NO BREACH OF THE CODE

CASE AUTH/3771/6/23

COMPLAINANT v GSK

Allegations about disguised promotion

CASE SUMMARY

This case related to a National Institute for Health and Care Excellence (NICE) treatment algorithm for chronic obstructive pulmonary disease (COPD) on a Trelegy promotional webpage that was alleged to be disguised promotion for GSK products, and for which prescribing information was not provided.

The outcome under the 2021 Code was:

No Breach of Clause 2	**Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry**
No Breach of Clause 5.1	**Requirement to maintain high standards at all times**
No Breach of Clause 12.1	**Requirement to include up-to-date prescribing information**
No Breach of Clause 15.6	**Requirement that promotional materials and activities must not be disguised**

This summary is not intended to be read in isolation.
For full details, please see the full case report below.

FULL CASE REPORT

A complaint was received from an anonymous, contactable complainant, who described themselves as a health professional and later became non-contactable, about GlaxoSmithKline UK Limited (GSK).

COMPLAINT

The complaint wording is reproduced below:

> 'A COPD [Chronic Obstructive Pulmonary Disease] guidelines algorithm produced by NICE [National Institute for Health and Care Excellence] was included on a page on a promotional website for COPD products supplied by GSK. The link to the page is [website link and document number provided]. Drug classes included on this algorithm discussed initiation therapy for COPD with LABA [long-acting beta 2-agonist]/LAMA [long-acting muscarinic antagonist] and ICS [inhaled corticosteroid]/LABA. GSK had products for both of these classes which included Anoro, a LABA/LAMA and Relvar a ICS/LABA. However, the prescribing information for these products was not provided on

the page despite the class of drugs being presented within the algorithm. This was disguised promotion as there was indirect reference to these products via the algorithm but prescribing information was not provided. Breaches included 15.6, 12.1, 5.1 & 2.'

When writing to GSK, the PMCPA asked it to consider the requirements of Clauses 15.6, 12.1, 5.1 and 2 of the Code.

GSK's RESPONSE

The response from GSK is reproduced below:

'Thank you for your letter dated 1st June 2023 in which you informed us that a healthcare professional raised concerns about a page on the GSK promotional website. GSK is committed to following both the letter and the spirit of the ABPI Code of Practice and all other relevant regulations.

The anonymous complainant alleges that the webpage in question [website link provided] contains disguised promotion for the GSK products Anoro (vilanterol trifenatate / umeclidinium bromide) and Relvar (fluticasone furoate / vilanterol trifenatate) and that prescribing information for these products has not been provided. The complainant has alleged breaches of Clauses 2, 5.1, 12.1 and 15.6 of the 2021 ABPI Code of Practice.

GSK's position is that it has complied with the requirements of the Code and denies breaches of these Clauses, and the reasons are detailed below.

General description of the Trelegy Ellipta Guidelines webpage in question

The webpage in question [enclosure number provided] is explicitly a promotional webpage for Trelegy Ellipta (fluticasone furoate / vilanterol trifenatate / umeclidinium bromide). Fluticasone furoate is an inhaled corticosteroid (ICS). Vilanterol trifenatate is a long-acting beta$_2$-agonist (LABA). Umeclidinium bromide is long-acting muscarinic antagonist (LAMA). Trelegy Ellipta is an ICS/LABA/LAMA indicated as a maintenance treatment in adult patients with moderate to severe chronic obstructive pulmonary disease (COPD) who are not adequately treated by a combination of an ICS and a LABA or a combination of a LABA and a LAMA.

The Trelegy Ellipta Summary of Product Characteristics (SmPC) for Great Britain (GB) is attached [enclosure number provided], and for Northern Ireland (NI) [enclosure number provided].

The webpage in question was certified and a final form inspection was conducted by a signatory of over 16 years' experience who is a registered medical practitioner [qualifications given]. The certificate is attached [enclosure number provided].

The PMCPA has asked how users would navigate to the webpage in question. Upon first attempting to navigate onto the GSK Pro promotional platform in their browser, a popup appears where the user is asked to click to confirm if they are a UK HCP in which case they proceed into the promotional site, or if they are a member of the public in which

case they are taken to a GSK non-promotional product page suitable for members of the public.

If they have confirmed they are an HCP, they are taken to the particular URL within the GSK Pro platform that they were attempting to access. On the GSK Pro promotional homepage, [website link provided] Trelegy Ellipta is shown as one of the featured products. When the product logo is clicked, the user is taken to the main Trelegy Ellipta promotional page [website link provided]. There is a collapsible menu item near the top of the page marked 'Trelegy Patient'. When this is expanded, one of the options is 'Guidelines'. Clicking this takes the user to the webpage in question [website link provided].

