CASE AUTH/3308/2/20

ANONYMOUS/DIRECTOR v GLAXOSMITHKLINE

GlaxoSmithKline website

An individual, who described him/herself as a health professional, complained about content on the Events section of a GlaxoSmithKline website referring to two webinars.

The complainant noted that in Case AUTH/3178/3/19, GlaxoSmithKline was ruled in breach of the Code in relation to the information provided about an upcoming asthma webinar. The complainant noted that the exact same webpage for advertising the webinar was still available on the website as of 11 February 2020. This showed a total lack of disregard for the case completion and the Code in general. There was no brand name next to Relvar (fluticasone/vilanterol) nor any prescribing information. Breaches of the Code were alleged including Clause 2 for failing to address the issues from the previous case.

The complainant also alleged a breach of the Code in relation to a link to the BTS/SIGN guideline as it should be made clear when a user was leaving a company website to go to another website not owned by the company.

The complainant noted that on the same events webpage there was a link to register to another webinar entitled 'For Treating an exacerbating COPD patient in 2019 - From guidelines to practice webinar'. The content of this webinar was clearly promotional, yet the description of the webinar did not state that it would contain promotion. The complainant alleged that it was disguised promotion as users might register expecting education which was non-promotional but were then presented with promotional content. The webinar description referred to a patient case study that required step up to a triple therapy treatment. The complainant noted that GlaxoSmithKline had a triple therapy product and therefore this was indirect promotion of that medicine. As a result, prescribing information for Trelegy (fluticasone/umeclidinium/vilanterol) should be provided. The complainant alleged breaches of the Code including Clause 2 as the company had not learned from the previous case. .

The complaint was also taken up in the name of the Director as the Authority was responsible for ensuring compliance with undertakings.

The detailed response from GlaxoSmithKline is given below.

The Panel noted GlaxoSmithKline's submission that the registration page for the webinar held on 1 May 2019 titled 'Engineered for Effectiveness: a next generation ICS molecule in asthma' that was the subject of Case AUTH 3178/3/19 last appeared on the GlaxoSmithKline website on 7 May 2019 contrary to the complainant's allegation that it was still available on the website on 11 February 2020. However a new registration page for a different webinar entitled, 'Effectiveness by Design: molecules engineered for efficacy and safety' went live on the GlaxoSmithKline events page on 24 October 2019 –

the day before it received the ruling in Case AUTH 3178/3/19 and was still available to view on 11 February 2020 when the current complaint was made. This registration page was not reviewed as part of GlaxoSmithKline's undertaking in Case AUTH 3178/3/19. The Panel considered that the webinar registration page promoted Relvar Ellipta and prescribing information was not provided nor was there a clear prominent statement as to where the prescribing information could be found. The Panel therefore ruled breaches of the Code as acknowledged by GlaxoSmithKline.

The Panel considered that the failure to provide the Relvar Ellipta prescribing information on the webinar registration page meant that GlaxoSmithKline had failed to maintain high standards. The company had also failed to comply with the undertaking given in Case AUTH/3178/3/19 and the Panel ruled breaches of the Code as acknowledged by GlaxoSmithKline.

The Panel considered that GlaxoSmithKline's failure to comply with its undertaking which underpinned self-regulation, amongst other things, brought discredit upon, and reduced confidence in, the pharmaceutical industry. A breach of Clause 2 was ruled.

The Panel noted that the list of references included the BTS/SIGN British Guideline on the Management of Asthma. 2019. Available from: htt12s://www.brit-thoracic.org.uktguality-imwovemenVguidelines/asthma/ (Accessed September 2019). In the Panel's view, linking to a reference might be different to linking to a website, however it was clear in this case that the link took the reader to the British Thoracic Society BTS/SIGN guidelines. The Panel therefore ruled no breach of the Code.

All rulings of breaches in relation to the above were accepted by GlaxoSmithKline.

With regard to the second webinar registration page, for a webinar titled 'Treating an exacerbating COPD patient in 2019 – From guidelines to practice', the Panel noted that the page contained a statement that the site was 'For UK Healthcare professionals' and 'This site contains promotional material' adjacent to a GlaxoSmithKline logo. The Panel further noted when users first arrived at the GlaxoSmithKline product website, they were presented with a pop-up to confirm that they were a UK health professional and to inform them that the site intended for UK health professionals might contain promotional information as explained by GlaxoSmithKline. The description of the webinar stated that a panel of GlaxoSmithKline experts, from both primary and secondary care, would give their opinions on both the pharmacological and non-pharmacological interventions for exacerbating COPD patients. This included a GlaxoSmithKline employee. In the Panel's view attendees would on the balance of probabilities consider that they were being invited to a promotional webinar where GlaxoSmithKline products would be discussed and in this regard the Panel did not consider that the webinar was a disguised promotional activity and thus ruled no breach of the Code.

The Panel noted that whilst the webinar registration page did not specifically mention GlaxoSmithKline's product, Trelegy, it referred to a case study in which a patient required a step up from an ICS/LABA onto a triple therapy to help manage exacerbations in line with the July 2019 NICE guidelines update.

The Panel disagreed with GlaxoSmithKline's submission that the reference to triple therapy generally on the webinar registration page was not a reference, either direct or

indirect, to any specific medicine. There were references to specific medicines in the material, these being ICS/LABA and triple therapy for exacerbating COPD patients. The Panel also noted that it was an accepted principle under the Code that it was possible for material to promote a medicine without mentioning that medicine by name. In the Panel's view the website promoted triple therapy and GlaxoSmithKline marketed a triple therapy, namely Trelegy. In the Panel's view, noting its comments above, the webinar registration page could not be considered anything other than promotional for Trelegy. The page should have included Trelegy prescribing information and a clear prominent statement of where it could be found and did not include either. The Panel therefore ruled breaches of the Code including that high standards had not been maintained. These rulings were appealed.

