CASE AUTH/3515/5/21

COMPLAINANT v GLAXOSMITHKLINE

Activities at a meeting and promotion of Seretide

An anonymous, non-contactable health professional complained about the promotion of Seretide (fluticasone/salmeterol) by GlaxoSmithKline UK Limited. The material at issue was an online registration page for a GlaxoSmithKline organised and funded webinar held in May 2021 and a claim on a Seretide webpage. Seretide was indicated in certain patients with asthma.

The detailed response from GlaxoSmithKline is given below.

A Webinar: 'Patient Management in Severe Asthma - Evolution & Evidence'

The complainant noted that the online registration page for the webinar referred to World Asthma Day in May and national respiratory expert speakers. There was a summary of the webinar content and prescribing information for various products. Three of the medicines mentioned were Trelegy (fluticasone/vilanterol/umeclidinium), Anoro (vilanterol/umeclidinium) and Incruse (umeclidinium), all of which were licensed for chronic obstructive pulmonary disease (COPD) not asthma. The complainant alleged that it was inappropriate to have mentions/prescribing links to medicines which were not asthma treatments and busy health professionals would think that these three medicines were licensed for asthma use.

The complainant also referred to a named speaker who was a medical department employee at GlaxoSmithKline and alleged that it was inappropriate for a non-promotional member of staff to be present on a promotional webinar to solicit questions for the medical team. This blurred lines between promotional staff and non-promotional staff.

The Panel noted that the registration page at issue promoted an asthma-focussed webinar and that it included links to prescribing information for a number of GSK medicines including Trelegy, Anoro and Incruse which were licensed for use in COPD but not in asthma.

The Panel considered that the immediate and overall impression was that the listed medicines including Trelegy, Anoro and Incruse were licensed for use in asthma, which was not so; a breach of the Code was ruled for each medicine as acknowledged by GlaxoSmithKline. The Panel considered that high standards had not been maintained and a breach of the Code was ruled.

The Panel considered that the reference to Trelegy, Anoro or Incruse on the registration page for the asthma-focussed webinar, within a list of medicines which could be used in asthma, was wholly inappropriate particularly given that Section 4.4, Special warning and precaution for use of the summary of product characteristics (SPC), for Trelegy, Anoro and Incruse stated that they should not be used in patients with asthma since they had

not been studied in that patient population. The Panel considered that the implied suggestion otherwise was such as to reduce confidence in the pharmaceutical industry and ruled a breach of Clause 2. On appeal by GlaxoSmithKline, the Appeal Board considered that the implied suggestion that the medicines could be used in asthma was a matter of patient safety and such as to reduce confidence in the pharmaceutical industry. The Appeal Board upheld the Panel's ruling of Clause 2.

The Panel did not consider that, in acting as Chair for the promotional webinar, the medical department employee had taken on the role of a representative ie that he/she called on members of the health professions and other relevant decision makers in relation to the promotion of medicines. The Panel did not consider that it was necessary for the employee to have taken an appropriate examination for medical representatives as alleged and ruled no breach of the Code.

The Panel noted its rulings and comments above and ruled no breaches of the Code including Clause 2.

B Web page claim: 'Seretide Evohaler - a combination ICS/LABA treatment for asthma. Now over £5 cheaper than Fostair at medium dose'.

The complainant alleged that the claim was misleading and not in line with the Seretide licence. The licensed indication for Seretide had specific age ranges for use and children less than four years old were not to use Seretide. The complainant alleged that the big, bold headline claim of 'asthma' patients at the outset of the webpage implied any patient with asthma was suitable for treatment with Seretide which was not the case and was a patient safety risk.

The Panel noted that the webpage at issue included an image of the three Seretide inhalers which were different strengths. Beneath the image of the three inhalers was the claim 'Seretide Evohaler - a combination ICS/LABA treatment for asthma Now over £5 cheaper than Fostair at medium dose'. The Panel noted that it was thus clear from the outset that Seretide was a combination product.

