CASE AUTH/2787/8/15

VOLUNTARY ADMISSION BY GLAXOSMITHKLINE

Online advertisements for Incruse and Relvar

GlaxoSmithKline voluntarily admitted that some online advertisements for Incruse Ellipta (umeclidinium bromide) plus Relvar Ellipta (fluticasone furoate and vilanterol trifenatate) were in breach of the Code. Relvar and Incruse could be used together in chronic obstructive pulmonary disease (COPD).

As Paragraph 5.6 of the Constitution and Procedure required the Director to treat a voluntary admission as a complaint, the matter was taken up with GlaxoSmithKline.

GlaxoSmithKline explained that it noted an advertisement on the Pulse website had a blurry non-proprietary name and only linked to the Incruse prescribing information. Two other advertisements had similar issues. On checking it was found that the final form of some advertisements had not been certified as the signatories had not seen the final form. All online advertisements for Incruse plus Relvar were removed and two further items were found with similar issues. Preventative actions had commenced with a voluntary admission to the PMCPA.

GlaxoSmithKline explained that from January 2015 it had promoted Incruse and Relvar together for patients for COPD; the medicines had previously been advertised separately. Advertising space planned originally for Incruse alone was assigned to Incruse plus Relvar. However the media plan continued to refer to 'Incruse' rather than 'Incruse + Relvar'.

GlaxoSmithKline noted that though one of the advertisements was stamped 'Amend and Progress' in ZINC, it was inadvertently sent to the company's media agency for publication in the belief that it had been certified. A second advertisement was released to the Nursing Times, signed only by one signatory.

GlaxoSmithKline's investigation showed that of seven job bags, a further two failed to meet the standards required by the Code. Of the five items published online, three were released before certification. Additionally, all five had a degree of illegibility and incomplete prescribing information from 20 April to 2 July.

GlaxoSmithKline explained that over a space of three weeks over Easter 2015, those working on the Incruse and Relvar advertisements had changed roles and responsibilities and the digital advertising plan, workload priorities and resources were reconsidered.

With regard to the prescribing information, GlaxoSmithKline explained that at certification and when all advertisements were published online a direct link for dual prescribing information was made available. However, the link broke and the media agency asked GlaxoSmithKline for replacement prescribing information 'for Incruse' (rather than for Incruse plus Relvar). Consequently, from 20 April until 2 July the five online advertisements only linked to Incruse prescribing information and not to the prescribing information for both medicines.

With regard to items being released before certification, GlaxoSmithKline stated that this error was likely to have been the result of a misread code for a similar certified item resulting in misidentification. Further, misinterpretation of a message might also have been either causal or contributory. Though released in good faith the item was, unfortunately, released in error in breach of the Code.

GlaxoSmithKline admitted that high standards had not been maintained.

Further details from GlaxoSmithKline are given below.

The Panel noted the three specific compliance issues with five digital advertisements for Incruse plus Relvar: poor legibility of the non-proprietary names, omission of prescribing information for Relvar and publication prior to certification. The poor legibility of the non-proprietary names and the omission of the Relvar prescribing information affected all five of the advertisements and three of the five advertisements were published before certification.

The Panel noted all five of the online advertisements for Incruse plus Relvar only linked to the prescribing information for Incruse. As the prescribing information for Relvar was not available via the link a breach of the Code was ruled as acknowledged by GlaxoSmithKline.

The Panel noted that although the advertisements at issue included the non-proprietary names in the correct position, the names were not readily readable. A breach of the Code was ruled as acknowledged by GlaxoSmithKline.

The Panel noted that three of the advertisements at issue had been published online before final certification. A breach of the Code was ruled as acknowledged by GlaxoSmithKline.

The Panel noted that the Code required promotional material on the Internet directed to a UK audience to comply with the Code. The Panel noted its rulings of breaches of the Code above and thus ruled a breach of the Code as acknowledged by

GlaxoSmithKline.

No evidence had been provided to the Panel to demonstrate that relevant personnel had not been trained. On balance the Panel ruled no breach of the Code.

Overall, the Panel considered that high standards had not been maintained. A breach of the Code was ruled as acknowledged by GlaxoSmithKline.

The Panel noted its comments and rulings above but did not consider that the circumstances warranted a ruling of a breach of Clause 2 of the Code which was a sign of particular censure and reserved for such use. No breach of that clause was ruled.

