

## **PHARMACIST v GLAXOSMITHKLINE**

### **Concerns regarding claims about Seretide**

An anonymous, non-contactable complainant who described him/herself as a pharmacist working within a primary care network, was concerned about the promotion of Seretide Evohaler (salmeterol/fluticasone propionate) by GlaxoSmithKline UK Limited.

The complainant was concerned about comparisons of the price of GlaxoSmithKline's medium dose product with Fostair 100/6 (100mcg beclometasone dipropionate/6mcg formoterol fumarate dihydrate; marketed by Chiesi) and claims that its product was over £5 cheaper. GlaxoSmithKline did not make much of the fact that at a higher dose its product was the same price as Fostair.

The complainant alleged that the real issue, however, was that GlaxoSmithKline was comparing two very different products. As well as being indicated for asthma, Fostair also had a chronic obstructive pulmonary disease (COPD) licence and in asthma might be used on a Maintenance and Reliever Therapy (MART) regimen. A fairer comparison would be to compare Seretide Evohaler with other fluticasone/salmeterol products. Here they were very much more expensive than directly comparable products like Sereflo (salmeterol/fluticasone propionate).

The detailed response from GlaxoSmithKline is given below.

The Panel considered that it was clear from the website that the cost of Seretide Evohaler as a treatment for asthma was being compared to the cost of Fostair as a treatment for asthma at medium dose. There was a difference of over £5 between the NHS costs of the two medicines at the medium dose. The Panel did not consider that the fact that Fostair was also licensed for COPD and Seretide Evohaler was not so licensed was relevant given the context of the claims at issue. Similarly, at the start of the website, there was no mention of other differences, for example that Fostair could be used for a MART regime and Seretide Evohaler could not. The Panel noted GlaxoSmithKline's submission that its modelling data suggested that the majority (56%) of patients in the UK who used any licensed metered dose inhaler for asthma would be on the medium dose and therefore more emphasis was placed on the medium dose regimen in its campaign including the price comparison. The Panel was concerned that at the low dose Seretide Evohaler was more expensive than Fostair and this would not be immediately apparent to viewers of the website. A graph further down the webpage gave the cost of the low dose of Fostair and the low dose of Seretide Evohaler; other sections of the website referred only to the cost of the low dose of Seretide Evohaler. Nonetheless, the Panel did not consider that it was misleading to compare the cost of Seretide Evohaler with Fostair in the treatment of asthma rather than comparing the cost of Seretide Evohaler to other fluticasone/salmeterol products.

**On balance, the Panel did not consider that the comparison was unfair as alleged; it was capable of substantiation. The Panel therefore ruled no breaches of the Code.**

**The Panel noted GlaxoSmithKline's submission that the journal advertisement was withdrawn in January 2021 and therefore decided to consider this matter under the 2019 Code.**

**The Panel noted its comments above regarding the comparison on the website and considered that they were also relevant to the journal advertisement.**

**The Panel considered that it was clear from the journal advertisement that the cost of Seretide Evohaler as a treatment for asthma was being compared to the cost of Fostair as a treatment for asthma at medium dose.**

**On balance, the Panel did not consider that the comparison was unfair as alleged; it was capable of substantiation. The Panel therefore ruled no breaches of the Code.**

An anonymous, non-contactable complainant who described him/herself as a pharmacist working within a primary care network, was concerned about the promotion of Seretide Evohaler (salmeterol/fluticasone propionate) by GlaxoSmithKline UK Limited.

## **COMPLAINT**

The complainant was concerned about a GlaxoSmithKline website where GlaxoSmithKline compared the price of its medium dose product with Fostair 100/6 (100mcg beclometasone dipropionate/6mcg formoterol fumarate dihydrate; marketed by Chiesi) and claimed that its product was over £5 cheaper. GlaxoSmithKline did not make much of the fact that at a higher dose its product was the same price as Fostair.

The complainant alleged that the real issue, however, was that GlaxoSmithKline was comparing two very different products. As well as being indicated for asthma, Fostair also had a chronic obstructive pulmonary disease (COPD) licence and in asthma might be used on a Maintenance and Reliever Therapy (MART) regimen. A fairer comparison would be to compare Seretide Evohaler with other fluticasone/salmeterol products. Here they were very much more expensive than directly comparable products like Sereflo (salmeterol/fluticasone propionate).

