CASE AUTH/2379/1/11

ANONYMOUS v CHIESI

Promotion of Fostair

An anonymous, non contactable complainant referred to material for Fostair (beclometasone and formoterol) on a Chiesi exhibition stand at a meeting of the British Thoracic Society (BTS). The material at issue was a copy of the journal Respiratory disease in practice which appeared to be sponsored by Chiesi and there was an advertisement for Fostair on the outside back cover. The article on the front cover of the journal was entitled 'The small airways: an important target in asthma and COPD [chronic obstructive pulmonary disease] treatment'.

The publication was of interest and relevance to the complainant's medical practice but after looking for data on the use of Fostair in COPD, given that the journal contained information about COPD and finding a web page which referred to seeking registration of Fostair for COPD, the complainant was surprised to learn that Fostair was only licensed for asthma. The complainant did not think that this important fact was clear enough on the Chiesi stand and while he would ensure that he and his colleagues had the appropriate information to inform their decisions he queried whether Chiesi's actions were appropriate.

The detailed response from Chiesi is given below.

The Panel noted that it was acceptable for companies to sponsor material. It had previously been decided, in relation to material aimed at health professionals, that the content would be subject to the Code if it was promotional in nature or if the company had used the material for a promotional purpose. Even if neither of these applied, the company would be liable if it had been able to influence the content of the material in a manner favourable to its own interests. It was possible for a company to sponsor material which mentioned its own products and not be liable under the Code for its content, but only if it had been a strictly arm's length arrangement with no input by the company and no use by the company of the material for promotional purposes.
The publication in question had been paid for and sponsored by Chiesi. It had been initiated as a result of a discussion between the publisher and Chiesi. The Panel noted that Respiratory disease in practice was described as an independent title supported by an unrestricted educational grant from Chiesi. This description appeared beneath the Chiesi logo.

The journal included two articles about COPD. The first was a four page article starting on the front page and was entitled 'The small airways: an important target in asthma and COPD treatment'. It mentioned the generic name of Fostair's active ingredients in relation to particle sizes and distribution in the lungs. The article referred to formulations with extrafine and ultrafine small particles that had been developed using newer hydrofluoroalkane (HFA) propellants in pressurised metered-dose inhalers pMDIs for a long acting beta$_2$-agonist (formoterol), corticosteroids (beclometasone dipropionate (BDP), ciclesonide, flunisolide) and fixed combinations (BDP/formoterol, ciclesonide/formoterol). Improved total lung deposition (TLD) had been observed with HFA inhalers compared with chlorofluorocarbon (CFC) propellant devices. The article referred to lung deposition data in asthma patients. It concluded that future studies were needed, particularly in COPD patients to determine whether improvements in distal lung deposition and small airways function with ultrafine particles were translated into clinically significant patient outcomes such as improved control of symptoms, better health-related quality of life, fewer adverse effects and reduced exacerbations.

The second article on COPD was a two page article on 'Investigation and treatment of severe chronic obstructive pulmonary disease'. The article referred to management of breathlessness and exacerbations and the National Institute for Health and Clinical Excellence (NICE) guidelines on COPD latest draft recommendations. Mention was made of inhaled steroids and long-acting beta-agonists as well as other medicines.

The editorial referred to the recently published National Clinical Strategy for COPD and that two new medicines were to be launched for COPD later in the year.

The webpage referred to by the complainant was that of a communication company which had been appointed by Chiesi to work on the prelaunch and launch of Fostair for COPD. The page included the Chiesi logo.

The advertisement for Fostair mentioned its use in asthma. It also referred to the delivery of twice as much medication to the lungs as standard metered-dose inhalers and that a third of the extrafine particles reached the small airways. It also included the claim 'For lungfuls of life'.

The publication was available from a Chiesi promotional stand at the BTS meeting. All material on the stand needed to comply with the Code. The Panel considered that the article had been used for a promotional purpose and thus its content was covered by the Code.

The question now to be addressed was whether the journal promoted Chiesi's product for an unlicensed indication. The Code stated that 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 (SPC).

