CASE AUTH/3178/3/19

ANONYMOUS V GLAXOSMITHKLINE

Webinar listing on website

An individual, who described him/herself as a concerned UK health professional, complained about the Events section of a GlaxoSmithKline website. The section focussed on fluticasone furoate which was one of the active ingredients in Relvar Ellipta (fluticasone furoate/vilanterol trifenatate), used in the treatment of asthma.

The complainant noted a webinar listed on the website as an upcoming event. There was no prescribing information available on either the front page of the website, or where the event was listed and no instructions as to where to find it.

The title of the webinar was 'Engineered for Effectiveness: a next generation ICS [inhaled corticosteroid] molecule in asthma'; the complainant considered that 'next generation' claimed an advanced feature over the last generation of steroids, when fluticasone furoate was just a different steroid ester which had been used previously. None of the cited references stipulated how generations were defined or why fluticasone furoate was the 'next generation' or indeed what the previous generation was.

The complainant further stated that the website appeared to promote fluticasone furoate for use in asthma although stating that it was not licensed for monotherapy. Stating that it was off-licence did not stop it being off-licence promotion – merely that it was knowingly undertaken. The website also appeared to indicate that the treatment was more effective for asthma control but the comparator was not stated.

The detailed response from GlaxoSmithKline is given below.

The Panel noted that the top of the registration page for the webinar in question had the GlaxoSmithKline logo and the statement 'For UK Healthcare Professionals' and beneath, in smaller text, stated 'This site contains promotional material'. The reader was invited to join UK respiratory experts to explore 'a once daily medicine for Asthma patients' and the following questions were listed: '50 years of pharmacological improvements: why is asthma still a problem?', 'Does potency in inhaled corticosteroids pose greater benefit or risk for asthma patients?' and 'How might you improve asthma control without increasing serious side effects in every day clinical practice?' Below these questions the following text was stated:

> **'Regular inhaled corticosteroid (ICS) therapy is the cornerstone of asthma management and central to enabling people with asthma to lead normal lives free from symptoms. However, suboptimal adherence to regular maintenance therapy remains a key barrier to patients achieving optimal asthma control. Fluticasone furoate was designed as a next generation inhaled corticosteroid molecule, developed to improve on the success of our previous inhaled steroids and**

improve asthma control' (referenced to Daley-Yates 2015, the Relvar Ellipta summary of product characteristics (SPC) and Woodcock *et al* 2017).

Below this text it was stated 'Fluticasone furoate not licensed as a Monotherapy' and readers were invited to register for the webinar.

The Panel noted that the complaint was made more than one month ahead of the webinar and that it did not have before it the content of the webinar. The Panel noted GlaxoSmithKline's submission that the webinar registration page had been certified as promotional and that the webinar would also be certified as promotional. The Panel further noted that GlaxoSmithKline had data to suggest that there was confusion about fluticasone furoate in relation to potency and dose equivalence and the webinar was intended to inform, educate and clarify fluticasone furoate's pharmacological properties as an inhaled corticosteroid.

In the Panel's view, the webinar registration page was positive about fluticasone furoate, one of the active ingredients in Relvar Ellipta. The Panel considered that the registration page promoted Relvar Ellipta. The Panel noted that the Relvar Ellipta prescribing information was not provided and a breach of the Code was ruled. This meant that GlaxoSmithKline had failed to maintain high standards and a further breach of the Code was ruled.

With regard to the alleged lack of prescribing information on the 'front page of the website', the Panel noted that neither the complainant nor GlaxoSmithKline had provided any information about the content of the 'front page' at the time of the complaint. The Panel considered that the complainant had not discharged his/her burden of proof that GlaxoSmithKline had breached the Code in this regard and it therefore ruled no breach of the Code.

