

PAION UK Ltd. and PAION Pharma GmbH Methodology Statement

1. Introduction

As a non-ABPI member complying with the Association of the British Pharmaceutical Industry, PAION UK Ltd. and PAION Pharma GmbH are committed to transparency around interactions with UK Healthcare Professionals (HCPs) and UK Healthcare Organisations (HCOs) and that these are captured and reported in line with all applicable transparency requirements.

2. Period Covered

January 1st to December 31st 2024

3. Scope

The disclosure covers all Transfers of Value required to be disclosed pursuant to the Medicines for Europe Code of Conduct which have been made by PAION UK Ltd. and PAION Pharma GmbH during the Period Covered to Healthcare Professionals, Healthcare Organizations and/or Patient Organisations; with regard to medicines.

4. 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 healthcare professions and any other persons in the course of their professional activities that may administer, prescribe, purchase, recommend or supply a medicine. Disclosure will also apply to 'other relevant decision makers' (ORDMs), this 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.

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.

5. Types of Transfers of Value

Donations and grants: collectively, mean providing funds, benefits in-kind or services freely given for the purpose of supporting healthcare, scientific research or education, with no consequent obligation on the recipient organisation, institution and the like to provide goods or services to the benefit of the pharmaceutical company in return. Donations and grants to individuals are prohibited.

In general donations are physical items, services or benefits in-kind which may be offered or requested. Grants are the provision of funds.

Sponsorship agreements with HCOs/third parties appointed by HCPs to manage an Event

Support for a specific event, activity or item which is organised and or produced by, or for, a third party. This may include financial support, goods or services. Examples of activities sponsored by PAION UK Ltd. and/or PAION Pharma GmbH in this way include: support for a speaker, rental of stand space.

Travel and Accommodation for Events

This subcategory relates to support in the form of payment of travel and accommodation when PAION UK Ltd. and/or PAION Pharma GmbH supports the attendance of HCPs at medical/scientific events organised by third parties. Examples include airfares, train tickets, mileage, taxis, tolls, parking fees and hotel accommodation.

Fees for contracted services

Fees agreed in a formal contract paid to HCPs or to their employees on their behalf for services rendered where there is legitimate business need. Examples include chairing and speaking at meetings, participation in advisory boards and training services.

Cross-border activities

PAION employees are required to capture and report all ToVs to UK HCPs and UK HCOs with their primary practice in the UK. The country of disclosure will be determined by the address of principal practice for HCPs and the address of registration for an HCO.

Research and Development (R&D) Transfers of Value

These are ToV to HCPs or HCOs related to the planning or conduct or one of the following categories:

- Non-clinical studies (as defined in the OECD Principles on Good Laboratory Practice)



- Clinical trials (as defined in Regulation 536/2014)
- Non-interventional studies that are prospective in nature and that involve the collection of patient data from or on behalf of individual or group

R&D ToV will be disclosed in an aggregate form in line with the ABPI's requirements.

Research activities by PAION UK Ltd. and/or PAION Pharma GmbH are not undertaken solely for the purpose of obtaining a marketing authorisation for medicinal products. Studies that are not intended for submission to the regulatory authorities do not fall under the R&D ToV disclosure category. These ToVs will still be disclosed but in either the "fees for contracted services" or the "donations and grants" to HCOs categories as applicable.

Out of Scope

Meals, drinks, samples, package deals, promotional aids, and items for patient support (all as defined by Clause 26.3 of the 2024 ABPI Code) are out of scope.

6. Disclosure Financial data

All disclosed ToVs are reported in local currency GBP and without VAT.

Invoice amounts issued in euros were converted using a conversion factor of 1 euro = 1.18 GBP.

Consent from the HCPs / ORDMs and HCOs to disclose these transfers of value have been obtained on an individual activity basis through signed consultancy agreements or other written communication. Where HCP and ORDM recipients of transfers of value cannot be identified for legal reasons, the amount attributable to such transfers have been disclosed on an aggregate basis. The number of recipients involved have been stated and the aggregate amount attributable to transfers of value to such HCP and ORDM recipients.

Disclosed payments relate to transfers of value where the payment transaction was completed in 2024.

The values of TOVs have been extracted from the finance system of PAION UK Ltd. and PAION Pharma GmbH. Following the HCPs/HCOs and relating amounts have been reviewed by the Commercial and Medical department.

7. Specific considerations

Payments to self-incorporated HCPs are listed within the specific section for named HCPs as direct TOVs.

PAION UK Ltd. is a subsidiary of PAION Pharma GmbH. PAION Pharma GmbH has been added to the Methodological Note as the 2024 disclosure includes TOVs from both companies to UK HCPs and HCOs.



The following points are not specifically mentioned in this methodological note, as they are not applicable for the 2024 ToV submission of PAION UK Ltd. and PAION Pharma GmbH: Multi-year contracts, TOVs to retired HCPs, TOVs to deceased HCPs, partial disclosures, disclosures beyond the ABPI code, TOVs in case of partial attendances or cancellation and refund, collaborative TOVs with other pharmaceutical companies, over-the-counter TOVs as well as Medical device TOVs.