

PTC Therapeutics, Ltd ABPI Disclosure (2018) Methodology

PTC Therapeutics, Ltd (PTC) is committed to working in an open and transparent way both with Healthcare Professionals (HCPs) 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. We are 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/HCOs within the UK. This document provides the methodological narrative to support the submission of our UK ABPI Disclosure Report for the year 2018.

Payments

Any transfer of value from PTC to an individual HCP 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 or HCOs are normally made in UK£ Sterling. Any payments made in other currencies are made via bank transfer with appropriate exchange rate (as described in the Currency section below).

Timing

For the purpose of the 2018 Disclosure, we have taken all payments made to UK HCPs or HCOs from 2 January 2018 to 31 December 2018 inclusive.

Contracts

Any transfer of value from PTC to an individual HCP 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.

PTC monitor individual payments, via our internal finance system, in order to track any individual HCP or HCO with a multi-year or ongoing open agreement/contract so that we are 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.

Currency

Payments to UK HCPs or HCOs are recorded within the Disclosure Report in local UK£ currency. Most payments made are in UK£, however some payments have been made in other currencies for example the Euro (i.e. where another European country has paid for a UK HCP to speak at a symposium in their country, the contract and payment would be in Euros) or US\$. Where a conference is in a country outside of Europe or the US any expenses incurred would be paid in UK£ with an exchange rate applicable on the day the expense was incurred (e.g. CHF). With limited ability to track exact exchange rates on any given day of monetary transfer we have taken an average exchange rate for 2018 of £1=Euro1.13 and also = \$1.34 and applied this to all Euro or US\$ payments made during 2018. This rate has been taken from the HMRC foreign exchange rate tables accessed on 1 March 2018 (<https://www.gov.uk/government/publications/exchange-rates-for-customs-and-vat-yearly>).

Cross-border payments

All payments made to UK HCPs or HCOs from outside the UK are tracked and managed centrally by our European 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 are able to track all external payments made to HCPs and HCOs within the UK.

VAT and Tax Considerations

Where an individual HCP or HCO is VAT registered then transfers of value made to that HCP/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 or HCOs do not include the payment of any tax. It is made clear within the agreement/contract that the individual or organisation are liable for any and all taxes on payments made to them by PTC.

Definitions

PTC have defined Grants and Donations through our internal Europe Middle East and Africa (EMEA) Region Standard Operating Procedure. PTC have defined Sponsorship through our internal Europe Middle East and Africa (EMEA) Region Standard Operating Procedure. 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 they must not have the promotion of products as their purpose. Grants and Donations must be based upon an unsolicited request. The outline of these is included below;

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.

Sponsorship – Sponsorship to attend third party medical education meetings refers to the support that PTC provides to HCPs to attend independent third party medical education meetings. The contribution will be towards registration fees and travel expenses. These are reviewed on a case by case basis. Sponsorship could be provided to an HCP or an HCO.

Sponsorship of an event refers to the financial support given by PTC for the educational aspects of said event. This would normally be by way of an exhibition stand from which PTC would distribute promotional materials relating to its products and/or disease awareness materials. Sponsorship in this case will normally be with an HCO or third party provider and not with an individual.

Consents

Consent for disclosure of information has been sought for all HCPs and HCOs through the signed agreements/contracts and further email follow up by PTC. 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 or HCO.

Following introduction of the General Data Protection Regulation (GDPR) during 2018, PTC also collected signed agreements from HCPs allowing the third party handling of their data to enable declaration via the ABPI.

For HCPs, where consent has not been given or withdrawn, transfer of value has been aggregated as per instructed within the UK Disclosure Report. If an HCP 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.

Non-monetary Transfers of Value

During the period of this 2018 Disclosure, PTC have not provided any non-monetary transfer of value to UK HCPs or HCOs.

Cross Company Working

During the period of this 2018 Disclosure, PTC have not engaged in any cross company working in the UK.

Over-the-counter Transfer of Value

During the period of this 2018 Disclosure, PTC have not engaged in any over-the-counter transfer of value in the UK.

Medical Device Transfer of Value

During the period of this 2018 Disclosure, PTC have not engaged in any medical device transfer of value in the UK.

Charitable contributions

Any transfer of value to a Patient Organisation will be declared on our UK PTC website.

