NO BREACH OF THE CODE

CASE AUTH/3363/6/20

COMPLAINANT v GLAXOSMITHKLINE

Alleged promotion of Anoro Ellipta on GlaxoSmithKline's website

A complainant who described him/herself as a concerned UK health professional, complained about the promotion of Anoro Ellipta (umeclidinium and vilanterol inhaler) on GlaxoSmithKline's website. Anoro Ellipta was indicated as a maintenance bronchodilator treatment to relieve symptoms in adults with chronic obstructive pulmonary disease (COPD).

The complainant alleged that the information provided on Anoro Ellipta would encourage a member of the public to ask his/her clinician for treatment - readers were referred to the patient information leaflet for more information, which, in the complainant's view, would be suitable for patients on treatment, but not the general public. The complainant stated that there was a pop-up box where GlaxoSmithKline refused to take responsibility for anything contained there - although in the two sentences beforehand the company advocated that readers refire (sic) the document.

The complainant noted that the language was also aimed at patients ie 'your breathing difficulties' and so it implied those who read the information would benefit from treatment.

The complainant stated that all the other links to medication on the first page did not display this level of inappropriate detail, so this raised concerns that it had not been certified for the use for the general public in the first place.

The complainant stated that the page stated that it had last been updated in May 2018 - over 2 years ago.

The detailed response from GlaxoSmithKline is given below.

The Panel noted that Clause 26.2 permitted information about prescription only medicines to be supplied directly or indirectly to the public, but such information must be factual, presented in a balanced way, must not raise unfounded hopes of successful treatment and must not encourage members of the public to ask their health professional to prescribe a specific prescription only medicine. The supplementary information to Clause 26.2 set out the detailed requirements for reference information which was intended to provide a comprehensive library resource for members of the public giving information relating to prescription only medicines which had marketing authorizations. Reference information must represent fairly the current body of evidence relating to a medicine and its benefit/risk profile and could include the PIL and SPC for a medicine.

The Panel noted GlaxoSmithKline's submission that the webpage in question was a product page aimed at members of the UK public who sought information about Anoro

Ellipta; readers could only land on the webpage by self-declaring as a non-healthcare professional. The Panel noted GlaxoSmithKline's submission that the information provided on Anoro Ellipta was reference information.

The Panel noted that the Anoro Ellipta product webpage stated the active substances within the product and featured the indication beneath a subheading 'What is Anoro Ellipta used for?' below a prominent photograph of the product followed by information on COPD. The webpage bore links to the SPC and PIL. The Panel queried whether a prominent picture of the product in material aimed at the public was appropriate.

The Panel, however, considered that the information about Anoro Ellipta on the webpage for the public which was the subject of the complaint was not unacceptable in relation to the requirements of reference information. Nor did the Panel consider it was for the purpose of encouraging members of the public to ask their health professional to prescribe a specific prescription only medicine. The Panel therefore ruled no breach of the Code.

Suggesting that the public consult the PIL for more information was not necessarily unacceptable. The information was part of the approved regulatory information and was in the public domain for anyone to consult for whatever reason. The reference to 'your breathing difficulties' was in the context of patients with COPD and in the Panel's view was not necessarily unacceptable. Neither was referring readers to the electronic Medicines Compendium (eMC) for up-to-date information and making it clear to readers accessing such information that they were being directed to a site which was not that of GlaxoSmithKline.

The Panel noted GlaxoSmithKline's submission that the footer on the website referred to by the complainant related to the website structure and not to the information on the page.

The Anoro Ellipta webpage was certified for use in November 2019 and related to the entire webpage, including the footer and was still being used within two years of certification. The Panel further noted GlaxoSmithKline's submission that GlaxoSmithKline had certified the footer in May 2018, and that it had subsequently been recertified in June 2020. The Panel therefore ruled no breaches of the Code.

The Panel did not consider that GlaxoSmithKline had failed to maintain high standards in this regard and no breach of the Code was ruled.

A complainant who described him/herself as a concerned UK health professional, complained about the promotion of Anoro Ellipta (umeclidinium and vilanterol inhaler) on GlaxoSmithKline's website. Anoro Ellipta was indicated as a maintenance bronchodilator treatment to relieve symptoms in adults with chronic obstructive pulmonary disease (COPD).

COMPLAINT

The complainant referred to a GlaxoSmithKline website which provided information about the company's products for the public. The complainant drew particular attention to the information provided on Anoro Ellipta and provided a screenshot of a relevant webpage.

The complainant alleged that the information provided would encourage a member of the public to ask his/her clinician for treatment - readers were referred to the patient information leaflet for more information, which, in the complainant's view, would be suitable for patients on treatment, but not the general public. The complainant stated that there was a pop-up box where GlaxoSmithKline refused to take responsibility for anything contained there - although in the two sentences beforehand the company advocated that readers refire (sic) the document.

The complainant noted that the language was also aimed at patients ie 'your breathing difficulties' and so it implied those who read the information would benefit from treatment.

The complainant stated that all the other links to medication on the first page did not display this level of inappropriate detail, so this raised concerns that it had not been certified for the use for the general public in the first place.