It appeared that GlaxoSmithKline had also failed to review this webinar registration page as part of its undertaking in Case AUTH 3178/3/19. Thus a second webinar registration page without prescribing information remained on the GlaxoSmithKline events website after the company had signed its undertaking in Case/3178/3/19 stating that it would take all possible steps to avoid similar breaches of the Code in future. The Panel considered that GlaxoSmithKline's failure to comply with its undertaking which underpinned self-regulation, amongst other things, brought discredit upon, and reduced confidence in, the pharmaceutical industry. A breach of Clause 2 was ruled. This ruling was appealed.

The Appeal Board considered that the reference to triple therapy could be any one of a number of different combinations of the three different inhalers available or one of the two available single fixed dose formulations available. The Appeal Board also noted the view that triple therapy was a mechanism for administration rather than a therapy class. In the Appeal Board's view the webinar registration page in question did not promote a specific medicine and therefore prescribing information was not required. The Appeal Board therefore ruled no breaches of the Code including Clause 2 as the company had not failed to comply with its undertaking. The appeal on all points in relation to the COPD webinar was successful.

An individual, who described him/herself as a health professional, complained about content on the Events section of a GlaxoSmithKline website.

Trelegy Ellipta (fluticasone/umeclidinium/vilanterol) was indicated for maintenance treatment in certain adults with moderate to severe chronic obstructive pulmonary disease (COPD). Revlar (fluticasone/vilanterol) was indicated for the regular treatment of asthma in adults and adolescents aged 12 years and older.

The complaint was also taken up in the name of the Director as the Authority was responsible for ensuring compliance with undertakings.

COMPLAINT

The complainant noted that in Case AUTH/3178/3/19, GlaxoSmithKline was ruled in breach of Clauses 4.1, 4.4 and 9.1 in relation to the information provided about an upcoming webinar. The complainant noted that the exact same webpage for advertising the webinar was still available on the website as of 11 February 2020. This showed a total lack of disregard for the case completion and the Code in general. There was no brand name next to Relvar nor any

prescribing information. Therefore, the complainant alleged another breach of Clauses 4.1, 4.4 and 9.1 and also Clause 2 for failing to address the issues from the previous case.

In addition, Reference 1, the BTS/SIGN British Guideline on the Management of Asthma 2019, available from: https://www.brit-thoracic.org.uk/quality-improvement/guidelines/asthma/ (accessed September 2019) was a hyperlink which, when clicked, took the reader to the BTS/SIGN guideline. The complainant alleged a breach of Clause 28.6 as it should be made clear when a user was leaving a company website to go to another website not owned by the company.

The complainant noted that on the same events webpage there was a link to register to another webinar entitled 'For Treating an exacerbating COPD patient in 2019 - From guidelines to practice webinar' (ref PM-GB-FVU-WCNT-190004 August 2019). The content of this webinar was clearly promotional, yet the description of the webinar did not state that it would contain promotion. The complainant alleged a breach of Clause 12.1 as users might register expecting education which was non-promotional but were then presented with promotional content. The webinar description mentioned the following text: 'Part 2: An exacerbating COPD patient case study – What to consider when offering triple therapy - This will focus on a patient case study that requires step up from an ICS/LABA on to a triple therapy treatment to help manage exacerbations in line with the July 2019 NICE guidelines update1'. The complainant noted that GlaxoSmithKline had a triple therapy product and therefore this was indirect promotion of that medicine. As a result, prescribing information for Trelegy should be provided. The complainant alleged a breach of Clauses 4.6 and 4.1. As a result, it was a breach of Clause 9.1 and as the company had not learned anything from previous cases and continued to act in disrespect to the ABPI Code requirements. A breach of Clause 2 was also alleged.

When writing to GlaxoSmithKline, the Authority asked it to consider the requirements of Clauses 2, 4.1, 4.4, 4.6, 9.1 and 29 of the Code in relation to the webinar registration page which was also at issue in Case AUTH/3178/3/19 and the alleged breach of undertaking; Clause 28.6 in relation to the hyperlink to the BTS/SIGN guidelines; Clauses 2, 4.1, 4.6, 9.1 and 12.1 in relation to the COPD webinar described in the complaint.

RESPONSE

GlaxoSmithKline noted the complainant's reference to Case AUTH/3178/3/19 and his/her assertion that the webpage, subject to that complaint, remained live and therefore that GlaxoSmithKline had failed to address the issues identified in that case. GlaxoSmithKline submitted that this was incorrect.

GlaxoSmithKline noted that the complainant had not provided any screenshots or supplementary evidence to support his/her assertion that the webinar page about which he/she complained was the 'exact same webpage' at issue in Case AUTH/3178/3/19. GlaxoSmithKline queried whether the complainant had, therefore, discharged his/her burden of proof in this complaint.

The webinar in question in Case AUTH/3178/3/19, entitled 'Engineered for Effectiveness: a next generation ICS molecule in asthma', (ref UK/FFT/0057/19) was held on 1 May 2019 (a copy of the webinar registration was provided). The webinar registration page last appeared on the GlaxoSmithKline website on 7 May 2019. GlaxoSmithKline therefore categorically denied the

complainant's allegation that the webpage that had previously been found in breach of the Code remained live on its website.

In the absence of any evidence to support the complaint, GlaxoSmithKline assumed that the complainant had viewed the two webinar registration pages on the GlaxoSmithKline Events website (https://gskpro.com/en-gb/events/) as at 11 February 2020 (when the complaint was made). These were:

- 'Effectiveness by Design: molecules engineered for efficacy and safety' (ref PM-GB-FFV-BRF-190025) held on 21 November 2019 (the 'asthma webinar') and

- 'Treating an exacerbating COPD patient in 2019 – From guidelines to practice' (ref PM-GB-FVU-WCNT-19004) held on 9 October 2019 (the 'COPD webinar').

The webinar titles themselves were hyperlinks, which took users to a new page if clicked (asthma webinar page and COPD webinar page (copies provided)). As both the webinars had already taken place, users saw a large banner with 'registration closed' above the webinar information page if these links were clicked. The GlaxoSmithKline webinar pages had been certified for promotional use prior to the content being made live.