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 and considered that prescribers would be mindful to always use the lowest dose of corticosteroid possible. The Panel noted that although only the lowest strength of Seretide Evohaler could be used in the age group four to eleven, there was nonetheless a formulation of Seretide which could be prescribed. The Panel further noted GlaxoSmithKline's submission that immediately below the claim in question was a section entitled 'What is Seretide Evohaler?' which included that Seretide Evohaler 50/25 was licensed for use in paediatric asthma for 'patients 4 years and above' and that further down the webpage was a tab entitled 'Paediatric license', which detailed the dosing requirements of Seretide in paediatric patients aged over four years when clicked.

The Panel noted its comments above and did not consider that health professionals would be misled by the claim as alleged. 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 breaches of the Code including no breach of Clause 2.

An anonymous, non-contactable health professional complained about the promotion of Seretide (fluticasone/salmeterol) by GlaxoSmithKline UK Limited. The material at issue was an online registration page (ref PM-GB-MPL-WCNT-210010 April 2021) for a GlaxoSmithKline organised and funded webinar and a claim on a Seretide webpage (ref PM-GB-FPS-WCNT-200001 (2.0) October 2020).

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

When writing to GlaxoSmithKline, the Authority asked it to consider the requirements of Clauses 2, 3.2, 7.2, 7.4, 9.1 and 16.3 of the Code as cited by the complainant.

A Webinar: 'Patient Management in Severe Asthma - Evolution & Evidence'

COMPLAINT

The complainant noted that the webinar, held on 25 May 2021, was entitled 'GSK Webinar: Patient Management in Severe Asthma - Evolution & Evidence'. The summary on the online registration page stated: 'This promises to be an informative and thought-provoking webinar that acknowledges the annual World Asthma Day in May, where we will hear from a panel of national respiratory experts'. On the left-hand side of the registration page there was the option to register for the webinar and on the right-hand side, there was a summary of what the webinar entailed and prescribing information for various products. The complainant stated that three of the medicines mentioned here were Trelegy (fluticasone/vilanterol/umeclidinium), Anoro (vilanterol/umeclidinium) and Incruse (umeclidinium) all of which were licensed for chronic obstructive pulmonary disease (COPD) but not asthma. The complainant alleged that it was inappropriate to have mentions/prescribing links to medicines which were not asthma treatments and busy health professionals would think that these three medicines were licensed for asthma use, considering this was a standalone promotional page. The complainant alleged breaches of Clauses 3.2 (x3), 9.1 (x3) and 2 (x3) in this regard.

The complainant also referred to a named speaker for the webinar who was a medical employee at GlaxoSmithKline. The complainant alleged that it was inappropriate for a non-promotional member of staff to be present on a promotional webinar to solicit questions for the medical team and that this blurred lines between promotional staff and non-promotional staff. The complainant alleged breaches of Clauses 16.3, 9.1 and 2.

RESPONSE

GlaxoSmithKline explained that the purpose of the webinar was to discuss a treatment approach for airways disease, severe asthma, severe asthma services and patient management. The GlaxoSmithKline medicine Nucala (mepolizumab) was licensed as an add-on treatment for severe refractory eosinophilic asthma in adults, adolescents and children aged 6 years and older and would be discussed in that context. GlaxoSmithKline provided the relevant summaries of product characteristics (SPCs) and copies of the meeting registration webpage, slides, agenda and emails to attendees who registered for the webinar.

In response to the allegations, GlaxoSmithKline acknowledged that the webinar registration page promoted an asthma-focussed webinar, and that Trelegy, Anoro and Incruse were not licensed for use in asthma. GlaxoSmithKline also acknowledged that links to prescribing information for Trelegy, Anoro and Incruse were provided on the registration page for the webinar; those links were the only mention of those medicines on the registration page.

