

ANONYMOUS v ROCHE

Promotion of Xenical

An anonymous and non-contactable complainant alleged that Roche Products had used payments to induce prescribing of Xenical (orlistat). In particular a named chemist chain had been paid £100,000 per year, to ensure Xenical was prescribed directly to patients via patient group directions (PGDs).

The complainant provided a copy of an email, sent in November, 2008, which referred to an email and a Xenical sales agreement highlighting a cumulative shortfall in payment from Roche for an identified sum.

The detailed response from Roche is given below.

The Panel noted that the complainant had provided very little information to support their allegation. A complainant had the burden of proving their complaint on the balance of probabilities.

Roche had denied that it had paid the chemist chain £100,000 per year as alleged but stated that it had, however, paid £100,000 in 2007 as a one-off contribution towards the cost of updating material pursuant to a change in policy by Roche. Roche also stated that this contribution would help restore the margin on sales that would have achieved without the additional overhead. Given the specific reference to £100,000 by the complainant, it was extremely disappointing that Roche did not refer to this one-off payment in its initial response. To wait until asked for further information was poor practice. Self-regulation, and the reputation of the industry in that regard, relied upon full and frank disclosure at the outset.

The Panel noted that Roche viewed the one-off payment as an arrangement concerning measures or trade practices relating to prices, margins or discounts which were in regular use by a significant proportion of the pharmaceutical industry on 1 January 1993 and, therefore, outside the scope of the Code. The Panel disagreed. Prices, margins and discounts were financial terms and in the Panel's view had to be directly linked to the volume or cost of a product or products purchased. The £100,000 payment was a contribution to the cost of updating weight-loss programme materials. The Panel considered that this payment could not take the benefit of the exemption from the Code afforded to trade practices and was thus within the scope of the Code. Although concerned about the impression given by the one-off payment of £100,000 the Panel did not have any information before it to show that it had been used to ensure that Xenical was prescribed directly to patients via PGDs. No breach of the Code was ruled.

An anonymous and non-contactable complainant complained about the promotion of Xenical (orlistat) by Roche Products Limited.

COMPLAINT

The complainant stated that Roche had used payments to induce prescribing. In particular a named chemist chain had been paid £100,000 per year to ensure Xenical was prescribed directly to patients via patient group directions (PGDs).

The complainant provided a copy of an email, sent in November, 2008, which referred to an email and a Xenical sales agreement highlighting a cumulative shortfall in payment from Roche for an identified sum.

When writing to Roche, the Authority noted that it was not clear as to whether the complaint came within the scope of the Code. Roche was asked to deal with this point in its response and to bear in mind the requirements of Clauses 2, 9.1 and 18.1 of the Code.

RESPONSE

Roche stated that it took any complaint relating to its compliance with the Code very seriously. Notwithstanding this, Roche requested that the Panel dismiss the complaint on the basis that the complainant had not provided any evidence to support the complaint and, as a result, the burden of proof had not been satisfied. Roche also requested that, when considering the complaint, the Panel should take into account the fact that the complainant was anonymous and it had not been established if the complainant had any commercial, financial or other interest in the matter of the complaint or in Roche.

Without prejudice to these requests, Roche recognised that the Authority was obliged to investigate complaints that it received that were related to the Code. Roche was committed to assisting the Authority in this regard including assisting in investigations such as those raised in this complaint.

Copies of the sales agreement and Xenical SPC were provided. However, Roche could not locate copies of the email chains referred to in the complaint, thus copies were not provided.

Was the complaint within the scope of the Code?

Roche submitted that the arrangements did not come within the scope of the Code as they were 'measures or trade practices relating to prices, margins or discounts which were in regular use by a significant proportion of the pharmaceutical industry on 1 January 1993', as set out in Clause 1.2.

Prescription of Xenical by PGD

Roche explained that PGDs were written instructions for the supply or administration of medicines to groups of patients who might not be individually identified before presentation for treatment. PGDs must be signed by a senior doctor and a pharmacist both of whom should have been involved in developing the direction. A PGD must also be authorised by an appropriate regulatory body as set out in the legislation applying to PGDs. As a result, a PGD could be used to allow an authorised person to supply or administer prescription only medicines to patients without necessarily referring back to a doctor for an individual prescription.

