CASE AUTH/3922/6/24 ***NO BREACH OF THE CODE***

COMPLAINANT v GSK

Alleged unlicensed promotion of Trelegy in a banner advertisement

CASE SUMMARY

This case was in relation to a revolving banner advertisement published on GSK's UK promotional website. The complainant alleged that the advertisement promoted Trelegy Ellipta (fluticasone furoate, umeclidinium, vilanterol) for an unlicensed indication because it was promoting a switch to Trelegy Ellipta from three inhalers (ICA/LABA + LAMA + SABA) and Trelegy Ellipta was licensed for patients not adequately treated on ICS/LABA only.

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 11.2 (x2)	**Requirement that 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**

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 UK Limited 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 with some typographical errors corrected:

> "Trelegy banner advert which was presented on the Trelegy homepage was promoting off-label use of Trelegy. The banner advert was 5 part and discussed the patient John. John was on 3 separate inhalers (triple therapy) which were Braltus (LAMA), Fostair (ICS/LABA) and Salamol (SABA). There were different texts which went over the image of John and text 2 that appeared stated - 58% of COPD triple therapy patients in the UK are juggling multiple devices, would a simpler routine make their lives easier. The claim was promoting the switch to Trelegy from John's current 3 inhalers. The text

discussed triple therapy patients and in the case of John this was ICS/LABA (Fostair) + LAMA (Braltus) + SABA (Salamol). ICS/LABA + LAMA + SABA was the open triple therapy in this instance. Trelegy is not licensed for patients not adequately treated on open triple therapy (ICS/LABA + LAMA + SABA). The indication for Trelegy is those not adequately treated on ICS/LABA only. The indication did not cover multiple therapies which included a LAMA and SABA. The banner advert was promoting switching to Trelegy from open triple therapy although the licence only allowed for switch from the ICS/LABA and not from the Salamol and Braltus devices John was on. Code breaches for off-label promoting of 11.2, 5.1 and 2. The webpage that the banner is on is [URL provided]. The page seems to be down at present but the code present at bottom of the page is August 2022 | PM-GB-FVU-WCNT-200014 (V5.0)."

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

GSK'S RESPONSE

The response from GSK is reproduced below with some typographical errors corrected:

"Thank you for your letter dated 10th June 2024 wherein you informed GSK that an anonymous complainant has alleged off-label promotion of Trelegy in a promotional banner on GSKPro, approved August 2022. GlaxoSmithKline UK Limited (GSK) takes all complaints very seriously and is committed to following both the letter and the spirit of the ABPI Code of Practice and all other relevant regulations. It is noteworthy that whilst this complaint was reported on 8th June 2024, GSK can confirm that the material at issue has been withdrawn since the 22nd June 2023. In addition, the PMCPA will be aware that an almost identical allegation (Case AUTH/3923/6/24) was submitted via the PMCPA's 'Make a complaint' portal within 36 hours of this case.

Banner Advertisement

The banner advert at issue was hosted on GSK's UK promotional site, [URL provided] (PM-GB-FVU-WCNT-200014, V5). GSKPro is intended for UK Healthcare professionals only and access to the site requires visitors to self-certify that they are a UK Healthcare professional prior to being able to view any site content. A link to the Trelegy prescribing information and the Trelegy indication is at the bottom of every page. The Trelegy indication is also at the start of the landing page, ahead of the banner advert at issue.

Of note, this same banner advert has been the subject of a previous complaint Case AUTH/3719/12/22, following failed intercompany dialogue with Chiesi. The new allegation differs from the previous case which did not allege a breach of Clause 11.2.

The banner is a 5-frame rotating image, designed to illustrate the profile of a typical COPD patient (John) who requires maintenance therapy with an ICS/LABA and a LAMA. Each of the 5 frames highlights a different message related to a typical UK COPD patient, by using colour and text boxes. The first frame of the five-frame advertisement depicted a man sitting at a table, with his elbows resting on the table, holding a bright orange cup of tea. Upon the table, to the left of the man, was a pile of unopened post and a bright blue 7-day pill organiser. To his right on the table was a black and off-white newspaper with the capitalised headline of 'Climate Emergency'

above, in much smaller print below, the caption, 'We're losing but we can win'. In front of the man were three inhalers coloured pink, blue and [green] and a spacer device. To the forefront of the table to the left was a brightly coloured bowl of fruit and to the right a white clock with a yellow post-it note on its side.

