CASE AUTH/2105/3/08 *NO BREACH OF CODE*

ANONYMOUS DOCTOR v PROCTER & GAMBLE

Alleged promotion of Asacol to the public

An anonymous doctor complained that a poster, which had been placed in an outpatients department and designed to recruit patients into a clinical study, had caused numerous patients to ask for a once-daily prescription of Asacol (mesalazine). This had led to lengthy discussions with patients who did not fit into the trial criteria, but who still wanted the once-daily Asacol. As far as the complainant was aware Asacol which was marked by Procter & Gamble had not been licensed for once daily use. The complainant considered that recruiting patients in this way was extremely unethical; it not only gave false hope of a once-daily preparation, but caused unnecessary tension between patients and the clinician.

The Panel noted that Procter & Gamble's involvement with the trial was limited to the provision of an educational grant. The sponsor, an NHS trust, was responsible for the study. Procter & Gamble had played no role in the generation or placement of the poster at issue; it had been independently produced by the NHS trust that ran the study. The Panel thus decided that Procter & Gamble was not responsible for the poster and no breach of the Code was ruled.

An anonymous, non-contactable doctor complained about a poster which had appeared in the out-patients department of a hospital. The poster was headed 'CODA Trial – Colitis: Once daily Asacol'. Readers were told that remembering to take their tablets when their ulcerative colitis was in remission was hard and that taking tablets once daily would help although there was no evidence that this was as good as taking tablets two or three times daily. It was stated that the CODA trial was designed to investigate whether taking Asacol once daily was as effective as taking the same dose split three times during the day in preventing flares of disease in patients whose ulcerative colitis was in remission. The poster invited readers to participate in the study if their colitis was in remission but had flared in the past two years. The poster featured a cartoon picture of an elephant's head with a knot in its trunk.

Asacol (mesalazine) was marketed by Procter & Gamble Pharmaceuticals UK Limited. The summary of product characteristics (SPC) stated that in maintenance therapy three to six tablets were to be taken a day in divided doses.

COMPLAINT

The complainant stated that as far as (s)he was aware Asacol had not been licensed as a once-daily option. Although the poster stated that a once-daily preparation might not have any benefit, the picture used (an elephant never forgets!) and the highlighting of key words in the poster pointed towards better compliance.

The complainant submitted that the poster had caused numerous patients to ask for a once-daily prescription of Asacol. It had also caused the complainant unnecessary stress, as (s)he had had to have lengthy discussions with patients who did not fit into the trial criteria, but still insisted on having the once-daily preparation of Asacol. The very fact that the poster was placed in the patients' waiting area of the hospital meant that it was targeting the general public. This was a sure way of getting patients' attention.

The complainant stated that (s)he did not have an issue with pharmaceutical companies recruiting patients for their clinical trials, but it should be done appropriately. Physicians should be given the relevant information and then decide on the appropriate patients who should enter the trials. The complainant had not been briefed by Procter & Gamble on the CODA trial.

The complainant provided two photographs of the outpatient department showing the location of the poster in question. The complainant wanted to remain anonymous, as Procter & Gamble had funded many projects at his/her hospital and (s)he did not want to be identified as the whistle blower that led to the company withdrawing its support.

The complainant considered that this type of behaviour was extremely unethical; it not only gave patients the false hope of a once-daily preparation, but caused unnecessary tension between the patient and the clinician during clinics.

When writing to Procter & Gamble the Authority asked it to respond in relation to Clauses 2, 9.1, 20.1 and 20.2 of the Code.

RESPONSE

Procter & Gamble stated that it had neither sponsored the CODA trial nor played any role whatsoever in the production or placement of the poster.

Procter & Gamble explained that CODA (Colitis Once Daily Asacol) was a 12 month randomised, multicentre, parallel group single-blind study to assess the efficacy and safety of dosing mesalazine 800mg tablets at 2.4g once daily vs divided doses three times daily in the maintenance of remission of ulcerative colitis. The trial also included a compliance sub-study. The study protocol was approved by the Multi Centre

Research Ethics Committee (MREC) and the Medicines and Healthcare products Regulatory Agency (MHRA). Procter & Gamble had funded the study via an educational grant, which covered study medicine, regulatory consulting and financial support (employment of a central study co-ordinator, recruitment costs, etc).

