CASE AUTH/3175/3/19

ANONYMOUS v GLAXOSMITHKLINE

Promotion of Anoro Ellipta

An anonymous, non-contactable individual, who described him/herself as a health professional, complained about a two-page advertisement (ref UK/UCV/0028/18) for Anoro Ellipta (umeclidinium and vilanterol) placed by GlaxoSmithKline UK Limited in the February 2019 edition of Guidelines in Practice. In the top left-hand corner of each page was a prominent blue circle inside which was stated 'NICE 2018'. Each page also had a prominent depiction of the Anoro Ellipta device.

Anoro Ellipta was a fixed dose combination of a long-acting muscarinic receptor antagonist (LAMA) (umeclidinium) and a long-acting beta$_2$-adrenergic agonist (LABA) (vilanterol), indicated as maintenance therapy to relieve symptoms in adults with chronic obstructive pulmonary disease (COPD).

The complainant alleged that to have a large circle stating 'NICE 2018' close to an even larger image of the Anoro Ellipta device inferred that NICE (the National Institute for health and Care Excellence) had recommended Anoro Ellipta.

The complainant further noted that page two stated '… reducing the risk of moderate to severe exacerbations …' again next to a large image of Anoro Ellipta and yet another large 'NICE 2018' circle. Anoro Ellipta was licensed to relieve symptoms, not to reduce exacerbations.

The detailed response from GlaxoSmithKline is given below.

The Panel noted that 'NICE 2018' appeared in a large blue circle in the top left-hand corner of page one of the advertisement. Below the circle was the statement in large bold red type 'New NICE COPD guidelines recommend LAMA/LABA for Initial Maintenance Therapy'. Directly under that statement was a sizeable picture of the Anoro Ellipta device. In smaller type, to the right of the picture and below the product logo was the claim 'A once daily LAMA/LABA for symptomatic, adult patients with COPD'.

The Panel considered that although page one of the advertisement included the statement 'New NICE COPD guidelines recommend LAMA/LABA for Initial Maintenance Therapy', overall, given the prominence of the NICE 2018 circle, which might be interpreted by some as a stamp of approval, and a prominent Anoro Ellipta image, it was not unreasonable to assume that some readers' immediate impression would be that Anoro Ellipta was specifically recommended by NICE which was not so. The Panel considered that, on balance, page one of the advertisement was misleading in that regard and a breach of the Code was ruled.

The Panel noted that the image of the Anoro Ellipta device on the right-hand side of the top half of page two of the advertisement was smaller and less prominent than the image on page one. The 'NICE 2018' blue circle again appeared in the top left-hand corner and beneath it was the statement in smaller bold red type 'For patients with COPD, evidence shows that compared with monotherapies, a LAMA/LABA:' directly followed by in normal blue type 'is better than other inhaled treatments for reducing the risk of moderate to severe exacerbations and is the most cost-effective option'. The Panel noted that whilst this statement had a superscript reference, to the NICE Guidelines on COPD, it might not be immediately obvious to some readers that the statement was taken from the NICE COPD guidelines. The Panel noted the content and layout of the page and considered that the reader's eye would be drawn to the NICE 2018 circle and the same blue colour banner which referred to Anoro Ellipta, alongside the image of the Anoro Ellipta device, and might assume that Anoro Ellipta was NICE's LAMA/LABA of choice which was not so. The Panel considered that page two of the advertisement was misleading and a breach of the Code was ruled.

The Panel noted that on page one of the advertisement there was a reference to maintenance therapy in the statement 'New NICE COPD guidelines recommend LAMA/LABA for Initial Maintenance Therapy'. The Panel noted that page two of the advertisement, however, only referred to reducing the risk of moderate to severe exacerbations of COPD and referred to Anoro Ellipta as 'A LABA/LAMA for symptomatic, adult patients with COPD'. In the Panel's view, the reduced risk of COPD exacerbations had not been set firmly within the context of Anoro Ellipta's licensed indication, a maintenance therapy to relieve symptoms; the implication was that Anoro Ellipta was licensed to reduce the risk of COPD exacerbations in symptomatic patients and that was not so. The Panel ruled a breach of the Code.