The Panel noted that the articles referred to the treatment of COPD with fixed combinations of BDP and formoterol as well as the advantages for HFA propellants. The Panel considered that the distribution of the journal from Chiesi's promotional stand in effect promoted Fostair for an unlicensed indication. In addition, the Panel noted that the Fostair advertisement in the journal referred to the extrafine particles reaching the small airways. In the Panel's view this linked to the article about the treatment of COPD and references to particle size. A breach of the Code was ruled. This was misleading and did not promote rational use. Thus further breaches were also ruled.

The Authority received an anonymous complaint about material for Fostair (beclometasone and formoterol) pressurised inhalation solution on a Chiesi Limited exhibition stand. A Fostair advertisement had been published in the journal Respiratory disease in practice, Volume 21 Number 1; the article on the front cover of the journal was entitled 'The small airways: an important target in asthma and COPD [chronic obstructive pulmonary disease] treatment'. Fostair was indicated for the regular treatment of asthma where use of a combination product inhaled corticosteroid and long acting beta$_2$-agonist was appropriate. The complainant could not be contacted.

COMPLAINT

The complainant explained that at a meeting of the British Thoracic Society (BTS), copies of the issue of Respiratory disease in practice in question were available on Cheisi's stand. The publication appeared to be sponsored by Chiesi and there was an advertisement for Fostair on the outside back cover. The publication was of interest and relevance to the complainant's medical practice but after looking for data on the use of Fostair in COPD, given that the journal contained information about COPD and finding a webpage which referred to seeking registration of Fostair for COPD, the complainant was surprised to learn that Fostair was only licensed for asthma.

The complainant did not think that this important fact was clear enough on the Chiesi stand and while he would ensure that he and his colleagues had the appropriate information to inform their decisions he queried whether Chiesi's actions were appropriate.

When writing to Chiesi, the Authority asked it to respond in relation to Clauses 3.2, 7.2 and 7.10 of the 2008 Code.

RESPONSE

Chiesi stated that Respiratory disease in practice was an independent journal title. In response to an approach from the publisher, Chiesi agreed to provide an unrestricted educational grant to fund a fixed number of issues over a set period of time. This fact was clearly declared on the front page of the journal. On page 3 of the journal, the publisher stated the following:

> 'The sponsor has no editorial input into, or control over the content of, this publication. Sponsorship is for four issues to be published in 2010. The data, opinions and statements appearing in the articles herein are those of the contributors(s) concerned; they are not necessarily endorsed by the sponsor, publisher, Editor or Editorial Board.'

The main focus of the cover article was about the role that small airways played in the pathophysiology of respiratory diseases and the various laboratory techniques used to measure small airways function. It was not concerned with the clinical management of these diseases nor their therapeutic options. When inhaled therapies were mentioned, it was with regard to their particle sizes and distributions within the lungs. The authors did not endorse or advocate any therapeutic options for any particular diseases.

Chiesi noted that the publication did not refer to Fostair by name. It was mentioned twice in the first article by the use of the generic names of its two active ingredients. In the first instance (page 3, towards the bottom), it was mentioned when the authors referred to particle sizes of inhalers. Chiesi noted that it was not mentioned in isolation but together with five other inhalers. In the second instance, (page 4, towards the top), its inhaled deposition within the lungs was mentioned. The lung deposition data quoted was from a radio-labelled imaging study. The lung deposition data was also mentioned for another inhaler in the preceding paragraph.

Chiesi submitted that neither mention of the product endorsed or advocated its use in any disease but merely stated its physical properties (particle size and its distribution pattern in the lungs after inhalation).

With regard to the advertisement for Fostair on the outside back cover, Chiesi noted that the complainant failed to mention the prescribing information which came with it. In the 'Indications' section it was clearly stated that Fostair was for use in the management of asthma. This was reinforced in two subsequent sections, 'Dosage and Administration' and 'Precautions'. The prescribing information did not state that Fostair was indicated for use in COPD. Chiesi was surprised that the complainant, who wrote as a health professional, had not read the prescribing information before submitting the complaint.