Background: GlaxoSmithKline Event Page

GlaxoSmithKline submitted that it hosted webinar sessions periodically with the purpose of informing, educating and clarifying aspects of respiratory disease, covering conditions such as asthma and COPD.

The GlaxoSmithKline events page, (listed at https://gskpro.com/en-gb/events/) hosted information on promotional webinars, both upcoming (open for registration) and past (closed for registration). Webinars were aimed at UK health professionals. Online access to the webinars was via the GlaxoSmithKline UK homepage for health professionals then by selecting 'Events' or the 'Register now' button for signing up for the latest webinars. The GlaxoSmithKline events landing page showcased the next upcoming webinar; only when scrolling past this was there an option to toggle between 'upcoming' and 'past' webinar tabs (copy provided). Past webinars were therefore isolated from the upcoming webinars but contained within the same domain name. These webinars were moved from the 'upcoming' tab to the 'past' tab after completion. The webinars themselves could not be viewed after the event but the description and speakers could still be viewed to give readers examples of the topics the webinars focused on. After the headline title of each webinar there was included a brief description about the webinar.

GlaxoSmithKline submitted that its event pages always maintained a prominent statements that the site was 'For UK Healthcare professionals' and 'This site contains promotional material' adjacent to a company logo at the top left-hand side of the page (copy provided). Additionally, when users first navigated to the GlaxoSmithKline professional page, they were presented with a pop-up to confirm that they were a UK health professional (copy provided) and to inform them that promotional material might be contained within. If the user was not a UK health professional they were directed to the company's public website (https://public.gsk.co.uk/).

1 Asthma Webinar registration page: 'Effectiveness by Design: molecules engineered for efficacy and safety' (ref PM-GB-FFV-BRF-190025) (Alleged breaches of Clauses 2, 4.1, 4.4, 4.6, 9.1, 28.6 and 29)

Background and timelines

GlaxoSmithKline stated that the events webpage at issue in Case AUTH/3178/3/19 contained the webinar entitled 'Engineered for Effectiveness: a next generation ICS molecule in asthma'. As the webinar registration page mentioned a 'once daily medicine for asthma patients' and the positive effects of fluticasone furoate, one of the active ingredients in Relvar Ellipta, the Code of Practice Panel had considered the page promoted Relvar Ellipta and as such should have included the prescribing information. Therefore, a breach of Clauses 4.1, 4.4 as well as 9.1 for failure to maintain high standards was ruled.

The previous complaint was received on 29 March 2019 and GlaxoSmithKline was informed of the Panel's ruling on 25 October. GlaxoSmithKline signed a form of undertaking and assurance on 31 October 2019 and confirmed that the corresponding webinar and webinar registration page (ref UK/FFT/0057/19) had last been used or appeared on the GlaxoSmithKline website on 7 May 2019.

A new registration page for a different webinar, 'Effectiveness by Design: molecules engineered for efficacy and safety' (ref PM-GB-FFV-BRF-190025) went live on the GlaxoSmithKline webinar page on 24 October 2019 – the day before GlaxoSmithKline received the Panel's ruling in Case AUTH/3178/3/19.

The registration page provided a brief summary of the webinar. The brand name 'Relvar' appeared therein as a subheading and within the text when describing 'fluticasone furoate' as one of the two molecules in Relvar but without its accompanying prescribing information. The registration pages were not, as the complainant alleged, the 'exact same', and GlaxoSmithKline noted that the complainant's job bag identifier code, referenced in the present complaint and the screenshot provided in the previous complaint, differed.

Clauses 4.1, 4.4, 4.6, 9.1 and 29

GlaxoSmithKline noted that Clause 4.1 required the prescribing information listed in Clause 4.2 to be provided in a clear and legible manner in all promotional material for a medicine except for abbreviated advertisements.

GlaxoSmithKline regrettably accepted that the Relvar prescribing information should have been be included either directly in the digital material itself or by a clear hyperlink. GlaxoSmithKline understood this was a requirement of the Code and therefore acknowledged high standards had not been maintained in relation to this omission. Although this was a separate registration page for a different webinar: GlaxoSmithKline submitted that its own high standards had not been maintained and it considered that this represented a breach of undertaking. GlaxoSmithKline affirmed it had acted swiftly to remove the webinar registration page on 14 February 2020 once this issue had been brought to its attention.

Clause 4.6 required the inclusion of a clear, prominent statement in digital promotional material as to where the prescribing information could be found. GlaxoSmithKline acknowledged, due to the absence of such a statement on the webinar registration page, there was also a breach of Clause 4.6.

In summary, GlaxoSmithKline acknowledged that the Relvar prescribing information should have been included on the webinar registration page for the asthma webinar and it was not.

GlaxoSmithKline confirmed that the asthma webinar was different to the registration page that was subject to Case AUTH/3178/3/19, and that that page had been withdrawn and measures taken to educate and communicate the ruling. Regrettably, the new registration page went live just before the company received the Panel's ruling in the previous case and signing the undertaking. GlaxoSmithKline regretted that this registration page was not reviewed as part of that undertaking. Therefore, GlaxoSmithKline unfortunately acknowledged that it was in breach of Clauses 4.1, 4.4. 4.6, 9.1 and 29.

Clause 28.6

GlaxoSmithKline noted that Clause 28.6 of the Code stated, 'It should be made clear when a user is leaving any of the company's sites, or sites sponsored by the company, or is being directed to a site which is not that of the company'. GlaxoSmithKline denied a breach of Clause 28.6 regarding the link to the BTS/SIGN guidelines. The British Thoracic Society (BTS) BTS/SIGN guidelines on the management of asthma were accessed through the link https://www.brit-thoracic.org.uk/quality-improvement/guidelines/asthma/. GlaxoSmithKline submitted that it was clear from the fact that the website name was written out in full text, which included the words 'brit-thoracic', 'guidelines' and the differentiating .org.uk component to the domain name within the hyperlink, firmly established that the user was being taken to an external non-GlaxoSmithKline website. As well as producing guidelines, the BTS also produced Thorax, its official respiratory medicine journal with an impact factor of 10.3. (copy provided). Consequently, as an established medical society, health professionals attending a respiratory webinar would know that the BTS was not affiliated, and separate to, the GlaxoSmithKline website.

