CASE/0273/08/24

COMPLAINANT v GSK

Allegations about a promotional website

CASE SUMMARY

This case was in relation to the 'hero banner' (a large, prominent image at the top of a webpage) on a Trelegy Ellipta promotional webpage. The hero banner consisted of an image of four people holding string instruments and boxed text reading "Conduct COPD care your way. Introduce Trelegy Ellipta". The complainant made allegations relating to both the text claim and the image.

The outcome under the 2021 Code was:

Breach of Clause 6.1	**Making an ambiguous claim**

No Breach of Clause 2 (x2)	**Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry**
No Breach of Clause 5.1 (x2)	**Requirement to maintain high standards at all times**
No Breach of Clause 6.2 (x2)	**Requirement that claims/information/comparisons must be capable of substantiation**
No Breach of Clause 6.3	**Requirement that all artwork must conform to the letter and spirit of the Code**
No Breach of Clause 6.6	**Requirement that another company's medicines, products or activities must not be disparaged**
No Breach of Clause 11.2	**Requirement not to promote a medicine for an unlicensed indication**

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 about GSK was received from an anonymous, contactable complainant who described themselves as a health professional. The complainant later became non-contactable.

COMPLAINT

The complaint wording is reproduced below:

> "The claims and imagery used on the Trelegy Ellipta promotional website are not compliant. The claims and imagery are present at the outset of [URL provided] July

2024 | PM-GB-FVU-WCNT-240003 (V1.0) The claim reads "conduct COPD care your way. Introduce Trelegy Ellipta". Adjacent to the claim is an image of young musicians. The following issues are present;
1. Trelegy is a maintenance treatment used for patients who are already initiated on treatment such as ICS+LABA or a LABA+LAMA. Trelegy was not licensed to be introduced as first line therapy as the claim states 'introduce Trelegy Ellipta'. This is misleading and not in line with the licence indication especially considering the immediate impression that claim conveys for use of Trelegy as first choice treatment. No qualification of the licence is provided directly next to the claim either. This is a breach of clause 6.2, 5.1 and 2.
2. Trelegy is only to be used in moderate to severe COPD patients. The young musicians picture is factually misleading considering the age group shown in the picture is not representative of a moderate to severe COPD population nor would Trelegy treatment allow a moderate to severe COPD patient to have a boost in energy levels and play musical instruments as shown in the image. This is a breach of clauses 6.2, 5.1 and 2.
There have been a number of breaches related to Trelegy so absolute care should be taken when promoting the product otherwise this was disparaging to the other fixed triple therapy products available."

When writing to GSK, the PMCPA asked it to consider the requirements of Clauses 2, 5.1, 6.1, 6.2, 6.3, 6.6, and 11.2 of the 2021 Code.

GSK'S RESPONSE

The response from GSK is reproduced below:

"Thank you for your letter dated 21st August 2024 wherein you informed GSK that an anonymous complainant has alleged that the claims and imagery on the Trelegy Ellipta promotional website (PM-GB-FVU-WCNT-240003 [V1.0], approved July 2024) were not compliant. GSK take all complaints very seriously and are committed to following both the letter and the spirit of the ABPI Code of Practice and all other relevant regulations.

The material at issue is a promotional website, intended for use by UK HCPs, approved for use in July 2024. The website can be accessed from a search engine and the landing pages are headed with the GSK logo, the intended audience (For UK Healthcare Professionals only) and the promotional nature of the content. The webpage in question is part of GSK's promotional website [URL provided] which is exclusively aimed at UK healthcare professionals (HCPs). Access to the site requires visitors to self-certify their user status, by clicking on a pop-up to confirm whether they are a UK HCP, or a member of the public. By confirming their HCP status, the user can access the website in question. Alternatively, members of the public are redirected to a UK public-dedicated website ([URL provided]).

The webpage at the centre of the allegation features a primary navigation bar with links to the: Login page, Registration page, Search function, and Adverse Event reporting functionality. Immediately below these links, the primary navigation bar displays (from left to right) the GSK logo, an audience disclaimer, and five tabs linking to the following

sections: Product, Therapy Areas, Resources, Webinars & Events, Supply & Sustainability, and Contact Us.

