NO BREACH OF THE CODE

CASE AUTH/3470/2/21

COMPLAINANT v GLAXOSMITHKLINE

Digital promotion of Seretide

An anonymous, contactable complainant who described him/herself as a health professional, complained about a digital advertisement (ref PM-GB-FPS-WBAN-190016, Date of production November 2019) for Seretide Evohaler (fluticasone/salmeterol) placed by GlaxoSmithKline UK. Seretide Evohaler was indicated in certain patients with asthma. Fluticasone was an inhaled corticosteroid (ICS) and salmeterol was a long-acting beta$_2$ agonist (LABA).

The first frame of the four frame advertisement had a purple Seretide Evohaler flying across and the claim 'For the regular treatment of your asthma patients with an ICS/LABA' which the complainant alleged was false and misleading. Seretide Evohaler came in a range of different strengths with specific age groups that could be treated. The complainant stated that the claim could not stand alone; busy health professionals or someone who only saw the first frame could wrongly assume that Seretide could be used for any/all asthma patients at any age range.

The complainant further noted that the Code stated 'where a digital advertisement was made up of a number of screens, no page or screen must be false or misleading when read in isolation'; he/she was concerned that such fundamentals of the Code had not been applied during the review of the advertisement. The complainant also noted that GlaxoSmithKline had previously been ruled in breach of the Code (Cases AUTH/3179/4/19 and AUTH/3148/1/19) and alleged a breach of the undertakings given in those cases.

The complainant noted that it was not clear how to access the prescribing information. The complainant stated that by simply stating 'PI', it was not clear or obvious as for many practising health professionals, 'PI' often meant product information. 'Prescribing information' should have been written in full.

The detailed response from GlaxoSmithKline is given below.

The Panel noted the frames of the banner advertisement transitioned at three second intervals and each included, on the right hand side, a photograph of a single child who appeared to possibly be a teenager, playing with a ball in a city ball park. Each frame was bisected with the image of the Seretide Evohaler and the left-hand side of each frame detailed the promotional messaging on a purple background.

The Panel noted that the complainant had referred to the first frame of the advertisement which featured, on the left-hand side, the Seretide product logo below which was the claim 'For the regular treatment of your asthma patients with an ICS/LABA'. The

complainant alleged that the claim was false and misleading and was concerned that a health professional who only saw that frame might wrongly assume that Seretide could be used for any/all asthma patients of any age.

The Panel considered that health professionals would be familiar with the well-defined, step-wise guidelines which existed for the treatment of asthma and that once they had considered that treatment with an ICS/LABA was appropriate, Seretide would be one of the available options. The Panel noted that Seretide Evohaler was available in three formulations; each delivered, per inhalation, 25 micrograms salmeterol and 50/125/250 micrograms of fluticasone. The Panel considered that prescribers would be mindful to always use the lowest dose of corticosteroid possible to control symptoms. The Panel noted that the maximum licensed dose of fluticasone propionate delivered by Seretide inhaler in children between the ages of four and eleven was 100 micrograms twice daily and so, although only the lowest strength of Seretide Evohaler could be used in that age group, there was nonetheless a formulation of Seretide which could be prescribed. The Panel noted that Seretide Evohalers were not licensed for use in those below the age of four and did not consider that the picture to the right of the claim implied that the product could be used in this subset of children. The Panel did not consider that health professionals would be misled by the claim as alleged; no breach of the Code was ruled. The Panel ruled no breaches of the Code as it did not consider that the claim was inconsistent with the Seretide Evohaler summary of product characteristics, nor that it could not be substantiated.

The Panel considered that high standards had been maintained; no breach of the Code was ruled. The Panel also ruled no breach of Clause 2.

The Panel noted that the complainant had implied that the frames of the digital advertisement were either false or misleading when read in isolation but had offered no explanation as to why that was so; it was not for the Panel to make out the complaint and no breach of the Code was ruled.

