



Methodological note to disclosures made under the ABPI Code of Conduct

June 2020

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 2019 to 31 December 2019, inclusive. For clarity, the date of the transfer from CLINUVEL to a recipient is used to determine the period in which it is disclosed.

Statement for the disclosure of 2019 data during the COVID-19 pandemic in 2020

As part of the pharmaceutical industry's annual disclosure of transfers of value to HCPs, ORDMs and HCOs via the Disclosure UK platform and in order to ensure accuracy of the published data, the ABPI writes to all of the HCPs, ORDMs and HCOs named in companies' disclosure data ahead of its publication on Disclosure UK at the end of June. (Over 20,000 in June 2019.)

Given the unprecedented pressure on the NHS and health care professionals in responding to the COVID-19 pandemic, in April 2020 the ABPI and PMCPA agreed that it would not be appropriate for industry to write to HCPs, ORDMs or HCOs to request that disclosure data be reviewed. Doing so would add additional work for NHS professionals at this time. To avoid this, and in-line with guidance provided by the ABPI, CLINUVEL's 2019 transfer of value data has been published on Disclosure UK in aggregate.

Commitment to transparency

The pharmaceutical industry is committed to preserving the integrity of Disclosure UK and transparency in our interactions with HCPs, ORDMs and HCOs. The ABPI continues to explore how the full disaggregated 2019 data can be submitted to Disclosure UK in line with data from previous years.

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 long term exchange rates used to convert any non-GBP payments in line with the Group's accounting policy.

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 2019 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.