The webpage in question is clearly marked near the top with a GSK logo adjacent to the prominent wording 'For UK Healthcare Professionals' and 'This site contains promotional material'.

Below this is a product logo for Trelegy Ellipta which includes the brand name and non-proprietary names of the constituent active substances. This logo remains visible as the user scrolls down the page. It is therefore clear to the user from the outset that this is a GSK promotional webpage for Trelegy Ellipta intended for UK HCPs.

A statement on the line below the product logo states 'Prescribing Information links are at the bottom of the page'. This statement also remains visible while the user scrolls down the page. At the bottom of the page is a prominent section that contains a hyperlink marked 'Trelegy Ellipta Prescribing Information (pdf)' which takes the user via a single-click to the current prescribing information for Trelegy Ellipta [website link and enclosure number provided].

Other products referred to by complainant

While Anoro and Relvar are not mentioned on the webpage in question, the complainant has alleged that they are indirectly referenced. GSK denies this allegation, for reasons that will be given later in this letter. For context, the indications for these products are given below.

Anoro Ellipta is a LAMA/LABA indicated as a maintenance bronchodilator treatment to relieve symptoms in adult patients with COPD.

The Anoro Ellipta SmPC for GB is attached [enclosure number provided], and for NI [enclosure number provided].

Relvar Ellipta is an ICS/LABA indicated for the symptomatic treatment of adults with COPD with a forced expiratory volume in 1 second (FEV_1) <70% predicted normal (post-bronchodilator) with an exacerbation history despite regular bronchodilator therapy.

Relvar Ellipta also has an indication for the regular treatment of asthma in adults and adolescents aged 12 years and older where use of a combination medicinal product (LABA and ICS) is appropriate:
• patients not adequately controlled with ICS and 'as needed' inhaled short acting $beta_2$-agonists (SABA).

• patients already adequately controlled on both ICS and LABA.
The Relvar Ellipta SmPC for GB is attached [enclosure number provided], and for NI [enclosure number provided].

Allegation of disguised promotion and lack of prescribing information

The complainant refers to 'a COPD guidelines algorithm produced by NICE' which is found on the Trelegy promotional webpage in question. On this webpage, in the section titled 'NICE COPD treatment guidelines', a summary of NICE Guideline NG115 (Chronic Obstructive Pulmonary Disease in Over 16s: Diagnosis and Management; [enclosure number provided] is given. As this is a Trelegy promotional page, the summary focusses on those aspects of the NICE Guideline that are relevant to ICS/LABA/LAMA and single inhaler therapy. It is made clear prominently in bold in this section that these NICE COPD recommendations are for classes of medicine and they do not specifically endorse Trelegy Ellipta or the Ellipta device.

Below this is the algorithm to which the complainant has referred. This is a visual summary of the non-pharmacological management and use of inhaled therapies found in NICE NG115 and is faithfully reproduced from the NICE website [website link provided] with no alterations [enclosure number provided] .

The algorithm shows the circumstances in which NICE recommends that particular classes of inhaled therapies should be offered or considered in COPD patients. No specific medicines are named in the algorithm.

The NICE algorithm states that in patients who are limited by symptoms or have exacerbations despite treatment with 'as needed' SABA or short-acting muscarinic antagonist (SAMA):

- Offer LABA + LAMA if there are no asthmatic features or features suggesting steroid responsiveness
- Revert to LABA + LAMA if there has been no improvement following a 3-month trial of LABA + LAMA + ICS in patients with day-to-day symptoms that adversely impact quality of life
- Consider LABA + ICS if there are asthmatic features or features suggesting steroid responsiveness

Below this section is a question 'Would you like to see the full NICE COPD treatment guidelines?' with a hyperlink underneath stating 'VISIT NICE'. This link takes the user to the NICE NG115 webpage [website link provided] where the full Guideline as well as the visual summary algorithm can be accessed. This enables the reader to appreciate the full context upon which NICE's visual summary is based.

Below this section is a single click link to the Trelegy Ellipta Prescribing Information, as described above. The reason that the Trelegy Ellipta Prescribing Information is given on this page, is that this is explicitly a promotional webpage for Trelegy Ellipta. It is within an area of the GSK Pro website that specifically promotes Trelegy Ellipta. The name of the product and the indication are given on the page. No other product is mentioned on this page and therefore no other prescribing information is given.

