistence have been disclosed, unless included in a 'day delegate rate' and BPL have been unable to separate the subsistence cost from the room hire.

## **Cross Border Payments**

BPL is part of the STADA Arzneimittel AG and operates globally via affiliates and partners. Cross border payments are communicated internally and reconciled locally to ensure all relevant UK ToVs are included within this disclosure. Any payments which were made in another currency have been converted to GBP based on the current March 2024 exchange rate.

## **Definitions**

**Health professional (HCP):** 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 (ABPI Code of Practice 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):** 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 health professionals or other relevant decision makers provide services. 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.

**Other relevant decision maker (ORDM):** includes someone 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 is not a health professional.

**Transfers of Value (ToVs):** 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.

**Direct ToVs:** made directly by a company for the benefit of an HCP/ORDM/HCO

**Indirect ToV:** made on behalf of a company for the benefit of an HCP/ORDM/HCO or through an intermediate and where the company knows or can identify the HCP/ORDM/HCO that will benefit from the ToV