GlaxoSmithKline submitted that there was no mention or promotion of Trelegy, Anoro or Incruse on the registration page, other than on the prescribing information links. GlaxoSmithKline recognised, however, that that could be perceived that those medicines might be used in asthma which was not the intent. The signatory's intention for including those links to prescribing information was based on the content of the webinar, which mentioned the use of classes of products, where some of the products in those classes were licensed for asthma, however, the GlaxoSmithKline medicines in those classes were not licensed in asthma. GlaxoSmithKline submitted that each prescribing information contained the licensed indication immediately after the description of the delivered dose and the inclusion of all of GlaxoSmithKline respiratory prescribing information's on promotional material was not in line with guidance given to signatories on the appropriate use of prescribing information.

GlaxoSmithKline acknowledged a breach of Clause 3.2. GlaxoSmithKline submitted that it had issued clear guidance to signatories and had robust procedures in place and in that regard high standards had been maintained and it denied a breach of Clause 9.1. The error was made by an individual who had been subject to further action (details provided) including a capability re-assessment.

However, GlaxoSmithKline believed that neither the intent behind nor the end result of the action, brought discredit upon, or reduced confidence in, the pharmaceutical industry, and therefore denied a breach of Clause 2.

GlaxoSmithKline submitted that, with regard to the presence of a medical department employee at the webinar, it was standard practice within the industry to have such personnel speak, chair and facilitate both promotional and non-promotional meetings. Often, they had expertise from their role that gave them particular insight they could bring by for example, having designed and run the clinical trial being discussed, having been the author of the paper, or the presenter of the data at a learned society meeting. Similarly, it was standard practice to engage external experts to do the same. GlaxoSmithKline submitted it was a Code requirement that all meetings had 'a clear educational content', even if they were promotional.

This meeting was organised and funded by GlaxoSmithKline and proactively discussed GlaxoSmithKline medicines, and so was classified as a promotional meeting. As such, it required clear disclosure, prescribing information, adverse event statement, generic names, black triangles, date, unique code and certification prior to use, all of which were in place. However, the meeting content itself was highly educational, with expert external speakers who were contracted to the company for the purpose of the meeting, and the medical department employee as Chair.

The role of the medical department employee was a non-promotional role, as acknowledged by the complainant. The role was office based and the incumbent managed a medical affairs team.

GlaxoSmithKline submitted that in the highly educational webinar, the medical department employee's intimate knowledge of the data and issues being discussed allowed him/her to expertly facilitate the meeting welcoming the audience, introducing the speakers, manage the Q&A session, keep to time and thank the speakers.

GlaxoSmithKline stated that being involved as Chair of a promotional meeting did not automatically make the person a representative requiring the representative's exam; if that were the case numerous external experts contracted to the company for the same role would be deemed to be representatives and this was patently not the case. GlaxoSmithKline noted that Clause 1.7 stated 'The term 'representative' meant a representative calling on members of the health professions and other relevant decision makers in relation to the promotion of medicines' and it was not the medical department employee's role to 'call on' members of the health professions and other relevant decision makers in relation to the promotion of medicines and as such was not a representative.

As the complainant also acknowledged, the medical department employee was a non-promotional member of staff and, as such, there was no requirement to take the representative examination and GlaxoSmithKline denied a breach of Clause 16.3.

For full disclosure, although the employee had taken the ABPI examination for a previous role, GlaxoSmithKline believed the examination was not required as the role did not satisfy the definition of 'representative'. GlaxoSmithKline submitted the role did not require him/her to 'call on' any health professionals in relation to the promotion of medicines and as such it defended his/her position as Chair for the meeting on the basis of being the best person for the job.

The complainant also alleged that it was inappropriate 'to solicit questions for the medical team and blur lines between promotional and non-promotional staff' yet had provided no evidence to support the allegation that lines had been blurred. The medical department employee, as acknowledged by the complainant, was a non-promotional role and was part of the 'medical team' involved in the webinar. The other panellists (the speakers) were all external expert health professionals. There were no promotional staff involved in the presentations.

GlaxoSmithKline stated that the role of the medical department employee in the webinar was not 'to solicit questions for the medical team and blur the lines between promotional staff and non-promotional staff.' as alleged by the complainant, although part of it was to encourage on-label questions from participants and direct them to the appropriate external speaker. He/she was also ready to ask questions him/herself if participants were reluctant to do so or if a technical hitch meant that no questions could be received. His/her role was clearly set out as the chairperson and facilitator of the meeting.