GlaxoSmithKline noted that in Case AUTH/3162/2/19, a marketing authorisation holder, as part of a disease awareness week, sent out a Twitter post that contained links to a society for that particular disease. In the Panel's view, 'it was clear the link took the reader to the Heart Failure Society of America's webpage for Heart Failure Awareness week 2019'. The Panel had ruled no breach of the Code. GlaxoSmithKline considered there were parallels between this case and a link to the BTS/SIGN asthma guidelines from an asthma webinar registration page and denied a breach of Clause 28.6.

Clause 2

GlaxoSmithKline noted that a ruling of a breach of Clause 2 was a sign of particular censure and was reserved for such circumstances. GlaxoSmithKline denied bringing discredit upon, or reducing confidence in, the pharmaceutical industry in relation to its webinar registration pages.

Upon receipt of the complaint and identification of the deficiencies in the asthma webinar registration page, GlaxoSmithKline promptly removed the relevant registration page on 14 February 2020, the next working day following receipt of the complaint.

GlaxoSmithKline strove to achieve and maintain high standards and took seriously its responsibility to operate within the parameters of the Code. Following the Panel's ruling in Case AUTH/3178/3/19, GlaxoSmithKline communicated the outcome of that case to relevant employees and in November 2019 conducted re-training of commercial and medical teams. The case was also discussed at GlaxoSmithKline's Code and Governance Forum (which was attended by commercial and medical employees) in January 2020. Regrettably, the asthma

webinar registration page had gone live just before the company received the Panel's ruling and had been signed off prior to the re-training.

GlaxoSmithKline noted, with regret, that the complaint suggested that the company had disregarded the undertaking given in Case AUTH/3178/3/19 by failing to take down the webinar page to which that case related. GlaxoSmithKline reiterated that this was not so and the page was not, as alleged by the complainant, the 'exact same webpage'. GlaxoSmithKline submitted that it did act according to the undertaking it gave and removed the relevant webinar page on 7 May 2019. GlaxoSmithKline regretted that a similar webinar page had gone live before receipt of the Panel's ruling.

In addition to the steps taken following the ruling from Case AUTH/3178/3/19, GlaxoSmithKline had refreshed its Code and Governance training cycles to further its employees' understanding of the Code. Training cycles were mandatory for new medical and commercial employees, with a minimum mandatory attendance required for completion.

GlaxoSmithKline regretted the omission of the prescribing information from the asthma webinar registration page. However, GlaxoSmithKline did not believe that the omission of the prescribing information had impacted patient safety. Notably, any health professionals reviewing the registration page would have been on the GlaxoSmithKline professional website, from which they could access the prescribing information and summary of product characteristics on the Product page and the prescribing information via the Therapy Area, Respiratory page.

GlaxoSmithKline stated that it took its obligations to the Code seriously and although it considered that this was an isolated case of prescribing information omission, a third party would conduct a quality check of all digital materials would to ensure there was no reoccurrence and, in addition; the copy approval process would also be reviewed.

In summary, GlaxoSmithKline recognised that a ruling of a breach of Clause 2 was a sign of particular censure and was reserved for such circumstances. GlaxoSmithKline denied bringing discredit upon, or reducing confidence in, the pharmaceutical industry. Due to the events and details outlined above, GlaxoSmithKline did not believe that this had breached Clause 2.

2 COPD Webinar Registration Page: 'Treating an exacerbating COPD patient in 2019 – From guidelines to practice' (ref PM-GB-FVU-WCNT-19004) (Alleged breaches of Clauses 2, 4.1, 4.6, 9.1 and 12.1)

GlaxoSmithKline submitted that this webinar, held on 9 October 2019, was intended to educate health professionals on the (then) new NICE 2019 COPD guidelines. It was split into two parts: practical advice for non-pharmacological interventions and then a hypothetical patient case study requiring treatment in relation to the guidelines. The webinar registration page included a description of the webinar to aid health professionals to the potential value they might derive from attending.

Clause 12.1

GlaxoSmithKline noted that Clause 12.1 required that promotional material and activities must not be disguised. In that regard the company noted that its events webpage stated, in a permanent banner at the top left of the page, located next to the corporate logo, the statement

'For UK Healthcare Professionals' and beneath this, 'This site contains promotional material'. Additionally, when users first navigated to the GlaxoSmithKline professional page, they were presented with a pop-up to confirm that they were UK health professionals and that the page might contain promotional material (copy provided).

Clauses 4.1 and 4.6

GlaxoSmithKline denied the allegation that it had indirectly promoted its medicine in the webpage description for the webinar. The webinar registration page provided background to a case study discussed in the webinar, where a patient required stepping up from ICS/LABA (inhaled corticosteroid/long acting B_2-agonist) to triple therapy; no specific brand or non-proprietary names were mentioned. Both ICS/LABA and triple therapy were well recognised classes of medicine used for COPD and the wording used to describe them was consistent with nomenclature recognised by the respiratory community including the international guidelines for COPD, the Global Initiative for Chronic Obstructive Lung Disease (GOLD), which referred to the combination of LABA plus LAMA (long-acting muscarinic antagonist) plus ICS as triple therapy (copy provided).

Numerous combinations of triple therapy were possible, using a variety of medicines and devices that were not marketed by GlaxoSmithKline.

GlaxoSmithKline noted definitive differences between the two webinar information pages highlighted by the complainant: the webinar registration page, 'Treating an exacerbating COPD patient in 2019 – From guidelines to practice' was differentiated from the webinar registration page 'Effectiveness by Design: molecules engineered for efficacy and safety' by its lack of direct or implied non-proprietary and/or brand references. This registration page did not imply any benefit of a particular medicine, and GlaxoSmithKline therefore believed that, following the Panel's ruling in Case AUTH/3178/3/19, there was no requirement to include prescribing information.

