

Profile Pharma Methodology for Disclosure of Transfers of Value

As part of the requirements of the EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations, which has been transposed in the ABPI Code, each company is required, at the same time as it discloses the data, to publish a methodological note. This is also be accessible via the central platform, and gives important additional information about, and context to, the disclosed data.

Clause 24.10 of the ABPI Code states: 'Each company providing transfers of value must publish a note summarising the methodologies used by it in preparing the disclosures and identifying each category of transfer of value. The note, including a general summary and/or country specific considerations, must describe the recognition methodologies applied and should include the treatment of multi-year contracts, VAT and other tax aspects, currency aspects and other issues relating to the timing and amount of transfers of value for the purposes of this Code.'

The term 'transfer of value' means 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. 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 on behalf of a company for the benefit of a recipient or through an intermediate *and* where the company knows or can identify the recipient that will benefit from the transfer of value. (Clause 1.10)

Profile will disclose all Transfers of Value to healthcare professionals (HCPs) and healthcare organisations (HCOs) in accordance with its commitment to the ABPI Code of Practice. All required transfers of value made in the relating to HCOs and HCPs from January 1st 2015 were disclosed on the central platform managed by the ABPI in 2016 and will continue to be declared there from 2016 onwards.

Transfers of value in the UK made by the following companies or their subsidiaries will be disclosed: Profile Pharma Ltd; this is the UK based wholly owned subsidiary of Zambon SpA based in Italy. Zambon SpA; is an Italian Headquarters pharmaceutical company. Transfers of Value to UK healthcare professional, other relevant decision makers and healthcare organisation within the UK made by either company will be disclosed by Profile Pharma.

Where a transfer of value has been made relating to a healthcare organisation or patient organisation registered in the UK then payments will be disclosed on an individual basis. Payments to individual healthcare professionals will be disclosed on an individual basis where such consent has been obtained, where no such consent exists aggregate amounts will be disclosed.

This document summarises the methodology Profile Pharma used in calculating the figures stated.

Definitions:

Healthcare organisation (HCO): The term 'healthcare organisation' 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 health professionals or other relevant decision makers provide services.

In the UK HCOs will include hospitals, Clinical Commissioning Groups (CCGs), GP practices and other places of work for HCPs treating patients or providing services related to the treatment of patients. Additionally, all medical societies (national or local) and all “networks” of associations (both formal and informal) for healthcare professional (HCPs) are regarded as healthcare organisations.

Healthcare professional (HCP):

For the purposes of disclosure, Profile regards all employees of the NHS or any private Health Care Provider involved in patient care as HCPs regardless of their professional status. In addition, Profile regards all registered or qualified healthcare professionals as within the scope of disclosure regardless of their NHS status. Thus retired HCPs fall within scope and academic staff who provide clinical services and support.

Donation:

A transfer of value where Profile received no reciprocal benefit

Grant:

A transfer of value given for a specific purpose, usually research or education

Sponsorship:

Payment in support of an event for which there may be some benefit to Profile such as a promotional stand. This can also refer to support for attendance at third party educational meetings.

Non-monetary transfers of value

Providing goods or services which would otherwise need to be paid for. A benefit in kind is recognised and a monetary value will be assigned for the purposes of declaration.

Data Privacy

Data Privacy law requires that Profile obtains permission from individual HCPs prior to disclosing personal data such as individual transfers of value.

Where permission has not been obtained, is ambiguous or where the individual HCP has refused permission, Profile has declared the total spend as an aggregate figure as a separate line entry within the relevant disclosure category.

Profile requests permission from all HCPs in writing and will keep that on record. Consent has been requested for the year in which activity took place. HCPs have been informed that the consent category applies to all activities in that year and the same will be applied to all transfers of value until Profile is informed of a change of circumstance. Profile will regularly review the consent status.

Profile fully supports the concepts of transparency and privacy. Information disclosed will remain in the public domain for at least three years from the time of disclosure and Profile will document all

disclosures and retain the records for at least five years after the end of the calendar year to which they relate.

How payments have been derived.