With regard to the allegation that 'next generation' claimed an advanced feature over the last generation of steroids, when fluticasone furoate was just a different steroid ester which had been used previously, the Panel noted GlaxoSmithKline's submission that the biochemical and pharmacological profiles of fluticasone furoate and fluticasone propionate were distinct and it was the intact molecules of both that were the pharmacologically active moieties; they were not esters that were converted to fluticasone and fluticasone was not a metabolite of either molecule.

The Panel noted GlaxoSmithKline's submission that fluticasone furoate was an advancement over previous generations of inhaled corticosteroids as described in Daley-Yates cited on the webinar registration page.

It appeared to the Panel, from the information provided by GlaxoSmithKline, that no peer-reviewed article or treatment guideline had specifically referred to fluticasone furoate as a 'next generation of inhaled corticosteroid'. However, Daley-Yates described the furoate ester in fluticasone furoate as being responsible for the greater lipophilicity, lower solubility and enhanced glucocorticoid receptor binding affinity compared with fluticasone propionate and other inhaled corticosteroid molecules. The Panel noted GlaxoSmithKline's submission that fluticasone furoate had features which resulted in 'prolonged lung retention' making it 'suitable for once daily dosing' and that a dictionary definition of 'generation' in reference to products and technology was 'a single stage in

the development of a type of product or technology'. GlaxoSmithKline submitted that 'next generation' therefore implied a progression in the stage of development of a product and that fluticasone furoate was an improvement on the previously approved inhaled corticosteroids.

The Panel noted its comments above and considered that the complainant had not discharged his/her burden of proof that the claim that fluticasone furoate was a 'next generation ICS molecule in asthma' was misleading or incapable of substantiation on the grounds alleged. The Panel ruled no breach of the Code.

With regard to the allegation that the webpage implied that fluticasone furoate was more effective for asthma control without stating the comparator, the Panel noted the statements on the webpage including 'Fluticasone furoate was designed as a next generation inhaled corticosteroid molecule, developed to improve on the success of our previous inhaled steroids and improve asthma control'. The Panel considered that fluticasone furoate was being compared with previous inhaled steroids and therefore it was not a hanging comparison. No breach of the Code was ruled in that regard.

With regard to the allegation that the website promoted fluticasone furoate 'off-licence' as a monotherapy treatment for asthma, the Panel noted its view, stated above, that the webinar registration page promoted Relvar Ellipta. The Panel noted GlaxoSmithKline's submission that fluticasone furoate on its own as an inhaled corticosteroid was not licensed in the UK and there was no SPC. The Code stated that the promotion of a medicine must be in accordance with the terms of its marketing authorization and must not be inconsistent with the particulars listed in its SPC. In the Panel's view, as there was no marketing authorisation and no SPC for fluticasone furoate monotherapy as an inhaled corticosteroid, that part of the Code was not applicable and no breach was ruled.

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

An individual, who described him/herself as a concerned UK health professional, complained about the Events section of a GlaxoSmithKline website in relation to fluticasone furoate. Fluticasone furoate was one of the active ingredients in Relvar Ellipta (fluticasone furoate/vilanterol trifenatate), which was used in the treatment of asthma and marketed by GlaxoSmithKline UK Limited.

COMPLAINT

The complainant stated that the Events tab of a GlaxoSmithKline website listed a webinar as an upcoming event. There was no prescribing information available on either the front page of the website, or where the event was listed and there were no instructions as to where to find it.

With regard to the title of the webinar, 'Engineered for Effectiveness: a next generation ICS [inhaled corticosteroid] molecule in asthma' the complainant considered that 'next generation' claimed an advanced feature over the last generation of steroids, when fluticasone furoate was just a different steroid ester which had been used previously. None of the cited references stipulated how generations were defined or why fluticasone furoate was the 'next generation' or indeed what the previous generation was supposed to be.

The complainant further stated that the website appeared to promote fluticasone furoate for use in asthma although it was stated further down that fluticasone furoate was not licensed for monotherapy. Stating that it was off-licence did not stop it being off-licence promotion – merely that it was knowingly undertaken. The website also appeared to indicate that the treatment was more effective for asthma control but the comparator was not stated.