The sponsor of the study was an NHS trust. The trust ran the study and was fully and independently responsible for the study protocol and the conduct and scientific evaluation of the study. The trust also owned all data and reports, including safety reporting and publishing of the results as obligated to do so under its national research governance framework for health and social care.

The poster was not Procter & Gamble's responsibility, nor was the company consulted on its content or its placement as referred to by the complainant. The poster was independently produced by the NHS trust. The wording was reviewed and approved by the Research Ethics Committee (REC); a copy of the approval letter forwarded to Procter & Gamble by the sponsor was provided.

The poster was distributed to the principal investigator at the hospital who completed contact details on the poster. These details were for the clinical nurse specialist at the hospital who was responsible for patient recruitment at the site (ie not a contact at Procter & Gamble). The poster was then placed by the clinical nurse specialist in the medical clinic which was where the gastroenterology clinic was held three days of the week. The position of the notice board had been specifically selected to be visible only to relevant patients with ulcerative colitis who might be interested in participating in the trial.

The complainant stated that the poster caused patients to ask for a currently not approved once daily prescription of Asacol. The purpose of the poster, however, was solely to raise awareness of the trial and aid recruitment. The poster clearly stated that the purpose of the trial was to investigate the open question, whether a once daily dosage regimen was equivalent to a divided dosage regimen; it also stated that there was currently no evidence that once daily was as good as divided dosing.

Procter & Gamble supported the complainant's statement that physicians should be given information to determine appropriate patients who should enter a trial; the company believed that the sponsor of the CODA trail did exactly this. Relevant staff at the hospital site and its research and development department were fully aware of the details of the CODA trial and had agreed to participate.

Procter & Gamble did not know why the complainant did not contact the clinical nurse specialist regarding the poster or the trial if it was causing unnecessary stress. It was also not clear how the complainant was able to discuss CODA trail inclusion and exclusion criteria with patients as these criteria were only known to the gastroenterology team and no other non gastroenterology physicians had contacted the clinical nurse specialist to request information.

In summary Procter & Gamble stated that it did not produce or distribute the poster and did not place it on the out-patient department's notice board.

The poster was produced independently by the NHS trust to aid patient recruitment. This was not a promotional activity. The wording in the poster was not promotional nor did it raise unfounded hopes of successful treatment.

With studies such as this, it was vital to maintain independence between the parties to give credibility to any results, to maintain high ethical standards and to ensure integrity should public scrutiny question the running of such a trial.

There was no promotion of a prescription only medicine and thus no breach of Clauses 20.1 or 20.2. Additionally, there had not been a failure to maintain high standards or any activity that would bring discredit upon, or reduce confidence in, the pharmaceutical industry and thus no breach of Clauses 9.1 or 2.

PANEL RULING

The Panel noted that it was a clearly established principle that companies were responsible under the Code for the activities of third parties acting on their behalf.

The Panel noted that Procter & Gamble's involvement in the CODA trial was limited to the provision of an educational grant and the sponsor, an NHS trust was responsible for the study. Procter & Gamble had played no role in the generation or placement of the poster at issue; it had been independently produced by the NHS trust that ran the study. The Panel thus decided that Procter & Gamble was not responsible for the poster and no breach of Clauses 20.1 and 20.2 was ruled. The Panel also ruled no breach of Clauses 9.1 and 2.

During its consideration of this case the Panel had some sympathy with the complainant's views; the poster did not refer to the NHS trust that had sponsored the study and the only product named was Procter & Gamble's Asacol. Although in this case Procter & Gamble had no involvement with the creation and placement of the poster, pharmaceutical companies similarly part funding studies would do well to remind those running studies that patient recruitment material must not inadvertently advertise prescription only medicines to the public or contain statements encouraging the public to ask a health professional to prescribe a specific prescription only medicine.

Complaint received 13 March 2008

Case completed 9 April 2008