ANONYMOUS v MERCK SHARP & DOHME

Cerazette rebate scheme

An anonymous, non-contactable complainant alleged that a retrospective rebate scheme for Cerazette, an oral contraceptive marketed by Merck Sharp & Dohme, was an inducement to prescribe in breach of Clause 2 of the Code.

The complainant noted that several different generic versions of Cerazette had recently become available, resulting in potential loss of market share. To counter this, Merck Sharp & Dohme had offered clinics, hospitals, etc a retrospective rebate.

The detailed response from Merck Sharp & Dohme is given below.

The Panel noted that the complainant was anonymous and uncontactable. Such complaints were accepted and like all complaints judged on the evidence provided by the parties. The complainant had the burden of proving his/her complaint on the balance of probabilities.

The Panel noted that the Code excluded from the definition of promotion, 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. Further, the supplementary information to the Code, Terms of Trade, stated that such measures or trade practices were excluded from the provisions of that clause. The terms prices, margins and discounts were primarily financial terms. The Panel noted that other trade practices were subject to the Code and had to comply with it.

The Panel noted that Merck Sharp & Dohme denied offering retrospective rebates as alleged by the complainant. It did have other discount arrangements in place but these were not retrospective. The Panel noted that it was not possible to contact the complainant for further information. The Panel considered that whilst the subject of complaint was potentially within the scope of the Code, in that there was no material before the Panel to demonstrate that retrospective discounts had been in regular use by a significant proportion of the pharmaceutical industry on 1 January 1993, there was no evidence that the company had undertaken such activity in relation to Cerazette as alleged. The complainant had not discharged his/her burden of proof and the Panel thus ruled no breach of the Code, including no breach of Clause 2.

An anonymous, non-contactable complainant complained about a retrospective rebate scheme for Cerazette, an oral contraceptive, marketed by Merck Sharp & Dohme Limited.

COMPLAINT

The complainant stated that several different generic versions of Cerazette had recently become available, resulting in potential loss of market share. To counter this, Merck Sharp & Dohme had offered clinics, hospitals, etc a retrospective rebate on their use of Cerazette over a 12 month period.

The complainant alleged that a retrospective rebate was an inducement to prescribe and therefore a *prima facie* breach of Clause 2 of the Code.

When writing to Merck Sharp & Dohme, the Authority asked it to consider the requirements of Clause 18.1 of the Code in addition to Clause 2 cited by the complainant.

RESPONSE

Merck Sharp & Dohme was not clear as to what the complainant referred in relation to the statement that it had offered clinics, hospitals etc a retrospective rebate on their use of Cerazette over a 12 month period. Merck Sharp & Dohme did not have any retrospective rebate schemes in place with clinics, hospitals or any other third party. Merck Sharp & Dohme stated that it did not believe that the Cerazette discount arrangements it had in place were relevant. Firstly, it had contracts in place to supply NHS hospitals in England, Scotland and Northern Ireland with Cerazette at a discount. These discounts had been agreed with the respective national purchasing authorities within formal tendering/ contracting procedures and not directly with specific hospitals, hospital departments or clinicians. Under this scheme, hospitals purchased the product at the agreed contract price and, as such, the discount was not retrospective. Secondly, Cerazette was provided to some family planning clinics at a discounted price but, again, the discount was agreed prior to product purchase and not retrospectively.

Merck Sharp & Dohme stated that the discounts on Cerazette did not appear to fit the description of the activity alleged in the complainant's letter. Merck Sharp & Dohme had always understood that discounts fell outside the scope of the Code (Clause 1.2) as they had been in regular use prior to 1993. As such, Merck Sharp & Dohme did not believe this matter should proceed to the Panel.

Merck Sharp & Dohme stated that if the matter did proceed, the Cerazette discounts had been agreed with the purchasing authorities, in the case of the hospital contracts, and with the appropriate decision makers in the case of family planning clinics. Merck Sharp & Dohme stated that no health

professional or administrative staff member had obtained any personal benefit as a result of its discount arrangements. Merck Sharp & Dohme did not consider that this activity constituted a breach of Clause 18.1, or by implication, a breach of Clause 2 which was reserved for particularly serious breaches of the Code.

Merck Sharp & Dohme stated that in common with other companies, it evaluated potential arrangements or schemes including discounts in a number of therapy areas, including contraception. If any of these were to be implemented in due course, they would be subjected to appropriate review and approval from both a legal and a Code perspective.

PANEL RULING

The Panel noted that the complainant was anonymous and uncontactable. Such complaints were accepted and like all complaints judged on the evidence provided by the parties. The complainant had the burden of proving his/her complaint on the balance of probabilities.

The Panel noted that Clause 1.2 excluded from the definition of promotion, 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. Further, the supplementary information to Clause 18.1, Terms of Trade, stated that such measures or trade practices were excluded from the provisions of that clause. The terms prices, margins and discounts were primarily financial terms. The Panel noted that other trade practices were subject to the Code and had to comply with it.

The Panel noted Merck Sharp & Dohme's submission that this case should not proceed to the Panel as, in its view, the practice of discounting fell outside the scope of the Code. Merck Sharp & Dohme referred to Clause 1.2 of the Code. The Panel noted that Clause 1.2 exempted certain trade practices from the definition of promotion as set out above. The Panel noted that the Constitution and Procedure did not permit the case preparation manger to decide whether such a matter was outside the scope of the Code; that was a matter for the Panel.

The Panel noted that Merck Sharp & Dohme denied offering retrospective rebates as alleged by the complainant. It did have other discount arrangements in place but these were not retrospective. The Panel noted that it was not possible to contact the complainant for further information. The Panel considered that whilst the subject of complaint was potentially within the scope of the Code, in that there was no material before the Panel to demonstrate that retrospective discounts had been in regular use by a significant proportion of the pharmaceutical industry on 1 January 1993, there was no evidence that the company had undertaken such activity in relation to Cerazette as alleged. The complainant had not discharged his/her burden of proof and the Panel thus ruled no breach of Clauses 18.1 and 2.

Complaint received **30 April 2013**

Case completed **30 May 2013**