The three inhalers on display, while unbranded can be identified by their shape and colour. The complaint correctly identified the pink inhaler as Fostair (combination inhaler of ICS/LABA MDI), the green inhaler as Braltus (LAMA DPI) and the blue inhaler as a reliever MDI. The complainant refers to the blue inhaler as Salamol which is not incorrect, as this image represents a salbutamol MDI which could be Ventolin, the originator, or numerous branded or unbranded generic alternatives such as Salamol.

Triple inhaler therapy as a maintenance therapy for patients with COPD refers to the combination of two bronchodilators, a LABA and a LAMA, and an inhaled corticosteroid (ICS). It can be prescribed through multiple inhaler triple therapy (MITT) or as a single inhaler triple therapy (SITT). The phrase MITT is a descriptor only. It does not refer to a class of medicines and there is no MITT licence per se, rather it is two separate medicines each prescribed for their respective indications for COPD. The imagery depicts multiple inhaler triple therapy (MITT) as one of the most prescribed MITTs in the UK, then and now, i.e. Fostair and Braltus. The complainant incorrectly includes the SABA, Salamol as part of triple therapy, however Salamol is a reliever MDI for acute use on top of the maintenance therapy that might be indicated. Blue inhalers are readily identifiable as acute 'reliever' treatments by HCPs and the majority of patients with respiratory conditions.

Frame 2 has the caption '58% of COPD Triple Therapy patients in the UK are juggling multiple devices. Would a simpler routine make their lives easier?' which is reference to GSK Data on file and substantiated by prescription data from IQVIA which analysed the percentage of MITT patients who had more than one type of inhaler device (e.g. MDI, DPI) as part of their daily regimen.

Allegation and PMCPA Clauses for consideration

The complainant alleges that the imagery of a COPD patient with multiple different inhalers, combined with the caption '58% of COPD Triple Therapy patients in the UK are juggling multiple devices. Would a simpler routine make their lives easier?', on a Trelegy branded webpage, is promoting Trelegy for use in COPD patients currently taking multiple inhaler triple therapy (open triple). The complaint states that Trelegy is not licensed for patients not adequately treated on open triple, that the indication does not cover multiple therapies including a LAMA and SABA and that the banner is promoting switching from multiple inhaler triple therapy to Trelegy.

GSK was asked to consider Clauses 11.2, 5.1 and 2. Clause 11.2 states:
'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...'

Trelegy SmPC

Trelegy is a once daily SITT containing the LAMA umeclidinium (UMEC), LABA vilanterol (VI) and ICS fluticasone furoate (FF). Trelegy is delivered through the Ellipta

device and marketing authorisation was granted on 15th Nov 2017. Section 4.1 of the SmPC gives the therapeutic indication as follows:
'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'.

Please note that throughout this response, reference to COPD will substitute for moderate to severe COPD unless otherwise stated.

GSK acknowledges that in promoting Trelegy for '*moderate to severe COPD* patients *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'* that this could include COPD patients on MITT. GSK can reassure the PMCPA that a careful and considered assessment of all relevant information was undertaken by GSK prior to the inclusion of any data on multiple inhaler triple therapy within Trelegy promotional material, to ensure compliance with Clause 11.2.

Section 5.1 Pharmacodynamic properties
The clinical efficacy and safety of Trelegy is supported by three Phase 3 studies, FULFIL, IMPACT and Study 200812 and detailed in Section 5.1 of the SmPC. Relevant text has been bolded for emphasis.

