

PTC Therapeutics, Ltd ABPI Disclosure (2024)

Methodological Notes for Annual Disclosure of Transfers of Value

PTC Therapeutics, Ltd (PTC) is committed to working in an open and transparent way with Healthcare Professionals (HCPs), other relevant decision makers (ORDMs) and Healthcare Organisations (HCOs), in order to better serve the needs of patients. Transparency is essential to building and maintaining trust in our organisation and the pharmaceutical industry. PTC is working in collaboration with the Association of the British Pharmaceutical Industry (ABPI) in order to make sure that we continue to set high standards of ethical interaction between PTC and HCPs/ORDMs/HCOs within the UK. This document provides the methodological narrative to support the submission of our UK ABPI Disclosure Report for the year 2024 to the Disclosure UK platform.

Timing

For the purpose of the 2024 Disclosure, we have taken all payments made to UK HCPs, ORDMs or HCOs from 2 January 2024 to 31 December 2024 inclusive.

Contracts and Payments

Any transfer of value from PTC to an individual HCP, ORDM or HCO requires development and return of a signed agreement/contract setting out the purpose of, and terms of, the funding. Each agreement/contract and total transfer of value for the calendar year are recorded and kept securely by PTC. No payment is made without a signed agreement/contract. Payments to UK HCPs, ORDMs or HCOs are normally made in British pound sterling (GBP). Any payments made in other currencies are made via bank transfer with appropriate exchange rate (as described in the Currency section below).

PTC monitor individual payments, via its internal finance system, in order to track any individual HCP, ORDM or HCO with a multi-year or ongoing open agreement/contract so that it is able to report payments made within each calendar year. For any ongoing agreement/contract, only where an invoice is received and paid within that calendar year will this be reported for that individual year.

Where PTC contracts indirectly with an HCP, or ORDM via a third-party consultancy the total amount contracted is disclosed to the individual HCP where consent to disclose has been gained. For HCPs contracted in this way where consent has not been given, or is withdrawn, transfer of value has been aggregated as per instructed within the UK Disclosure Report.

Currency

Payments to UK HCPs, ORDMs or HCOs are recorded within the Disclosure Report in local GBP currency. Most payments made are in GBP, however some payments have been made in other currencies for example the Euro (EUR) (i.e. where another European country affiliate has paid for a UK HCP to speak at a symposium in their country, the contract and payment would be in EUR) or United States dollar (USD). Where a conference is in a country outside of Europe or the US any expenses incurred would be paid in GBP with an exchange rate applicable on the day the expense was incurred. With limited ability to track exact exchange rates on any given day of monetary transfer we have taken an average exchange rate for 2024 of £1=EUR 1.18, = 4.79 SAR and also = \$1.28 USD and applied this to all EUR, SAR or USD payments made during 2024. This rate has been taken from yearly average rates from OFX.com accessed on 17 February 2025. (<https://www.ofx.com/en-gb/forex-news/historical-exchange-rates/yearly-average-rates/>).

Cross-border payments

All payments made to UK HCPs, ORDMs or HCOs from outside the UK are tracked and managed centrally by our Global team. All information is contained within our financial system outlining full payments made including travel and associated expenses. Contracts are also shared with the UK office containing full payment details for each engagement. The PTC Finance Team is able to track all external payments made to HCPs, ORDMs and HCOs within the UK.

VAT and Tax Considerations

Where an individual HCP, ORDM or HCO is VAT registered then transfers of value made to that HCP/ORDM/HCO by PTC will include VAT where appropriate. All other transfers of value are exclusive of VAT.

All transfers of value made by PTC to HCPs, ORDMs or HCOs do not include the payment of any tax. It is made clear within the agreement/contract that the individual or organisation is liable for any and all taxes on payments made to them by PTC.