GlaxoSmithKline submitted that all documentation for the webinar made it explicitly clear it was a promotional meeting and that it was GlaxoSmithKline organised and funded. GlaxoSmithKline stated that the medical department employee was clearly identified as being from GlaxoSmithKline, and the external speakers made clear their relationships with GlaxoSmithKline and other pharmaceutical companies. Audience members would be in no doubt as to the status of the meeting. High standards were maintained, and the industry was not brought into disrepute. As such, GlaxoSmithKline denied breaches of Clauses 9.1 and 2.

PANEL RULING

The Panel noted that the registration page at issue was titled 'GSK Webinar: Patient Management in Severe Asthma – Evolution & Evidence' and promoted an asthma-focussed webinar. The Panel noted that the registration page included links to prescribing information for a number of GSK medicines. The list started with Nucala, Relva, Seretide, Ventolin, Flixotide, Trelegy, Anoro and Incruse giving non-proprietary names and links to the prescribing information. Trelegy, Anoro and Incruse were licensed for use in COPD but not in asthma.

The Panel noted GlaxoSmithKline's submission that there was no mention or promotion of Trelegy, Anoro or Incruse on the registration page, other than on the prescribing information links; it appeared that the links had been included because the webinar content mentioned the use of classes of products where some of the products in those classes were licensed for asthma. The Panel noted, however, that the three GlaxoSmithKline medicines at issue all contained umeclidinium and that no medicine containing that compound was licensed for use in asthma. It appeared that the inclusion of the prescribing information for those medicines was contrary to company guidance on the use of prescribing information.

The Panel considered that the immediate and overall impression of the webinar registration page to a busy health professional was that the listed medicines including Trelegy, Anoro and Incruse were licensed for use in asthma, which was not so; a breach of Clause 3.2 was ruled for each medicine as acknowledged by GlaxoSmithKline. The Panel considered that high standards had not been maintained and a breach of Clause 9.1 was ruled.

The Panel considered that the reference to Trelegy, Anoro or Incruse on the registration page for the asthma-focussed webinar, within a list of medicines which could be used in asthma, was wholly inappropriate particularly given that Section 4.4, Special warning and precaution for use of the SPCs, for Trelegy, Anoro and Incruse stated that they should not be used in patients with asthma since they had not been studied in that patient population. The Panel considered that the implied suggestion otherwise was such as to reduce confidence in the pharmaceutical industry. A breach of Clause 2 was ruled. This ruling of Clause 2 was appealed by GlaxoSmithKline.

With regard to GlaxoSmithKline's medical department employee acting as Chair for the promotional webinar, the Panel noted the complainant's allegation that it was inappropriate for a non-promotional member of staff to be present on a promotional webinar to solicit questions for the medical team and that this blurred lines between promotional staff and non-promotional staff.

The Panel did not consider that, in acting as Chair for the promotional webinar, the medical department employee had taken on the role of a representative ie that he/she called on members of the health professions and other relevant decision makers in relation to the promotion of medicines. The Panel further noted the expertise that such an individual would bring to a promotional meeting and that it was customary in the industry for members of the medical department to attend promotional meetings where appropriate. The Panel did not consider that, to have fulfilled his/her role as Chair of a promotional meeting, it was necessary for the employee to have taken an appropriate examination for medical representatives as alleged and so in that regard it ruled no breach of Clause 16.3.

The Panel noted its rulings and comments above and no breach of Clause 9.1 was ruled. The Panel also ruled no breach of Clause 2.

APPEAL FROM GLAXOSMITHKLINE

GlaxoSmithKline appealed the Panel's ruling of a breach of Clause 2 noting that the online registration webpage was to register for a GlaxoSmithKline organised and funded meeting, entitled 'GlaxoSmithKline Webinar: Patient Management in Severe Asthma – Evolution & Evidence' that took place on 25 May 2021.