The complainant has alleged that the mention of the LABA/LAMA class and the ICS/LABA class in the NICE algorithm, and the fact that GSK has products in these classes, means that there has been indirect reference and hence disguised promotion of Anoro and Relvar, respectively, in breach of Clause 15.6. Consequently the complainant alleges that prescribing information for Anoro and Relvar have not been provided on a promotional material, in breach of Clause 12.1. GSK denies that this webpage contains disguised promotion for these products and denies a breach of Clause 15.6. For this reason, GSK does not believe that the prescribing information for Anoro and Relvar are required to be provided on the webpage in question, and denies a breach of Clause 12.1. The detailed reasons for denying these alleged breaches are given below.

While GSK markets Anoro (a LABA/LAMA) and Relvar (an ICS/LABA), there are many other products licensed in both of these classes for COPD.

Examples of other single inhaler LABA/LAMAs and their manufacturers include:
AstraZeneca's Duaklir Genuair (aclidinium bromide / formoterol fumarate dihydrate) and Bevespi Aerosphere (glycopyrronium bromide / formoterol fumarate dihydrate);
Boehringer Ingelheim's Spiolto Respimat (tiotropium bromide monohydrate / olodaterol hydrochloride);
Novartis' Ultibro Breezhaler (glycopyrronium bromide / indacaterol maleate).

Examples of other single inhaler ICS/LABAs and their manufacturers include:
AstraZeneca's Symbicort metered dose inhaler (budesonide / formoterol fumarate dihydrate) and Symbicort Turbohaler;
Chiesi's Fostair metered dose inhaler (beclomethasone dipropionate / formoterol fumarate dihydrate) and Fostair NEXThaler;
Glenmark's Stalpex (salmeterol xinafoate / fluticasone propionate);
GSK's Seretide Accuhaler (fluticasone propionate / salmeterol xinafoate);
Lupin's Luforbec (beclometasone dipropionate / formoterol fumarate dihydrate);
Orion's Fobumix Easyhaler (budesonide / formoterol fumarate dihydrate) and Fusacomb Easyhaler (fluticasone propionate / salmeterol xinafoate);
Sandoz' AirFluSal Forspiro (fluticasone propionate / salmeterol xinafoate);
Teva's DuoResp Spiromax (budesonide / formoterol fumarate dihydrate);
Thornton's Fixkoh Airmaster (fluticasone propionate / salmeterol xinafoate);
Wockhardt's WockAIR (budesonide / formoterol fumarate dihydrate).

It is to be noted that in addition to the numerous single inhaler therapy examples given above, both 'LABA + LAMA' and 'ICS + LABA' therapies may be given as two separate inhalers, which means there are many more possible combinations of therapies that fall into these categories. The NICE COPD visual summary algorithm that has been specifically referenced by the complainant does not distinguish between single inhaler therapies or separate inhalers.

There is no suggestion in the NICE algorithm or anywhere else on the webpage in question that any particular LABA/LAMA or ICS/LABA is being referred to, whether this be a brand name, a non-proprietary name or a device type. There is certainly no suggestion that either Anoro or Relvar are specifically being referred to, as alleged by the complainant. The prominent statement given above the NICE algorithm that 'NICE COPD recommendations are for classes of medicine' emphasises this point.

While it is an established principle under the Code that it is possible to promote a product without mentioning its name, this would require some form of indirect link, such as the product being the only one available in the class being mentioned, or having a unique feature that is mentioned, or by using branding that the reader would associate with a particular medicine. None of these apply in the case of the webpage in question in relation to Anoro or Relvar. The only branding and product mention on this webpage is for Trelegy Ellipta, for which prescribing information is provided.

GSK's approach to the provision of Prescribing Information on the GSK Pro platform is to consider the content of each page, including direct and indirect references to specific products, to ensure that the correct Prescribing Information links are provided, and that there is no disguised promotion.

We would like to draw attention to a previous ruling by the Appeal Board in case AUTH/3308/2/20 [enclosure number provided]. In that case, an allegation had been made that GSK had indirectly promoted its medicine in a webinar registration page; ICS/LABA and triple therapy [in this context meaning ICS/LABA/LAMA] had been mentioned in the description of the webinar in relation to COPD. The complainant had alleged that prescribing information for GSK's triple therapy product, Trelegy Ellipta, should have been provided, which it was not. GSK had responded that no specific brand or non-proprietary names had been mentioned in the registration page. Numerous combinations of triple therapy were possible using a variety of medicines and devices that were not marketed by GSK. Initially the Panel took the view that 'there were references to specific medicines in the material, these being ICS/LABA and triple therapy' and that 'the website promoted triple therapy and GlaxoSmithKline marketed a triple therapy, namely Trelegy'. The Panel ruled that prescribing information for Trelegy should have been provided. However, GSK appealed this ruling, stating that the terms 'ICS/LABA' and 'triple therapy' referred to classes of medicines and did not identify any individual product. The Appeal Board agreed with GSK and took the view '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'. Prescribing information for Trelegy was therefore not needed and no breach was ruled on this point on appeal.