All payments recorded in the tracking/ approval system by Profile Pharma in the UK have been checked against the finance system and vice versa. All third parties who make payments on our behalf are asked to provide a list of all such payments which are cross checked with contracts. All payments made by Zambon SpA to UK HCPs/HCOs have been provided through the corporate headquarters compliance system.

All non-monetary transfers of value are approved and recorded in a tracking system for disclosure purposes.

Research and Development

All payments to healthcare professionals, healthcare organisation and patient organisations related to research and development are disclosed as aggregate figures in accordance with the ABPI Code of Practice.

Currency

Where payments were made in a currency other than UK sterling and the sterling amount is not known, the amount in pounds sterling will be calculated using the Profile/ Zambon budget exchange rate for 2018. This was €0.85 to £1.

VAT

All transfers of value are without VAT.

Reporting Period

Profile will disclose the details of the payment on the date the activity took place, not on the date payment was made. All transfers of value are paid only after the engagement has taken place.

Multi-year projects:

Where projects run for several years Profile will declare the amount paid relevant to the year in which each activity or agreed milestone took place. Thus a project which spans 2 calendar years and includes several individual transfers of value during that time will have two associated disclosures; one for each calendar year showing the value of the transfer incurred in each calendar year.

Payments to healthcare organisations for services provided by individual HCPs

On occasion, a healthcare organisation will insist that any services provided by its HCP employees cannot be contracted with the individual HCP but must be a service contracted through the healthcare organisation.

Since Profile or Zambon is contracting for the services of a named HCP, the fee ultimately received by the HCP will be disclosed under that HCP's entry. Any fee charged by the healthcare organisation will be disclosed as a fee for service to that organisation.

If the HCP does not receive any additional payment for the service (e.g. because the activity is during normal working hours and they are being paid by the HCO) then the full amount paid will be disclosed against the healthcare organisation as a fee for service.

Private companies and associated charities

Where an HCP runs a private company or partnership, etc, for the purposes of their private income any payments to that organisation will be regarded for disclosure purposes as a payment to the HCP directly.

Payments to third party organisations for services provided by individual HCPs

Profile or Zambon may contract with agencies for services related to its business. On occasion, the work commissioned might be contracted out to an individual HCP. Our policy is that all such services must be disclosed to Profile by the contracted service agency. Any payments made to the individual HCP by the service agency will be disclosed as if the payment had been made directly by Profile or Zambon to that HCP.

Contributions to meetings

Profile will disclose all payments made to medical associations, healthcare organisations, etc in relation to meetings in the UK. This includes direct funding such as sponsorship fees or the right to erect an exhibition stand, and indirect support such as providing a logistics agency. The cost of any sponsorship related directly to food is outside the scope of disclosure. All costs associated with meetings run solely by Profile or Zambon are outside the scope of disclosure except for fees paid to individual HCPs providing services as speakers, etc.

Sponsorship for HCPs to attend medical meetings

Profile supports the attendance of HCPs at bonafide medical meetings. Profile will disclose the associated transfers of value against the individual attendee if this is known. Where costs are not individually itemised (e.g. the cost of a bus transferring a group of HCPs from an airport to a conference venue), the total cost will be split equally between all those receiving the benefit. Costs declared include transport, registration fees and accommodation. Costs related to subsistence are not declared.

Grants to HCOs for support to attend medical meetings

Profile may be asked by an HCO to provide a financial grant to assist its employees to attend medical meetings. Where the payment is associated with named individuals, the disclosure is made as if the money was transferred directly to the named HCP. Where Profile is not aware of the names of the HCPs receiving the support, the grant is declared against the named healthcare organisation.

Payments to non-UK HCPs or HCOs

All disclosures are made in the country in which the HCP practices or in which the HCO is located. This is controlled by Zambon SpA. Payments made to UK-based organisations by Zambon's overseas operations are disclosed within the UK regardless of the source of funding. The disclosure figures are provided by Zambon's corporate headquarters.

Donations and Grants including non-monetary transfers of value to HCO

Where Profile has provided a benefit in kind to support patient care, where this is not related to a package deal, the transfer will be declared against the HCO that benefited even where it has gone to individual patients. If the value is not known or costed an estimate based on all available information will be made.

Patient Organisations

Profile did not provide support of this kind during the disclosure period.