When writing to GlaxoSmithKline, the Authority asked it to consider the requirements of Clauses 2, 3.2, 4.1, 4.4, 7.2, 7.4, and 9.1 of the 2016 Code.

RESPONSE

GlaxoSmithKline stated that the registration page for the webinar 'Engineered for Effectiveness: a next generation ICS molecule in asthma' was certified for promotional use and was intended for UK health professionals only. Health professionals had to confirm their status by clicking 'I'm a UK healthcare professional' in order to access the webpage. The company explained that in 2018 it had received a number of queries from health professionals about the pharmacological properties of fluticasone furoate. The queries related to the potency of fluticasone furoate and how the two doses of fluticasone furoate contained within the two available doses of Relvar related to other low, medium and high dosage strengths which were available in other asthma inhalers. It became apparent from the number of queries and insights gathered that there was significant confusion about fluticasone furoate in relation to potency and dose equivalence. The purpose of the webinar was thus to inform, educate and clarify the pharmacological properties of fluticasone furoate as an inhaled corticosteroid in the *in vivo* and *in vitro* setting and it would be certified as a promotional activity.

Fluticasone furoate was not licensed as an ICS for use for asthma or any other indication in the UK. Although efficacy and safety had been demonstrated in the *in vitro*, *in vivo* and clinical settings for asthma, GlaxoSmithKline had not sought a licence for it as a monotherapy ICS in the UK.

With regard to the complainant's concerns, GlaxoSmithKline stated that fluticasone furoate was, by definition, a 'next generation' ICS and that its molecular properties were a clear advancement over previous generations of inhaled corticosteroids. The substantiation of the molecular properties of fluticasone furoate compared with other ICS molecules was provided by Daley-Yates cited on the webinar registration page. Further, GlaxoSmithKline noted that the Oxford English dictionary defined 'generation' in reference to products and technology as 'a single stage in the development of a type of product or technology'. A next generation therefore implied a progression in the stage of development of a product.

GlaxoSmithKline explained that beclomethasone dipropionate was the first ICS therapy to be developed for the treatment of asthma in the 1970s and as the first-generation ICS, it was still the UK reference standard against which the potency of all other ICSs were measured according to the British Thoracic Society/Scottish Intercollegiate Guidelines Network (BTS/SIGN) Guidelines. Early ICSs, (such as beclomethasone dipropionate, triamcinolone acetonide, flunisolide, budesonide) were short acting and so needed to be dosed 2-4 times daily. They also included molecules with significant oral absorption (11-41%) of the swallowed dose which increased systemic exposure to the steroid dose. These molecules had been referred to as first generation ICSs (Lipworth 2005). Subsequent ICS molecules (such as fluticasone propionate and mometasone furoate) had lower oral absorption of the swallowed

dose but did not provide a full 24-hour duration of action. Lipworth referred to these as second generation ICSs.

The next generation of ICS molecules included ciclesonide and fluticasone furoate which had shared features of high glucocorticoid receptor activity, negligible oral bioavailability, low systemic exposure, were highly lipophilic which resulted in prolonged lung retention and so this made them suitable for once daily dosing (Lipworth 2005 and Daley-Yates 2015). They were therefore seen as an improvement on the previously approved ICSs (Daley-Yates 2015, Lipworth 2005 and Boulet *et al* 2006). GlaxoSmithKline provided a schematic which illustrated a timeline by decade of ICS development.

GlaxoSmithKline stated that adherence to ICS therapy was often suboptimal with rates of use ranging from 30-70% of the prescribed dose (Wells *et al* 2013). Poor adherence correlated with several poor asthma-related outcomes and appeared to account for the majority of asthma-related hospitalizations (Williams *et al* 2004). Studies in a variety of chronic conditions had found less frequent dosing was associated with higher medication adherence (Wells *et al* 2013). In a retrospective study of 1,302 patients, once daily ICS treatment was associated with higher adherence than multiple daily dosing regimens (Wells *et al* 2013).