GlaxoSmithKline submitted that the purpose of the meeting was to discuss a treatment approach for severe asthma, severe asthma services and patient management. This was a highly scientific meeting and the speakers were all well recognised experts in severe asthma.

GlaxoSmithKline submitted that the NHS recognised that patients with severe asthma needed to be considered as a separate group from most people with mild to moderate disease. Those with severe asthma required systematic assessment and specialist care in tertiary respiratory centres. It was a small proportion of patients, estimated at less than 5% of all people with asthma, that had severe asthma (https://www.england.nhs.uk/wp-content/uploads/2017/04/specialised-respiratory-services-adult-severe-asthma.pdf).

GlaxoSmithKline stated that biologic prescribing in severe asthma was limited to a restricted number of tertiary centres as it was commissioned as a specialised service by NHS England. The SPC for Nucala (mepolizumab), a monoclonal antibody indicated for severe refractory eosinophilic asthma, required that it should be prescribed by physicians experienced in the diagnosis and treatment of severe refractory eosinophilic asthma and it was these physicians and their expert colleagues involved in the delivery of this specialist provision, that were the target audience for this highly scientific meeting.

GlaxoSmithKline submitted that these specialist health professionals were emailed an invitation to join the webinar and provided with a link to the webinar registration page at issue. The registration page incorrectly included a link to all GlaxoSmithKline respiratory medicines product information, starting with Nucala at the top, and moving down through Relvar, Seretide, Ventolin, Flixotide, and finally Trelegy, Anoro and Incruse. Regrettably and incorrectly, this included umeclidinium containing medicines, namely Incruse (umeclidinium), Anoro (umeclidinium/vilanterol) and Trelegy (umeclidinium/ vilanterol/fluticasone furoate) which, as the Panel noted, were not licensed in asthma.

GlaxoSmithKline had filed for a licence in asthma for Trelegy in February 2020; this was refused by the EMA in February 2021, due to the data demonstrating improvement in lung function, but not significant reduction in exacerbations; as was required by the EMA.

GlaxoSmithKline agreed and had acknowledged in its initial response that their inclusion was not appropriate for a registration page that was promoting a severe asthma webinar and therefore accepted a breach of Clause 3.2 for each of the three products inappropriately listed.

GlaxoSmithKline also accepted the Panel's ruling of Clause 9.1, that it had not maintained high standards. However, GlaxoSmithKline appealed the ruling of a breach of Clause 2.

The supplementary information to Clause 2 stated 'A breach of Clause 2 was a sign of particular censureand was reserved for such circumstances'. GlaxoSmithKline believed that the four rulings accepted above, were adequate sanctions for the behaviour and that considered as whole, no further censure was needed.

GlaxoSmithKline noted the Panel's consideration that

> 'the immediate and overall impression of the webinar registration page to a busy health professional was that the listed medicines including Trelegy, Anoro and Incruse were licensed for use in asthma, which was not so; a breach of Clause 3.2 was ruled for each medicine as acknowledged by GlaxoSmithKline. The Panel considered that high standards had not been maintainedand a breach of Clause 9.1 was ruled.'

And went on

> 'The Panel considered that the reference to Trelegy, Anoro or Incruse on the registration page for the asthma-focussed webinar, within a list of medicines which could be used in asthma, was wholly inappropriate particularly given that Section 4.4, Special warning and precaution for use of the SPCs, for Trelegy, Anoro and Incruse stated that they should not be used in patients with asthma since they had not been studied in that patient population. The Panel considered that the implied suggestion otherwise was such as to reduce confidence in the pharmaceutical industry. A breach of Clause 2 was ruled.'

GlaxoSmithKline submitted that it appeared that the Panel ruled in breach of Clause 2 because the SPCs stated the products should not be used in asthma, when they had already ruled on that, by giving the three Clause 3.2 breaches, because the impression was that they were licensed in asthma when they were not.