Chiesi denied any breach of the Code.

PANEL RULING

The Panel noted that the complainant was anonymous and non-contactable. As set out in the introduction to the Constitution and Procedure, complainants had the burden of proving their complaint on the balance of probabilities. Anonymous complaints were accepted and like all complaints were judged on the evidence provided by the parties.

The Panel noted that it was acceptable for companies to sponsor material. It had previously been decided, in relation to material aimed at health professionals, that the content would be subject to the Code if it was promotional in nature or if the company had used the material for a promotional purpose. Even if neither of these applied, the company would be liable if it had been able to influence the content of the material in a manner favourable to its own interests. It was possible for a company to sponsor material which mentioned its own products and not be liable under the Code for its content, but only if it had been a strictly arm's length arrangement with no input by the company and no use by the company of the material for promotional purposes.

The publication in question had been paid for and sponsored by Chiesi. It had been initiated as a result of a discussion between the publisher and Chiesi. The Panel noted that Respiratory disease in practice was described as an independent title supported by an unrestricted educational grant from Chiesi. This description appeared beneath the Chiesi logo.

The journal included two articles about COPD. The first was a four page article starting on the front page and was entitled 'The small airways: an important target in asthma and COPD treatment'. It mentioned the generic name of Fostair's active ingredients in relation to particle sizes and distribution in the lungs. The article referred to formulations with extrafine and ultrafine small particles that had been developed using newer hydrofluoroalkane (HFA) propellants in pressurised metered-dose inhalers pMDIs for a long acting beta2-agonist (formoterol), corticosteroids (beclometasone dipropionate (BDP), ciclesonide, flunisolide) and fixed combinations (BDP/formoterol, ciclesonide/formoterol). Improved total lung deposition (TLD) had been observed with HFA inhalers compared with chlorofluorocarbon (CFC) propellant devices. The article referred to lung deposition data in asthma patients. It concluded that future studies were needed, particularly in COPD patients to determine whether improvements in distal lung deposition and small airways function with ultrafine particles were translated into clinically significant patient outcomes such as improved control of symptoms, better health-related quality of life, fewer adverse effects and reduced exacerbations.

The second article on COPD was a two page article on 'Investigation and treatment of severe chronic obstructive pulmonary disease'. The article referred to management of breathlessness and exacerbations and the National Institute for Health and Clinical Excellence (NICE) guidelines on COPD latest draft recommendations. Mention was made of inhaled steroids and long-acting beta-agonists as well as other medicines.

The editorial referred to the recently published National Clinical Strategy for COPD and that two new medicines were to be launched for COPD later in the year.

The webpage referred to by the complainant was that of a communication company which had been appointed by Chiesi to work on the prelaunch and launch of Fostair for COPD. The page included the Chiesi logo.

The advertisement for Fostair mentioned its use in asthma. It also referred to the delivery of twice as much medication to the lungs as standard metered-dose inhalers and that a third of the extrafine particles reached the small airways. It also included the claim 'For lungfuls of life'.

The publication was available from a Chiesi promotional stand at the BTS meeting. All material on the stand needed to comply with the Code. The Panel considered that the article had been used for a promotional purpose and thus its content was covered by the Code.

The question now to be addressed was whether the journal promoted Chiesi's product for an unlicensed indication. Clause 3.2 stated that 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 (SPC).

The Panel noted that the articles referred to the treatment of COPD with fixed combinations of BDP and formoterol as well as the advantages for HFA propellants. The Panel considered that the distribution of the journal from Chiesi's promotional stand in effect promoted Fostair for an unlicensed indication. In addition, the Panel noted that the Fostair advertisement in the journal referred to the extrafine particles reaching the small airways. In the Panel's view this linked to the article about the treatment of COPD and references to particle size. A breach of Clause 3.2 was ruled. This was misleading and did not promote rational use. Thus breaches of Clauses 7.2 and 7.10 were also ruled.

Complaint received **4 January 2011**

Case completed **1 April 2011**