GlaxoSmithKline noted the Panel's ruling in Case AUTH/2941/2/17 whereby no breach of the Code was ruled when a company emailed an invitation for a live webcast. The invitation, certified as promotional, had no direct or implied mention of a medicine. The invitation did not have prescribing information included alongside, or linked to it, as it did not promote any specific medicines. The Panel ruled no breach of Clause 4.1. GlaxoSmithKline considered that there were parallels between the webinar registration page text used as a pre-registration overview for its webinars, and the content that could reasonably be expected to be included in an email invitation, as both served to aid health professionals about the content of the webinar/webcast.

GlaxoSmithKline denied any breach of Clauses 4.1 and 4.6.

Summary

GlaxoSmithKline denied breaches of Clauses 4.1, 4.6 and 12.1. The webinar registration page did not promote a GlaxoSmithKline specific medicine, either directly or implied and website users were informed via both the permanent website heading and pop-up that the website hosted promotional materials.

GlaxoSmithKline did not consider that it had brought the industry into disrepute and had not maintained high standards in relation to the webinar, 'Treating an exacerbating COPD patient in 2019 – From guidelines to practice therefore' and so it denied breaches of Clauses 9.1 and 2.

Conclusion

GlaxoSmithKline asserted that the webinar registration pages relating to Cases AUTH/3178/3/19 (ref UK/FFT/0057/19) and AUTH/3308/2/20 (ref PM-GB-FFV-BRF-190025) were for different webinars evidenced by different titles and identifiers. Therefore they had different registration pages, contrary to the complainant's allegations. The webinar registration page from Case AUTH/3178/3/19 had been removed from online viewing on 7 May 2019, before the company received the final ruling from the PMCPA on 25 October.

GlaxoSmithKline did, however, acknowledge that the registration pages for the two webinars were similar, and that the undertaking required GlaxoSmithKline to remove 'any similar material'.

GlaxoSmithKline acknowledged, with regret, that prescribing information had not been included on the asthma webinar registration page (ref PM-GB-FFV-BRF-190025). GlaxoSmithKline acknowledged that high standards were not maintained and that this could constitute a breach of undertaking. GlaxoSmithKline therefore acknowledged breaches of Clauses 4.1, 4.4, 4.6, 9.1 and 29.

GlaxoSmithKline denied a breach of Clause 28.6, as it was clear from the hyperlink and domain name that users were directed to the British Thoracic Society website, a reputable disease society website, and away from the GlaxoSmithKline website.

With regard to the COPD webinar, 'Treating an exacerbating COPD patient in 2019 – From guidelines to practice', GlaxoSmithKline denied breaches of Clauses 4.1 and 4.6. As no brand or non-proprietary names were included in the webinar registration page, or indirectly referenced, the page did not promote any specific GlaxoSmithKline medicine that would require inclusion of prescribing information.

GlaxoSmithKline denied a breach of Clause 12.1; the events webpage contained permanent headings and a mandatory pop-up regarding the inclusion of promotional materials within.

GlaxoSmithKline acknowledged the serious nature of the complainant's allegations and reaffirmed that it took all obligations under the Code extremely seriously. By promptly removing materials that were in breach, as well as promoting an environment for long-term learning around Code cases and compliance concerns and working jointly with external companies to improve its standards and compliance, GlaxoSmithKline asserted a commitment to its obligations. Based on this, GlaxoSmithKline strongly denied acting in a manner that would bring discredit upon, or reduce confidence in, the pharmaceutical industry, and therefore denied a breach of Clause 2.

PANEL RULING

1 Asthma webinar details

The Panel noted GlaxoSmithKline's submission that the registration page for the webinar held on 1 May 2019 titled 'Engineered for Effectiveness: a next generation ICS molecule in asthma' (ref UK/FFT/0057/19) that was the subject of Case AUTH 3178/3/19 last appeared on the GlaxoSmithKline website on 7 May 2019 contrary to the complainant's allegation that it was still available on the website on 11 February 2020.

The Panel noted GlaxoSmithKline's submission that a new registration page for a different webinar entitled, 'Effectiveness by Design: molecules engineered for efficacy and safety' [PM-GB-FFV-BRF-190025] went live on the GlaxoSmithKline events page on 24 October 2019 – the day before it received the Panel's ruling in Case AUTH 3178/3/19 and was still available to view on 11 February 2020 when the current complaint was made. This registration page was not reviewed as part of GlaxoSmithKline's undertaking in Case AUTH 3178/3/19. The page provided a brief summary of the webinar and stated as a subheading 'Relvar – asthma control with precision potency' and within the text stated 'Fluticasone Furoate, one of the two molecules in Relvar, was engineered and developed to improve on the success of our previous inhaled steroids and improve asthma control'. The Panel considered that the webinar registration page promoted Relvar Ellipta and prescribing information was not provided on the webinar registration page nor was there a clear prominent statement as to where the prescribing information could be found as required by the Code. The Panel therefore ruled a breach of Clauses 4.1, 4.4 and 4.6 as acknowledged by GlaxoSmithKline.

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

There had thus been a failure to comply with the undertaking given in Case AUTH/3178/3/19 and a breach of Clause 29 was ruled as acknowledged by GlaxoSmithKline. High standards had not been maintained and the Panel also ruled a breach of Clause 9.1 as acknowledged by GlaxoSmithKline. A similar webinar registration page without prescribing information remained on the GlaxoSmithKline events website after the company had signed its undertaking in Case/3178/3/19 stating that it would take all possible steps to avoid similar breaches of the Code in future. The Panel considered that GlaxoSmithKline's failure to comply with its undertaking which underpinned self-regulation, amongst other things, brought discredit upon, and reduced confidence in, the pharmaceutical industry. A breach of Clause 2 was ruled.

The Panel noted that Clause 28.6 stated that it should be made clear when a user was leaving any of the company's sites, or sites sponsored by the company, or was being directed to a site which is not that of the company. The Panel noted that the list of references included the BTS/SIGN British Guideline on the Management of Asthma. 2019. Available from: htt12s://www.brit-thoracic.org.uktguality-imwovemenVguidelines/asthma/ (Accessed September 2019). In the Panel's view, linking to a reference might be different to linking to a website, however it was clear in this case that the link took the reader to the British Thoracic Society BTS/SIGN guidelines. The Panel therefore ruled no breach of Clause 28.6.