Beneath the primary navigation bar, a secondary navigation bar (depicted in dark blue) displays the Trelegy logo with its non-proprietary name adjacent to it. This bar includes links to the Home, “COPD Patients”, “Safety Information”, “One Device”, and “Our Experts” pages. A white ribbon, prominently positioned beneath the secondary navigation bar, displays the Prescribing Information link and a statement signposting where adverse event reporting information is located. The secondary navigation bar and the ribbon underneath remain fixed at the top of the screen, ensuring it is always visible regardless of where the reader scrolls on the page.

A brand-identifying hero banner featuring four clearly stylised musicians playing string instruments against a striped background that matches the colours of the four Ellipta devices is prominently displayed. The claim ‘Conduct COPD care your way. Introduce Ellipta’ can be seen within the banner in large black font in a white rectangle.

The body of the webpage begins with a section titled “The Burden of COPD” where two statements are displayed near two blue icons. One icon depicts a medical briefcase alongside the first statement that reads: *“There are around 1.4 million GP consultations per year due to COPD, and it is the second largest cause of emergency hospital admissions in the UK.* The second icon shows two stylised inhalers and beside it, the second statement reads: *“Approximately 67% of patients with COPD treated with multiple-inhaler triple therapy are juggling multiple device types.*”

These statements inform the reader about the current burden of COPD on general practices and patients living with the condition in the UK. They highlight that the majority of patients on triple therapy have been prescribed more than one device. Consequently, they are required to operate several different inhalers correctly in order to receive all required elements of their prescribed COPD treatment regimen.

The subsequent section of the webpage, titled *“Who could benefit from Trelegy* Ellipta?” features three images of age-appropriate, fictional COPD patients, Jon, Bev, and Ali, with each representing a different patient’s profile. The three profiles depict three frequently seen COPD clinical scenarios and unmet patient needs, in line with Trelegy’s licensed indication. Jon is a COPD patient not adequately treated by multiple inhaler therapy, Bev is not adequately treated by a combined long-acting beta-agonist (LABA) and long-acting muscarinic antagonist (LAMA) approach and Ali is not adequately managed by inhaled corticosteroid (ICS)/ LABA treatment.

Beneath this, the third and last section, titled “Consider Trelegy Ellipta as your triple therapy of choice,” displays a Trelegy Ellipta device. This is accompanied by an important, clinically relevant call-to-action message to: “*Identify patients with moderate/severe COPD who are not adequately treated with an ICS/LABA or LAMA/LABA. Review patients in accordance with your local, national, or international guidelines and recommendations.”*

Following the main content of the webpage, corporate and administrative information is displayed at the bottom. The site page was live from 21st July to 28th August 2024.

Allegation and PMCPA Clauses for consideration:

The complainant alleged that the claims and imagery on the Trelegy Ellipta promotional website were not compliant for the following reasons:

1. "Conduct COPD Care Your Way. Introduce Trelegy Ellipta" is misleading and not in line with the licensed indication".
2. "The young musicians picture is factually misleading considering the age group is not representative of a moderate-to-severe COPD population".

The complainant alleged breaches of Clauses 6.2, 5.1 and Clause 2. Additionally, the PMCPA asked GSK to bear in mind the requirements of Clauses 6.1, 6.6 and 11.2. Given the allegation that the image used to depict the young musicians was considered to be factually misleading, GSK sought clarification from the PMCPA over the complainant's reference to Clause 6.2 (information, claims or comparisons) as opposed to Clause 6.3 relating to artwork. As a result of this enquiry, GSK were asked to consider Clause 6.3 as well as all others raised by the complainant and the PMCPA. Accordingly, all seven Clauses are considered below in detail.

There are four considerations to address under Clause 6 which relates to Information, Claims, Comparisons and Disparagement:

Clause 6.1: Information, claims and comparisons must be accurate, balanced, fair, objective and unambiguous.

In addition, materials must not mislead either directly or by implication, by distortion, exaggeration or undue emphasise. Clause 6.1 further requires information to be sufficiently complete to enable recipients to form their own opinion of the therapeutic value of the medicine.

The Scientific and Clinical Rationale for Trelegy.

Trelegy, an established treatment for COPD, was granted a Marketing Authorisation on 15 November 2017. It is a once-daily single inhaler triple therapy (SITT), containing umeclidinium (UMEC), vilanterol (VI) and fluticasone furoate (FF). It is a pre-dispensed powder delivered by inhalation through the Ellipta device.

Section 4.1 of the SmPC states, *'Trelegy Ellipta is 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 either an inhaled corticosteroid and a long-acting β 2-agonist or a combination of a long-acting β 2-agonist and a long-acting muscarinic antagonist'*.