GlaxoSmithKline voluntarily admitted that a number of digital advertisements for Incruse Ellipta (umeclidinium bromide) plus Relvar Ellipta (fluticasone furoate and vilanterol trifenatate) were published online without meeting the requirements of the 2015 Code.

As Paragraph 5.6 of the Constitution and Procedure required the Director to treat a voluntary admission as a complaint, the matter was taken up with GlaxoSmithKline.

On 2 July 2015 a GlaxoSmithKline a senior employee saw an advertisement on the Pulse website with a blurry non-proprietary name, clicked through to the prescribing information and noticed that only the Incruse prescribing information was available. Two other advertisements had similar issues. The employee then checked the ZINC job bag and found that for some, final certification had not occurred as the final form had not been viewed and the signatories had been waiting for this. After escalating this issue to senior management, all online advertisements for Incruse plus Relvar were removed the same day. An investigation commenced and a further two items were found with similar issues and an understanding as to the circumstances had been documented. Preventative actions had commenced with a voluntary admission to the PMCPA.

VOLUNTARY ADMISSION

GlaxoSmithKline stated that Incruse was indicated as a maintenance bronchodilator treatment to relieve symptoms in adults with chronic obstructive pulmonary disease (COPD). Relvar was available in two strengths for asthma; the lower dose (92/22) was also indicated for symptomatic treatment of adults with COPD with a FEV1 <70% predicted normal (post bronchodilator) with an exacerbation history despite regular bronchodilator therapy. Relvar and Incruse could be used together in COPD. As there were three active ingredients this was sometimes termed 'triple therapy'.

In January 2015 it was decided to promote Incruse and Relvar together for patients for COPD; the medicines had previously been advertised separately. Advertising space that was planned originally for Incruse alone was assigned to Incruse plus Relvar. However, in spite of this change, the media plan continued to refer to 'Incruse' rather than the more precise and accurate descriptor of 'Incruse + Relvar'. The intention had been to create 32 advertisements for publication in 13 online journals over the course of 2015. During February and March a junior employee was assigned to work on 13 advertisements for publication in Nursing Times, Nursing in Practice, GP online and Pulse.

The senior employee saw a banner advertisement (ref UK/FFT/0030/15a) coincidentally on 2 July in the online edition of Pulse. The advertisement had been certified in its final form via an appropriate staging link on 16 March 2015, however a degree of blurring particularly affecting the non-proprietary names was noted. This was not how the senior employee recalled seeing the item in March. Moreover, it was noted that the URL to the prescribing information linked to the Incruse prescribing information only. This was both confusing and concerning as, when examined on staging, the advertisement had linked correctly to prescribing information for both medicines. Furthermore, the senior employee recalled that the copy was fully legible at the certification stage. As a result the senior employee decided to look further at this and other related items in ZINC.

It became apparent from reviewing the item and a further two items that all three were similarly affected from a legibility point of view. There were also issues of certification with these two items.

UK/FFT/0032/15 had not been certified in its final form. At the certification stage (17 March), the two signatories noted that the staging link failed and the item could not be visualised in its final form; the advertisement thus could not be certified as intended on that date. Though stamped 'Amend and Progress' in ZINC, a junior employee inadvertently released the advertisement to the media agency for publication the following day believing that it had been certified as scheduled the day before.

UK/FFT/0032/15a had been released to the Nursing Times signed by only one signatory.

Having appropriately checked the initial advertisement and the further two advertisements identified, the senior employee alerted marketing colleagues to his findings. These were then escalated to the relevant medical and commercial directors as a priority.

The media agency was promptly instructed to recall the online digital advertising for Incruse plus Relvar with the result that all online advertisements were taken down on 2 July and the deviations reported to the relevant internal governance committee. An investigation was initiated immediately to ascertain how and why such discrepancies could have occurred following the advertisements' online appearance in various digital publications.

<u>Investigation findings</u>

The investigation provided a full review of all digital

advertising items created for Incruse plus Relvar during quarter 1 2015. Of seven job bags, a further two items were identified as failing to meet the standards required by the Code and details were provided.

GlaxoSmithKline submitted that of five items fully progressed and published online, three were released before certification. Additionally, all five items demonstrated a degree of illegibility and incomplete prescribing information from 20 April to 2 July.

Text resolution and legibility considerations: on 23 March a senior employee noticed that the non-proprietary names for Incruse and Relvar were not as clear as they might be on the live site. This had not been a feature when seen at staging. Before changing roles, the junior employee contacted the media agency and the company's design team to put on hold any further advertisements that were being developed at that time. The design team worked to enhance resolution and update the images.

