CASES AUTH/2467/12/11 and AUTH/2468/12/11

ANONYMOUS v BOEHRINGER INGELHEIM and PFIZER

Promotion of Spiriva

An anonymous respiratory physician complained about conference material for a meeting of the British Thoracic Society and about materials made available from the joint Boehringer Ingelheim and Pfizer stand at that meeting. The two companies co-promoted Spiriva (tiotropium inhalation powder) and Spiriva Respimat (tiotropium solution for inhalation). Spiriva powder was administered via a Handihaler and Spiriva Respimat via a Respimat inhaler. Spiriva was indicated as maintenance bronchodilator treatment to relieve symptoms of chronic obstructive pulmonary disease.

The detailed response from Boehringer Ingelheim and Pfizer is given below.

The complainant was concerned that the brief description of the Boehringer Ingelheim and Pfizer stand, contained in the conference booklet, stated that Spiriva and the Respimat inhaler were 'new' when in fact both were several years old.

The Panel noted that the Code required that 'new' must not be used to describe, *inter alia*, any product or presentation which had been generally available for more than twelve months in the UK. Both Spiriva and Spiriva Respimat had been generally available for more than 12 months when the meeting in question was held. The Panel ruled a breach of the Code as acknowledged by the companies.

The complainant stated that Boehringer Ingelheim representatives had handed out samples and devices of both the HandiHaler and Respimat at the promotional stand and this was not allowed.

The Panel noted the companies' submission that the items at issue were placebo demonstration devices. The Panel thus considered that they were not samples as defined by the Code and no breach of the Code was ruled in that regard.

The Panel noted that the Code stated, inter alia, that health professionals might be provided with items which were to be passed on to patients and which were part of a formal patient support programme. Such items must be inexpensive and directly benefit patient care; they must not be given out from exhibition stands. Supplementary information to the Code noted that in limited circumstances, such items might be made available for use by health professionals even though they were not to be passed on to patients for them to keep, eg inhalation devices. The Panel considered, however, that the supplementary information did not over-ride the requirement that patient support items could not be given out to health professionals from exhibition stands. The Panel disagreed with the companies' submission that this requirement did not apply to items that were not to be passed to patients. With regard to the provision of the demonstration Handihalers and Respimat inhalers from an exhibition stand the Panel thus ruled a breach of the Code.

An anonymous respiratory physician, complained about conference material for the Winter 2011 meeting of the British Thoracic Society (BTS) and about materials made available from the joint Boehringer Ingelheim Limited and Pfizer Limited stand at that conference. The two companies co-promoted Spiriva (tiotropium inhalation powder) and Spiriva Respimat (tiotropium solution for inhalation). Spiriva powder was administered via a Handihaler and the Spiriva Respimat via a Respimat inhaler. Spiriva was indicated as maintenance bronchodilator treatment to relieve symptoms of patients with chronic obstructive pulmonary disease (COPD).

Boehringer Ingelheim responded on behalf of both companies.

A Conference programme and abstracts booklet

A page of the conference programme and abstracts booklet headed 'Exhibitors' Information', included a brief description of Boehringer Ingelheim's and Pfizer's joint stand which included a statement that Boehringer Ingelheim was '... committed to delivering high-quality respiratory care through the discovery of new respiratory medicines (Spiriva) and delivery systems (Respimat) ...'. This was followed by a short paragraph about Pfizer Inc.

COMPLAINT

The complainant was concerned that the exhibitors' information used the word 'new' when the medicines mentioned were several years old and there was nothing new about them.

When writing to Boehringer Ingelheim and Pfizer, the Authority asked each to respond in relation to Clause 7.11 of the Code.

RESPONSE

Boehringer Ingelheim accepted that the word 'new' in relation to Spiriva HandiHaler and Spiriva Respimat was used inappropriately; the oversight was regretted and the statement had been withdrawn. It would be amended if used again. In order to ensure this did not happen again, training would be provided to relevant personnel. Processes would be implemented to ensure future exhibitor information was certified appropriately.

Boehringer Ingelheim submitted that Spiriva was first authorized in May 2002 and Spiriva Respimat in September 2007.

