

Methodological note to disclosures made under the ABPI Code of Conduct

March 2019

Introduction

The CLINUVEL Group is guided by a principal set of values, which reflect how we operate and expand our business. As a member of the Association of the British Pharmaceutical Industry (ABPI), CLINUVEL (UK) LTD has committed to complying with the ABPI's Code of Practice for the Pharmaceutical Industry, including disclosing all transfers of value to UK based healthcare professionals (HCPs) and healthcare organisations (HCOs). All disclosures are facilitated through the ABPI platform Disclosures UK.

This document outlines CLINUVEL's methodology for disclosing transfers made during the period 01 January 2018 to 31 December 2018, inclusive. For clarity, the date of the transfer from CLINUVEL to a recipient is used to determine the period in which it is disclosed.

Tax and VAT

All payments disclosed are inclusive of all appropriate taxes where applicable, including but not limited to Value Added Tax (VAT).

Reporting currency

All transfers are disclosed in British Pounds (GBP), with exchange rates on the day of the payment used to convert any non-GBP payments.

Consent

Where a transfer is considered to meet the requirements of individual disclosure, CLINUVEL seeks explicit written consent from the HCP and/or HCO involved. Where consent cannot be obtained, transfers are disclosed in the relevant aggregate fields. In 2018 no transfers requiring consent were made.

Multi-year contracts

Only payments made during the reporting period for multi-year contracts are disclosed, regardless of the length of the contract.

Over the counter and medical devices transfers

CLINUVEL does not operate business segments relevant to over the counter services or medical devices and no related transfers require disclosure.

International payments

Only payments to UK based HCPs and HCOs are currently disclosed through the Disclosures UK.

R&D aggregate

Expenditure for Research and Development include transfers of value to HCPs or HCOs in relation to the planning or conduct of:

- Pre-clinical studies;
- Clinical trials;
- Non-interventional studies where data are collected prospectively from patients and/or physicians; and/or
- Further research into the fields relevant to CLINUVEL's development of its products.

This may also include travel and accommodation to events where the main purpose of the event is to facilitate discussion or work related to one or more of the above situations (such as investigator meetings). Grants – where unrestricted funds are given to a HCP or HCO explicitly for the purposes of R&D work – are also included in the aggregate. Sponsorship or donations explicitly for the purpose of HCPs to attend scientific congresses are not generally considered R&D expenditure.