On 27 March the junior employee took up a different role in a different location within GlaxoSmithKline. The digital advertising plan was handed over to colleagues who decided to pause until after Easter when further consideration could be given to capacity to deliver the plan. At that stage it was not clearly understood that some items were being re-worked by the design team.

On 13 April the plan, workload priorities and resources were duly reconsidered by the marketing team. The decision to do no additional advertising in quarter 2 was confirmed. As a consequence, no new advertisements were created and pending items not yet approved were cancelled.

Prescribing information considerations: on 9 March GlaxoSmithKline sent the prescribing information URL to its media agency as a prelude to online publication of the digital advertisements being progressed through ZINC. The URL linked to a 'dual PI' pdf document created specifically for the Incruse plus Relvar advertisements and certified as a separate item in its own right.

At certification and when all advertisements were published in the various online journals, this direct link made prescribing information available for both Incruse and Relvar within each item as required by the Code. However the URL to the prescribing information broke and on 20 April the agency asked for replacement prescribing information 'for Incruse' (rather than for Incruse plus Relvar) with the result that from 20 April until 2 July, the replacement link in the five advertisements only linked to prescribing information for Incruse alone and not, as intended and as certified, to the prescribing information for both medicines.

Release prior to certification: The investigation had shown that this error was likely to have been the result of one, or possibly two, causes. Firstly, a misreading of the item's ZINC code for a similar certified item might have resulted in misidentification. Secondly, misinterpretation of a ZINC message might also have been either causal or contributory; the notification read, 'This job has completed its circulation and was passed to you by [the named signatory]'. The same notification was generated regardless of the outcome of a review or a certification cycle. In this case, there had been no reason to doubt that such a straightforward item would not have been certified as scheduled. Though released in good faith the item was, unfortunately, released in error thereby breaching Clauses 4.1, 4.2, 4.3, 4.4, 14.1, 16.1 and 28.1 of the Code.

GlaxoSmithKline admitted that as a result of the investigation, high standards had not been maintained in breach of Clause 9.1.

GlaxoSmithKline stated that a number of preventative actions had been initiated, including re-training of the team in the requirements of the Code, a review of the interface with digital agencies and a review of current promotional materials.

When writing to confirm that the matter would be taken up under the Code, the Authority asked GlaxoSmithKline to provide any further comments it might have in relation to Clause 2.

RESPONSE

GlaxoSmithKline confirmed that with respect to Clauses 4.1, 4.2, 4.3, 4.4, 9.1, 16.1 and 28.1 it had no further comments to add to those detailed previously.

However, with respect to Clause 2, GlaxoSmithKline acknowledged that whilst high standards were not maintained at all times, it noted that Clause 2 was retained for circumstances that warranted particular censure. It submitted that neither patient nor public health had been prejudiced by the above breaches, nor was there risk of inducement or pre-authorization promotion.

GlaxoSmithKline stated it had actively initiated a comprehensive preventative programme to address the issues highlighted during the investigation of this case. These activities included:

1 A statement to the organisation on 13 August to highlight the need to maintain the highest of standards and comply fully with both the GlaxoSmithKline internal governance framework and the Code.

2 A review (completed 21 August) of current digital advertising materials across all therapy teams.

3 Two senior managers presented on the recent voluntary admissions to the PMCPA to the UK respiratory team at a meeting on 26 August.

4 A further briefing on the case together with updates to ongoing CAPA (corrective actions, preventative actions) related to digital advertising would be rolled out to individual therapy brand teams within the respiratory therapeutic area by the end of August 2015.

5 When the case was concluded with the PMCPA, it would be presented in detail at an internal GlaxoSmithKline Code Forum meeting (anticipated October 2015).

6 It was planned to conclude detailed re-training on the requirements of the Code by November 2015 across all the in house therapy teams.

7 A comprehensive review of the interfaces between GlaxoSmithKline and its various digital agencies had been initiated and was scheduled for completion in November 2015.

With respect to the differences in legibility between the certified advertisements and those that appeared online, the scientific name of the product was illegible due to blurring. The company had taken a deeper look at the technical specifications required. The advertisements did not seem to fully meet the technical specification which could result in distortion. Some of the differences in pixels were small and what difference they would make was unclear. Further investigation was ongoing.