The Panel noted its rulings of breaches of the Code above and considered that high standards had not been maintained. A breach of the Code was ruled.

The Panel noted that a ruling of a breach of Clause 2 was a sign of particular censure and reserved for such. The Panel noted its rulings and comments above but considered that the matters were not such as to bring discredit upon, or reduce confidence in, the industry. No breach of Clause 2 was ruled.

An anonymous, non-contactable individual, who described him/herself as a health professional, complained about a two-page advertisement (ref UK/UCV/0028/18) for Anoro Ellipta (umeclidinium and vilanterol) placed by GlaxoSmithKline UK Limited in the February 2019 edition of Guidelines in Practice. In the top left-hand corner of each page was a prominent blue circle inside which was stated 'NICE 2018'. Each page also had a prominent depiction of the Anoro Ellipta device.

Anoro Ellipta was a fixed dose combination of a long-acting muscarinic receptor antagonist (LAMA) (umeclidinium) and a long-acting beta$_2$-adrenergic agonist (LABA) (vilanterol), indicated as a maintenance bronchodilator treatment to relieve symptoms in adults with chronic obstructive pulmonary disease (COPD).

COMPLAINT

The complainant alleged that it was deceptive to have a large circle stating 'NICE 2018' close to an even larger image of the Anoro Ellipta device. From his/her perspective, GlaxoSmithKline was clearly trying to infer that NICE (the National Institute for Health and Care Excellence) had recommended Anoro Ellipta.

The complainant further noted that on page two it was stated '… reducing the risk of moderate to severe exacerbations …' again next to a large image of Anoro Ellipta and yet another large 'NICE 2018' circle. All LAMA/LABA products were licensed to relieve symptoms and were not licensed to reduce exacerbations.

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

RESPONSE

GlaxoSmithKline submitted that COPD maintenance therapy included the use of inhaled long-acting muscarinic antagonists (LAMAs) and long-acting beta2 agonists (LABAs) as monotherapy (LAMA or LABA) or dual therapy (LAMA/LABA). There had been considerable debate amongst respiratory experts as to whether initial maintenance therapy for COPD should be monotherapy or dual therapy. The updated NICE COPD guideline (NG115), December 2018, changed its previous guidance from monotherapy to dual therapy with LAMA/LABA and this had widely been considered an important change. Anoro's licensed indication was as a maintenance bronchodilator treatment to relieve symptoms in adult patients with COPD.

The purpose of the advertisement in question was to increase awareness of the NICE COPD guideline recommendation for LAMA/LABA therapy as initial maintenance therapy and to promote Anoro as one such LAMA/LABA. It was neither stated nor implied that NICE recommended Anoro specifically.

The intent of the first page of the advertisement was to draw the reader's attention to the new NICE COPD guideline recommendations for LAMA/LABA use as initial maintenance therapy in COPD; it was acceptable to then promote Anoro within that class. GlaxoSmithKline considered that the advertisement was very clear that NICE had recommended the LAMA/LABA class, rather than specific products within that class; the advertisement did not imply that NICE recommended Anoro in particular.

GlaxoSmithKline submitted that the recommendation from NICE about the LAMA/LABA class in general (and not for a specific product) was in large bold font '**New NICE COPD guidelines recommend LAMA/LABA for Initial Maintenance Therapy***'. The guidance was expanded in the footnote. The footnote gave extra information but was not required to clarify the claim about the NICE guidance. The image of Anoro and the text to the right clearly showed that Anoro was a LAMA/LABA and so could be used where NICE recommended the LAMA/LABA class. The licence for Anoro was clearly stated as 'symptomatic, adult patients with COPD'.