The claim, ***"Conduct COPD Care Your Way. Introduce Trelegy Ellipta"*** was intended solely to promote Trelegy, in line with the requirements of the Code and in manner that was not inconsistent with its SmPC. Cognisant of these requirements, GSK's aim was to highlight that Trelegy, where appropriate, could be introduced as a therapeutic option for the treatment of COPD. Trelegy is not authorised for initial maintenance therapy. Accordingly, while recognising this as the crux of the complainant's allegation, there was no intention whatsoever by GSK to mislead, or to imply, that it could or

should be used as “first line therapy”. Rather, it was intended to convey Trelegy as a step-up option for appropriate patients in line with its licensed indication.

Once a patient is deemed suitable for triple therapy, it is entirely up to the HCP to select the most appropriate form of therapy. Amongst other considerations, this selection considers the patient’s current and prior therapy, and any device preference expressed by the patient. Effective COPD management requires routine medication reviews, assessments of inhaler technique, adjustments to existing treatment(s) and changes to a patient's therapy, when deemed appropriate by the prescribing HCP. Within what is a standard, guideline-driven therapeutic landscape, the claim at issue was intended to serve solely as a reminder for prescribers to consider introducing an alternative therapeutic option, if and/ or when appropriate. GSK’s intent was to promote Trelegy Ellipta as a suitable consideration only under such circumstances. The claim intended to highlight the need to review, individualise and thereby optimise care for patients with ongoing COPD symptoms despite current treatment. Consequently, ‘Introduce Trelegy’ presented a clinically relevant, licensed option to HCPs when COPD management of their patient’s symptoms warranted such consideration.

That said, the complainant has noted, “no qualification of the Trelegy licence was provided directly next to the claim”. As a result, we believe this led to a wholly unintended misinterpretation of the claim. GSK accepts the need for materials to be sufficiently complete to enable recipients to form their own opinions of the therapeutic value of medicines. Rational prescribing together with patient safety are of paramount importance to us and we continually strive to ensure that our materials are clear and do not cause misinterpretation or misunderstanding. We acknowledge that on this occasion the complainant’s interpretation of the claim contained in the material differed significantly from GSK’s intent. Given this, we are committed to ensuring that any future iterations of the claim are unambiguous and cannot be similarly misinterpreted. Following receipt of this complaint, we undertook a comprehensive review and removed ‘Conduct COPD care your way’ from all materials. We also confirmed that ‘Introduce Trelegy’ was not present in any other material and briefing materials were updated to advise our sales representatives accordingly.

Clause 6.2: Any information, claim or comparison must be capable of substantiation.

While accepting in hindsight, the scope for misinterpretation of GSK’s intended claim, we suggest with respect, that the claim within the full context of its licensed indication for Trelegy, is capable of full substantiation. Aside from the clinical particulars set out in Section 4 of its SmPC, there is extensive substantiation of the pharmacodynamic effects including Trelegy’s clinical efficacy. The significant impact of Trelegy on lung function, exacerbations of moderate/ severe COPD, relief from symptoms, control, use of rescue medication, health-related quality of life and night-time awakenings are substantiated within Section 5 of the SmPC, the EPAR and in the key study publications for Trelegy. Consequently, given the extensive substantiation available for Trelegy’s licensed indication, we would contend that the Company is not in breach of Clause 6.2.

Clause 6.3: All artwork, including illustrations, graphs and tables must conform to the letter and the spirit of the Code.

The complainant highlighted a concern around the imagery, citing ***"****The young musicians (sic) picture is factually misleading considering the age group shown in the picture is not representative of a moderate to severe COPD population".*

This particular Trelegy campaign centred around a musical, theme, with a considered, creative look and feel of musicians playing string instruments. The marketing execution was designed intentionally to engender memorability and campaign recognition/ recall. In addition, the use of wind instruments was deliberately avoided, to prevent any suggestion that might be representative of people living with COPD. Similarly, demographics typical of COPD patients were also carefully and deliberately avoided. Furthermore, later in the webpage, three photographs of age-appropriate people, chosen to represent fictional COPD patients – Jon, Bev & Ali – were included. Each patient had a link to their own individualised patient scenario and how they have managed their COPD symptoms. This approach aimed to resonate with healthcare professionals and illustrate patients they would typically see with COPD in their practice. Furthermore, the prevalence of COPD increases with age. In clear contrast to the age of the musicians, the average age of patients with moderate to severe COPD who entered the Trelegy registration studies was between 63.8-66.3 (+/- 8.6) years.