The Panel did not consider that it was unclear as to how to access the prescribing information. It was preferable to use the term in full for prescribing information so that there could be no confusion; nonetheless, the obligatory information was available when the link was clicked. The Panel did not consider that, in the circumstances, the use of the abbreviation PI meant that the prescribing information had not been provided. No breaches of the Code were ruled.

With regard to the alleged breach of the undertakings given in Cases AUTH/3148/1/19 and AUTH/3179/4/19, the Panel did not consider that those undertakings were relevant to the case now before it. The Panel therefore ruled no breaches of the Code.

An anonymous, contactable complainant who described him/herself as a health professional, complained about a digital advertisement (ref PM-GB-FPS-WBAN-190016, Date of production November 2019) for Seretide Evohaler (fluticasone/salmeterol) placed by GlaxoSmithKline UK.

Seretide Evohaler was indicated in certain patients with asthma. Fluticasone was an inhaled corticosteroid (ICS) and salmeterol was a long-acting beta$_2$ agonist (LABA).

COMPLAINT

The complainant noted that the first frame of the four frame advertisement had a purple Seretide Evohaler flying across and the claim 'For the regular treatment of your asthma patients with an ICS/LABA'. The complainant alleged that the claim was false and misleading. Seretide Evohaler came in a range of different strengths with specific age groups that could have treatment with the inhaler. Furthermore, the summary of product characteristics (SPC) (link to the electronic medicines compendium (eMC) provided) stipulated a very specific licence: Section 4.1, Therapeutic indications, stated:

> '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.'

Section 4.2, Posology and method of administration stated:

> 'Recommended Doses:
>
> *Adults and adolescents 12 years and older*:
>
> - Two inhalations of 25 micrograms salmeterol and 50 micrograms fluticasone propionate twice daily or
>
> - Two inhalations of 25 micrograms salmeterol and 125 micrograms fluticasone propionate twice daily or
>
> - Two inhalations of 25 micrograms salmeterol and 250 micrograms fluticasone propionate twice daily.
>
> *Paediatric population children 4 years and older*:
>
> Two inhalations of 25 micrograms salmeterol and 50 micrograms fluticasone propionate twice daily.
>
> The maximum licensed dose of fluticasone propionate delivered by Seretide inhaler in children is 100 microgram twice daily.
>
> The safety and efficacy of Seretide inhaler in children aged under 4 years has not been established.'

The complainant stated that the claim could not stand alone; busy health professionals or someone who only saw the first frame could wrongly assume that Seretide could be used for any/all asthma patients at any age range, whereby the actual licence and specific tailored ages for use were not covered by the misleading claim on the first frame. The complainant alleged breaches of Clauses 3.2, 7.2, 7.4, 9.1 and 2.

The complainant further alleged a breach of Clause 6.2 as the Code stated, 'where a digital advertisement was made up of a number of screens, no page or screen must be false or misleading when read in isolation'. The complainant was concerned that such fundamentals of the Code had not been applied during the review of the advertisement and release to health professionals. In addition, the complainant noted that other digital advertisements by GlaxoSmithKline had previously been ruled in breach of the Code over the last few years and the company had still not learnt how to apply the Code in a fair manner when reviewing digital advertisements.

The complainant noted that other frames of the advertisement mentioned that the Seretide Evohaler was £5 cheaper than Fostair 100/6 and the last frame included references. On those frames, it was not clear how to access the prescribing information and in that regard, the complainant alleged a breach of Clause 4.1 as the Code stated 'The first part of an advertisement in an electronic journal, such as the banner, is often the only part of the advertisement that is seen by readers. It must therefore include a clear, prominent statement as to where the prescribing information can be found'. The complainant stated that by simply stating 'PI', it was not clear or obvious as 'PI' could often mean product information for many practising health professionals. Prescribing information should have been written out in full as opposed to an abbreviation and made clear. Breaches of Clauses 4.1, 4.4, 9.1 and 2 were alleged.