GlaxoSmithKline explained that the high binding affinity of fluticasone furoate brought distinctive characteristics which qualified that fluticasone furoate was a next generation molecule:

- A lower inhaled dose was required to occupy the same numbers of glucocorticoid receptors in the airways, which resulted in a lower daily dose for equivalent efficacy.

- Fluticasone furoate was also retained longer in the airways and more slowly absorbed into the systemic circulation. Hence a lower dose and less frequent dosing was required for efficacy.

- The low dose led to low and slow absorption from the lung; which together with its low bioavailability of the swallowed fraction of the dose, resulted in low systemic exposure to the medicine.

- The higher potency of fluticasone furoate and its physicochemical properties that increased lung retention, resulted in high efficacy with low doses. This together with the low systemic exposure (low dose, low oral bioavailability and high systemic clearance) had led to an improved therapeutic index of fluticasone furoate compared with other ICS molecules.

GlaxoSmithKline submitted that the above data provided substantiation of the technological advance that underlay the development of fluticasone furoate and was taken from Daley-Yates, which was referenced on the registration page.

GlaxoSmithKline submitted that the complainant was incorrect to allege that fluticasone furoate was just a different steroid ester that had previously been used. The biochemical and pharmacological profiles of fluticasone furoate and fluticasone propionate were completely distinct and it was the intact molecules of both that were the pharmacologically active moieties; they were not esters that were converted to fluticasone. Furthermore, fluticasone was not a metabolite of fluticasone furoate or fluticasone propionate and even if it were formed *in vivo* it would have no pharmacological activity (Daley-Yates 2015, Salter *et al* 2007).

Fluticasone furoate was an ICS molecule with a 24-hour duration of action with a once daily dosing regimen because of enhanced glucocorticoid receptor affinity and greater retention in the lung. Fluticasone furoate had a longer duration of action than fluticasone propionate which was dosed twice daily in the context of Relvar and Seretide treatment respectively. Fluticasone furoate was also 1.7 times more potent than fluticasone propionate (Daley-Yates 2015, Salter *et al*).

In summary, GlaxoSmithKline noted that Clause 7.2 required information, claims and comparisons to be accurate, balanced, fair, objective and unambiguous. The description of fluticasone furoate as 'a next generation ICS molecule' was consistent with the advanced molecular properties described, in particular higher binding affinity to the glucocorticoid receptor, 24 hour duration of action and higher therapeutic index compared with other ICS molecules. GlaxoSmithKline therefore denied a breach of Clause 7.2.

Clause 7.4 stated that a claim must be capable of substantiation. The molecular properties of fluticasone furoate were described in comparison with other ICS molecules in detail in Daley-Yates, cited on the webinar registration page. As noted above there was also a wider body of evidence that could support the 'next generation' claim. GlaxoSmithKline therefore denied breaches of Clauses 7.2 and 7.4.

GlaxoSmithKline noted that the complainant alleged that the webinar registration page indicated that fluticasone furoate was more effective for asthma control although the comparator was not stated. GlaxoSmithKline submitted that the webinar registration page in fact stated that fluticasone furoate was designed as a next generation molecule developed to improve on the success of the company's previous inhaled steroids and improve asthma control. This statement clarified that the intention behind the development and design of a more advanced ICS, fluticasone furoate, was to improve on previous ICS molecules and improve asthma control as would be the case for any next generation ICS.

The substantiation for the statement was provided by all three references provided: Daley-Yates which specified the next generation molecular properties of fluticasone furoate which had been used in the development of a once daily asthma medicine (Relvar). The Relvar Ellipta SPC confirmed the medicine was to be used once daily and Woodcock *et al* (2017) demonstrated the benefit/risk of Relvar in a robust 52-week randomised control trial (n=4,233). Eligible patients were on either ICS or ICS/LABA maintenance treatment prior to randomisation. Initiation of Relvar was shown to be superior to continuing on usual care on asthma control as measured by the Asthma Control Test (ACT) at week 24 (ACT; OR 2.00, 95% CI 1.70, 2.34; $p<0.001$).