The complainant stated that he/she had also seen in journals an advertisement which made the same claims (GB-FPS-ADVT-190005 v2.0 March 2020). Again, this was very much comparing apples with pears and failed to mention that many other less expensive versions of products with the same molecules were available.

When writing to GlaxoSmithKline, the Authority asked it to consider the requirements of Clauses 6.1, 6.2 and 5.1 of the 2021 Code.

## **RESPONSE**

GlaxoSmithKline submitted that it was committed to following both the letter and the spirit of the ABPI Code and all other relevant regulations.

The complainant has made allegations regarding Seretide Evohaler (fluticasone propionate/salmeterol xinafoate) claims in two materials:

- 1 Seretide Evohaler website on the GSK Pro platform for HCPs [health professionals] (PM-GB-FPS-WCNT-200001 (2.0); date of preparation October 2020).
- 2 Journal advertisement (PM-GB-FPS-ADVT-190005; date of preparation March 2020).

GlaxoSmithKline stated that whilst the website was still active, the journal advertisement was last printed in November 2020, and withdrawn from GlaxoSmithKline's approval system in January 2021. GlaxoSmithKline asked the PMCPA to consider, therefore, if the journal advertisement should be considered under the 2019 Code which was, in effect, while the journal advertisement was active, under the corresponding Clauses 7.2, 7.4 and 9.1, respectively. For the purposes of this response, however, GlaxoSmithKline would proceed under the 2021 Code for both materials, as requested.

GlaxoSmithKline's position was that it had complied with the requirements of the Code and denied breaches of the clauses cited.

### **Price comparisons**

GlaxoSmithKline referred to the supplementary information to Clause 6.1 which stated:

'Valid comparisons can only be made where like is compared with like. It follows, therefore, that a price comparison should be made on the basis of the equivalent dosage requirement for the same indications.'

There were thus two factors to consider – dosage requirements and indications.

The doses of Seretide and Fostair that were considered to be low, medium and high, were defined in Table 12 of the British Thoracic Society (BTS)/Scottish Intercollegiate Guidelines Network (SIGN) British Guideline on the Management of Asthma, which was the reference used in the materials. This Guideline defined medium dose Seretide Evohaler as 125/25 two puffs twice a day, and medium dose Fostair as 100/6 two puffs twice a day.

GlaxoSmithKline submitted that in the price comparisons in the materials at issue it had used the definitions of medium dose from this nationally recognised Guideline, and it had been clear which doses it was comparing.

The asthma indications for the two products as per Section 4.1 of the summaries of product characteristics (SPCs) were:

#### **'Seretide Evohaler 125/25 indication**

Seretide is indicated in the regular treatment of asthma where use of a combination product (long- acting  $\beta_2$  agonist and inhaled corticosteroid) is appropriate:

- patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled short-acting  $\beta_2$  agonist.

or

- patients already adequately controlled on both inhaled corticosteroid and long-acting  $\beta_2$  agonist.

### **Fostair 100/6 indication**

#### Asthma

Fostair is indicated in the regular treatment of asthma where use of a combination product (inhaled corticosteroid and long-acting beta<sub>2</sub>-agonist) is appropriate:

- patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled rapid-acting beta<sub>2</sub>-agonist or
- patients already adequately controlled on both inhaled corticosteroids and long-acting beta<sub>2</sub>-agonists.'

GlaxoSmithKline submitted that the asthma indications for both products were the same. All claims made in the materials were in relation to this asthma indication. While Fostair did indeed have an additional indication in COPD as stated by the complainant, this was not an indication for Seretide Evohaler and was not mentioned in the materials and no comparison with Seretide Evohaler was made in this regard. The complainant also noted that Fostair might be used in MART. No claim was made in the materials that Seretide Evohaler could be used in MART (indeed it could not be used for this purpose), and this did not factor into any pricing comparison with Fostair.

GlaxoSmithKline submitted with regard to the complainants view that 'The real issue here, however, is that they are comparing 2 very different products', that whilst the active compounds in the medicines were different, and Fostair had additional indications and use to Seretide Evohaler, the materials were very clear that pricing comparisons were based on equivalent dosing requirements for the same indications as required by Clause 6.1 of the 2021 Code.