In view of previous GlaxoSmithKline cases with regard to Seretide digital advertisements (Cases AUTH/3179/4/19 and AUTH/3148/1/19), the complainant alleged that the Seretide advertisement now at issue was a breach of the undertakings from those previous cases, in breach of Clause 29 as GlaxoSmithKline had failed to learn.

When writing to GlaxoSmithKline, the Authority asked it to consider the requirements of Clauses 2, 3.2, 4.1, 4.4, 6.2, 7.2, 7.4, 9.1 and 29 of the Code as cited by the complainant and to respond to the requirements of Clause 2 of the Code with regard to the alleged breach of undertaking.

RESPONSE

By way of background, GlaxoSmithKline explained that asthma was a very common disease usually managed by GPs and hospital physicians. In the UK, the pharmacological treatment of asthma was initiated in a stepwise manner depending on the severity of the disease which was based on patients' respiratory symptoms. The types of treatment and the timings for initiation of them were very well-defined according to the British Thoracic Society/Scottish Intercollegiate Guidelines Network guidelines (BTS/SIGN Guidelines, copy provided) which were widely used and referred to by health professionals who commonly managed asthma and they were therefore familiar with exactly when to use the different treatments. There were also guidelines from the National Institute for health and Care Excellence (NICE) for the management of asthma which were used by prescribers (copy provided). The mainstay of the regular treatment of asthma in the UK was low dose inhaled corticosteroids (ICS). When low dose ICS was inadequate at controlling symptoms on its own, other types of treatment could be added on. The BTS/SIGN Guidelines stated that the first choice of add-on treatment to ICS was inhaled long acting $beta_2$ agonists (LABA). A combination inhaler containing both ICS and LABA was often used for ease when this was the case.

Seretide Evohaler was one such combination ICS/LABA inhaler and was licensed for use in:

- patients not adequately controlled with ICS and 'as needed' inhaled short-acting β_2 agonist (SABA)

or

- patients already adequately controlled on both ICS and LABA.

The claim in the banner advertisement related to all patients within the licence who were eligible for ICS/LABA in both situations. The advertisement had been run in several different well-known professional online journals, each aimed at an appropriate audience in the UK on several occasions and was still in circulation. It had a transition time of three seconds between pages.

GlaxoSmithKline stated that Seretide was licensed for use from the age of 4 years and above (including adults) and in that regard was indicated for the broadest age-range of any of the ICS/LABAs currently on the market. The dose to be used depended on the age of the patient and so Seretide was available in three different doses for that purpose. There were several other commonly used ICS/LABA combination inhalers available, one of which was Fostair. Not all ICS/LABA combination inhalers were licensed for use in as wide a range of ages as Seretide. Fostair for example, was not licensed for use in patients under the age of 18 years. The BTS/SIGN Guidelines defined the treatments which could be used in all age groups and as stated above, health professionals commonly referred to the guidelines to inform their management decisions.

GlaxoSmithKline submitted that Seretide was one of the longest established products for asthma in the UK. As such it was a very well-known and recognised product which was prescribed frequently by the relevant health professionals who commonly managed asthma.

GlaxoSmithKline submitted that from the claim on the first page of the banner advertisement that Seretide was 'for the regular treatment of your asthma patients with an ICS/LABA', it would be understood that Seretide should only be used for those for whom an ICS/LABA was appropriate as defined by the BTS/SIGN and NICE Guidelines.

Separately, the banner advertisement then referred to the cost comparison vs Fostair for a particular dose of each product. That was a separate claim to the one on page one and GlaxoSmithKline contended that the claim could stand alone and was also substantiated. GlaxoSmithKline submitted that, importantly, the second claim was different from the first claim on page one and so GlaxoSmithKline did not consider that it had promoted Seretide outside of the terms of its marketing authorisation and strongly refuted the allegation that it had breached Clauses 3.2 and 7.2.