GlaxoSmithKline denied a breach of Clause 7.2 on the basis that the statement was accurate, balanced, fair, objective and unambiguous and aimed only to make clear that the intention behind the development of fluticasone furoate was to create an ICS molecule that would deliver improved asthma control which was substantiated by the three references provided.

GlaxoSmithKline noted the complainant's allegations that the mention of fluticasone furoate use in asthma amounted to off-licence promotion in breach of Clause 3.2 which stated that promotion of a medicine must be in accordance with the terms of its marketing authorization and must not be inconsistent with the particulars listed in its SPC. The focus of the webinar, and indeed the webinar registration page, was fluticasone furoate for which there was no marketing

authorization in the UK as an ICS molecule for any indication and therefore there was no SPC and therefore no capacity to promote off label. The registration page was clear that fluticasone furoate was not licensed as a monotherapy. The mention of asthma control related to the use of fluticasone furoate as a constituent molecule of Relvar Ellipta which was licensed for use in asthma and was substantiated by the references supplied on the webinar registration page. GlaxoSmithKline denied a breach of Clause 3.2.

With regard to the provision of prescribing information, GlaxoSmithKline stated that the registration page did not promote a medicine. There was no mention of a licensed UK medicine on the registration page, with reference only being made to an ICS molecule, fluticasone furoate. Fluticasone furoate had no marketing authorization as an ICS for any indication in the UK and therefore there was no SPC or prescribing information. Furthermore, fluticasone furoate was only one constituent of Relvar Ellipta and therefore in reference to the webinar registration page, which was focused on fluticasone furoate, it would be confusing to supply prescribing information for Relvar. GlaxoSmithKline therefore denied any breach of Clauses 4.1 and 4.4.

In conclusion, GlaxoSmithKline denied any breach of the Code in relation to the webinar registration page on the following basis:

- The page focused on fluticasone furoate, an ICS molecule which was not licensed on its own for use in the UK for any indication. Nor was it available for sale or purchase within the UK. There was therefore no associated prescribing information and no capacity for off-licence promotion under Clauses 3.2, 4.1 and 4.4.

- The molecular properties of fluticasone furoate which substantiated the claim that fluticasone furoate was a next generation molecule, in being more advanced than the previous generations of ICSs due to features including higher binding affinity to the glucocorticoid receptor, 24 hour duration of action and higher therapeutic index compared with other available ICS molecules. These features were described in Daley-Yates – a reference provided on the webinar registration page. GlaxoSmithKline denied breaches of Clauses 7.2 and 7.4.

- The aim of the development and design of fluticasone furoate was to improve asthma control which was an accurate, balanced, fair, objective and unambiguous statement substantiated by the references provided and therefore was not in breach of Clause 7.2.

GlaxoSmithKline denied that it had not upheld high standards in the pharmaceutical industry or had brought the industry into disrepute; the company denied breaches of Clauses 9.1 and 2.

PANEL RULING

The Panel noted that the Events section of the website featured a registration page for the webinar titled ‘Engineered for Effectiveness: a next generation ICS molecule in asthma’. The top of this webinar registration page had the GlaxoSmithKline logo and the statement ‘For UK Healthcare Professionals’ and beneath, in smaller text, stated ‘This site contains promotional material’.

The webinar registration page gave the title and date of the webinar alongside an image which appeared to depict particles within the human lung. The reader was invited to join UK respiratory experts to explore 'a once daily medicine for Asthma patients' and the following questions were listed: '50 years of pharmacological improvements: why is asthma still a problem?', 'Does potency in inhaled corticosteroids pose greater benefit or risk for asthma patients?' and 'How might you improve asthma control without increasing serious side effects in every day clinical practice?' Below these questions the following text was stated:

> 'Regular inhaled corticosteroid (ICS) therapy is the cornerstone of asthma management and central to enabling people with asthma to lead normal lives free from symptoms. However, suboptimal adherence to regular maintenance therapy remains a key barrier to patients achieving optimal asthma control. Fluticasone furoate was designed as a next generation inhaled corticosteroid molecule, developed to improve on the success of our previous inhaled steroids and improve asthma control' (referenced to Daley-Yates 2015, Relvar Ellipta summary of product characteristics (SPC) and Woodcock *et al* 2017).

