

Methodology Statement - Actelion Pharmaceuticals UK Ltd.

ABPI 2016 Disclosure

Introduction

Actelion Pharmaceuticals Ltd (Actelion) is a biopharmaceutical company headquartered in Switzerland. 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 publically 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 all 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.

Agreements and consent to 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 2016, provisions regarding TOV and consent of the recipient to its disclosure were included in the standard agreement.

New EU legislation - the General Data Protection Regulation (GDPR) - comes into force on 25th May 2018. Under this new legislation, consent gained within a contract is not deemed valid consent, and therefore Actelion Pharmaceuticals UK Ltd, does not have valid consent to disclose individual HCP data from 2016. Actelion is therefore disclosing this data in aggregate form to comply with GDPR and the ABPI Code of Practice.

From 2018, Actelion is obtaining consent from HCPs in a separate consent form to the agreement in order to comply with GDPR.

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. All transfers of value are paid only after the project/activity has taken place.

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. Thus a project which spans two calendar years and includes several individual TOVs during that time, will have two associated disclosures; one for each calendar year, showing the value of the transfer made in that specific calendar year.

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 2016. From 2018, Actelion is obtaining TOV consent in a separate form to comply with GDPR. The UK will be advised of the proposed activity and the HCP will be 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 POs are disclosed directly on the Actelion website. www.actelion.com

VAT

Where VAT is applicable TOV is be reported excluding VAT.

Tax

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