The complainant stated that at the base of the page, there the footer stated that it had last been updated in May 2018 - over 2 years ago. Although this was far less important, it still should be investigated. A screen shot was provided.

When writing to GlaxoSmithKline, the Authority asked it to consider the requirements of Clauses 9.1, 14.3, 14.5 and 26.2 of the Code.

RESPONSE

GlaxoSmithKline noted the complainant's allegation that the public webpage about Anoro Ellipta would encourage the public to ask for treatment and that the webpage had expired.

GlaxoSmithKline submitted that the webpage referred to by the complainant was a product page aimed at members of the UK public who sought information about Anoro Ellipta. GlaxoSmithKline provided an explanation, with accompanying images, of how a user navigated to the material in question and the options presented to the user at each stage. The user could only land on the webpage by self-declaring as a non-healthcare professional.

GlaxoSmithKline stated that the webpage provided information on what Anoro Ellipta was and what it was used for, which was taken directly from the patient information leaflet (PIL). In addition, there were links to the Anoro Ellipta summary of product characteristics (SPC) and the PIL. GlaxoSmithKline submitted that this was entirely appropriate for members of the UK public and in line with the Code. A downloaded copy of the webpage was provided.

GlaxoSmithKline noted the complainant's allegation that the webpage would encourage members of the public to ask their clinician for treatment. The complainant had also noted that readers were referred to the patient information leaflet for more information, but that that would be suitable for patients on treatment and not for the general public.

GlaxoSmithKline noted that the supplementary information to Clause 26.2 stated: 'Reference information is intended to provide a comprehensive up to date resource that companies should make available on their websites or by way of a link from their website or by some other means. The primary purpose of reference information is to be a library resource for members of the public giving information relating to prescription only medicines which have marketing authorizations. Pharmaceutical companies are not obliged to provide reference information but it is considered good practice to provide as a minimum the regulatory information comprising the

SPC, the PIL and the public assessment report (PAR) (UK or European) where such a document exists.'

GlaxoSmithKline noted, with regard to the complainant's allegation that the webpage would encourage the general public to ask their clinician for treatment, that the content of the webpage had been taken directly from the PIL. The webpage therefore was clearly in line with Clause 26.2, in following recommended good practice by including regulatory information from the PIL, for members of the public. This explained why the language used was in line with patient language. GlaxoSmithKline therefore denied a breach of Clause 26.2.

GlaxoSmithKline noted that the complainant had also commented that there was a pop-up box on the webpage where GlaxoSmithKline refused to take responsibility for anything contained there. GlaxoSmithKline assumed this was in relation to the pop-up message that appeared when clicking the links to the SPC and PIL, a copy of this box was attached provided.

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.'

The links to the SPC and PIL on the webpage were hosted on an external website, therefore, to comply with the Code it was necessary to make it clear to the user that he/she was leaving a GlaxoSmithKline website. The popup merely stated: 'You are now leaving GSK's website This link will take you to a non-GlaxoSmithKline website'.

GlaxoSmithKline stated that it did not recommend, endorse, or accept liability for sites controlled by third parties, with the option to 'Continue' or 'Go Back'. As this was in line with Clause 28.6, GlaxoSmithKline denied a breach of the Code, including Clause 26.2.

With regard to the complainant's concern about the varying level of detailed information provided on different UK product webpages for the public, GlaxoSmithKline noted that it had 30 UK product webpages listed on its member of the public UK product listing webpage (a downloaded copy of the product listing was provided together with copies of the relevant linked webpages).

GlaxoSmithKline stated that, as a minimum, its UK product webpages for the public contained links to the relevant SPC and PIL. Additionally, some products had information taken directly from the PIL displayed on the public webpage, in line with Clause 26.2. The product webpages were the responsibility of the different teams and individuals within the company aligned to different products. Some provided more information than others on the actual page where the links could be found. There was no other reason for the disparity. All information provided (either directly on the webpages or through links provided) was in line with the Code. These webpages provided reference information relating to prescription only medicines which had marketing authorizations and was not intended to encourage any member of the public to request a specific medicine.

GlaxoSmithKline referred to Case AUTH/3204/6/19 in which the complainant alleged that a GlaxoSmithKline website for members of the public had links to the various company products and included the brand name of the medicine, non-propriety name and the indication and thus promoted to members of the public and encouraged them to ask for these medicines. The complainant referred to the Nucala (mepolizumab) member of the public UK product webpage.

GlaxoSmithKline noted that the Nucala webpage had information comparable to that contained on the Anoro Ellipta webpage now in question. The Panel ruled that the information about Nucala on the webpage for the public was acceptable, in relation to the requirements of reference information as referred to in the supplementary information in Clause 26.2; no breaches of Clause 26.1 and 26.2 were ruled. GlaxoSmithKline submitted that the ruling in Case AUTH/3204/6/19 underlined that the information presented on the Anoro Ellipta webpage complied with Clause 26.2.