GlaxoSmithKline believed that a finding of a breach of Clause 3.2 was a sufficient sanction in this instance. Clause 2 findings were reserved for instances where particular censure was required and this was not the case in this instance, when no evidence was provided by the complainant that any health professional had been misled, or that patient safety had been prejudiced. Given the highly expert audience who were the only people directed to this registration page, GlaxoSmithKline believed it was extremely unlikely any of them would have been misled as all of these products had been authorised for a number of years (2014 (Anoro and Incruse) and 2017 (Trelegy)) and they would have been very familiar with them.

GlaxoSmithKline submitted that the links to the prescribing information were the only mentions of the aforementioned products on the registration page; there were no claims made in relation to the use of these medicines in asthma. When the prescribing information was accessed, the indication of that medicine was clearly stated.

GlaxoSmithKline submitted that the Panel correctly commented that the inclusion of all GlaxoSmithKline respiratory prescribing information on promotional material was contrary to company guidance. The appropriate placement of prescribing information had been discussed at several educational signatory forums, which the signatory that certified this particular material had attended and clear direction given by senior medical signatories. The signatory of this item acted in direct contradiction to this direction.

GlaxoSmithKline stated that it had several controls in place to ensure it was maintaining high standards and following processes, particularly in relation to copy approval. One such measure was regular management monitoring of promotional and non-promotional materials. This process involved an experienced signatory retrospectively reviewing fully certified items to ensure that they comply with GlaxoSmithKline specific guidance as well as the Code. Any

deviations from process were referred to a committee comprised of medical,compliance and human resource (HR) members. The outcomes of the committee review included line managers discussion with those who had incorrectly approved the material and the instigation of a HR process where required.

GlaxoSmithKline submitted that during this process, on 24 March 2021, several quality issues were identified from this signatory. This was addressed with the team, the signatory and their manager. The details were provided including the measures put in place by the company.

GlaxoSmithKline submitted that the complaint was received on 24 May 2021 and highlighted behaviour that clearly had not complied with GlaxoSmithKline standards and associated training given to signatories. Therefore, following receipt, GlaxoSmithKline investigated the root cause as well as raising a deviation report. Details were provided. GlaxoSmithKline submitted that upon identification of the error, it had corrected the registration page.

In summary, GlaxoSmithKline submitted that it took its obligation to adhere to the Code very seriously. This included the standard and capabilityof employees who were involved in copy approval, in particular, final signatories.

GlaxoSmithKline submitted that there was no intention to promote Incruse, Anoro or Trelegy in the treatment of asthma. Unfortunately, GlaxoSmithKline had been badly let down by the actions of an individual employee acting in direct contravention of company instruction.

GlaxoSmithKline submitted that it had robust approval and management monitoring processes in place and the actions of one individual were unacceptable. The response to this complaint within the organisation was such to uphold confidence in the industry, by quickly and specifically dealing with the individual concerned and ensuring this was not a systemic issue. GlaxoSmithKline had not been complacent in this matter but had acted proactively and robustly prior to any ruling to ensure this could not happen again. This was not a process or systems issue within the company. GlaxoSmithKline had accepted the relevant breaches of the Code however Clause 2 being a sign of censure and was reserved for this, GlaxoSmithKline did not consider this to be case in this particular instance.

GlaxoSmithKline submitted that it took this very seriously and very much regretted that this had happened, hence the immediate action that was taken. GlaxoSmithKline respectfully requested that the Appeal Board consider whether this had brought discredit to and reduced confidence in the industry and therefore was a breach of Clause 2.

COMMENTS FROM COMPLAINANT

The complainant became uncontactable, so there could be no comments on the appeal.

APPEAL BOARD RULING

The Appeal Board noted the arrangements at GlaxoSmithKline for monitoring signatories and their work.

Whilst noting the company's submissions regarding the use of biologics in the treatment of asthma and that this would be carried out in a tertiary centre as a specialist service, it further noted that health professionals who referred asthma patients might also have been invited; the

Appeal Board was therefore not convinced that the registration page for the webinar was limited to a specialist audience as submitted by GlaxoSmithKline. Given the audience would not have entirely, on the balance of probabilities, consisted of specialist health professionals, the Appeal Board did not accept the company's submission that the reference to Trelegy, Anoro or Incruse on the registration page was unlikely to lead to a prescribing error.