> *'5.1 Pharmacodynamic properties*
> *Clinical efficacy and safety*
> *The efficacy of Trelegy Ellipta (92/55/22 micrograms), administered as a once-daily treatment, has been evaluated in patients with a clinical diagnosis of COPD in two, active-controlled studies and in a single, non-inferiority study. All three studies were multicentre, randomised, double-blind studies that required patients to be symptomatic with a COPD Assessment Test (CAT) score ≥ 10 and on daily maintenance treatment for their COPD for at least three months prior to study entry.*
>
> *FULFIL (CTT116853) was a 24-week study (N=1,810), with an extension up to 52 weeks in a subset of subjects (n=430), that compared Trelegy Ellipta (92/55/22 micrograms) with budesonide/formoterol 400/12 micrograms (BUD/FOR) administered twice-daily.' ….*
>
> *'IMPACT (CTT116855) was a 52-week study (N=10,355) that compared Trelegy Ellipta (92/55/22 micrograms) with fluticasone furoate/vilanterol 92/22 micrograms (FF/VI) and umeclidinium/vilanterol 55/22 micrograms (UMEC/VI).'…*
>
> *'At study entry**, the most common COPD medications reported in the FULFIL and IMPACT studies were ICS+LABA+LAMA (28%, 34% respectively)**, ICS+LABA (29%, 26% respectively), LAMA+LABA (10%, 8% respectively) and LAMA (9%, 7% respectively). These patients may have also been taking other COPD medications (e.g. mucolytics or leukotriene receptor antagonists).'*

Study 200812 was a 24-week, non-inferiority study (N=1 055) that ***compared Trelegy Ellipta (92/55/22 micrograms) with FF/VI (92/22 micrograms) + UMEC (55 micrograms), co-administered once daily as a multi-inhaler therapy*** *in patients with a history of moderate or severe exacerbations within the prior 12 months.*'

As stated in the SmPC above, all three Phase III studies supporting the clinical efficacy and safety of Trelegy included a significant proportion of patients previously treated with multiple inhaler triple therapy.

In FULFIL, 28% of patients (n=513) were previously on a combination of ICS+LABA+LAMA, making it one of the largest cohorts of patients in the study. A subgroup analysis for FULFIL, published by Halpin *et al*, confirmed that irrespective of the class of prior COPD medication received, treatment with Trelegy demonstrated a significantly greater improvement in lung function compared to BUD/FOR at 24 and 52 weeks. In addition, Trelegy, when compared to BUD/FOR, reduced the mean annual exacerbation rate up to week 24 (range 24–63%) in all prior medication subgroups, except LAMA+LABA (annual exacerbation rate reduction −44%).

In IMPACT, 34% (n=3563) of patients were previously treated on a combination of ICS+LABA+LAMA, making it the largest proportion of patients within the study. Details on medication combinations at trial entry are provided in Table S4 in the Supplementary Appendix of the primary manuscript. A post hoc analysis of IMPACT by Singh *et al*, analysed the primary and secondary endpoints across the COPD medication subgroups. This showed that COPD patients previously treated with ICS+LAMA+LABA, who were randomised to Trelegy had significantly reduced annual moderate/severe and annual severe exacerbation rates, significantly improved lung function (FEV1) and significantly improved quality of life (SGRQ) versus either comparator FF/VI or UMEC/VI.

The third study referred to in Section 5.1 of the SmPC, Study 200812, was a 24-week, non-inferiority study (N=1 055) which directly compared the SITT Trelegy to the same triple therapy molecules, ICS/LABA (FF/VI) + LAMA (UMEC), delivered using multiple inhalers. Of the 1055 patients, 445 (42%) were patients being treated with multiple inhaler triple therapy at baseline. The mean change from baseline in trough FEV1 at Week 24 was 113 mL (95% CI 91, 135) for Trelegy and 95 mL (95% CI 72, 117) for FF/VI + UMEC; the between-treatment difference of 18 mL (95% CI -13, 50) confirmed that single inhaler triple therapy with Trelegy was considered non-inferior to FF/ VI + UMEC (MITT). At Week 24, the proportion of responders based on St George's Respiratory Questionnaire Total score (a disease specific quality of life questionnaire) was 50% (FF/UMEC/VI) and 51% (FF/VI + UMEC); the proportion of responders based on the Transitional Dyspnea Index focal score was similar (56% both groups).

A similar proportion of patients experienced a moderate/severe exacerbation in the FF/UMEC/VI (24%) and FF/VI + UMEC (27%) groups; the hazard ratio for time to first moderate/ severe exacerbation with FF/UMEC/VI versus FF/VI + UMEC was 0.87 (95% CI 0.68, 1.12). The incidence of adverse events was comparable in both groups (48%); the incidence of serious adverse events was 10% (FF/UMEC/VI) and 11% (FF/VI + UMEC).

