CASE/0266/08/24 ***NO BREACH OF THE CODE***

COMPLAINANT v GSK

Alleged unlicensed promotion of Trelegy on a webpage

CASE SUMMARY

This case was in relation to a patient profile on a promotional website. The complainant alleged that it promoted Trelegy Ellipta (fluticasone furoate, umeclidinium, vilanterol) for an unlicensed indication because it stated that the patient was not adequately treated by multiple inhaler triple therapy and Trelegy Ellipta was indicated only for patients not adequately treated on ICS/LABA or LABA/LAMA therapy.

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	**Requirement 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**

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 a contactable complainant who described themselves as a health professional.

COMPLAINT

The complaint wording is reproduced below:

> "A Trelegy Ellipta promotional website was promoting the use of Trelegy Ellipta for a unlicensed indication. The webpage is [URL provided] July 2024 | PM-GB-FVU-WCNT-240003 (V1.0) Towards the end of the page, 3 patient profiles are given with a heading above the profiles that states who could benefit from Trelegy Ellipta? The patient profile Jon states Jon is not adequately treated by multiple inhaler triple therapy. Trelegy Ellipta is indicated only for patients not adequately treated on ICS/LABA or LABA/LAMA therapy. The regulators had not provided a license to Trelegy Ellipta for those patients not adequately treated on multiple inhaler triple therapy. Jon is not a suitable patient for Trelegy Ellipta as he is on multiple inhaler triple therapy (outside of

therapy indications of Trelegy) and not on ICS/LABA or LABA/LAMA. If GSK wanted to promote Trelegy as an option for patients not adequately treated on multiple inhaler triple therapy they should apply to the regulatory bodies for a relevant license to cover multiple inhaler triple therapy as this is not currently in the Trelegy SmPC therapeutic indications section (section 4.1). Off-label promotion is a concerning matter that needs thorough investigation. Breaches of clause 11.2 + 5.1 + 2 Thanks."

When writing to GSK, the PMCPA asked it to consider the requirements of Clauses 2, 5.1 and 11.2 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 10/08/2024 wherein you informed GSK that an anonymous complainant has alleged off-label promotion of Trelegy on our promotional website: [URL provided], approved July 2024.

GSK would like to highlight that similar allegations have been submitted in three other complaints filed in between June and August 2024:

- Case AUTH/3922/06/24,
- Case AUTH/3923/06/24,
- Case/0257/08/24.

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. Please note that the webpage of this current complaint ([URL] page (PM-GB-FVU-WCNT-240003 (V1.0)) was live in between the 23rd of July 2024 and 28th of August 2024.

The webpage in question is part of GSK's promotional website [URL provided] which is exclusively aimed at UK healthcare professionals. 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 healthcare professional 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 blue) showcases 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 hero banner featuring four musicians playing string instruments against a striped background that matches the colours of the Ellipta devices is prominently displayed. 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 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 in the UK. They highlight that the majority of patients on triple therapy have been prescribed more than one device and, consequently, are managing several types of inhalers simultaneously.

The subsequent section of the webpage, titled *'Who could benefit from Trelegy Ellipta?'*, features three images of fictional COPD patients—Jon, Bev, and Ali—each representing a specific patient type. Jon is a COPD patient not adequately treated by multiple inhaler therapy, Bev is not adequately treated by LABA/LAMA and Ali not adequately treated by ICS/LABA. Beneath this, the third and final section, titled 'Consider Trelegy Ellipta as your triple therapy of choice,' displays a Trelegy Ellipta device alongside a message stating: '*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.

Allegation and PMCPA Clauses for consideration

The complainant alleges that the above webpage is promoting the use of Trelegy Ellipta for an unlicensed indication and in particular states that Trelegy is not licensed for patients not adequately treated with multiple inhaler triple therapy. Furthermore, the compliant [*sic*] states that *'Jon is not suitable patient for Trelegy Ellipta as he [Jon] is on multiple inhaler triple therapy and not on ICS/LABA or LABA/LAMA'*.
GSK was asked to consider Clauses 11.2, 5.1 and 2.

Clause 11.2

- 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…'*

Single *vs*. Multiple inhaler triple therapy, Trelegy and Trelegy SmPC

- Triple inhaler therapy for managing COPD involves the use of two bronchodilators—a long-acting beta-agonist (LABA) and a long-acting muscarinic antagonist (LAMA)—alongside an inhaled corticosteroid (ICS). This treatment can be delivered either through multiple inhalers (MITT) or a single inhaler that combines all three medications (SITT).
- The terms MITT (multiple inhaler triple therapy) and SITT (single inhaler triple therapy) simply indicate the number of inhalers prescribed to the patient. They do

not denote different classes of medications, and there is no specific licensing for MITT or SITT as distinct treatments.

- 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'*.

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 patients 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.

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 (like our fictional patient Jon), are not on a combination therapy as per a licensed indication, but rather on two separate medicines independently, each with a specific indication. For example: 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.

In the case of our fictional patient Jon, he is described as already being on triple therapy (therefore he has failed either LABA/LAMA or ICS/LABA) and at present he is receiving his medications via 2 (or more) inhalers. The fact that Jon's triple therapy consists of different molecules from the same classes of medicines present in Trelegy, and that these are administered via different devices than the Ellipta, does not imply that Jon *'is not a suitable patient for Trelegy Ellipta'* as alleged. It only indicates that Jon's treatment pathway involved initiating a triple therapy via MITT rather than via SITT.