As part of the comprehensive review (point 7 above), GlaxoSmithKline had shared information on the deviation with the agency and agreed to hold regular teleconferences to monitor progress against agreed actions. Such actions included, but were not limited to, enhanced quality control checks, review on different browsers and devices and reiteration of the importance of publishing only certified material.

GlaxoSmithKline explained that the term 'staging site' described a website used to review and test new content or functionality. The staging site was a mirror image of the 'live site' to ensure content could be displayed in its final form before being released on the live site (technically referred to as the Production Site). The staging site was held securely behind a login to ensure that content that did not pass testing could not be viewed.

It was common practice in web design and content creation for organisations to have three distinctly separate areas of a website, namely, the development environment, where hardware or software was created, the staging environment, where there was review and testing and finally a release or publishing to the live production environment.

GlaxoSmithKline submitted that it operated a standardized process for the review and approval of all digital material, whether on its own web assets or via a third party. When the material had been reviewed in ZINC, it moved to the development environment. Once creation was complete the final version was passed to the staging site and a screen shot and link to the staging environment was passed to signatories for review and final certification. This enabled the review of the static screen shot and the built version so as to test links, functionality of dynamic content etc., exactly as it would appear on the live site. Once the certificate had been received by the originator, the item was published.

PANEL RULING

The Panel noted GlaxoSmithKline had identified three specific compliance issues with five digital advertisements for Incruse plus Relvar: poor legibility of the non-proprietary names, omission of prescribing information for Relvar and publication prior to certification. The poor legibility of the non-proprietary names and the omission of the Relvar prescribing information affected all five of the advertisements and three of the five advertisements were published before certification.

The Panel noted all five of the online advertisements for Incruse plus Relvar were promotional; however the link to the prescribing information only provided prescribing information for Incruse. The prescribing information for Relvar was not available via the link as required. In that regard, the Panel noted that when it was decided to advertise the two medicines together there had been a failure to correctly reassign the advertisements from 'Incruse' to 'Incruse plus Relvar'. The advertisements had remained on the media plan as 'Incruse' only. Following a broken link to the combined prescribing information, the media agency had requested replacement prescribing information for Incruse alone. Clause 4.2 listed the components of prescribing information which had to be provided according to the requirements of 4.1. Clause 4.4 described how the prescribing information as required by Clause 4.1 could be provided on digital material. It was not possible to breach either Clause 4.2 or 4.4; failure to provide the required information would be a breach of Clause 4.1. As the Relvar prescribing information had not been provided a breach of Clause 4.1 was ruled as acknowledged by GlaxoSmithKline. The Panel thus made no ruling in relation to Clauses 4.2 and 4.4.

The Panel noted that Clause 4.3 required the non-proprietary name of a medicine to appear immediately adjacent to the most prominent display of the brand name; for electronic advertisements the non-proprietary name had to be in a size such that it was readily readable. The Panel noted that although the advertisements at issue included the non-proprietary names in the correct position, the names were not readily readable. A breach of Clause 4.3 was ruled as acknowledged by GlaxoSmithKline.

The Panel noted that three of the advertisements at issue had been published online before final certification. A breach of Clause 14.1 was ruled as acknowledged by GlaxoSmithKline.

The Panel noted that Clause 28.1 of the Code required promotional material about prescription only medicines on the Internet and directed to a UK audience to comply with all of the relevant requirements of the Code. The Panel noted its rulings of breaches of the Code above and thus ruled a breach of Clause 28.1 as acknowledged by GlaxoSmithKline.

The Panel further noted that GlaxoSmithKline had admitted a breach of Clause 16.1 which required all relevant personnel concerned in anyway with the preparation or approval of material or activities

covered by the Code to be fully conversant with the Code and relevant laws and regulations. The Panel noted that although mistakes had been made it did not necessarily mean that personnel were not fully conversant with the Code; human error was always possible. No evidence had been provided to the Panel to demonstrate that relevant personnel had not been trained. On balance, the Panel ruled no breach of Clause 16.1.

Overall, the Panel considered that the failure to certify prior to publication, the omission of prescribing information for Relvar and the blurred non-proprietary names within the online advertisements meant that high standards had not been maintained. A breach of Clause 9.1 was ruled as acknowledged by GlaxoSmithKline.

The Panel noted its comments and rulings above but did not consider that the circumstances warranted a ruling of a breach of Clause 2 of the Code which was a sign of particular censure and reserved for such use. No breach of that clause was ruled.

Complaint received **7 August 2015**

Case completed **30 September 2015**