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During the consideration of Point 1, the Panel was concerned about two matters. Firstly, the title of the asthma webinar 'Effectiveness by Design: molecules engineered for efficacy and safety'. The Panel noted that Clause 7.9 stated, *inter alia*, that it must not be stated that a product has no adverse reactions, toxic hazards or risks of addiction or dependency. The word

'safe' must not be used without qualification. The supplementary information further stated that the restrictions on the word 'safe' apply equally to grammatical derivatives of the word such as 'safety'. For example, 'demonstrated safety' or 'proven safety' are prohibited under this clause. The Panel queried whether the webinar title in combination with the reference to Relvar complied with the requirements of Clause 7.9 and asked that GlaxoSmithKline be advised of its concerns.

Secondly, the Panel noted that the complainant alleged that there was no brand name next to 'Relvar' on the registration page for the webinar. This had not been taken up by the case preparation manager and GlaxoSmithKline had not been asked to comment. Clause 4.3 of the Code required that the non-proprietary name appeared immediately after the most prominent display of the brand name. The most prominent display of the brand name Relvar on the page was not immediately followed by the non-proprietary name. The Panel requested that GlaxoSmithKline be so advised.

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2 COPD webinar details

The Panel noted that the complainant alleged that a second webinar registration page that could be viewed on the GlaxoSmithKline Events on 11 February 2020 for a webinar titled 'Treating an exacerbating COPD patient in 2019 – From guidelines to practice' (ref PM-GB-FVU-WCNT-19004) which was held on 9 October 2019 was clearly promotional yet the description of the webinar did not state that it would contain promotion.

The Panel noted that GlaxoSmithKline's event pages contained a statement in the top left-hand corner that the site was 'For UK Healthcare professionals' and 'This site contains promotional material' adjacent to a GlaxoSmithKline logo which could be seen when viewing the webinar registration page at issue. The Panel further noted when users first arrived at the GlaxoSmithKline product website, they were presented with a pop-up to confirm that they were a UK health professional and to inform them that the site intended for UK health professionals might contain promotional information as explained by GlaxoSmithKline. The description of the webinar stated that a panel of GlaxoSmithKline experts, from both primary and secondary care, would give their opinions on both the pharmacological and non-pharmacological interventions for exacerbating COPD patients. This included a GlaxoSmithKline employee. In the Panel's view attendees would on the balance of probabilities consider that they were being invited to a promotional webinar where GlaxoSmithKline products would be discussed and in this regard the Panel did not consider that the webinar was a disguised promotional activity and thus ruled no breach of Clause 12.1.

In relation to the complainant's allegation that as the webinar description mentioned triple therapy and GlaxoSmithKline had such a product, it was indirect promotion of that medicine and prescribing information for Trelegy should have been provided. The Panel noted that whilst the webinar registration page did not specifically mention Trelegy, it referred to a case study in which a patient required a step up from an ICS/LABA onto a triple therapy to help manage exacerbations in line with the July 2019 NICE guidelines update.

The Panel disagreed with GlaxoSmithKline's submission that the reference to triple therapy generally on the webinar registration page was not a reference, either direct or indirect, to any specific medicine. There were references to specific medicines in the material, these being

ICS/LABA and triple therapy for exacerbating COPD patients. The Panel also noted that it was an accepted principle under the Code that it was possible for material to promote a medicine without mentioning that medicine by name. In the Panel's view the website promoted triple therapy and GlaxoSmithKline marketed a triple therapy, namely Trelegy. In the Panel's view, noting its comments above, the webinar registration page could not be considered anything other than promotional for Trelegy. The Panel considered that the webinar registration page should have included Trelegy prescribing information and a clear prominent statement of where it could be found and did not include either. The Panel therefore ruled a breach of Clauses 4.1 and 4.6.

The Panel considered that failing to include this information meant that GlaxoSmithKline had failed to maintain high standards and a breach of Clause 9.1 was ruled.

The Panel noted that although the webinar had been held (9 October 2019) it appeared that GlaxoSmithKline had also failed to review this webinar registration page as part of its undertaking in Case AUTH 3178/3/19. Thus a second webinar registration page without prescribing information remained on the GlaxoSmithKline events website after the company had signed its undertaking in Case/3178/3/19 stating that it would take all possible steps to avoid similar breaches of the Code in future. The Panel considered that GlaxoSmithKline's failure to comply with its undertaking which underpinned self-regulation, amongst other things, brought discredit upon, and reduced confidence in, the pharmaceutical industry. A breach of Clause 2 was ruled.

APPEAL BY GLAXOSMITHKLINE

GlaxoSmithKline appealed the Panel's rulings of breaches of Clauses 2, 4.1, 4.6, and 9.1 relating to COPD webinar details (Ref PM-GB-FVU-WCNT-19004) at Point 2 above. GlaxoSmithKline submitted that by referring to a class of therapy where there was more than one medicine available, the webinar registration page did not identify any particular medicine in that class and therefore the requirement for prescribing information was not triggered.

Background

GlaxoSmithKline submitted that the webinar, held on 9 October 2019, intended to educate health professionals on the (then) new NICE 2019 COPD guidelines (Chronic obstructive pulmonary disease in over 16s: diagnosis and management Inhaled triple therapy NICE guideline NG115). NG115 recommended administering various classes of inhaled pharmacologic agents in a stepwise fashion to effectively manage COPD. A visual summary of NICE (2019) treatment options was included with the response to the complaint. Patients could 'step-up' into different combinations (and classes) of inhaled therapies, depending on clinical presentation, rate of disease progression, and disease severity. In this instance, the webinar registration page referred to a case study discussed in the webinar, where a patient required stepping up from ICS/LABA (inhaled corticosteroid/long acting B_2-agonist) to triple therapy (both classes of medicines were commonly used in COPD).