We would also like to draw attention to the Panel and Appeal Board's decision in Case AUTH/2482/2/12 [enclosure number provided]. In that case, the complainant had alleged that Novo Nordisk had sent an email invitation to a meeting that mentioned 'modern insulins' but had not provided prescribing information for any insulin products. Novo Nordisk marketed three different insulin products and a further five were available from other companies at the time. The Panel ruling stated that 'The Panel did not consider that the email promoted any particular insulin and thus no prescribing information for insulin was required. No breach of Clause 4.1 [of the 2011 Code] was ruled. There was no disguised promotion of any insulin and no breach of Clause 12.1 [of the 2011 Code] was ruled.' The complainant appealed, however the Appeal Board upheld the Panel's ruling and the appeal on these points was not successful.

GSK acknowledges that each case should be considered on its merits, but believes that Case AUTH/3308/2/20 and Case AUTH/2482/2/12 are of particular relevance to this current case, due to the very similar natures of the complaints alleging indirect references to specific products where only classes of products are mentioned.

We would further like to draw attention to the Panel's rulings in Cases AUTH/1898/10/06 and AUTH/1900/10/06 [enclosure number provided] which were separate complaints about a letter sent by Procter & Gamble to HCPs. Of particular interest in these cases was that even though the non-proprietary name (mesalazine) of a branded product that the company marketed had been used in a letter that had been sent by that company, the Panel did not view this as promotion of that company's product, because other versions of mesalazine were available from other companies. GSK believes this is of relevance in the current case because there are multiple manufacturers of LABA/LAMA and ICS/LABA inhalers, and no particular brand has been singled out on the webpage in question.

In summary, on the point of disguised promotion, GSK strongly believes that the webpage in question does not directly or indirectly promote Anoro or Relvar, and therefore this cannot constitute disguised promotion. Therefore GSK denies a breach of Clause 15.6. Consequently, prescribing information for Anoro and Relvar do not need to be provided and so GSK denies a breach of Clause 12.1.

Clauses 5.1 and 2

As GSK denies the complainant's allegations regarding the webpage in question as detailed above, we firmly believe that high standards have been maintained and therefore a breach of Clause 5.1 is denied. Consequently, GSK does not believe that it has brought discredit upon, or reduced confidence in, the pharmaceutical industry, and a breach of Clause 2 is denied.

Confidentiality

[GSK commented about confidentiality.]

Summary

In summary, GSK takes its responsibilities of working within the letter and the spirit of the ABPI Code of Practice very seriously. GSK strongly denies breaches of Clauses 2, 5.1, 12.1 and 15.6 as there has been no disguised promotion of Anoro or Relvar on the webpage in question, and therefore no requirement to provide prescribing information for these products on the webpage in question.'

PANEL RULING

The Panel noted the complaint related to the inclusion of a National Institute for Health and Care Excellence (NICE) treatment algorithm for chronic obstructive pulmonary disease (COPD) on a Trelegy promotional webpage and alleged that this was disguised promotion as there was indirect reference to GSK products, Relvar and Anoro, via the algorithm which referred to LABA/LAMA and ICS/LABA but prescribing information was not provided.

The Panel noted Trelegy's licensed indication as a maintenance treatment in adult patients with moderate to severe COPD who are not adequately treated by a combination of an ICS and a LABA or a combination of a LABA and a LAMA. The Panel noted the references to ICS and a

LABA or a combination of a LABA and a LAMA within the context of Trelegy's licensed indication, Trelegy was to be used when treatment with these classes of medicine was not adequate.

The Panel noted that the webpage at issue was an integral part of a promotional website for GSK products. The webpage was marked at the outset as containing promotional material for health professionals. A navigation bar with tabs to other sections of the promotional website and links to report adverse events and to the prescribing information appeared at the top. Below was a white banner with the webpage title 'COPD triple therapy treatment guidelines: Are you up-to-date?' and a statement informing viewers that the page provided a summary of the recommendations when treating moderate-to-severe patients with COPD.