In summary, all three clinical studies which support the registrational efficacy and safety of Trelegy, and are referenced in the SmPC, enrolled a substantial number of patients who were being treated with multiple inhaler triple therapy at baseline. Trelegy demonstrated superior efficacy and quality of life scores in a MITT population compared to the dual bronchodilator combination (BUD/FOR, UMEC/VI) or ICS/LABA combinations (FF/VI). Study 200812 confirmed that delivering Trelegy through a single inhaler was at least as effective and posed no additional safety risk compared to administering the three components through two separate inhalers.

GSK therefore concluded that the promotion of Trelegy in COPD patients not adequately treated on multiple (open) triple therapy is in accordance with the terms of the Trelegy marketing authorisation and not inconsistent with the particulars listed in the Trelegy SmPC as required under Claure 11.2.

Section 4.1 Therapeutic Indications

'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'.

This indication is the same for all UK SITTs and no SITT inhaler has MITT stated as part of the indication. Similarly, no dual combination or monotherapy COPD inhalers have a licence which states use as part of a MITT regimen. Patients on MITT are not on a combination therapy as per a licensed indication, but rather on two separate medicines independently, each with a specific indication. Fostair (100/6) pMDI is indicated for the *'Symptomatic treatment of patients with severe COPD (FEV1 < 50% predicted normal) and a history of repeated exacerbations, who have significant symptoms despite regular therapy with long-acting bronchodilators*.' Braltus is indicated as '*a maintenance bronchodilator treatment to relieve symptoms in patients with chronic obstructive pulmonary disease (COPD)'*. As mentioned before, there is no MITT indication per se as MITT describes a combination of separate medicines each prescribed for their respective indications for COPD.

All COPD patients on triple therapy, either MITT or SITT, have failed to be adequately treated by either a LABA/LAMA or ICS/LABA. This treatment paradigm is seen within national guidelines, including the NICE COPD treatment algorithm which has a series of step wise, evidence-based treatment recommendations. Dual maintenance therapy (LABA/LAMA or ICS/LABA depending on phenotype) is recommended by NICE for use in COPD patient who are limited by symptoms or have experienced exacerbations despite treatment with short acting bronchodilators. If despite these treatments a patient still has day-to-day symptoms that adversely impact their quality of life, or one severe or two moderate exacerbations within a year, then NICE recommend considering triple therapy.

The Trelegy indication, and that of all other SITTs, specifies 'not adequately treated' as opposed to an objective endpoint such as lung function or exacerbation risk. This terminology reflects the complexity in managing COPD, where different factors often beyond the choice of molecule can negatively impact the clinical outcome for an individual patient. MITT is inherently complex for patients. Data from the NHS site

www.RightBreathe.com on COPD inhalers licenced in the UK, shows the degree of choice available. Currently there are:

8 different LABA inhalers
8 different LAMA inhalers
5 different dual bronchodilator LABA/LAMA inhalers
14 different combination ICS/LABA inhalers

This means there could be as many of 112 different on-licence combinations of MITT available for prescription. A patient's daily routine must incorporate different dosing regimens (one or two puffs either once or twice daily) and/or different inhalation techniques for each separate inhaler. In the example illustrated in the banner advert. 'John' would have to take one puff of Fostair twice daily and one puff of Braltus once daily, using two inhalers with different inhalation techniques since Fostair is a pressurised metered dose inhaler and Braltus, a dry powdered inhaler.

There is consistent evidence, including within the UK, that MITT is associated with low adherence and persistence. Sansbury *et al* showed that around three-quarters of patients discontinued MITT in the UK before reaching the end of a 12-month observation period. As per the 2024 GOLD strategic report, non-adherence to COPD medication has been associated with poor symptom control, increased risk of exacerbation, increased healthcare utilization and costs, decreased health-related quality of life and higher mortality risk. This contrasts with real-world data showing that patients initiating SITT have improved adherence and/or treatment persistence compared with MITT. In a large retrospective cohort study analysing UK primary and secondary care databases, Halpin *et al* demonstrated that patients initiating SITT (either Trelegy or Trimbow pMDI), had significantly better adherence and persistence compared with patients initiating MITT at 6,12- and 18-months post-initiation ($p<0.001$ for all comparisons) and that these improvements persisted for at least 18 months following treatment initiation. A study by Van der Palen has shown that COPD patients make substantially fewer critical errors with a single placebo Ellipta inhaler versus triple therapy delivered through multiple inhalers (Diskus+Handihaler or Turbuhaler+Handihaler).