The chemist chain operated a weight-loss programme. Roche understood that, as part of this programme, Xenical was prescribed using a private PGD. Under these arrangements patients paid for their treatment rather than obtaining it via an NHS prescription. The chemist chain was responsible for the development of this PGD and the content of the weight-loss programme. The arrangements pre-dated the availability of OTC orlistat and related solely to Xenical.

Payment of £100,000

Roche submitted that it did not pay £100,000 to ensure the prescription of Xenical via PGDs. However, £100,000 was paid in 2007 as a financial contribution to the costs the chemist chain would incur in updating weight-loss programme materials consequential to a change of policy by Roche in relation to patient support activities.

Roche explained that it operated a support service for Xenical patients, referred to as MAP (motivation, advice, pro-active support). The service was intended to provide advice on Xenical and how it worked and also information on healthy eating. This service was for the benefit of any patient, not just those enrolled on the chemist chain's weight-loss programme. Previously, booklets and advice sheets were posted to patients periodically. The service was switched to a web-based system, EMAP, during 2006.

The chemist chain had to inform its existing patients of the change to EMAP and to alter its communications materials given to new patients as a result of Roche switching to the EMAP service. The chemist chain had not known that it would incur these costs when it established its weight-loss programme. Roche agreed to contribute £100,000 to assist as an acknowledgement that additional costs had arisen only because Roche had switched to the EMAP service. The content of the communications was determined by the chemist chain and the £100,000 was not conditional on any content changes being approved by Roche. The payment did not benefit individual pharmacists, but helped restore the margin on sales.

Roche submitted that the above payment was possibly the payment referred to by the complainant.

However, the payment was not made to ensure the prescription of Xenical via PGDs and was not paid annually as alleged. The payment was a one-off, paid as part of a commercial arrangement to recognise additional unforeseen costs as a result of a change in Roche's internal systems. For the purpose of the Code, Roche viewed the payment as an arrangement relating to measures or trade practices relating to prices, margins or discounts which were in regular use by a significant proportion of the pharmaceutical industry on 1 January 1993 and, therefore, outside the scope of the Code.

PANEL RULING

The Panel noted that the complainant had provided very little information to support their allegations. The Constitution and Procedure stated that a complainant had the burden of proving their complaint on the balance of probabilities. The complainant was anonymous and non-contactable and so could not be asked to supply further details.

Roche had denied that it had paid £100,000 per year as alleged but stated that it had, however, paid the chemist chain £100,000 in 2007 as a one-off contribution towards the cost of updating material pursuant to a change in policy by Roche. Roche also stated that this contribution would help restore the margin on sales that would have been achieved without the additional overhead. Given the specific reference to £100,000 by the complainant, it was extremely disappointing that Roche did not refer to this one-off payment in its initial response. To wait until asked for further information was poor practice. Self-regulation, and the reputation of the industry in that regard, relied upon full and frank disclosure at the outset.

The Panel noted that, for the purposes of the Code, Roche viewed the one-off payment as an arrangement concerning measures or trade practices relating to prices, margins or discounts which were in regular use by a significant proportion of the pharmaceutical industry on 1 January 1993 and, therefore, outside the scope of the Code. The Panel disagreed. Prices, margins and discounts were financial terms and in the Panel's view had to be directly linked to the volume or cost of a product or products purchased. The £100,000 payment was a contribution to the cost of updating weight-loss programme materials. The Panel considered that this payment could not take the benefit of the exemption from the Code afforded to trade practices and was thus within the scope of the Code. Although concerned about the impression given by the one-off payment of £100,000 the Panel did not have any information before it to show that it had been used to ensure that Xenical was prescribed directly to patients via PGDs. No breach of Clause 18.1 was ruled.

Complaint received	19 November 2009
Case completed	10 February 2010