There was no intention that the marketing approach and its use of artwork of young musicians, would be viewed as "factually misleading". Indeed, as noted by the complainant, "considering their age group the musicians are not representative of a moderate to severe COPD population". Given that the musician artwork was not included as a representation of COPD patients, it follows that there was never any intention to suggest "Trelegy treatment would allow a moderate to severe COPD patient to have a boost in energy levels and play musical instruments". Additionally, the inclusion of relevant imagery representing an age-appropriate cohort of patients with COPD, attests to the clear differences and rationales for inclusion of the musician artwork and the relevance of including fictionalised COPD patient photographs. Therefore, we maintain that the musician artwork used in the Trelegy marketing materials conforms to the letter and spirit of the Code and, consequently, GSK is not in breach of Clause 6.3.

Clause 6.6: The medicines, products and activities of other pharmaceutical companies must not be disparaged.

The complainant further alleged that the promotional webpage "was disparaging to the other fixed triple therapy products available". The rationale, however, for this allegation was not made clear although there was reference to other PMCPA complaints. Returning to the specifics of this complaint; triple inhaler therapy for managing COPD involves the use of two bronchodilators, viz. a long-acting beta-agonist (LABA) and a long-acting muscarinic antagonist (LAMA). These bronchodilators are administered with an inhaled corticosteroid (ICS). This treatment approach can be delivered through either multiple inhalers delivering triple therapy (MITT) or via a single inhaler triple therapy (SITT) approach that combines all three medications in one device. MITT and SITT therefore, give a basic indication of the possible number of inhalers prescribed for an individual patient. Neither acronym denotes specific choices, nor identifies named

medicinal products within the LAMA, LABA or ICS classes. Neither term points to particular combinations of medicines, nor to an identifiable inhaler device.

Advances such as the (now well-established) approach with SITT, were developed to address the practical clinical need for simpler ways to support patients' adherence and improve compliance with their COPD management. SITT can also address ease of inhaler use issues. With SITT, patients need only to self-administer three distinct medicines correctly and effectively from a single device. This contrasts with MITT that requires familiarity with, and the correct use of, multiple devices that may operate differently. As identified earlier, the prevalence of COPD increases with age and MITT can be affected increasingly with age-related factors, such as dexterity and coordination.

The fictional patient 'Jon' is representative of a patient where a LAMA, LABA and an ICS are clinically indicated. However, 'Jon' might struggle with the complexity of MITT, such as combining a dry powder inhaler requiring fast, deep inhalations to disaggregate the dry powder with a metered dose inhaler, MDI. The MDI, by contrast, requires a slow and steady inhalation of aerosol particles to ensure effective delivery. The situation may be complicated further by the need to combine different dosing regimens e.g. one actuation from one inhaler versus two actuations from a second, different device. To optimise the management of the medicines required to treat 'Jon' effectively, it could be helpful to deliver all the necessary classes of medicines via a single inhaler.

The Trelegy website highlights the option to combine all the necessary medicines prescribed by the HCP for appropriate patients via the triple therapy approach. This was the intended sense inherent within the statement: "*Conduct COPD care your way. Introduce Trelegy Ellipta*".

Once triple therapy is deemed suitable for an individual patient, it is up to the HCP to select the most appropriate way to deliver the three medicines. The Code recognises the legitimacy of Companies to promote their own medicinal products within the terms of their marketing authorisations. Trelegy is licensed for appropriate COPD patients not adequately treated on multiple (open) triple therapy. It is entirely reasonable that prescribers are aware of Trelegy and consider it alongside other suitable alternatives. GSK promoted Trelegy in its material to relevant potential prescribers as a suitable option for 'Jon'. In so doing, we did not at any stage mention or disparage the medicines, products or activities of any other pharmaceutical company in our material. Consequently, GSK denies the alleged breach of Clause 6.6.

Clause 11.2: The promotion of a medicine must be in accordance with the terms of its marketing authorisation and must not be inconsistent with the particulars listed in its SmPC.