On the second page the intent was to inform readers of the rationale for NICE's recommendations for the use of LAMA/LABA. The NICE recommendations for LAMA/LABA use were as follows:

> 'Offer LAMA+LABA to people who have spirometrically confirmed COPD **and** do not have asthmatic features/features suggesting steroid responsiveness **and** remain

> breathless or have exacerbations despite having used or have been offered treatment for tobacco dependence if they smoke **and** optimised non-pharmacological management and relevant vaccinations **and** using a short-acting bronchodilator.'

NICE's rationale for the above recommendation included 'a better reduction in the risk of moderate to severe exacerbations than other inhaled treatments' and this was included on page 2 of the advertisement with the licensed indication for Anoro stated in capitals, 'A LAMA/LABA FOR SYMPTOMATIC, ADULT PATIENTS WITH COPD', to ensure that prescribers knew that the primary reason for prescribing was to relieve symptoms.

GlaxoSmithKline noted that in Case AUTH/2841/4/16 regarding the promotion of Anoro, the Panel considered that 'reference to exacerbations might be included in the promotion of COPD maintenance therapy … any reference to reduced COPD exacerbations must be set within the context of the product's licensed indication and thus the primary reason to prescribe ie maintenance therapy to relieve symptoms'. In relation to the advertisement now at issue, Anoro had been promoted within its licensed indication as initial maintenance therapy. By twice stating the licensed indication it was clear that prescribing was for symptoms and that there were added benefits in the form of the potential reduction in exacerbations.

GlaxoSmithKline submitted that the promotion of Anoro was within its licensed indication as a maintenance bronchodilator treatment to relieve symptoms in adults with COPD and not inconsistent with the summary of product characteristics (SPC). The licensed indication was clearly stated on both pages of the advertisement to ensure, particularly on page 2, that the primary reason for prescribing was to relieve symptoms, whilst NICE had acknowledged added benefits from LAMA/LABAs in the form of the potential reduction in exacerbations. GlaxoSmithKline denied a breach of Clause 3.2.

GlaxoSmithKline considered that the advertisement made it very clear that the NICE guidance was about the LAMA/LABA class and not a specific inhaled therapy brand within that class. The advertisement specifically stated that 'New NICE COPD guidelines recommend LAMA/LABA for Initial Maintenance Therapy'. GlaxoSmithKline submitted that the information was fair, balanced and unambiguous and did not mislead; the company denied a breach of Clause 7.2.

GlaxoSmithKline submitted that it had maintained high standards and that the advertisement had not brought discredit upon, nor reduced confidence in, the pharmaceutical industry. The company denied breaches of Clauses 9.1 and 2.

PANEL RULING

The Panel noted that the two pages of the advertisement at issue had to be read separately – they were not facing. The Code required that where the pages of a two page advertisement were not facing then neither page must be false or misleading when read in isolation.

The Panel noted that it was not necessarily unacceptable to refer to NICE or NICE guidelines in promotional material provided that the way in which it was done complied with the requirements of the Code.

The Panel noted that 'NICE 2018' appeared in a large blue circle in the top left-hand corner of page one of the advertisement. In the Panel's view, this might give the misleading impression to some readers that it was a stamp of approval from NICE. Below this circle on page one was

the statement in large bold red type 'New NICE COPD guidelines recommend LAMA/LABA for Initial Maintenance Therapy'. Directly under that statement was a sizeable picture of the Anoro Ellipta device. In smaller type, to the right of the picture and below the product logo was the claim 'A once daily LAMA/LABA for symptomatic, adult patients with COPD'.

The Panel considered that although page one of the advertisement included the statement 'New NICE COPD guidelines recommend LAMA/LABA for Initial Maintenance Therapy', overall, given the prominence of the NICE 2018 circle, which might be interpreted by some as a stamp of approval, and a prominent Anoro Ellipta image, it was not unreasonable to assume that some readers' immediate impression would be that Anoro Ellipta (a combined LAMA/LABA) was specifically recommended by NICE which was not so. The Panel considered that, on balance, page one of the advertisement was misleading in that regard and it ruled a breach of Clause 7.2 in relation to page one.