The complainant also stated 'A fairer comparison would be to compare Seretide Evohaler with other fluticasone/salmeterol products'. The complainant later stated 'This... fails to mention that many other less expensive versions of products with the same molecule are available'. The materials were specifically about comparing Seretide Evohaler and Fostair at equivalent dosing requirements for the same indication, and this was clear to the reader. The availability of other generic fluticasone/salmeterol products would be common knowledge to the intended audience of prescribers in asthma and there was no requirement in the Code to compare to every other available generic if no claims were made about those products. GlaxoSmithKline submitted that the price comparison between Seretide Evohaler and Fostair at medium dose for asthma was balanced, fair, objective and unambiguous. It did not mislead in any way. It met the requirements of Clause 6.1 of the 2021 Code and its supplementary information.

The pricing for Seretide Evohaler and Fostair at medium dose were taken from MIMS (Monthly Index of Medical Specialities) for packs containing 120 puffs which were the only pack sizes available in the UK (copies of MIMS Fostair prices and MIMS Seretide Evohaler prices were provided). As medium dosing in asthma for either medicine was 2 puffs twice a day, each pack would last 30 days. The prices given were therefore standardised to 30 days of use. The price for Seretide Evohaler 125/25 at medium dose for asthma was £23.45 and the price for Fostair 100/6 at medium dose for asthma was £29.32. Seretide Evohaler was, therefore, over £5

cheaper than Fostair at medium dose. The comparison was accurate and based on an up-to-date evaluation of all the evidence and reflected that evidence clearly. It therefore met the requirements of Clause 6.1 of the 2021 Code. The comparison was also substantiated by MIMS and the BTS/SIGN British Guideline for the Management of Asthma. This therefore met the requirements of Clause 6.2 of the 2021 Code.

GlaxoSmithKline drew attention to a recent PMCPA ruling in Case AUTH/3515/5/21. In this case the complainant alleged that GlaxoSmithKline's webpage headline 'Seretide Evohaler - a combination ICS [inhaled corticosteroid]/LABA [long-acting  $\beta$ 2-agonist] treatment for Asthma. Now over £5 cheaper than Fostair at medium dose' was in breach of the 2019 Code. This was a similar allegation to the current case. However, the Panel disagreed that there was a breach regarding this claim and ruled:

'The Panel noted its comments above and did not consider that health professionals would be misled by the claim 'Seretide Evohaler - a combination ICS/LABA treatment for asthma. Now over £5 cheaper than Fostair at medium dose' as alleged. No breach of Clause 7.2 was ruled. The Panel did not consider that the claim was inconsistent with the particulars listed in the Seretide Evohaler SPC, nor that the claim could not be substantiated, and so it ruled no breach of Clauses 3.2 and 7.4 respectively.

The Panel noted its rulings and comments above and did not consider that the company had failed to maintain high standards and therefore ruled no breach of Clause 9.1. The Panel consequently also ruled no breach of Clause 2.'

This claim had therefore recently been ruled by the Panel to not be in breach of the Code.

**Seretide Evohaler website on the GSK Pro platform for HCPs (PM-GB-FPS-WCNT-200001 (2.0); date of preparation October 2020)**

GlaxoSmithKline stated that the website was certified on 28 October 2020.

Users were required to confirm they were UK healthcare professionals before entering the promotional site, and the site itself was clearly marked at the top as being intended for UK healthcare professionals.

The complainant made comments specifically about the website which GlaxoSmithKline addressed here.

GlaxoSmithKline stated that with regard to the complainant's view that 'They do not make much of the fact that at a higher dose their product is the same price as Fostair', this fact was actually mentioned twice on the webpage in question.

Firstly, under the heading 'What is Seretide Evohaler?', in the third column with sub-heading 'Price', there was the following wording:

'High Dose (250/25 two puffs B.D)  
**£29.32**  
*same price as Fostair 200/6 (two puffs B.D).'*

The high dose regimens being referred to here were consistent with those specified in the BTS/SIGN British Guideline for the Management of Asthma reference. The prices were taken from MIMS. It was also clear from the first column of this section that the indication being referred to was asthma.

