HEAD OF PRESCRIBING SUPPORT UNIT v BOEHRINGER INGELHEIM

Promotion of Striverdi Respimat

A prescribing support pharmacist complained that a leavepiece for Striverdi (olodaterol) Respimat issued by Boehringer Ingelheim did not accurately reflect the medicines likely effect in chronic obstructive pulmonary disease (COPD). The front cover showed the photograph of an older woman, smiling and at ease, cycling apparently slightly uphill past a village church. The bicycle basket held a newspaper and a bunch of flowers. The complainant found it hard to believe that the use of Striverdi Respimat would enable COPD patients to cycle away.

The detailed response from Boehringer Ingelheim is given below.

The Panel noted Boehringer Ingelheim's submission regarding the inclusion criteria for the two studies cited in the leavepiece and that the results meant that on average, patients treated with Striverdi could cycle at 75% of their maximal work rate for 7 minutes in one study and 6.6 minutes in the other.

The Panel did not accept Boehringer Ingelheim's submission that it was implied that the woman was cycling for no more than 6 or 7 minutes. There was no unambiguous indication of the nature and duration of the journey.

The Panel noted Boehringer Ingelheim's submission that the target patient group for Striverdi included those within the mildest COPD category. The Panel had no information about the severity of COPD of the patients in the studies submitted by Boehringer Ingelheim. The Panel noted that the difference between placebo and Respimat in adjusted mean endurance times after 6 weeks was 52 seconds (p=0.002) in one study and 42 seconds (p=0.0018) in the other study. Guidelines from the National Institute for Health & Clinical Excellence (NICE) recommended bronchodilators as generally the first treatment options to be offered to COPD patients. The Panel considered that given the data provided by Boehringer Ingelheim, including that 36% of patients would be classified as the mildest COPD category and the indication for Striverdi, the artwork was not misleading as alleged. No breach of the Code was ruled.

A prescribing support pharmacist complained about a leavepiece (ref UK/SVR – 141004(1)) for Striverdi (olodaterol) Respimat issued by Boehringer Ingelheim Limited. Striverdi Respimat was indicated as a maintenance bronchodilator treatment in patients with chronic obstructive pulmonary disease (COPD) and was a long-acting beta2-adrenergic agonist (LABA).

The front cover of the leavepiece showed the photograph of an older woman, smiling and at ease, cycling apparently slightly uphill past a village church. The basket on the back of the bicycle held a newspaper and a bunch of flowers.

COMPLAINT

The complainant alleged that the depiction of a lady cycling on her bicycle did not truely reflect the likely effect of Striverdi Respimat in patients with COPD. Although the inside of the leavepiece referred to a significant increase in exercise endurance time vs control (referenced to data on file) the complainant found it hard to believe that the use of Striverdi Respimat would enable patients with COPD to cycle away.

The complainant referred to the supplementary information for Clause 7.8 which stated that care must be taken to ensure artwork did not mislead as to the nature of a medicine or any claim or comparision. The complainant alleged that the image portrayed by the artwork was misleading.

RESPONSE

Boehringer Ingelheim stated that in its two paired, six-week exercise endurance studies cited in the leavepiece, the mean age of subjects was 60.6 ± 7 years. Whilst there were more males than females in each study (116 vs 35 and 116 vs 41) the number of women who smoked and consequently developed COPD in the UK had risen over the last decade.

The inclusion criteria for the studies included a diagnosis of COPD and post-bronchodilator FEV1 (Forced Expiratory Volume in 1 sec) <80% of predicted normal and post-bronchodilator FEV1/FVC of <70% at visit 1; patients also had to be able to perform technically acceptable pulmonary function tests, multiple exercise tests and maintain records.

The primary outcome measure of both studies was exercise endurance time during constant work rate cycle ergometry to symptom limitation at 75% of maximal work capacity, after 6 weeks of treatment. Boehringer Ingelheim submitted that the results meant that on average patients treated with Striverdi Respimat could cycle at 75% of their maximal work rate for 7 minutes in one study and 6.6 minutes in the other.

Boehringer Ingelheim stated that the imagery in the leavepiece was appropriate to the clinical data. The subject was a late, middle aged female undertaking gentle exercise as demonstrated by the use of an old, single-geared bicycle. Her hair did not flow behind her and she did not appear to be exerting herself unduly. The newspaper and flowers in her basket implied that she had ridden a short distance to the

village shop, a journey that could be completed in 6 to 7 minutes.

Boehringer Ingelheim submitted that there might be a general misconception that symptoms in typical COPD patients severely limited their activities of daily living; that they were perhaps housebound or on oxygen. Recently published epidemiological data (Haughney *et al* 2014) which looked at the UK COPD population demonstrated that 36% of patients would be classified with the mildest disease category – Global Initiative for Chronic Obstructive Lung Disease (GOLD) subgroup A (lower risk of exacerbations and fewer symptoms) based on the 2011 assessment criteria.

Both the GOLD and the National Institute for Health and Care Excellence (NICE) guidelines recommended that these were the patients in whom LABA monotherapy such as Striverdi Respimat was considered an appropriate treatment option.

Boehringer Ingelheim submitted that the leavepiece therefore included an image that was appropriate to the target COPD population and included the patient undertaking exercise as supported by clinical trial data. The image did not suggest benefits that could not be substantiated and as such was not in breach of Clause 7.8 of the Code.

PANEL RULING

The Panel examined the illustration of an older woman riding a traditional bicycle with a newspaper and flowers in a basket; bright motion swirls had been added around the pedals, the back wheel and for a distance behind the bicycle. The background scenery was a church with a house a short distance away; the road had an incline.

The Panel noted Boehringer Ingelheim's submission regarding the inclusion criteria for the two studies referenced in the leavepiece and that the primary outcome measure for the studies was exercise endurance time during constant work rate cycle ergometry of maximal work capacity, after 6 weeks of treatment. The results meant that on average, patients treated with Striverdi could cycle at 75% of their maximal work rate for 7 minutes in one study and 6.6 minutes in the other.

The Panel did not accept Boehringer Ingelheim's submission that it was implied that the woman would cycle for no more than 6 or 7 minutes. There was no unambiguous indication of the nature and duration of the journey.

The Panel noted Boehringer Ingelheim's submission that the target patient group for Striverdi included those within the mildest COPD category. The Panel had no information about the severity of COPD of the patients in the studies. The Panel noted that the difference between placebo and Respimat in adjusted mean endurance times after 6 weeks was 52 seconds (p=0.002) in one study and 42 seconds (p=0.0018) in the other study. NICE guidelines recommended bronchodilators as generally the first treatment options to be offered to COPD patients. The Panel considered that given the data provided by Boehringer Ingelheim, including that 36% of patients would be classified as the mildest COPD category and the indication for Striverdi, the artwork was not misleading as alleged. No breach of Clause 7.8 was ruled.

Complaint received	**26 September 2014**
Case completed	**14 November 2014**