The Panel noted that the image of the Anoro Ellipta device appeared on the right-hand side of the top half of page two of the advertisement and was smaller and less prominent than the image on page 1. The Panel noted that on page two of the advertisement the 'NICE 2018' blue circle again appeared in the top left-hand corner and beneath it was the statement in smaller bold red type 'For patients with COPD, evidence shows that compared with monotherapies, a LAMA/LABA:' directly followed by in normal blue type 'is better than other inhaled treatments for reducing the risk of moderate to severe exacerbations and is the most cost-effective option'. The Panel noted that whilst this statement had a superscript reference, which when reading the list of references at the bottom of the page was the NICE Guidelines on COPD, it might not be immediately obvious to some readers that the statement was taken from the NICE COPD guidelines. The Panel noted that the visual on page 2 comprised half a page and thus the NICE 2018 circle, text and picture of the device were much closer together. Below the image of the device was the claim 'Start with Anoro Ellipta'. The Panel noted that the NICE 2018 circle, the impression of which might be that it represented a stamp of approval from NICE, the statement 'is better than other inhaled treatments for reducing the risk of moderate to severe exacerbations and is the most cost-effective option' and the banner below which included the Anoro Ellipta logo and the statement 'A LAMA/LABA FOR SYMPTOMATIC, ADULT PATIENTS WITH COPD' were all in the same blue colour. The Panel noted the layout of the page and considered that the reader's eye would be drawn to the NICE 2018 circle and the same blue colour banner which referred to Anoro Ellipta, alongside the image of the Anoro Ellipta device, and might assume that Anoro Ellipta was NICE's LAMA/LABA of choice which was not so.

Overall, given its comments above and the prominence and impression of the reference to NICE within a circle, the Panel considered that it was not unreasonable that some readers of page two of the advertisement would assume that Anoro Ellipta was specifically recommended by NICE which was not so. The Panel considered that page two of the advertisement was misleading in that regard and it ruled a breach of Clause 7.2 in relation to page two of the advertisement.

The Panel noted that Anoro Ellipta was indicated as a maintenance bronchodilator treatment to relieve symptoms in adults with COPD. Section 5.1 of the SPC referred to its positive impact on the risk of COPD exacerbations. In the Panel's view, there was a difference between COPD symptoms, which were chronic events, and exacerbations of COPD which were acute episodes, although it accepted that patients whose symptoms were well controlled might be less likely to experience an exacerbation of their condition than patients with poorly controlled symptoms. In that regard, the Panel considered that reference to exacerbations might be included in the promotion of COPD maintenance therapy but that there was a difference between promoting a

medicine for a licensed indication and promoting the benefits of treating a condition. In the Panel's view, any reference to reduced risk of COPD exacerbations must be set within the context of the product's licensed indication and thus the primary reason to prescribe ie maintenance therapy to relieve symptoms.

The Panel noted that on page one of the advertisement there was a reference to maintenance therapy in the statement 'New NICE COPD guidelines recommend LAMA/LABA for Initial Maintenance Therapy'. The Panel noted that page two of the advertisement, however, which appeared to be the subject of the complainant's allegation in this regard, only referred to reducing the risk of moderate to severe exacerbations of COPD and referred to Anoro Ellipta as 'A LABA/LAMA for symptomatic, adult patients with COPD'. In the Panel's view, the reduced risk of COPD exacerbations had not been set firmly within the context of Anoro Ellipta's licensed indication, a maintenance therapy to relieve symptoms; the implication was that Anoro Ellipta was licensed to reduce the risk of COPD exacerbations in symptomatic patients and that was not so. The Panel ruled a breach of Clause 3.2.

The Panel noted its rulings of breaches of the Code above and considered that high standards had not been maintained. A breach of Clause 9.1 was ruled.

The Panel noted that a ruling of a breach of Clause 2 was a sign of particular censure and reserved for such. The Panel noted its rulings and comments above but considered that the matters were not such as to bring discredit upon, or reduce confidence in, the industry. No breach of Clause 2 was ruled.

Complaint received **22 March 2019**

Case completed **18 October 2019**