CASE AUTH/2586/3/13

VOLUNTARY ADMISSION BY FERRING

Symposium flyers

Ferring Pharmaceuticals voluntarily admitted that two flyers for symposia to be held at a European congress in Milan had been sent to UK delegates by its global colleagues by mistake.

As the Constitution and Procedure required the Director to treat a voluntary admission as a complaint, the matter was taken up with Ferring. Ferring explained that some of the sessions in the symposia were outside the current UK licences for its products and so the flyers were not intended to be sent to UK delegates. It was attempting to stop and recall the mailings where it could.

The response from Ferring is given below.

The Panel noted that the company's corporate office in Geneva had sent invitations to two company sponsored symposia to, *inter alia*, 436 UK registered delegates. Data presented at the symposia about Ferring's products included material about indications and doses not licensed in the UK. The Panel noted that under the Code Ferring UK was responsible for activity in the UK of its global colleagues where such activity was within the scope of the Code.

The Panel considered that the distribution of invitations to UK delegates for an overseas meeting came within the scope of the Code. In addition, the Panel noted that the Code required all meetings which involved travel outside the UK to be certified in advance.

The Panel noted that one of the invitations was headed 'Ferring invites you to a satellite symposium: New data on androgen deprivation with a GnRH [gonadotrophin releasing hormone] antagonist: improving patient outcomes in prostate cancer'. Reference was made to an increasing volume of comparative data now available for the GnRH antagonist degarelix (Ferring's product, Firmagon) and LHRH (leuteinizing hormone-releasing hormone) agonists. The Panel noted that the invitation mentioned the product and therapy area and thus the Panel considered that it was promotional material. It had not been certified as required by the Code and a breach was ruled.

The second invitation was to a symposium entitled 'Nocturia: definitive diagnosis for better patient outcomes' which included presentations on 'Breaking the Patient stereotype'; 'What is different about Nocturia?', 'Non-antidiuretic vs antidiuretic pharmacology for nocturia'; followed by a round up of patient case studies. The invitation explained that research supported the treatment as a distinct disorder and explained that it was not necessarily driven by lower urinary tract symptoms but that it could result from multiple underlying causes. A strapline at the bottom of the invitation stated 'Ferring does not have a product licensed for Nocturia in Italy'.

The Panel noted that in the UK Ferring's product Desmospray (desmopresin) was indicated for, *inter alia*, the treatment of nocturia associated with multiple sclerosis where other treatments had failed. Desmomelt and Desmotabs (both desmopressin) were each indicated for the treatment of primary nocturnal enuresis. The Panel noted that whilst the invitation did not directly mention Ferring's products it did discuss nocturia and that the condition could be caused by conditions other than those involving the bladder, prostate, or urethra. The Panel considered that the invitation went beyond a general discussion of nocturia and was closely linked to the licensed indication for Desmospray. The invitation was promotional in this regard. It had not been certified as required by the Code and a breach was ruled.

The Panel noted that according to Ferring each symposium included data that was outside each product's UK licence. This was not clear from either invitation which included only a general description of the products' licensed indications. The Panel noted that Ferring's admission related solely to the invitations and on that basis the Panel ruled no breach of the Code as neither invitation promoted the products in a manner that was inconsistent with their marketing authorizations.

Ferring Pharmaceuticals Ltd voluntarily admitted that two flyers for symposia to be held at a European congress in Milan had been sent to UK delegates by its global corporate office by mistake.

As Paragraph 5.6 of the Constitution and Procedure required the Director to treat a voluntary admission as a complaint, the matter was taken up with Ferring.

COMPLAINT

Ferring advised the Authority that a letter with two invitation flyers for Ferring-sponsored symposia, to be held at the European Association of Urology (EAU) Annual Congress in Milan on 17/18 March 2013, was sent in error to all UK delegates registered to attend the congress. The flyers were sent by global colleagues on 5 March 2013 without UK approval. The two symposia were: Nocturia: Definitive diagnosis for better patient outcomes and new data on androgen deprivation with a [gonadotrophin releasing-hormone] GnRH antagonist: Improving patient outcomes in prostate cancer.