GlaxoSmithKline submitted that the complainant alleged that as the webinar description mentioned triple therapy and GlaxoSmithKline had such a product, it was indirect promotion of that medicine and prescribing information for Trelegy should have been provided. GlaxoSmithKline submitted in response to that complaint, that reference to a class of medicines where multiple medicines and medicine combinations were available was not promotional,

neither direct nor indirect. However, the Panel disagreed with GlaxoSmithKline that the reference to 'triple therapy' on the webinar registration page was not a reference, either direct or indirect, to any specific medicine and incorrectly asserted that 'There were references to specific medicines in the material, these being ICS/LABA and triple therapy for exacerbating COPD patients'. Further, the Panel noted 'the website promoted triple therapy and GlaxoSmithKline marketed a triple therapy, namely Trelegy'.

GlaxoSmithKline appealed as in its view using the terms 'ICS/LABA' or 'triple therapy', referred to classes of medicines and did not identify any individual product and GlaxoSmithKline marketed more than one triple therapy. As such, Trelegy was not promoted on the webpage in question and therefore prescribing information was not required.

Definition of 'triple therapy'

The NICE guidelines used the term 'triple therapy' defined as 'Triple therapy is delivery of a combination of all three inhaled drugs (LAMA+LABA+ICS). Triple therapy can be prescribed as a single inhaler which delivers all three drugs in one dose or as multiple inhalers which deliver separate doses of each drug'. The guidelines did not specify which medicine from which classes should be used, but simply referred to the classes throughout.

'**Triple therapy' did not indirectly identify Trelegy**

GlaxoSmithKline submitted that there were a **huge** number of ICS/LABAs and triple therapy combinations available, which were very well known to the UK health audience that were part of this webinar communication.

The Inhaler Identifier Chart from an NHS Clinical Commissioning Group (provided) showed the numerous different ICS/LABA inhalers available, of which 7 were licensed in COPD. To construct triple therapy, one of these would be used with one of the 9 different LAMAs listed. There were over 50 ways to prescribe triple therapy in COPD from nine different pharmaceutical companies — either as ICS/LABA plus LAMA or as a combined inhaler of ICS/LAMA/LABA.

GlaxoSmithKline supplied three forms of 'triple therapy' for COPD

GlaxoSmithKline submitted that it had two medicines within the ICS/LABA class licensed for COPD (Relvar 92/22mcg and Seretide Accuhaler 50/500mcg) and one medicine within the LAMA class (Incruse) as well as single inhaler triple therapy, Trelegy, thus providing three different ways to provide triple therapy from GlaxoSmithKline alone. Referring to the classes of medicines in general without directly or indirectly identifying individual medicines meant that a specific medicine had not been promoted and therefore the requirement for prescribing information and other obligatory information was not triggered.

Moreover, GlaxoSmithKline submitted that had it used the term 'triple inhaler' rather than the broader 'triple therapy', it would have narrowed the choices down to two inhalers as seen on the chart; Trelegy from GlaxoSmithKline and Trimbow from Chiesi. Importantly, even this approach would not have (theoretically) referred to a specific branded inhaler *per se*.

GlaxoSmithKline submitted that the non-specific, broader 'triple therapy' term, and the **huge** possibility of various different inhaler combinations reinforced that referring to triple therapy was not an indirect reference specifically to Trelegy but simply an umbrella term that referred to the

concomitant use of three different inhaled classes of medicines (ICS, LAMA and LABA) as described in the NICE definition.

Similarly, the term ICS/LABA referred to a combination of two classes of medicines available from a number of different manufacturers as seen on the chart and did not constitute '… references to specific medicines' as considered by the Panel. The Panel was incorrect in its assertion that 'references to specific medicines in the material, these being ICS/LABA and triple therapy…' and incorrectly concluded that '…the webinar registration page could not have been anything but promotional'. As there was no mention of specific medicines within the material this could not be the case.

The page did not promote Trelegy directly or indirectly

The Panel also noted that 'it was an accepted principle under the Code that it was possible for material to promote a medicine without mentioning that medicine by name'. GlaxoSmithKline acknowledged this, however, for material to do this it needed to identify the particular product indirectly for example:

- by being the only medicine available in the class being mentioned
- mentioning a unique distinguishing feature (eg 'the only once daily inhaler')
- by using product branding familiar to the reader that they would associate with a specific medicine.

GlaxoSmithKline submitted that the webinar page at issue did none of these. It outlined a common scenario encountered routinely in clinical practice and one that NICE had very recently updated the guidelines for, describing how the webinar would discuss the factors that need to be considered when initiating triple therapy. None of the text inferred the use of a specific medicine — the phrase 'triple therapy treatment' covered a plethora of possible combinations and did not point directly or indirectly to Trelegy specifically. Advocating the use of triple therapy in general was not the same as promoting a specific medicine.

Invitations to promotional events were not automatically promotional themselves

GlaxoSmithKline submitted that it was an established principle under the Code that invitations to promotional events were not automatically considered to be promoting a particular medicine, but each piece of material must be considered on its own merits.

GlaxoSmithKline referred to a number of previous cases including a tweet from an events company (Case AUTH/2612/6/13) advertising a promotional symposium ('Places available at the Nottingham symposium on uterine fibroids') was ruled not in breach as it did not promote a specific medicine. A separate tweet about the same symposium ('Register for the event "Sharing surgical experience after the use of ulipristal acetate in fibroid patients"') was in breach for mentioning both the generic name and indication and as such being promotional. This case illustrated how it could be acceptable to advertise a promotional meeting without the advertisement or invitation itself promoting a particular medicine.

Previous rulings cited by GlaxoSmithKline to support its position

Case AUTH/2482/2/12 offered useful parallels with the case under consideration. It concerned an emailed invitation and registration page to a promotional meeting. Novo Nordisk had

supplied prescribing information for its glp-1 receptor agonist as it only had one of them and also mentioned it by name in the registration page. However, the email also mentioned a class of medicines 'modern insulins' which Novo Nordisk had three of and they did not supply prescription information for any of them. The complainant appealed the Panel's ruling of no breach.