In addition, with regards to the alleged breach of Clause 7.4, GlaxoSmithKline contended that the references cited in the advertisement fully and unequivocally substantiated the claims used. Those include the Seretide Evohaler SPC (copy provided), MIMS list price of Fostair (copy provided), and the BTS/SIGN Guideline for the management of asthma. GlaxoSmithKline therefore denied a breach of Clause 7.4.

GlaxoSmithKline noted that the complainant also alleged that the advertisement was in breach of Clause 6.2. Clause 6.2 required that each page of an advertisement must not be misleading if read in isolation. GlaxoSmithKline contended that the first page of the banner advertisement stood alone as explained above.

GlaxoSmithKline therefore strongly contended that each page of the banner advertisement did not mislead if read in isolation and it denied breaches of Clauses 3.2, 6.2, 7.2 and 7.4.

GlaxoSmithKline disputed the complainant's allegation that links to prescribing information in the advertisement had not been provided in accordance with the Code and also contended that while each page must not be misleading in isolation, requirements such as the non-proprietary name and links to prescribing information and adverse event reporting statement were not necessarily required on each page. GlaxoSmithKline noted that the Panel did not make any comments about that being an issue in Case AUTH/3148/1/19. Despite that, GlaxoSmithKline submitted that links to the prescribing information and adverse event reporting statement had been provided on every frame of the banner advertisement.

With regard to the use of 'PI', GlaxoSmithKline contended that it was a very widely accepted and recognised practice to abbreviate 'prescribing information' to 'PI'. The complainant made a reference to 'PI' potentially being misconstrued as product information by health professionals. GlaxoSmithKline also strongly contended that the aim of providing the prescribing information was to provide adequate information to support a prescriber making a decision about prescribing a product and even if they were to misunderstand that 'PI' stood for product information, the aim of providing the link and the requirement of the Code would have been met.

The complainant mentioned that it was not clear how to access the prescribing information on the other frames of the banner advertisement. GlaxoSmithKline stated that it did not recognise this as every frame of the approved banner advertisement had the link to the prescribing information and adverse event statement available on it.

For that reason, GlaxoSmithKline strongly contended that it had met all the requirements of Clause 4.1 and 4.4.

GlaxoSmithKline noted that Case AUTH/3148/1/19 was related to the non-proprietary name not being adjacent to the brand name at the first mention of Seretide on a 'static' image of the banner advertisement to be used as a back-up in the event of there being problems with displaying the banner advertisement on some platforms. GlaxoSmithKline had been found in breach of Clause 4.3 in that context in the case by the Panel.

GlaxoSmithKline strongly rejected the allegation of a breach of undertaking in this context as the complaint did not relate to a missing non-propriety name for Seretide which was present at the first mention of Seretide in the banner advertisement.

GlaxoSmithKline submitted that Case AUTH/3179/4/19 was a follow up complaint to Case AUTH/3148/1/19, in which the Panel ruled that the 'static image' was viewed as a separate piece and therefore should have had certification whereas it had not. GlaxoSmithKline was therefore ruled in breach of Clause 14.1 by the Panel. Once again, this current complaint did not relate to the findings of Case AUTH/3179/4/19 as the complaint on this occasion did not relate to the non-certification of a 'static image'.

GlaxoSmithKline therefore refuted the allegation that it had breached Clause 29.

Since the aforementioned cases, GlaxoSmithKline had undertaken several steps to avoid the risk of the static image being used which was non-compliant and not having been certified. GlaxoSmithKline changed its internal guidance on banner advertisements to incorporate

wording about separately needing to certify a static image unless it was specified to third parties that white space was to be employed in the event of any problems (copy of banner advertisement checklist provided).

In summary, GlaxoSmithKline stated that it took its responsibility in abiding strictly to the Code very seriously and it strongly contended that for the reasons above, it had not breached Clauses 4.1, 4.4, 6.2, 7.2 or 7.4.