The Appeal Board noted GlaxoSmithKline's submission that the invitation to the meeting had the correct prescribing information and that once the error had been identified, the registration page was corrected. The Appeal Board noted that, whilst the company had considered contacting those who had registered for the meeting, it decided not to.

The Appeal Board considered that the reference to Trelegy, Anoro or Incruse on the registration page for the asthma-focussed webinar, within a list of medicines which could be used in asthma, was wholly inappropriate particularly given that Section 4.4, Special warnings and precautions for use of the SPCs, for Trelegy, Anoro and Incruse stated that they should not be used in patients with asthma since they had not been studied in that patient population. The company had accepted rulings of breaches of Clauses 3.2 and 9.1 in that regard. However, the Appeal Board considered that the implied suggestion that the medicines could be used in asthma was a matter of patient safety and such as to reduce confidence in the pharmaceutical industry. A breach of Clause 2 was ruled. The appeal on this point was unsuccessful.

B Web page claim: 'Seretide Evohaler - a combination ICS/LABA treatment for asthma. Now over £5 cheaper than Fostair at medium dose'.

This claim appeared at the top of the Seretide webpage in question, directly underneath a depiction of the three available strengths of Seretide Evohaler.

COMPLAINT

The complainant noted that the claim was in big font and stood out straightaway to anyone who accessed the information; the claim was allegedly misleading and not in line with the Seretide licence. The licensed indication for Seretide was specific and it was stated in the SPC as: 'indicated in the regular treatment of asthma where use of a combination product (long- acting β2 agonist and inhaled corticosteroid) is appropriate: - patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled short-acting β2 agonist. or - patients already adequately controlled on both inhaled corticosteroid and long-acting β2 agonist'. The complainant submitted that Seretide also had specific age ranges for use, as children less than four years old were not allowed to use Seretide as noted in the SPC. The complainant alleged that the big, bold headline claim of 'asthma' patients at the outset of the webpage implied any patient with asthma was suitable for treatment with Seretide which was not the case and was a patient safety risk. Thus, the complainant alleged breaches of Clauses 3.2, 7.2, 7.4, 9.1 and 2. The complainant stated that these were all basic errors which was possibly due to inexperienced signatories contributing to the recent poor case history record.

RESPONSE

GlaxoSmithKline explained that the constituent components of Seretide had been available since 1990 and 1993 and had been used in the treatment of asthma since that time. Seretide Evohaler was launched in the UK as the first combined ICS/LABA over 20 years ago and was well known by the GP audience to whom advertisement was aimed.

GlaxoSmithKline submitted that the licensed indication for Seretide was as broad as it could be, with no restriction on the type or severity of asthma, and was the same as it had been since 2000 when simplifying treatment in well controlled patients from two inhalers to one became part of the indication (initially it was only indicated for those who were not well controlled on inhaled steroid plus short acting beta agonist (reliever inhaler) ie when treatment needed to be stepped up to include a LABA), but the broader indication allowed it to also be prescribed when the individual components had been found to be working:

> 'the regular treatment of asthma where use of a combination product (long-acting β2 agonist and inhaled corticosteroid) is appropriate:
>
> - patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled short-acting β2 agonist
>
> or
>
> - patients already adequately controlled on both inhaled corticosteroid and long-acting β2 agonist.'

GlaxoSmithKline stated that the claim in question made very clear that Seretide was an ICS/LABA treatment for asthma, and was directly compared to Fostair, another well-known ICS/LABA. The British Thoracic Society (BTS) first produced a guideline on asthma and its management in 1990. The first collaborative guideline with the Scottish Intercollegiate Guideline Network (SIGN) was published in 2003 (copy provided). It had since become a mainstay of asthma management across the UK and beyond with updates published regularly every 18–24 months. The stepwise approach to asthma management that it advocated revolutionised asthma treatment and was embedded as part of every physician's approach to treatment. The National Institute for health and Care Excellence (NICE) had also published guidelines for the management of asthma which prescribers referred to (copy provided).