In that case the Appeal Board noted that the email also mentioned modern insulins. As Novo Nordisk produced three insulin analogues (Levemir, NovoRapid and NovoMix) of the available eight and no particular insulin was identified, no prescribing information for any was provided. On the registration page, which also included the company logo, the agenda referred to liraglutide, and the prescribing information was again provided. Insulins were discussed but as none were identifiable no prescribing information was provided. The Appeal Board considered that neither the email nor the registration page promoted any particular insulin and thus no prescribing information was required. The Appeal Board upheld the Panel's ruling of no breach of Clause 4.1.

Case AUTH/1898/10/06 involved a letter about mesalazine and how different formulations were not interchangeable. The company responsible marketed only one mesalazine product, Asacol. The Panel noted that the letter did not mention any particular brand of oral mesalazine either by name or by implication. In that regard, given the general nature of the letter, the Panel did not consider that it promoted Asacol and thus did not require prescribing information.

GlaxoSmithKline submitted that what was of interest in this case was that mesalazine was in fact a product (within the class of non-steroidal anti-inflammatory medicines). Here the Panel had considered the mention of a non-proprietary name, where many branded and generic versions exist, and deemed prescribing information not to be needed, even though the company concerned marketed only one.

GlaxoSmithKline submitted that the same letter was subject to another complaint (Case AUTH/1900/10/06) and the Panel ruled similarly, 'As the letter only referred to the class of medicine, mesalazine, and did not mention any particular brand, it could not be considered a promotional piece'.

Conclusion

GlaxoSmithKline submitted that the webinar page in question did not promote any particular medicine, there was no mention of a medicine by name (generic or brand), nor was there reference to any particular distinguishing feature. In referring to a class of medicines, for which there were several from more than one company, could not be considered 'anything other than promotion' as concluded in the Panel ruling and in fact was contrary to previous Panel rulings and Appeal Board considerations.

Therefore, GlaxoSmithKline submitted that it had not breached Clauses 4.1 and 4.6 regarding the requirement of the prescribing information and statement as to where it could be found and was appealing the Panel's rulings. GlaxoSmithKline also disputed the Panel finding that it had not maintained high standards and was appealing a breach of Clause 9.1 as the webinar page was compliant with the provisions of the Code for the reasons stated above.

The Panel's finding of a breach of Clause 2 was made on the basis of a breach of undertaking associated with the Panel ruling that the webinar page was promotional for Trelegy and

therefore required prescribing information and as such was a similar breach to Case AUTH/3178/3/19. In Case AUTH/3178/3/19, a GlaxoSmithKline webinar registration page referred to a webinar entitled 'Engineered for Effectiveness: a next generation ICS [inhaled corticosteroid] molecule in asthma'. The page stated that '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 ruled that in mentioning fluticasone furoate, an ICS component of Relvar Ellipta, the registration page promoted Relvar Ellipta and consequently breaches of Clauses 4.1 and 4.4 as no prescribing information was provided. GlaxoSmithKline had accepted this ruling. However, the current case did not come within the scope of the undertaking given in Case AUTH/3178/3/19 as there was no mention of a generic or brand name; therefore, for the reasons outlined above, the material did not promote Trelegy. Thus, GlaxoSmithKline submitted that there was no breach of undertaking and consequently, no breach of Clause 2.

APPEAL BOARD RULING

The Appeal Board noted that two of the previous cases cited by GlaxoSmithKline to support its appeal, had been the subject of appeal and that each case was considered on its own particular merits. There were differences between those cited and the current case before the Appeal Board.

The Appeal Board noted that the material at issue in the current case was the GlaxoSmithKline registration page for the webinar titled 'Treating an exacerbating COPD patient in 2019 – From guidelines to practice'. The webinar was held on 9 October 2019. The Appeal Board noted from GlaxoSmithKline that a number of matters including the NICE guidance were discussed at the webinar itself before Trelegy was introduced. As Trelegy was discussed at the webinar prescribing information was provided as part of the webinar.

The registration page contained a statement in the top left-hand corner that the site was 'For UK Healthcare professionals' and 'This site contains promotional material' adjacent to a GlaxoSmithKline logo. The Appeal Board further noted when users first arrived at the GlaxoSmithKline product website, they were presented with a pop-up to confirm that they were a UK health professional and to inform them that the site intended for UK health professionals might contain promotional information.

The Appeal Board noted that the webinar registration page referred to a case study in which a patient required a step up from an ICS/LABA onto a triple therapy to help manage exacerbations in line with the July 2019 NICE guidelines update. The Appeal Board noted that within the webinar the triple therapy discussed within the case study was Trelegy. The NICE guidance included that 'Triple therapy is delivery of a combination of all three inhaled drugs (LAMA+LABA+ICS). Triple therapy can be prescribed as a single inhaler which delivers all three drugs in one dose or as multiple inhalers which deliver separate doses of each drug'. The Appeal Board noted GlaxoSmithKline's submission that there were two single dose triple therapy formulations currently available, one of which was a GlaxoSmithKline product, Trelegy. Further that the reference to triple therapy generally on the webinar registration page was not a reference, either direct or indirect, to any specific medicine. Trelegy was not mentioned on the registration page.

The Appeal Board considered that the reference to triple therapy could be any one of a number of different combinations of the three different inhalers available or one of the two available

single fixed dose formulations available. The Appeal Board also noted the view that triple therapy was a mechanism for administration rather than a therapy class. In the Appeal Board's view the webinar registration page in question did not promote a specific medicine and therefore prescribing information was not required. The Appeal Board therefore ruled no breach of Clauses 4.1 and 4.6. The appeal on this point was successful.

The Appeal Board did not consider that GlaxoSmithKline had failed to maintain high standards and ruled no breach of Clause 9.1. Consequently the Appeal Board considered that its rulings meant that there was no failure to comply with the undertaking given in relation to previous rulings of breaches of the Code in Case AUTH/3178/3/19. The Appeal Board therefore ruled no breach of Clause 2. The appeals on these points were successful.

Complaint received **11 February 2020**

Case completed **17 September 2020**