PANEL RULING

The Panel noted that Clause 7.11 required that the word 'new' must not be used to describe any product or presentation which had been generally

available, or any therapeutic indication which had been generally promoted, for more than twelve months in the UK. The Panel noted Boehringer Ingelheim's submission that marketing authorizations had been granted for Spiriva in 2002 and for Spiriva Respimat in 2007. Both products had therefore been generally available for more than 12 months when the BTS Winter meeting 2011 was held. The Panel noted that Boehringer Ingelheim had acknowledged that the use of the word 'new' was inappropriate. A breach of Clause 7.11 was ruled.

B Provision of demonstration inhaler devices from an exhibition stand

COMPLAINT

The complainant alleged that Boehringer Ingelheim representatives had handed out samples and devices of both the HandiHaler and Respimat at the promotional stand. The complainant was sure that this was not allowed.

When writing to Boehringer Ingelheim and Pfizer, the Authority asked each to respond in relation to Clauses 17.3 and 18.2 of the Code.

RESPONSE

Boehringer Ingelheim submitted that active samples were not distributed from the promotional stand therefore Clause 17.3 did not apply. Boehringer Ingelheim company policy was not to distribute active samples on request. Placebo HandiHaler and placebo Respimat devices were demonstrated and made available to health professionals by representatives upon request as permitted under Clause 18.2. The representatives at the stand had twenty such devices available to them.

Boehringer Ingelheim noted that the supplementary information for Clause 18.2 stated that:

> 'Although items which are to be passed on to patients may not be given out from exhibition stands, they may be exhibited and demonstrated on stands and requests for them accepted for later delivery.' (emphasis added)

Boehringer Ingelheim considered that since these were not items to be passed to patients the above requirement of Clause 18.2 that giving out such items at exhibition stands should not take place did not apply.

Boehringer Ingelheim noted that the supplementary information to Clause 18.2 further stipulated, particularly citing the example of inhalation devices, that such items might be made available to health professionals in promotional calls or other circumstances:

> 'Patient support items may be provided to health professionals by representatives during the course of a promotional call and representatives may deliver such items when they are requested by health professionals, for example on reply paid cards. Provided that they have been appropriately documented and certified in advance as required by Clause 14.3, in limited circumstances patient support items may be made available for the use of health professionals even though they are not to be passed on to patients for them to keep. This is where their purpose is to allow patients to gain experience in using their medicines whilst under the supervision of a health professional. Examples include inhalation devices (with no active ingredient) and devices intended to assist patients to learn how to self-inject.' (emphasis added)

Boehringer Ingelheim submitted that it had complied with the requirements of Clause 18.2 in making placebo inhalation devices available to health professionals.

PANEL RULING

The Panel noted that Clause 17.3 required that samples were only supplied in response to written requests which had been signed and dated. The supplementary information to Clause 17 defined a sample as a small supply of a medicine provided to health professionals so that they might familiarise themselves with it and acquire experience in dealing with it. The supply of a product which was not a medicine because it did not contain the active ingredient was not regarded as the supply of a sample.

The Panel noted Boehringer Ingelheim's submission that the items at issue on the exhibition stand were placebo demonstration devices. The Panel thus considered that they were not samples as defined by the Code and so Clause 17.3 did not apply. No breach of Clause 17.3 was ruled.

The Panel noted that Clause 18.2 stated, *inter alia*, that health professionals might be provided with items which were to be passed on to patients and which were part of a formal patient support programme. The items provided must be inexpensive and directly benefit patient care. They might bear the name of the company providing them. They must not be given out from exhibition stands. The supplementary information to Clause 18.2, Patient Support Items, noted that in limited circumstances, such items might be made available for use by health professionals even though they were not to be passed on to patients for them to keep. Inhalation devices were cited as an example of such items. The Panel considered, however, that the supplementary information did not over-ride the requirement of Clause 18.2 that patient support items could not be given out to health professionals from exhibitions stands. The Panel disagreed with Boehringer Ingelheim's submission that this requirement did not apply to items that were not intended to be passed to patients.

The Panel considered that the provision of the demonstration Handihalers and Respimat inhalers from an exhibition stand was contrary to Clause 18.2 and a breach of that clause was ruled.

Complaint received **19 December 2011**

Case completed **7 February 2012**