Below this text it was stated 'Fluticasone furoate not licensed as a Monotherapy' and readers were invited to register for the webinar.

The Panel noted that the complaint was made more than one month before the date of the webinar and the Panel did not have before it the content of the webinar. The Panel noted GlaxoSmithKline's submission that the webinar registration page had been certified as promotional and that the webinar would also be certified as promotional. The Panel further noted GlaxoSmithKline's submission that the webinar was organised following the company's receipt of a number of queries about the pharmacological properties of fluticasone furoate, one of the active ingredients in Relvar Ellipta, and that the number of queries and other insights gathered suggested that there was significant confusion about fluticasone furoate in relation to potency and dose equivalence and the webinar was intended to inform, educate and clarify fluticasone furoate's pharmacological properties as an inhaled corticosteroid.

The Panel noted the complainant's allegation that there was no prescribing information on either the 'front page of the website' or where the webinar in question was listed.

The Panel noted the claims on the webinar registration page including 'a once daily medicine for asthma patients' and 'Fluticasone furoate was designed as a next generation inhaled corticosteroid molecule, developed to improve on the success of our previous inhaled steroids and improve asthma control', which was referenced to, *inter alia*, the Relvar Ellipta SPC. The Panel further noted GlaxoSmithKline's submission that the mention of 'asthma control' related to use of fluticasone furoate as a constituent molecule of Relvar Ellipta. In the Panel's view, the webinar registration page in question was positive about fluticasone furoate which was one of the active ingredients in Relvar Ellipta. The Panel noted its comments above and considered that the webinar registration page promoted Relvar Ellipta. The Panel noted that the Relvar Ellipta prescribing information was not provided on the webinar registration page as required by the Code and the Panel ruled a breach of Clauses 4.1 and 4.4.

The Panel considered that the failure to provide the Relvar Ellipta prescribing information as required by the Code on the webinar registration page meant that GlaxoSmithKline had failed to maintain high standards and a breach of Clause 9.1 was ruled.

With regard to the alleged lack of prescribing information on the 'front page of the website', the Panel noted that neither the complainant nor GlaxoSmithKline had provided any information about the content of the 'front page' at the time of the complaint. The Panel considered that the complainant had not discharged his/her burden of proof that GlaxoSmithKline had breached the Code in this regard and it therefore ruled no breach of Clauses 4.1 and 4.4.

With regard to the allegation that 'next generation is claiming an advanced feature over the last generation of steroids, when it is just a different steroid ester which has previously been used', the Panel noted GlaxoSmithKline's submission that the biochemical and pharmacological profiles of fluticasone furoate and fluticasone propionate were distinct and it was the intact molecules of both that were the pharmacologically active moieties; they were not esters that were converted to fluticasone and fluticasone was not a metabolite of either. The Panel noted GlaxoSmithKline's submission that the molecular properties of fluticasone furoate were an advance over previous generations of inhaled corticosteroids and the substantiation of the molecular properties of fluticasone furoate in comparison with other ICS molecules was described in Daley-Yates (2015) which was cited as a reference on the webinar registration page.