Definitions

PTC has defined Grants and Donations through its internal UK Standard Operating Procedures. These Procedures supplement and do not replace external requirements including local laws and regulations, HCP professional codes of conduct, industry codes and standards. If there is a conflict or inconsistency between these Procedures and any external requirements, the more stringent rule shall apply. Grants and Donations can only be provided to reputable healthcare or healthcare-related institutions or organisations and not to individuals. Grants and Donations must be provided without agreement or intent to receive a tangible return in exchange and are strictly non-promotional activities and are not connected with the promotion or use of any individual product. The outline of these is included below;

Grants and Donations

Grants are financial support 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 and must be based on unsolicited requests. Activities that could be considered for grant funding may include production costs for a health organisation's clinical treatment guidelines, running costs for an organisation's website, administration costs for a medical society or patient group, contribution towards hospital postgraduate education funds and contribution towards local practice nurse group education funds

Donations are non-financial support 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 may be proactively offered and include goods, services or time (e.g. the secondment of company employees, use of company resources, training, books and computers) and can be provided to any type of organisation.

Grants – The purpose of Educational Grants must be to support either (a) specific, independent professional educational programmes (accredited or non-accredited) where the grant recipient is responsible for developing the content and for managing the event or materials, or (b) institutional fellowship or scholarship programmes. Educational Grants must not interfere with the independence of grants recipients and their associates. PTC may not control the content of the programme or the

faculty, and the grant recipient controls the selection and invitation of any healthcare professionals. Fellowship or Scholarship Programmes must be open and competitive to relevant institutions or candidates in a given geographic or therapeutic area and widely communicated. The selection of subsidised fellow/scholarship holders must be solely within the discretion of the recipient receiving the grant and comply with applicable national laws, guidelines and professional codes of conduct. The purpose of educational grants may not be for general education funds. PTC may consider providing monetary support to other type of activities, for example: a) infrastructure grants to healthcare-related institutions that are in need of improving their medical infrastructure, provided the grant is enhancing patient care and it is not intended to cover the internal operating expenses of the recipient; b) grants to patients associations/organisations to increase disease awareness or to provide psycho-social support during and after diagnosis or treatment; c) grants to support advocacy or research activities regarding healthcare public policies and legislations.

Donations – The purpose of a Donation is to support various initiatives, projects or non-profit organisations. Donations can only be provided to non-profit certified organisations focusing on services to patients, caregivers, and the health and well-being of the general public. This may include non-profit hospitals and foundations, medical or professional associations, disease-based research, education or patient advocacy organisations and similar non-profit organisations. If the donation is to support a fundraising activity, that should be widely publicised and solicit contributions from numerous organisations.

PTC has defined Support and Sponsorship through its internal UK Standard Operating Procedures as follows:

Support to attend third party medical education meetings refers to the support that PTC provides to HCPs or ORDMs to attend independent third-party medical education meetings. The contribution will be towards registration fees, accommodation and travel expenses. These are reviewed on a case by case basis. Support could be provided to an HCP or ORDM. During 2024 there were no instances of partial attendance or any cancellations.

Sponsorship is a contribution towards an activity initiated by an independent organisation where PTC receives something in return. Sponsorship of an event may refer to the financial support given by PTC for the educational aspects of said event such as a sponsorship fee or the right to exhibit a stand. Sponsorship in this case will normally be with an HCO or third-party provider and will not be with an individual.

Research & Development (R&D)

Transfers of value relating to R&D are disclosed in aggregate. These may include payments to HCPs or HCOs related to the planning and conduct of non-clinical studies, clinical trials and prospective non-interventional studies.

Consents

Effective from 10 February 2023 PTC transitioned from relying on written consent from HCPs and ORDMs to legitimate interests as the legal basis of processing and disclosing transfers of value data under the applicable data protection legislation (the EU General Data Protection Regulation, as supplemented in the UK by the UK Data Protection Act 2018).

PTC believes that the publication of transfer of value data, particularly on a named basis, serves important legitimate interests because it serves to:

- protect and instil public confidence in the integrity of the relationship between the pharmaceutical industry and HCP/ORDMs;
- represent a step towards fostering greater transparency and building greater trust between the pharmaceutical industry, the medical community and society;
- enable PTC to most fully comply with its disclosure obligations, for instance under the Association of the British Pharmaceutical Industry (ABPI) Code of Practice.