Notwithstanding our responses to Clause 6.1 and especially 6.2 above, GSK fully intended its promotion of Trelegy to be in accordance with the terms of its marketing authorisation, granted 15 November 2017, and its SmPC which was last revised 20 October 2023. As advised in our response to an alleged breach of Clause 6.2, Trelegy is GSK's once-daily single inhaler triple therapy containing umeclidinium, vilanterol and fluticasone furoate. Delivered through the Ellipta device, it is indicated as a

maintenance therapy in adult patients with moderate to severe COPD who are not adequately treated by a combination of either an ICS and a LABA or a combination of a LABA and a LAMA. The complainant alleged that the claim*, "Conduct COPD Care Your Way. Introduce Trelegy Ellipta"* was "misleading and not in line with the licence indication especially considering the immediate impression that claim conveys for use of Trelegy as first choice treatment".

Patient images on the webpage, titled "Who could benefit from Trelegy Ellipta?", featured three fictional COPD patients, Jon, Bev, and Ali, each intended to represent a specific, recognisable clinical situation. Jon was not adequately treated by multiple inhaler therapy; Bev was not adequately treated by LABA/LAMA and Ali was inadequately treated with ICS/LABA. These patient profiles clearly address familiar scenarios faced by HCPs viz. patients inadequately treated with their current therapeutic regimens. The clinically relevant focus of the campaign is that Trelegy Ellipta, a SITT regimen, is an option for such patients. There is a clear rationale for its introduction as such patients, despite their current combination therapy, continue to experience symptoms or exacerbations due to suboptimal control of their COPD. In the section titled "Consider Trelegy Ellipta as your triple therapy of choice," a Trelegy Ellipta device is shown with the statement: "*Identify patients with moderate/severe COPD who are not adequately treated with an ICS/LABA or LAMA/LABA. Review patients in accordance with your local, national, or international guidelines and recommendations."*.

As advised earlier, the statement 'Introduce Trelegy' was intended solely to inform prescribers that Trelegy could be introduced as an option, in line with its licensed indications. Trelegy's licensed indication clearly precludes its use as initial maintenance therapy. Persisting symptoms, a history of COPD exacerbations and an inadequate response to current therapy were and remain the focus of Trelegy promotion. Under such circumstances, SITT is an appropriate therapeutic approach specifically developed to improve individuals' COPD management. Trelegy Ellipta is a valid, clinically valuable treatment option given its marketing authorisation. GSK's sole intent was to promote Trelegy in accordance with the terms of its marketing authorisation and in a manner that was not inconsistent with its SmPC particulars. Optimising disease management, enhancing therapeutic efficacy and ensuring patient safety are of paramount importance to GSK. Accordingly, we strive to ensure that promotional materials are relevant, clear and will not be misinterpreted. We appreciate the considerations raised by the complainant's interpretation of our materials and have taken appropriate corrective steps. GSK is committed to ensuring that future Trelegy campaigns cannot give rise to similar misinterpretations. Given our acceptance of a breach of Clause 6.1, and with respect, we are of the view that GSK is not otherwise in breach of Clause 11.2. This is for the reasons stated above and, additionally, for those already outlined in our response to the separate allegation of a breach of Clause 6.2.

Clauses 5.1: High standards must be maintained at all times.

As set out in the response to Cause 6.1, GSK had considered the marketing authorisation, the relevant requirements of the Code and Trelegy's SmPC while generating this campaign. We had not considered the possibility that the claim might be interpreted other than as we envisioned it would be. Notwithstanding our disappointment at the unintended interpretation of the claim and imagery brought to our

attention by the complainant, GSK's own internal code, ethos and promotional culture remain fully aligned to the letter and spirit of the Code. We aim to uphold high standards in all our activities including promotional materials. We recognise self-regulation requires high standards to be maintained at all times and GSK continues to support self-regulation fully. Accordingly, we do not agree with the complainant's alleged breach of Cause 5.1.

Clause 2 states: Activities or materials must never be such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry.

The complainant alleged in addition that GSK had breached Clause 2, "…especially considering the immediate impression that claim conveys for use of Trelegy as first line treatment." While we have already acknowledged there was scope for misinterpretation of the claim, we cannot agree that this was the immediate impression conveyed by the claim. GSK notes Clause 2 is considered when activities or materials bring discredit upon or reduce confidence in the pharmaceutical industry. We recognise that a ruling of a breach of this Clause is a sign of particular censure. It is reserved for circumstances that include, *inter alia,* prejudicing patient safety and/or public health, excessive hospitality, inducements to prescribe and unacceptable payments. We, therefore, do not believe that the matters raised by the complainant constituted a breach of Clause 2.