Ferring explained that some of the sessions in the symposia were outside the current UK licences for its products and so the flyers were not intended to be

sent to UK delegates. The company was attempting to stop and recall the mailings where it could. The matter had been discussed with global colleagues and robust measures were now in place to improve internal communication and prevent such incidents from happening again.

When writing to Ferring, the Authority asked it to respond to Clauses 3.2 and 14.1 of the Code.

RESPONSE

Ferring submitted that the annual EAU Congress was one of the world's leading, independent, research based urology conferences. In conjunction with this congress, Ferring sponsored two scientific symposia that were organised and conducted by a number of experts from the relevant therapeutic fields. These symposia were:

'Nocturia: Definitive diagnosis for better patient outcomes' which aimed to provide an overview of the variety of clinical characteristics of patients with nocturia, and the multifactorial nature of the mechanism of the disease. The symposium included presentations that reviewed the prevalence and consequences of nocturia, discussed case studies of patients with nocturia and their diagnoses, reviewed current understanding of the mechanism of nocturia and discussed treatment algorithms and guidelines, and finally summarised the evidence for efficacy of available pharmacotherapies for nocturia.

'New data on androgen deprivation with a GnRH antagonist: Improving patient outcomes in prostate cancer' which aimed to present recent data on androgen deprivation therapy for prostate cancer, in a clinically meaningful way that facilitated improved patient care.

Ferring submitted that the two symposia provided scientific information about actual trial data and analyses. While in many countries Ferring marketed desmopressin for the treatment of nocturia and a GnRH antagonist, degarelix (Firmagon), for the treatment of prostate cancer, the symposia did not promote these medicines. Rather they were traditional scientific symposia under the control of independent scientific experts. Information presented at the symposia included clinical data about desmopressin and degarelix, including data about indications and dose regimes not licensed in the UK.

Sponsored satellite symposia were organised within the official EAU Congress scientific programme and the speakers' honoraria directly paid by EAU. The scientific outline was endorsed by the chairman and communicated to health professionals attending the congress. Flyers were usually printed to inform the delegates about the topic and, in this case, had been handed out by many companies sponsoring similar symposia at this meeting. The flyers reflected the content of the symposia described above, which provided information about the state of the art for nocturia and prostate cancer disease management and treatments. Neither the symposia, nor the flyers were promotional.

Ferring stated that the flyers were approved by the company's corporate office and its Italian affiliate and complied with the relevant Italian regulations. The timelines for approval by the Italian regulatory authority were given.

Ferring noted that the relevant standard operating procedure (SOP) (CS-10237, Approval of therapy area and product specific promotional and non-promotional marketing material) stated on page 5 that 'When Global Marketing Material is produced for a congress, the [regulatory affairs manager] and/or General Manager of the country where the congress will be held must review the material and ensure that it complies with the local regulation'. This SOP had been strictly followed in the preparations for the symposia.

The Ferring corporate office decided to send the flyers to the list of EAU pre-registered delegates provided by EAU. Unfortunately, all 436 UK registered delegates were mistakenly included in the bulk mailing sent by the mailing company, although this activity had not been notified to, or approved by Ferring UK. The flyers were sent to all registered delegates, approximately two weeks before the congress.

Ferring noted that Clause 3.2 stated that the promotion of a medicine must be in accordance with the terms of its marketing authorization and must not be inconsistent with the particulars listed in its summary of product characteristics. Ferring further noted that the flyers did not mention the name of any particular medicine and the symposia at issue were balanced programmes for the purpose of legitimate scientific exchange.

Ferring noted that Clause 14.1 stated that promotional material must not be issued unless its final form, to which no subsequent amendments would be made, had been certified by two persons on behalf of the company. In this case Ferring was uncertain whether the flyers were promotional items as they did not include the name of any specific product. However, Ferring UK would normally certify such items to ensure compliance with the Code, and it was because they were distributed without such review or certification that it had made the voluntary admission.