Secondly, under the heading 'Compare Seretide with Fostair in asthma' with a selectable sub-heading 'Price', there was a graph comparing the costs of low, medium and high dosing regimens of Seretide Evohaler and Fostair. This graph showed that at high dose, both Seretide Evohaler and Fostair were the same price £29.32. The graph also showed that at low dose, Fostair was cheaper than Seretide Evohaler. These low dose prices were taken from MIMS, standardised to 30 days to provide an equivalent comparison (as at low dose, one puff twice a day, a pack of Fostair 100/6 would last 60 days which would not be a fair comparison to make). It was also clear that the graph was referring to dosing regimens for the asthma indication only. GlaxoSmithKline had been transparent in providing a balanced price comparison of all three recognised dosing regimens.

The reason that more emphasis had been placed on the medium dose regimen in this campaign than on the other dose regimens, was that GlaxoSmithKline's modelling data suggested that 56% of patients in the UK who used any licensed metered dose inhaler for asthma were on a medium dose regimen, compared with 20% on a low dose regimen, and 24% on a high dose regimen. This modelling was based on Practice Prescribing Data from England, Scotland, Wales and Northern Ireland to estimate the annual volume of inhalers prescribed at each dose level, and data from The Health Improvement Network (THIN) primary care database to estimate the proportion of these that were prescribed for asthma. There was therefore a clear rationale to place more emphasis on the medium dose regimen in a promotional campaign, as that was what the majority of patients were prescribed.

GlaxoSmithKline's position was that the website met the requirements of Clauses 6.1 and 6.2 of the 2021 Code.

#### **Journal advertisement (GB-FPS-ADVT-190005; date of preparation March 2020)**

GlaxoSmithKline stated that the journal print advertisement PM-GB-FPS-ADVT-190005 was certified on 27 March 2020. The material was withdrawn in GlaxoSmithKline's approval system on 5 January 2021 and thus was no longer in use.

The advertisement was printed in journals intended for an audience of health professionals on four occasions. These being the BMJ (British Medical Journal) – April 2020 and November 2020, Pulse, June 2020 and MGP Guidelines, November 2020.

The journal advertisement stated in the headline that 'Seretide (salmeterol/fluticasone propionate) Evohaler is over £5 cheaper than Fostair at medium dose'. It was thus clear from the outset which two medicines were being compared and at which equivalent dosing regimen. Below this, the advertisement showed the actual costs, '£23.45 Seretide Evohaler 125/25 (2 puffs b.d)' vs '£29.32 Fostair 100/6 (2 puffs b.d)', showing that Seretide Evohaler was £5.87 cheaper than Fostair at medium dose.

The advertisement further stated:

‘Step up your uncontrolled asthma patients on ICS to Seretide Evohaler instead of Fostair pMDI, when clinically appropriate.’

The use of either Seretide Evohaler or Fostair pMDI in uncontrolled asthma patients on ICS (inhaled corticosteroids) was consistent with the terms of the marketing authorisations for both products, and it was clear to the reader that the advertisement was about asthma.

GlaxoSmithKline submitted that the claims in the journal advertisements were substantiated by MIMS and the BTS/SIGN British Guideline on Management of Asthma. The claims in the journal advertisements therefore met the requirements of Clauses 6.1 and 6.2 of the 2021 Code.

### Conclusion

In closing, GlaxoSmithKline’s position was that the webpage and journal advertisements were consistent with the requirements of Clauses 6.1 and 6.2 of the 2021 Code and it denied breaches of these clauses. Consequently, GlaxoSmithKline had maintained high standards and it denied a breach of Clause 5.1 of the 2021 Code.

### PANEL RULING

The Panel did not accept GlaxoSmithKline’s submission that the allegation in Case AUTH/3515/5/21 was similar to the allegations at issue in the current case (Case AUTH/3557/9/21). The allegation in Case AUTH/3515/5/21 was that the claim was misleading and not in line with the Seretide licence and implied that any patient with asthma was suitable for Seretide which was not so and allegedly a patient safety risk. The comparison with Fostair had not been considered in that case.