A wealth of real-world evidence now exists in support of potential clinical and economic benefits of SITTs versus MITT. Spanish data from Alcázar-Navarrete et al showed that at 12-month follow-up, SITT patients had a 37% improvement in persistence compared with MITT patients, leading to a 33% risk reduction in all-cause mortality and a 32% risk reduction in the incidence of exacerbations. Similar improvement in clinically relevant outcomes was reported in a European 24-week multicentre, randomized, open-label, phase IV effectiveness study which showed treatment with the SITT Trelegy resulted in significantly more patients gaining health status improvement and greater lung function improvement versus non-Ellipta MITT. A recently published UK study which examined patient data from linked primary and secondary databases also showed that patients who had changed from MITT to SITT (Trelegy) had significantly decreased the rate of COPD exacerbations, COPD-related healthcare resource use and direct medical costs in the 6 months following the switch compared with the 6 months prior.

The potential advantages of SITTs are reflected in the most recent UK and global guidelines and strategy documents. The 2023 Primary Care Respiratory Society (PCRS) guideline on Triple Therapy for COPD states:

> *'Consider a single inhaler triple therapy device to improve adherence, reduce inhaler technique errors and reduce inhaler burden.'*

Similarly, the 2024 Global Initiative for Chronic Obstructive Lung Disease (GOLD) strategy document, based on the best-available evidence, states:

> *'Although patient preferences may vary, prescribing strategies that could help improve adherence often include selecting devices with a similar inhalation technique (in the case of multiple inhalers) and combination therapy*.'

NICE makes recommendations within section 1.2.19, Inhaled combination therapy, on what the choice of drugs and inhalers should be based on, namely:

> - *how much they improve symptoms*
> - *the person's preference and ability to use the inhalers.*
> - *the drugs' potential to reduce exacerbations*
> - *their side effects*
> - *their cost.*
>
> *Minimise the number of inhalers and the number of different types of inhaler used by each person as far as possible.*

From the patient perspective, new advances such as SITTs were developed to address a clinical need. The prevalence of COPD increases with age and 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. As represented by 'John' in this banner advertisement, patients who clinically need a LAMA, LABA and an ICS, but struggle with the complexity of 2 different inhalers with different techniques i.e. a DPI inhaler which requires a fast and deep inhalation to disaggregate the dry powder and an MDI which requires a slow and steady inhalation of aerosol particles, combined with different dosing regimens i.e. one puff vs two puffs, either once daily vs twice daily, should be considered for the option of receiving the same classes of medicine in one single inhaler. Even for patients with simpler MITT regimens, e.g. Relvar and Incruse which both use the same device, there are practical advantages and efficiencies to be gained by reducing the number of inhalers to one.

Were the alleged complaint to be found in breach, such patients would be out of scope for the promotion of all SITTs, pharmaceutical advances developed specifically to meet their needs. The use of SITT instead of MITT in appropriate patients means cost saving for the NHS. Although the NICE guidelines did not make a recommendation in favour of single or multiple inhaler devices, the NICE committee did comment on the economic evidence that using a single inhaler device for triple therapy in COPD was more cost effective. Fewer inhalers to use and dispose of, particularly pMDIs which make up 70% of prescribed inhalers in the UK and contain potent greenhouse propellant gases, helps the NHS meet its carbon emission targets. The British Thoracic Society position statement on The Environment and Lung Health 2020 sets out a number of recommendations including the importance of using low carbon inhalers such as propellant-free DPIs or reusable Soft Mist Inhalers where possible and improved recycling/disposal schemes.

In summary, GSK considers that the phrase 'not adequately treated' allows clinicians to prescribe Trelegy for patients with COPD who are clinically impacted by factors such

as poor adherence, device errors and poor inhalation technique, inconvenience, or even cost. As all MITT patients are on a combination of a LABA+ LAMA + ICS, when such patients are not adequately treated despite their current therapy, be that due to poor adherence, device errors, poor inhalation techniques, inconvenience or even cost, GSK considers that such MITT patients are within the scope of the Trelegy licenced indication.