This was followed by a blue section containing two white boxes the first of which was headed 'NICE COPD treatment guidelines' followed, in small font, by a summary of the NICE recommendations relevant to triple therapy; specifically, to consider starting triple therapy if COPD patients on dual therapy had either symptoms that adversely impact quality of life or have had 1 severe or 2 moderate exacerbations within a year, and to undertake a 3 month trial with triple therapy for COPD patients on LAMA/LABA whose symptoms adversely impact quality of life and to revert to LAMA/LABA if there were no improvements.

This section also included a reminder that whilst NICE did not make a specific recommendation about whether triple therapy should be delivered in multiple inhalers or a single inhaler it had commented on this matter. The webpage then highlighted NICE comments that were favourable to Trelegy: 'From the economic evidence, using a single inhaler device was more cost effective'; and 'Minimise the number of inhalers and different types of inhalers used by each person where possible'. The Panel noted the use of a larger, bold font and adjacent icons ensured these statements stood out to viewers. A reminder that the NICE COPD recommendations were for classes of medicines and did not specifically recommend Trelegy Ellipta or the Ellipta device was included at the bottom of the first white box.

In the second white box the NICE COPD guidelines algorithm, which was a summary of the NICE recommendations of non-pharmacological management and use of inhaled therapies, was reproduced in full. The Panel noted it referred to classes of medicines and did not name any specific medicines. A link to the full NICE COPD Guideline (NG115) was included at the bottom of the guidelines algorithm visual and also in a separate grey section below which was followed by a link to the Trelegy Ellipta prescribing information.

The Panel considered that the webpage in question was clearly promotional for Trelegy Ellipta, a promotional banner for Trelegy Ellipta appeared at the top of the webpage which highlighted the benefits of using a single inhaler and the webpage included its indication and prescribing information.

The Panel noted the NICE COPD treatment algorithm referred to classes of medicines and included reference to their use in the treatment of COPD. While short-acting beta2 agonists (SABA), short-acting muscarinic antagonists (SAMA), LABA/LAMA (dual therapy), LABA/ICS (dual therapy) and LABA/LAMA/ICS (triple therapy) were referred to no medicines were named.

The Panel noted the complainant alleged that the failure to provide prescribing information for Anoro (GSK's LABA/LAMA medicine) and Relvar (GSK's LABA/ICS medicine) was disguised

promotion as the NICE treatment algorithm summary referred to the classes of medicine and thus indirectly referred to the products. The Panel noted the NICE COPD treatment algorithm itself did not place any emphasis on any specific medicine and while GSK marketed medicines in the LABA/LAMA and LABA/ICS classes, so did a number of other companies.

The Panel noted GSK's submission that as the material was a Trelegy promotional webpage the summary focussed on those aspects of the NICE Guideline that were relevant to ICS/LABA/LAMA and single inhaler therapy and that it was made clear prominently in bold in this section that these NICE COPD recommendations were for classes of medicine and did not specifically endorse Trelegy Ellipta or the Ellipta device. The Panel noted triple therapy (ICS/LABA/LAMA) could be delivered via a single or multiple inhaler devices.

The Panel considered that it first had to decide whether the references to LABA/LAMA and LABA/ICS in the summary algorithm meant that the promotional Trelegy webpage was also promotional for Anoro and Relvar. The Panel considered that whether a reference to a class of medicines amounted to a reference to a specific medicine/s should be decided on a case by case basis, context was important. The Panel, noting all of its comments above including Trelegy's licensed indication, that it was to be used when treatment with these classes of medicine was not adequate and in particular the number of potential medicines within these classes made by a number of pharmaceutical companies considered that the webpage was not promotional for Aonro and Relvar as alleged.

Noting its decision that the webpage in question was not promotional for Relvar or Anoro the Panel did not consider that the complainant had established that the webpage constituted disguised promotion for Anoro and Relvar as alleged. The Panel ruled **no breach of Clause 15.6**.

The Panel considered that transparency was important and that companies were encouraged to be open and transparent in situations where they could be considered to have a commercial interest. The Panel noted Clause 12.1 required prescribing information to be provided in all promotional material for a medicine. In this instance the Panel considered that Trelegy Ellipta was the only medicine that had been promoted on the webpage in question and a link to its prescribing information was included on the webpage. In the Panel's view whilst it might have been helpful to include the Anoro Ellipta and Relvar Ellipta prescribing information there was no requirement to include it as in the Panel's view the webpage was not promotional for those products. Accordingly the Panel ruled **no breach of Clause 12.1.**

Noting its comments and rulings above, the Panel did not consider that the complainant had established that GSK had failed to maintain high standards and **no breach of Clauses 5.1** was ruled. In light of its rulings of no breach the Panel ruled **no breach of Clause 2.**

Complaint received **31 May 2023**

Case completed **26 June 2024**