Furthermore, GlaxoSmithKline also strongly contended that given the rationale above, it had not breached Clauses 2 or 9.1.

With respect to the allegations of breach of undertaking, GlaxoSmithKline strongly refuted that it had breached Clause 29.

PANEL RULING

The Panel did not know the context in which the complainant had seen the advertisement at issue but noted GlaxoSmithKline's submission that it had been placed in online professional journals. The frames of the banner advertisement transitioned at three second intervals and each included, on the right hand side, a photograph of a single child who appeared to possibly be a teenager, playing with a ball in a city ball park. Each frame was bisected with the image of the Seretide Evohaler and the left-hand side of each frame detailed the promotional messaging on a purple background.

The Panel noted that the complainant had referred to the first frame of the advertisement which featured, on the left-hand side, the Seretide product logo below which was the claim 'For the regular treatment of your asthma patients with an ICS/LABA'. The complainant alleged that the claim was false and misleading and was concerned that a busy health professional who only saw that frame might wrongly assume that Seretide could be used for any/all asthma patients of any age.

The Panel considered that health professionals would be familiar with the well-defined, step-wise guidelines which existed for the treatment of asthma and that once they had considered that treatment with an ICS/LABA was appropriate for a patient, Seretide, as a brand, would be one of the available options. The Panel noted that Seretide Evohaler was available in three formulations; each formulation delivered, per inhalation, 25 micrograms salmeterol and 50, 125 or 250 micrograms of fluticasone. The Panel considered that prescribers would be mindful to always use the lowest dose of corticosteroid possible to control symptoms. The Panel noted that the maximum licensed dose of fluticasone propionate delivered by Seretide inhaler in children between the ages of four and eleven was 100 micrograms twice daily and so, although only the lowest strength of Seretide Evohaler could be used in that age group, there was nonetheless a formulation of Seretide which could be prescribed. The Panel noted that the Seretide Evohalers were not licensed for use in those below the age of four and did not consider that the picture to the right of the claim implied that the product could be used in this subset of children. The Panel did not consider that health professionals would be misled by the claim 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.

The Panel noted its rulings and comments above and considered that high standards had been maintained; no breach of Clause 9.1 was ruled. The Panel also ruled no breach of Clause 2.

The Panel noted that the complainant had alleged a breach of Clause 6.2 and as such had implied that the frames of the digital advertisement were either false or misleading when read in isolation. The complainant had offered no explanation as to why that was so and it was not for the Panel to make out the complaint. The Panel ruled no breach of Clause 6.2.

The Panel noted that in the left-hand bottom corner of every frame, in white text on the purple background, was the statement 'Click here for PI and Adverse Event Reporting'. In that regard, the Panel did not consider that it was unclear as to how to access the prescribing information as alleged. No breach of Clause 4.1 was ruled. With regard to the use of the abbreviation PI for prescribing information, the Panel considered that it was preferable to use the term in full so that there could be no confusion; nonetheless, the obligatory information was available when the link was clicked. The Panel did not consider that, in the circumstances, the use of the abbreviation meant that the prescribing information had not been provided. The Panel ruled no breach of Clauses 4.1, 4.4, 9.1 and 2 in that regard.

With regard to the alleged breach of the undertakings given in Cases AUTH/3148/1/19 and AUTH/3179/4/19, the Panel did not consider that those undertakings were relevant to the case now before it, Case AUTH/3470/2/21. The previous cases related to the provision of the non-proprietary name in an advertisement and certification of an advertisement respectively. There were no allegations in Case AUTH/3470/2/21 regarding either the provision of the non-proprietary name nor whether the material at issue had been certified; the Panel was thus not required to make rulings on those matters and so there could be no breach of the undertakings given in the previous cases. The Panel therefore ruled no breach of Clause 29 and consequently no breach of Clauses 9.1 and 2 with regard to each undertaking.

Complaint received **8 February 2021**

Case completed **29 July 2021**