Conclusion

Based on the factors described above, GSK remains confident that the promotion of Trelegy for patients not adequately treated on multiple inhaler triple therapy is firstly, in accordance with Trelegy's indication and not inconsistent with the particulars of the SmPC; secondly, clinically sound and in the best interest of appropriate COPD patients based on available evidence supporting SITT versus MITT and the clinical unmet need; and finally, consistent with national and international recommendations. For these reasons, GSK strongly refutes the allegation and denies any breach of Clauses 11.2

As set out, GSK had carefully and consciously considered the requirements of the Code prior to promoting Trelegy for COPD patients not adequately treated with multiple inhaler triple therapy. Consequently, GSK denies breaches of Clauses 5.1 and 2.

The material at issue has not been used in the UK since 22nd June 2023. The PMCPA requested commentary on why the webpage at issue was unavailable. Due to the spike in anonymous complaints in the last number of years and the effort required to defend these allegations, GSK has not had promotional material for Trelegy live on GSKPro since 6th July 2023. This is less than ideal of customers and GSK will relaunch a modified site soon."

PANEL RULING

The complaint concerned a revolving banner advertisement which was published on a Trelegy promotional webpage on GSK's UK promotional website. The banner advertisement was a 5-frame rotating image. Each of the five frames featured the same image, superimposed with a different caption. In the first frame, the image was in full colour; in the subsequent frames, the image was mostly in greyscale. Each of the five frames highlighted a different message related to a UK COPD patient.

The Panel noted GSK's submission that while this complaint was made on 8 June 2024, the material at issue had been withdrawn since 22 June 2023.

The first frame of the five-frame advertisement depicted a man sitting at a table, with his elbows resting on the table, holding a bright orange cup of tea. Upon the table, to the left of the man, was a pile of unopened post and a bright blue 7-day pill organiser. To his right on the table was a black and off-white newspaper with the capitalised headline of 'Climate Emergency'. In front of the man were three inhaler devices coloured pink, blue and green and a spacer device. To the forefront of the table to the left was a brightly coloured bowl of fruit and to the right a white clock with a yellow post-it note on its side. Text invited the reader to "Meet John" and to click through to "find out more about his life". There were arrows beneath the image to allow the user to click through the five frames of the advertisement.

In the second frame of the advertisement, the caption read “58% of COPD Triple Therapy patients in UK are juggling multiple devices. Would a simpler routine make their lives easier?”, with a link to find out more. The image was in greyscale except for the inhalers and spacer device, which were in colour.

The third frame discussed comorbidities. The image was in greyscale except for the 7-day pill organiser. The fourth frame discussed low carbon inhalers, with a link to find out more. The image was in greyscale except for the newspaper.

In the fifth frame of the advertisement, the caption read “83% of COPD Triple Therapy patients on multiple inhalers in UK are managing once and twice daily dosing concurrently. Make their lives easier with Trelegy Ellipta – UK’s only once-daily, single device COPD triple therapy”. The image was in greyscale except for the post-it note.

The complainant described the second frame of the advertisement and alleged that it promoted a switch to Trelegy from the patient’s current three inhalers depicted in the advertisement. The complainant stated that the patient in the advertisement was on three separate inhalers (triple therapy): Braltus (LAMA), Fostair (ICS/LABA) and Salamol (SABA) and alleged that Trelegy was not licensed for patients not adequately treated on “open triple therapy (ICS/LABA + LAMA + SABA)” and that Trelegy was licensed for patients not adequately treated on ICS/LABA only.

While the complainant alleged that Trelegy was licensed for patients “not adequately treated on ICS/LABA only”, the Panel noted that 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 ICS/LABA or a combination of a LABA/LAMA.

The Panel noted GSK’s detailed submission regarding relevant guidelines, the efficacy of Trelegy Ellipta, SITTs and the three Phase III registration studies referred to in the Trelegy Ellipta summary of product characteristics which included patient cohorts that had transferred to Trelegy Ellipta from MITT.