GlaxoSmithKline submitted that these guidelines were used by health professionals and advised use of ICS/LABA in line with the Seretide indication (ie when ICS plus short-acting beta agonist reliever was inadequate), thus the claim would not mislead prescribers in to thinking Seretide was for 'any' asthma patient as alleged, but for those in whom an ICS/LABA was appropriate.

GlaxoSmithKline noted the complainant's concern that Seretide was not indicated in children under the age of 4, but submitted that nothing in the claim or associated artwork implied promotion for use in that age group. GlaxoSmithKline stated that the comparator, Fostair, was well known to only be indicated in adults and in fact, as Seretide had the broadest age-range of any ICS/LABA there was no risk of a health professional confusing it with an ICS/LABA that could be prescribed more widely.

Furthermore, GlaxoSmithKline submitted that immediately below the claim, there was a section entitled 'What was Seretide Evohaler?'. That section had the full indication for Seretide in asthma stated verbatim from the SPC (copy provided), and information related to the dosing in paediatric asthma for 'patients 4 years and above' thus making it explicitly clear.

Further down on the same webpage, in the section entitled 'Compare Seretide with Fostair in asthma', there was a tab boldly entitled 'Paediatric licence'. Clicking on that presented the

details about dosing of Seretide in paediatric patients aged over 4 years once again. GlaxoSmithKline believed that that provided further unambiguous clarity to health professionals.

GlaxoSmithKline stated that health professionals were extremely familiar with Seretide and the place of ICS/LABAs in the treatment of asthma. The licensed indication did not limit the type or severity of asthma that could be treated and described when it was appropriate to introduce ICS/LABAs which was consistent with the BTS/SIGN Guidance that UK GPs had used for decades. GlaxoSmithKline believed no reasonable health professional would assume that the advertisement promoted the use of Seretide outside its licence or that it was misleading. GlaxoSmithKline could substantiate the claim being contested and as such refuted all allegations of breaches of Clauses 3.2, 7.2 and 7.4. As such, GlaxoSmithKline believed it had maintained high standards and it refuted a breach of Clause 9.1.

GlaxoSmithKline believed patient safety to be of the utmost importance and the complainant had provided no evidence that patient safety had been put at risk. The body of the advertisement contained the full indication and explicit mention of the dosing in children over 4. Prescribing information with further prescribing details and the SPC was linked to the top of the page. GlaxoSmithKline did not believe patient safety was compromised or that it had brought the industry into disrepute and as such refuted the allegations of a breach of Clause 2.

PANEL RULING

The Panel noted that the webpage at issue started with the Seretide brand logo, including its non-proprietary name, followed by an image of the three Seretide inhalers which were different strengths. Beneath the image of the three inhalers was the claim 'Seretide Evohaler - a combination ICS/LABA treatment for asthma Now over £5 cheaper than Fostair at medium dose'. The Panel noted that it was thus clear from the outset that Seretide was a combination product.

The Panel noted the complainant had referred to the claim's prominence and had alleged that it was misleading and not in line with the licence for Seretide; the complainant was concerned that the claim implied that Seretide was a suitable treatment for any/all asthma patients of any age which was not so.

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 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 further noted GlaxoSmithKline's submission that immediately below the claim in question was a section entitled 'What is Seretide Evohaler?' which included that Seretide Evohaler 50/25 was licensed for use in paediatric asthma for 'patients 4 years and above' and that further down the webpage was a tab entitled 'Paediatric license', which detailed the dosing requirements of Seretide in paediatric patients aged over four years when clicked. The Panel noted GlaxoSmithKline's submission that

Seretide was indicated for the broadest age range of patients of any ICS/LABA and so in that regard there was no risk of health professionals confusing it with any other ICS/LABA that could be used in patients younger than 4 years of age; Fostair, to which Seretide was compared, was for use in adults aged 18 years and above.

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.

Complaint received **21 May 2021**

Case completed **16 November 2021**