PANEL RULING

The Panel noted that the company's corporate office in Geneva had produced invitations to two company sponsored symposia and distributed them to, *inter alia*, 436 UK registered delegates. Data presented at the symposia about Ferring's products included material about indications and doses not licensed in the UK. The Panel noted that it was an established principle under the Code that the UK company was responsible for acts and omissions of its overseas affiliates that came within the scope of the Code. Ferring UK was thus responsible under the Code for the activity of its global corporate office in the UK.

The Panel noted Ferring's submission that the symposia were for the purpose of legitimate

scientific exchange and were thus not promotional. In the Panel's view it did not have to consider whether the meetings fell within the supplementary information to Clause 3 Marketing Authorization which permitted the legitimate exchange of medical and scientific information during the development of a medicine provided such exchange did not constitute promotion prohibited under Clause 3 or any other clause. The voluntary admission was only in relation to the invitations and not the actual meetings. The Panel thus made no decision on the actual meetings. The Panel considered that the distribution of 436 invitations to UK delegates for an overseas meeting was an activity which came within the scope of the Code and had to comply with it irrespective of the status of the meeting in relation to the supplementary information to Clause 3. In addition the Panel noted that the Code required all meetings which involved travel outside the UK to be certified in advance. The Panel did not know whether any UK delegates had been sponsored by Ferring to attend the conference.

The Panel noted that the four page invitation to the symposium about prostate cancer was headed 'Ferring invites you to a satellite symposium: New data on androgen deprivation with a GnRH antagonist: Improving patient outcomes in prostate cancer'. The invitation included mention of an increasing volume of comparative data now available for the GnRH antagonist degarelix and LHRH agonists. Examination of the growing database also allowed a direct comparison between these products for safety endpoints. The meeting started at 17.45 with a welcome and was followed by 4 presentations; Radiotherapy and androgen deprivation,' 'Is intermittent androgen deprivation really equivalent to continuous therapy?', 'Disease control: Comparative data from degarelix vs. LHRH agonists', and 'Cardiovascular risk and ADT: New data, new insights' and finished with a panel discussion and concluding remarks. The Panel noted that Ferring's product, degarelix, was the only medicine mentioned. The front page and outside back cover featured Ferring's corporate logo within a statement 'Supported by an educational grant from Ferring Pharmaceuticals'.

The Panel noted that Firmagon (degarelix) was a gonadotrophin releasing hormone antagonist for the treatment of advanced hormone dependent prostate cancer. The Panel noted that the invitation mentioned the product and therapy area and considered that it was promotional material. It had not been certified as required by Clause 14.1 and a breach of that clause was ruled.

The Panel noted that the second invitation was for an evening symposium sponsored by Ferring entitled 'Nocturia: Definitive diagnosis for better patient outcomes' which according to its agenda covered presentations on 'Breaking the Patient stereotype'; 'What is different about Nocturia?', 'Non-antidiuretic vs antidiuretic pharmacology for nocturia'; followed by a round up of patient case studies concluding with a question and answer session. The invitation explained that research supported the treatment as a distinct disorder and explained that it was not necessarily driven by lower urinary tract symptoms but that it could result from multiple underlying causes. A strapline at the bottom of the invitation stated 'Ferring does not have a product licensed for Nocturia in Italy'.

The Panel noted that in the UK Ferring's product Desmospray (desmopressin) was indicated for, *inter alia*, the treatment of nocturia associated with multiple sclerosis where other treatments had failed. Desmomelt and Desmotabs (both desmopressin) were each indicated for the treatment of primary nocturnal enuresis. The Panel noted that whilst the invitation did not directly mention Ferring's products it did discuss nocturia and that the condition could be caused by conditions other than those involving the bladder, prostate, or urethra. The Panel considered that the invitation went beyond a general discussion of nocturia and was closely linked to the licensed indication for Desmospray. The invitation was promotional in this regard. It had not been certified as required by Clause 14.1 and a breach of that clause was ruled.

The Panel noted that according to Ferring each symposium included data that was outside each product's UK licence. This was not clear from either invitation which included only a general description of the products' licensed indications. The Panel noted that Ferring's admission related solely to the invitations and on that basis the Panel ruled no breach of Clause 3.2. Neither invitation promoted the products in a manner that was inconsistent with their marketing authorizations.

Complaint received **11 March 2013**

Case completed **25 April 2013**