The Panel considered that the primary issues to consider were:

- Whether the banner advertisement promoted a switch from the three inhalers pictured (ICS/LABA, LAMA and SABA) to Trelegy Ellipta (LAMA, LABA and ICS), and whether this was outside Trelegy Ellipta’s licensed indication.
- Whether promoting “a simpler routine” for “COPD triple therapy patients” who “are juggling multiple devices” was outside Trelegy Ellipta’s licensed indication; whether it was merely a change in the delivery mechanism for triple therapy or whether GSK needed to be satisfied that all MITT patients satisfied the requirement set out in section 4.1 of the Trelegy Ellipta summary of product characteristics, namely that they were not adequately treated by LAMA/LABA or ICS/LABA therapy.

The Panel noted that both the complainant and GSK appeared to agree that the pink and green inhalers pictured represented Fostair (an ICS/LABA) and Braltus (a LAMA). GSK submitted that the imagery depicted multiple inhaler triple therapy (MITT) using one of the most prescribed MITTs in the UK, i.e. Fostair and Braltus.

The Panel noted GSK’s submission that, while the complainant referred to the blue inhaler as Salamol, the image represented a salbutamol MDI which could be Ventolin, the originator, or

numerous branded or unbranded generic alternatives, such as Salamol. GSK further explained that Salamol is a reliever MDI for acute use on top of the maintenance therapy that might be indicated. GSK submitted that blue inhalers are readily identifiable as acute 'reliever' treatments by health professionals and the majority of patients with respiratory conditions.

In the Panel's view, blue inhalers were commonly associated with acute reliever treatments, but it also noted that there was no universal standard for inhaler colours. The Panel accepted that although certain inhaler devices were well known, companies should be confident that there was no potential for confusion when depicting such devices, particularly given the number of marketed devices. It appeared that both parties agreed that the blue inhaler was a SABA. The Panel noted that the complainant had included the SABA reliever medication as part of triple therapy. The Panel agreed with GSK's submission that this was incorrect and that a reliever medication would be for acute use on top of the maintenance triple therapy (ICS/LABA and LAMA).

In the Panel's view, and on balance, most readers would assume that the blue inhaler was a reliever medication and that the pink and green inhaler devices therefore represented the multiple inhaler triple therapy referred to in the text. Certain readers might be aware that the multiple inhaler triple therapy devices were the most widely prescribed combination, Fostair (ICS/LABA) and Braltus (LAMA). The complainant had not inferred that the blue inhaler was anything other than a SABA. Noting the licensed indication for Trelegy Ellipta set out above, and the depiction of the devices in the advertisement the Panel did not consider that the advertisement promoted a switch from ICS/LABA + LAMA + SABA as alleged. The Panel therefore ruled **no breach of Clause 11.2**.

GSK submitted that the phrase "not adequately treated" allows clinicians to prescribe Trelegy Ellipta for patients with COPD who are clinically impacted by factors such as poor adherence, device errors and poor inhalation technique, inconvenience, or even cost. In the Panel's view, however, the phrase was used within section 4.1 of the Trelegy Ellipta summary of product characteristics in relation to patients not adequately treated by a combination of an ICS/LABA or a combination of a LABA/LAMA; it did not refer to patients not adequately treated by a triple therapy. The Panel disagreed with GSK's submission that the phrase allowed clinicians to prescribe Trelegy Ellipta for patients with COPD who are impacted by cost.

The Panel bore in mind GSK's submission that all COPD patients on triple therapy, either MITT or SITT, have failed to be adequately treated by either a LABA/LAMA or ICS/LABA and that this treatment paradigm is seen within national guidelines, including the NICE COPD treatment algorithm which has a series of stepwise, evidence-based treatment recommendations.

The Panel considered in principle that it was not necessarily unacceptable to promote a switch from MITT to Trelegy Ellipta. Whether a such a claim was acceptable would depend on the circumstances of each case; context was important.

On the narrow ground alleged and on balance the Panel did not consider that the complainant had established that Trelegy Ellipta was being promoted outside of its licensed indication and therefore ruled **no breach of Clause 11.2**.

Noting its rulings of no breach 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 Clauses 5.1 and 2**.

Complaint received **8 June 2024**

Case completed **17 July 2025**