It appeared to the Panel, from the information provided by GlaxoSmithKline, that no peer-reviewed article or treatment guideline had specifically referred to fluticasone furoate as a 'next generation of inhaled corticosteroid'. Lipworth (2005) made reference to first, second and third-generation inhaled corticosteroids, however, the article made no mention of fluticasone furoate. Lipworth referred to attempts by the pharmaceutical industry to 'refine topically active higher-potency second-generation inhaled corticosteroids, such as fluticasone propionate…with claims of lower systemic bioactivity and hence a superior therapeutic ratio, as compared to the older first-generation drugs…'. Lipworth also referred to ciclesonide as a third-generation inhaled corticosteroid and stated that ciclesonide's active moiety exhibited high glucocorticoid receptor activity and was described as 'highly lipophilic, which along with formation of intracellular fatty acid conjugates results in prolonged lung tissue retention, making it suitable for once-daily dosing'. The Panel noted that Daley-Yates (2015) described the furoate ester in fluticasone furoate as being responsible for the greater lipophilicity, lower solubility and enhanced glucocorticoid receptor binding affinity compared with fluticasone propionate and other inhaled corticosteroid molecules. The Panel noted GlaxoSmithKline's submission of a timeline by decade of inhaled corticosteroid development and the company's submission that the 'next generation' of inhaled corticosteroid molecules included ciclesonide and fluticasone furoate which, according to GlaxoSmithKline, shared features which resulted in 'prolonged lung retention' making them 'suitable for once daily dosing'. The Panel further noted GlaxoSmithKline's submission that the Oxford English dictionary defined generation in reference to products and technology as 'a single stage in the development of a type of product or technology'. GlaxoSmithKline submitted that 'next generation' therefore implied a progression in the stage of development of a product and that ciclesonide and fluticasone furoate were an improvement on the previously approved inhaled corticosteroids.

The Panel noted its comments above and considered that the complainant had not discharged his/her burden of proof that the claim that fluticasone furoate was a 'next generation ICS molecule in asthma' was misleading or incapable of substantiation on the grounds alleged. The Panel ruled no breach of Clauses 7.2 and 7.4.

With regard to the allegation that the webpage implied that fluticasone furoate was more effective for asthma control without stating the comparator, the Panel noted the statements on

the webpage including 'Fluticasone furoate was designed as a next generation inhaled corticosteroid molecule, developed to improve on the success of our previous inhaled steroids and improve asthma control'. The Panel considered that fluticasone furoate was being compared with previous inhaled steroids and therefore it was not a hanging comparison. No breach of Clause 7.2 was ruled in that regard.

With regard to the allegation that the website promoted fluticasone furoate 'off-licence' as a monotherapy treatment for asthma, the Panel noted its comments above that, in its view, the webinar registration page promoted Relvar Ellipta. In the Panel's view, the information on the webinar registration page did not promote Relvar Ellipta in a manner that was inconsistent with its SPC but noted that the complainant had not made an allegation in that regard. The Panel noted GlaxoSmithKline's submission that fluticasone furoate on its own as an inhaled corticosteroid had no marketing authorisation in the UK for any indication nor was it available for sale or purchase in the UK and there was no SPC. The Panel noted that GlaxoSmithKline did market fluticasone furoate on its own as a nasal spray (Avamys) for use in allergic rhinitis, however, the Panel considered that the webinar registration page in question was clearly in relation to fluticasone furoate as an inhaled corticosteroid and, in the UK, fluticasone furoate as an inhaled corticosteroid was only available in fixed-dose combination products, including GlaxoSmithKline's Relvar Ellipta (fluticasone furoate/vilanterol trifenatate).

Clause 3.2 of the Code stated that the promotion of a medicine must be in accordance with the terms of its marketing authorization and must not be inconsistent with the particulars listed in its SPC. In the Panel's view, as there was no marketing authorisation and no SPC for fluticasone furoate monotherapy as an inhaled corticosteroid, Clause 3.2 was not applicable and therefore it ruled no breach of Clause 3.2 in this regard.

Clause 2 was a sign of particular censure and was reserved for such use. The Panel noted its comments and rulings above and considered that in the particular circumstances of this case, a breach of Clause 2 was not warranted and it ruled no breach accordingly.

Complaint received **28 March 2019**

Case completed **1 November 2019**