Our website considers the availability of various combinations of medicines and devices within the triple therapy approach with the statement: '*Consider Trelegy Ellipta as your triple therapy of choice*'. Once a patient is deemed suitable for triple therapy, it is up to the HCP and the patient to select the most appropriate form of therapy, which

can be reviewed, adjusted, and changed when and if deemed appropriate. Therefore, GSK's position is that Jon is a suitable patient for Trelegy, given that he is already on a treatment regimen which includes a dual therapy on which Jon is not adequately controlled with. Furthermore, 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 as 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. Being on a MITT regimen our fictional patient 'Jon' would have to use multiple inhalers with different inhalation techniques. 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 Turbohaler+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, randomised, 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.

Our fictional patient 'Jon' represents a typical patient who clinically needs a LAMA, LABA and an ICS, but might struggle with the complexity of MITT (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), such a patient could 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 (Ellipta) – 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 several 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.

Use of Trelegy in patients on MITT:

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 Dyspnoea 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 patients that were on MITT at baseline, compared to those on 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 Clause 11.2.

Clause 5.1 and 2

Clause 5.1 states: *High standards must be maintained at all times.*

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

As previously discussed, GSK believes that the clinical profile of our fictional patient Jon aligns with the details provided in the Trelegy Summary of Product Characteristics (SmPC). Additionally, three Phase III studies supporting the clinical efficacy and safety of Trelegy included a significant proportion of patients who were previously treated with multiple inhaler triple therapy, like Jon. Therefore, GSK firmly believes that high standards have been consistently maintained, and GSK's actions in this matter have not discredited or diminished confidence in the pharmaceutical industry.

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 Clause 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."

PANEL RULING

The complaint alleged that a patient profile on a Trelegy Ellipta promotional website promoted Trelegy Ellipta for an unlicensed indication.

The webpage in question, beneath primary and secondary navigation bars, was headed "Conduct COPD care your way. Introduce Trelegy Ellipta". The primary navigation bar featured the Trelegy Ellipta brand name. The webpage was divided into three sections: The burden of COPD; Who could benefit from Trelegy Ellipta?; and Consider Trelegy Ellipta as your triple therapy of choice. The Panel noted that the section titled "The burden of COPD" included the statement, "Approximately 67% of patients with COPD treated with multiple-inhaler triple therapy are juggling multiple device types" which was referenced to IQVIA Triple Dynamic Prescribing, 2023. The Panel did not have a copy of this study. The third section, "Consider Trelegy Ellipta as your triple therapy of choice" invited readers to identify patients with moderate/severe COPD who are not adequately treated on an ICS/LABA or LAMA/LABA and featured a link to find out more information about Trelegy Ellipta.

The second section, titled “Who could benefit from Trelegy Ellipta?”, presented three patient profiles. Each profile consisted of a photograph of a person, the person’s name, a short description, and a link to “Read more”. There was a statement beneath the profiles that “The images above are not real patients”.

The patient profile in question, “Jon”, was the first of the three profiles. Its description read “Patient not adequately treated by multiple-inhaler triple therapy”. The second and third patient profiles, respectively, read: “Patient not adequately treated by LAMA/LABA therapy”; and “Patient not adequately treated by ICS/LABA therapy”.

The complainant alleged that Jon was not a suitable patient for Trelegy Ellipta as he was on multiple inhaler triple therapy not ICS/LABA or LABA/LAMA. The complainant alleged that use of Trelegy as an option for patients not adequately treated with multiple inhaler triple therapy was not currently in the Trelegy licensed indication.

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 bore in mind GSK’s submission that the fictional patient was described as already being on triple therapy (therefore he had failed either LABA/LAMA or ICS/LABA) and at present he was receiving his medications via two (or more) inhalers. GSK submitted that the fact that the patient’s triple therapy consists of different molecules from the same classes of medicines present in Trelegy, and that these are administered via different devices than the Ellipta, does not imply that the patient *‘is not a suitable patient for Trelegy Ellipta’* as alleged. It only indicates that Jon’s treatment pathway involved initiating a triple therapy via multiple inhalers (MITT) rather than via a single inhaler (SITT).

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 noted that the primary issue to consider was whether promoting a switch from patients not adequately treated by MITT to Trelegy Ellipta as set out on the webpage in question 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 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 further bore in mind GSK’s reference to “Jon’s” treatment pathway and that once a patient is deemed suitable for triple therapy, it is up to the health professional and the patient to select the most appropriate form of therapy, which can be reviewed, adjusted, and changed when and if deemed appropriate.

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

webpage at issue. However, the Panel noted that the complainant bore the burden of proof and, noting the narrow nature of the allegation, did not consider they had established that the reference to “not adequately treated by multiple-inhaler triple therapy” was inconsistent with the licensed indication as set out in section 4.1 of the Trelegy Ellipta summary of product characteristics. The Panel therefore ruled **no breach of Clause 11.2**.

Noting its ruling of no breach above, the Panel did not consider that there were any additional factors which indicated that GSK had failed to maintain high standards or had brought discredit upon, or reduced confidence in, the pharmaceutical industry. The Panel therefore ruled **no breach of Clauses 5.1 and 2**.

Complaint received **10 August 2024**

Case completed **22 July 2025**