Turning to the case now at issue, Case AUTH/3557/9/21, the Panel noted that the webpage in question had the Seretide brand logo which included its non-proprietary name, followed by an image of the three Seretide inhalers which were different strengths and the claim:

‘Seretide Evohaler – a combination ICS/LABA [inhaled corticosteroid/long acting beta2 agonist] treatment for asthma  
Now over £5 cheaper than Fostair at a medium dose.’

The webpage had a ‘Compare Prices’ button beneath which was the price comparison which stated:

‘£23.45 Seretide Evohaler 125/25 (2 puffs b.d) vs £29.32 Fostair 100/6 (2 puffs b.d).’

Further information was included under the section ‘What is Seretide Evohaler?’ under three columns: ‘Asthma Indication’, ‘Dosing’ and ‘Price’. The section headed ‘Price’ included the cost of the low, medium and high doses of Seretide Evohaler, the claim ‘over £5 cheaper than Fostair 100/6 (two puffs BD)’ in relation to the medium dose and that the high dose was the ‘same price as Fostair 200/6 (two puffs BD)’. Following this was a video beneath the heading ‘Find out how Seretide could help support your patients who have asthma’ and beneath this there was, *inter alia*, a graph headed ‘Compare Seretide with Fostair in asthma’ which appeared to have a number of options to select to compare the products, price being one of them (regular

ICS/LABA vs MART appeared to be one of the other three options, however, no details of that content were before the Panel).

In the Panel's view, it was clear from the graph that although Seretide Evohaler was less expensive at the 'medium dose', it was more expensive at the 'low dose' and the products were the same price for the 'high dose'.

The Panel considered that it was clear from the website that the cost of Seretide Evohaler as a treatment for asthma was being compared to the cost of Fostair as a treatment for asthma at medium dose. There was a difference of over £5 between the NHS costs of the two medicines at the medium dose. The Panel did not consider that the fact that Fostair was also licensed for COPD and Seretide Evohaler was not so licensed was relevant given the context of the claims at issue. Similarly, at the start of the website, there was no mention of other differences, for example that Fostair could be used for a MART regime and Seretide Evohaler could not. The Panel noted GlaxoSmithKline's submission that its modelling data suggested that the majority (56%) of patients in the UK who use any licensed metered dose inhaler for asthma would be on the medium dose and therefore more emphasis was placed on the medium dose regimen in its campaign including the price comparison. The Panel was concerned that at the low dose Seretide Evohaler was more expensive than Fostair and this would not be immediately apparent to viewers of the website. The graph further down the webpage gave the cost of the low dose of Fostair and the low dose of Seretide Evohaler; other sections of the website referred only to the cost of the low dose of Seretide Evohaler. Nonetheless, the Panel did not consider that it was misleading to compare the cost of Seretide Evohaler with Fostair in the treatment of asthma rather than comparing the cost of Seretide Evohaler to other fluticasone/salmeterol products.

On balance, the Panel did not consider that the comparison was unfair as alleged; it was capable of substantiation. The Panel therefore ruled no breach of Clauses 6.1 and 6.2 of the 2021 Code. It also ruled no breach of Clause 5.1.

The Panel noted GlaxoSmithKline's submission that the journal advertisement was withdrawn in January 2021 and therefore decided to consider this matter under the 2019 Code. The journal advertisement in question stated:

'Seretide (salmeterol/fluticasone propionate) Evohaler is over £5 cheaper than Fostair at medium dose.'

This was followed by:

'£23.45 Seretide Evohaler 125/25 (2 puffs b.d) vs £29.32 Fostair 100/6 (2 puffs b.d.)

How much could you save?

Step up your uncontrolled asthma patients on ICS to Seretide Evohaler instead of Fostair pMDI, when clinically appropriate.'

The Panel noted its comments above regarding the comparison on the website and considered that they were also relevant to the journal advertisement.



The Panel considered that it was clear from the journal advertisement that the cost of Seretide Evohaler as a treatment for asthma was being compared to the cost of Fostair as a treatment for asthma at medium dose.

On balance, the Panel did not consider that the comparison was unfair as alleged; it was capable of substantiation. The Panel therefore ruled no breach of Clauses 7.2 and 7.4 of the 2019 Code. It also ruled no breach of Clause 9.1.

**Complaint received**      **3 September 2021**

**Case completed**        **26 April 2022**