In summary, GlaxoSmithKline stated that the information provided on Anoro Ellipta, was reference information, a library resource for patients or members of the public on a prescription only medicine, that had a marketing authorization. The information was factual, presented in a balanced way, did not raise unfounded hopes and was not misleading with respect to the safety of the product. There were no statements made for the purpose of encouraging members of the public to ask their health professional for Anoro Ellipta. GlaxoSmithKline denied a breach of Clause 26.2.

With regard to the complainant's reference to the footer stating that the webpage had last been updated in May 2018, GlaxoSmithKline submitted that the Anoro Ellipta webpage was certified for use in November 2019. The job code and date of preparation relating to the webpage were provided at the bottom of the white section of the page. The certificate showed that the certification related to the entire webpage, including the footer.

GlaxoSmithKline stated that the job number and date of preparation at the bottom of the webpage cited by the complainant, related not to the content of the webpage, but to the 'footer' of the webpage which was part of the structure of the website. Whilst it was not a requirement of the Code for it to be certified, GlaxoSmithKline had certified the footer in May 2018, and it had subsequently been recertified in June 2020.

GlaxoSmithKline stated that this was in line with the requirements for Clause 14.3 for non-promotional material intended for the public. As this item was being used within two years of certification, it was also in line with Clause 14.5. GlaxoSmithKline denied a breach of Clause 14.3 or 14.5.

In summary GlaxoSmithKline stated that the information provided on the webpage was certified for use and had not expired whilst continuing to be used. the company denied a breach of Clause 14.3 or 14.5.

GlaxoSmithKline stated that the information provided on the webpage was reference information, intended as a library resource for patients or members of the public giving information on prescription only medicines, that had a marketing authorization. The information was factual, presented in a balanced way, did not raise unfounded hopes and was not misleading with respect to the safety of the product. There were no statements made for the purpose of encouraging a member of the public to ask his/her health professional for Anoro Ellipta. GlaxoSmithKline denied a breach of Clause 26.2.

GlaxoSmithKline stated that the information provided on the webpage was certified for use and had not expired whilst continuing to be used. GlaxoSmithKline denied a breach of Clause 14.3 or 14.5.

Given that the material in question was in line with the requirements set out in the Code GlaxoSmithKline was confident that high standards had been maintained and it denied a breach of Clause 9.1.

PANEL RULING

The Panel noted that Clause 26.2 permitted information about prescription only medicines to be supplied directly or indirectly to the public but such information must be factual, presented in a balanced way, must not raise unfounded hopes of successful treatment and must not encourage members of the public to ask their health professional to prescribe a specific prescription only medicine. The Panel noted that the supplementary information to Clause 26.2 set out the detailed requirements for reference information which was intended to provide a comprehensive library resource for members of the public giving information relating to prescription only medicines which had marketing authorizations. Reference information must represent fairly the current body of evidence relating to a medicine and its benefit/risk profile and could include the PIL and SPC for a medicine.

The Panel noted GlaxoSmithKline's submission that the webpage referred to by the complainant was a product page aimed at members of the UK public who sought information about Anoro Ellipta; readers could only land on the webpage by self-declaring as a non-healthcare professional. The Panel noted GlaxoSmithKline's submission that the information provided on Anoro Ellipta was reference information.

The Panel noted that the Anoro Ellipta product webpage stated the active substances within the product and featured the indication beneath a subheading 'What is Anoro Ellipta used for?' below a prominent photograph of the product followed by information on COPD. The webpage bore links to the SPC and PIL. The Panel queried whether a prominent picture of the product in material aimed at the public was appropriate.

The Panel, however, considered that the information about Anoro Ellipta on the webpage for the public which was the subject of the complaint was not unacceptable in relation to the requirements of reference information as referred to in the supplementary information to Clause 26.2. Nor did the Panel consider it was for the purpose of encouraging members of the public to ask their health professional to prescribe a specific prescription only medicine. The Panel therefore ruled no breach of Clause 26.2.

Suggesting that the public consult the PIL for more information was not necessarily unacceptable. The information was part of the approved regulatory information and was in the public domain for anyone to consult for whatever reason. The reference to 'your breathing difficulties' was in the context of patients with COPD and in the Panel's view was not necessarily unacceptable. Neither was referring readers to the eMC for up-to-date information and making it clear to readers accessing such information that they were being directed to a site which was not that of GlaxoSmithKline.

The Panel noted GlaxoSmithKline's submission that the material had been certified and the dates of this certification, noting that the footer on the website referred to by the complainant related to the website structure and not to the information on the page.

The Anoro Ellipta webpage was certified for use in November 2019 and related to the entire webpage, including the footer and was still being used within two years of certification. The

Panel further noted GlaxoSmithKline's submission that GlaxoSmithKline had certified the footer in May 2018, and that it had subsequently been recertified in June 2020. The Panel therefore ruled no breach of Clauses 14.3 and 14.5.

The Panel noted its comments and rulings above and did not consider that GlaxoSmithKline had failed to maintain high standards in this regard and no breach of Clause 9.1 was ruled.

Complaint received **15 June 2020**

Case completed **18 January 2021**