

Methodology Statement - Actelion Pharmaceuticals UK Ltd.

ABPI 2018 Disclosure

Introduction

Actelion Pharmaceuticals Ltd (Actelion) is a Janssen pharmaceutical company of Johnson & Johnson. Actelion focuses on the discovery, development and commercialisation of treatments for rare diseases with high unmet medical needs. In order to conduct its business, Actelion engages legitimately with healthcare professionals (HCPs), other relevant decision makers (ORDMs) and healthcare organisations (HCOs). Depending on the activity provided or received, a direct or indirect transfer of value (TOV) may be attached.

The Association of British Pharmaceutical Industry (ABPI) Code of Practice requires that all pharmaceutical companies document and publicly disclose certain TOVs made directly or indirectly to HCPs, ORDMs and HCOs. A TOV is defined as 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.

Actelion is committed to disclosing all TOV to HCPs and HCOs in accordance with its commitment to the ABPI Code of Practice in alignment with the European Federation of Pharmaceutical Industries and Associations (EFPIA) Code on Disclosure on Transfers of Value.

Each company providing TOVs is required to publish a note summarising the methodologies used in preparing the disclosures, identifying each category of transfer of value. Actelion's methodology in this respect is summarised below. Actelion UK's disclosure report is available for a period of at least three years after its disclosure and its relevant records will be retained for a period of at least five years after the end of the calendar year to which they relate.

Definitions

1. Healthcare professional (HCP)

For the purposes of disclosure, Actelion regards all registered or qualified HCPs as within the scope of disclosure, regardless of their health service status.

2. Healthcare organisation (HCO)

Actelion regards all hospitals and other places, where HCPs work for the benefit of patients or provide associated advice or management services directly related to the treatment of patients, as healthcare organisations and within the scope of disclosure.

Transfers of value to health professionals and healthcare organisations

Actelion has captured and declared certain TOVs made directly or indirectly to HCPs and HCOs in line with the ABPI Code clause 24.2 including: joint working, donations, grants and benefits-in-kind provided to institutions, organisations and associations (HCOs).

In addition, sponsorship of attendance by HCPs and ORDMs at meetings, which may include sponsorship of registration fees, travel and accommodation; fees and expenses paid to HCPs and ORDMs, or to their employers on their behalf, for services provided (see below);

contributions towards the costs of meetings paid to HCOs or to third parties managing events on their behalf, have been captured and are declared.

Use of HCPs as Consultants

Healthcare professionals and ORDMs may legitimately assist Actelion as Consultants and be reimbursed at a fair market value for their time and efforts. Actelion may engage them as consultants and advisors, whether in groups or individually, for services such as speaking at and chairing meetings, involvement in medical/scientific studies, clinical trials or training services, participation at advisory board meetings, and participation in market research where such participation involves remuneration and/or travel.

Consent for disclosure

When Actelion engages a HCP, ORDM or HCO in a professional capacity, Actelion seeks to obtain consent for disclosure on an agreement by agreement basis. In 2017, provisions regarding TOV and consent of the recipient to its disclosure were included in the standard agreement.

Since the introduction of the General Data Protection Regulation (GDPR) in 2018, Actelion has obtained consent from HCPs in a separate consent form to the agreement. As consent is obtained on an agreement by agreement basis, Actelion is disclosing data only from HCPs from whom it has disclosure consent for every activity undertaken. If consent is missing or the HCP has chosen not to consent for disclosure of payment for a particular activity, all payments for that individual are disclosed in aggregate.

Healthcare professional request to redirect TOV payment

On occasion, a HCP who has provided a service to Actelion may request for their fee to be paid to charity. Actelion does not encourage or support this activity and all payments are made directly to the HCP and disclosed as such.

Reporting date of TOV

There is an inevitable delay between the date on which a payment is approved within Actelion and the date on which the payment is made. Actelion discloses the details of the payment as the date on which the transfer was completed. This may mean that some projects/activities taking place at the end of one year are disclosed in the following year, because the payment may not occur until January when the invoice has been received and settled.

Multi-year projects

Where projects run for several years, Actelion declares the amount paid relevant to the year in which each part of the payment was made. For example, a project which spans two calendar years and includes several individual TOVs during that time, would have two associated disclosures; one for each calendar year, showing the value of the transfer made in that specific calendar year.

Meeting Sponsorship

Where Actelion pays a third-party to organise a meeting on behalf of an HCO, these payments are disclosed against the HCO.

Where Actelion has fully or partially sponsored a meeting organised by more than one HCO, the

total payment amount has been divided by the number of organising HCOs and disclosed equally between each organising HCO.

Cross border transfers of value

On occasions, a UK HCP may be requested and agree to provide a service to Actelion headquarters (based in Switzerland) or an Actelion overseas affiliate. As for UK engagements, provisions regarding TOV and consent of the recipient to its disclosure were included in the agreement for 2017. From 2018, Actelion has obtained TOV consent in a separate form to comply with GDPR. The UK is advised of the proposed activity and the HCP is paid in line with UK fair market rates. Actelion UK discloses all payments made to UK HCPs for providing services overseas. For disclosure purposes, where payments are made to the HCP in non-UK currency the value of the payment is reported in GBP based on the exchange rate on the date of the TOV.

Research and Development

All payments to HCPs, HCOs and patient organisations (POs) related to research and development are disclosed as aggregate figures.

Payments to Patient Organisations

Payments made to UK Patient Organisations are disclosed directly on the Janssen website.

VAT

Where VAT is applicable TOV is reported excluding VAT.

Tax

Where payment of taxes are due they are the responsibility of the recipient and not Actelion.