Conclusions

GSK recognises that the claim in question was misinterpreted. With hindsight such a misinterpretation would have been unambiguous, had it been qualified in the manner identified by the complainant. Steps have been taken to avoid any such future misinterpretations. Without minimising the significance of any breach of the Code, GSK has carefully and consciously considered the requirements of the remaining Clauses raised. Our responses to each of these Clauses have been detailed above and, as a result, we are not able to agree that there were further breaches of Clauses 6.2, 6.3, 5.1 or Clause 2, as cited by the complainant. Additionally, and as requested specifically by the PMCPA, we have borne in mind and addressed the requirements of Clauses 6.6 and 11.2 and have also concluded that in our view neither of these has been breached."

PANEL RULING

This complaint concerned the 'hero banner' (a large, prominent image at the top of a webpage) on a Trelegy Ellipta promotional webpage. The hero banner was the first content at the top of the webpage below the webpage header and navigational menu, below a link to prescribing information. The hero banner consisted of an image of four people holding string instruments and boxed text reading "Conduct COPD care your way. Introduce Trelegy Ellipta". The complainant made allegations relating to both the text claim and the image.

The claim: "Conduct COPD care your way. Introduce Trelegy Ellipta"

The complainant alleged that the claim was not compliant with the Code because it stated "Introduce Trelegy Ellipta". The complainant alleged that this conveyed the immediate impression that Trelegy could be used as first-choice treatment, while Trelegy was licenced as a

maintenance treatment for patients already initiated on dual therapy (ICS/LABA or LABA/LAMA). The complainant noted that the licensed indication was not provided (as qualification) adjacent to the claim.

Section 4.1 of the Trelegy summary of product characteristics stated that Trelegy Ellipta was 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 inhaled corticosteroid and a long-acting beta-2-agonist (ICS/LABA) or a combination of a long-acting beta-2-agonist and a long-acting muscarinic antagonist (LABA/LAMA).

GSK submitted that the claim, "Conduct COPD care your way. Introduce Trelegy Ellipta" was intended to highlight that Trelegy, where appropriate, could be introduced as a therapeutic option for the treatment of COPD. It was intended to convey Trelegy as a step-up option for appropriate patients in line with its licensed indication, and there was no intention to promote Trelegy in a manner that was not consistent with its summary of product characteristics. GSK submitted that the intention was for the claim to highlight the need to review, individualise and thereby optimise care for patients with ongoing COPD symptoms despite current treatment. GSK acknowledged, however, that the licensed indication was not presented alongside the claim and, as a result, the claim could be misinterpreted.

Clause 6.1 required, among other things, that information, claims and comparisons must be unambiguous and must not mislead. Material must be sufficiently complete to enable recipients to form their own opinion of the therapeutic value of the medicine.

In the Panel's view, the phrase "Introduce Trelegy Ellipta", without further explanation or context, was ambiguous and could be interpreted to refer to the use of Trelegy Ellipta as a step-up option (as intended by GSK), as a first-line treatment option (as interpreted by the complainant), or even as an add-on to existing treatment. The Panel took into account that the licensed indication was not present anywhere on the webpage at issue. The Panel therefore ruled a **breach of Clause 6.1**, as acknowledged by GSK.

The complainant alleged a breach of Clause 6.2 in relation to this matter. The complainant made no allegation specific to the requirement that any information, claim or comparison must be capable of substantiation. It was not for the Panel to make out the complaint. In the Panel's view, the complainant's allegations were most appropriately considered under Clause 6.1. The Panel considered that its concerns had been adequately addressed by the ruling of a breach of Clause 6.1. The Panel ruled **no breach of Clause 6.2**.

The complainant also alleged breaches of Clauses 5.1 and 2 in relation to this matter but made no additional allegations specific to these clauses. The Panel took into account GSK's submission that it had removed "Conduct COPD care your way" from all materials, had confirmed that "Introduce Trelegy" was not present in any other material, and had updated briefing materials to advise sales representatives accordingly. Noting its rulings above, the Panel did not consider that the circumstances of this case indicated that high standards had not been maintained or that GSK had brought discredit upon, or reduced confidence in, the pharmaceutical industry. The Panel ruled **no breach of Clause 5.1** and **no breach of Clause 2**.