To balance the legitimate interests described above against the interests, rights and freedoms of the relevant individual HCP/ORDMs, PTC provides HCP/ORDMs with information in the form of a signed agreement/contract about how and why their personal data will be processed and disclosed with specific instructions to contact ukoffice@ptcbio.com if they wish to exercise their right to object to disclosure on an identifiable basis.

Prior to 10 February 2023 consent for disclosure of information including third-party handling of personal data has been sought for all HCPs, ORDMs and HCOs through signed agreements/contracts in line with General Data Protection Regulation (GDPR) requirements. Where consent has been gained this has been recorded in writing and held on file by PTC. These data have been declared via the UK Disclosure Report. Consent has been sought for each activity with each HCP/ORDM or HCO.

Provided an HCP/ORDM did not object to PTC processing and disclosing their personal data in this way, the total sum of all transfers of value made by PTC to the HCP/ORDM was disclosed on an individual named basis.

For HCPs/ORDMs, where consent has not been given or has been withdrawn, transfer of value has been aggregated as per instructed within the UK Disclosure Report. If an HCP/ORDM has received a number of transfer of values from PTC within the same reporting period and decides not to agree to disclosure of one or more of those transfer of values, then PTC discloses all of that individual's transfer of value in its aggregate amount.

Any HCPs contracting with their own Limited Company have been disclosed using their NHS principal practice role and institution name.

During this 2024 Disclosure period, there was one individual who was contracted under the old-style agreement and did not consent to disclose and one individual who objected to PTC disclosing their personal data, therefore their payments for 2024 have been disclosed in aggregate.

Fees for service and consultancy

PTC defines fees as any remuneration paid for services provided under an agreement and could include (but is not limited to) advisory boards, speaker engagements, medical writing, general consulting, development of educational materials etc.

Related expenses for fees for service and consultancy

PTC defines related expenses as those claimed during delivery of said service or consultancy, e.g. accommodation, travel etc, but excluding meals and drinks.

Meals and drinks

Meals and drinks are not covered by the ABPI disclosure requirements and are therefore not disclosed. If meals and drinks cannot be split from other transfers of value, the full amount will be allocated in the relevant disclosure category.

Non-monetary Transfers of Value

During the period of this 2024 Disclosure, PTC has not provided any non-monetary transfer of value to UK HCPs, ORDM's or HCOs.

Cross Company Working

During the period of this 2024 Disclosure, PTC has not engaged in any cross company working in the UK.

Collaborative Working

During the period of this 2024 Disclosure, PTC has not engaged in any collaborative working in the UK.

Over-the-counter Transfer of Value

During the period of this 2024 Disclosure, PTC has not engaged in any over-the-counter transfer of value in the UK.

Medical Device Transfer of Value

During the period of this 2024 Disclosure, PTC has not engaged in any medical device transfer of value in the UK.

Transfer of Value to Patient Organisations and members of the public

Any transfer of value to a Patient Organisation and member of the public including patients and journalists will be declared on PTC's UK website.

Summary of Internal company pre-disclosure quality checks

All transfer of value data collected during the period of disclosure are collated together in a source file by the Office Manager and then transferred to the mandatory disclosure template by the Senior Director, Marketing. This template is then independently reviewed and approved by the Appropriately Qualified Person (AQP) and Medical Final Signatory cross-checking where necessary against the source file.

Prior to submitting the template to the ABPI Disclosure portal each individual HCP, ORDM and HCO is contacted by the Senior Director, Marketing with details of their ToV figure, a reminder of the related activity and legal basis for processing and disclosing transfers of value data. At least one calendar week is given for review of the ToV and the opportunity to resolve any discrepancies. If a response is not received by the deadline, the ToV is submitted to the ABPI Disclosures portal.