The image

The Panel observed that the image at issue consisted of photographs of four people against a background of four coloured stripes. The people were dressed in colours corresponding to the coloured stripes; GSK submitted that the colours corresponded to the colours of the four Ellipta devices. The people looked to be young adults aged approximately 20–30 and each was holding a stringed instrument (violin, viola or cello). In the Panel's view, the image was highly stylised in its appearance – this was in contrast to three photographs of people further down the webpage at issue which were intended to illustrate fictional patient profiles.

Clause 6.3 required, among other things, that all artwork must conform to the letter and spirit of the Code. The supplementary information to this clause included that care must be taken to ensure that artwork does not mislead as to the nature of a medicine or any claim or comparison and that it does not detract from any warnings or contraindications.

The complainant alleged that the image was misleading because the age of the musicians was not representative of patients with moderate to severe COPD, and Trelegy Ellipta treatment would not allow such a patient to have "a boost in energy levels and play musical instruments".

The Panel took account of GSK's submission that the marketing campaign centred around a musical theme and that the use of wind instruments was deliberately avoided to prevent any suggestion that the images might be representative of people living with COPD. For the same reason, GSK also submitted that it had deliberately avoided using images of people with demographics typical of patients with COPD.

The Panel noted GSK's submission that the average age of patients with moderate to severe COPD who entered the Trelegy registration studies was between 63.8 years and 66.3 years. The Panel considered that both the complainant and GSK agreed that the age of the people in the image at issue was not representative of patients with moderate-to-severe COPD. In the Panel's view, it was likely that UK health professionals (the target audience of the webpage at issue) would be familiar with the typical demographics of a patient with COPD.

The Panel took into account the context and style of the image at issue, and the target audience of the webpage. While it was not clear to the Panel how the musical imagery was intended to relate to Trelegy Ellipta or COPD, the Panel considered that it was unlikely that UK health professionals would interpret the image as representing patients with COPD. In the Panel's view, the target audience of the webpage would not be misled as alleged and the Panel therefore ruled **no breach of Clause 6.3**.

The complainant alleged a breach of Clause 6.2 in relation to this matter. The complainant made no allegation specific to the requirement that any information, claim or comparison must be capable of substantiation. It was not for the Panel to make out the complaint. In the Panel's view, the complainant's allegations were most appropriately considered under Clause 6.3. The Panel therefore ruled **no breach of Clause 6.2**.

The complainant also alleged breaches of Clauses 5.1 and 2 in relation to this matter but made no additional allegations specific to these clauses. Noting its rulings, above, of no breaches in relation to the image, the Panel did not consider that the circumstances of this case indicated that high standards had not been maintained or that GSK had brought discredit upon, or

reduced confidence in, the pharmaceutical industry. The Panel ruled **no breach of Clause 5.1** and **no breach of Clause 2**.

Overall impression

The Panel noted that the case preparation manager had raised Clause 11.2 in relation to the complainant's allegations. The Panel considered the overall impression of the 'hero banner', including both the claim and the imagery.

Clause 11.2 required that the promotion of a medicine must be in accordance with the terms of its marketing authorisation and must not be inconsistent with the particulars listed in its summary of product characteristics.

The Panel considered that the key issue with the wording of the claim was one of ambiguity and that a ruling of a breach of Clause 6.1 adequately covered the matter. The Panel observed that the licensed indication for Trelegy specified "adults" and the people pictured were of an age group that could theoretically form part of the patient population for Trelegy Ellipta. Taking into account the stylised nature of the imagery, and the context provided by the rest of the content on the webpage at issue, the Panel considered that it was unlikely that a health professional would reasonably interpret the imagery to represent the target patient population.

The Panel did not consider that the complainant had established that Trelegy had been promoted in a manner inconsistent with its summary of product characteristics and ruled **no breach of Clause 11.2**.

Alleged disparagement

The Panel noted that the case preparation manager had raised Clause 6.6 in relation to the complainant's statement that "There have been a number of breaches related to Trelegy so absolute care should be taken when promoting the product otherwise this was disparaging to the other fixed triple therapy products available."

Clause 6.6 required that the medicines, products and activities of other pharmaceutical companies must not be disparaged.

The Panel considered that the complainant had not provided examples of previous breaches related to Trelegy and had not explained what they considered to be disparaging of other triple therapy products. It was not for the Panel to make out the complaint and the complainant could not be contacted for more information. The Panel therefore ruled **no breach of Clause 6.6**.

Complaint received **17 August 2024**

Case completed **13 August 2025**