CASE AUTH/3923/6/24 ***NO BREACH OF THE CODE***

COMPLAINANT v GSK

Alleged unlicensed promotion of Trelegy in a sales aid

CASE SUMMARY

This case was in relation to a representatives' sales aid. The complainant alleged that it promoted Trelegy Ellipta (fluticasone furoate, umeclidinium, vilanterol) for an unlicensed indication because it promoted Trelegy Ellipta for use in patients not adequately treated on multiple inhaler triple therapy and Trelegy Ellipta was indicated only for such patients on dual therapy (ICS/LABA or LABA/LAMA).

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 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:

> "Trelegy sales aid used by GSK COPD sales representatives throughout 2023 was off-label promotion for Trelegy. Trelegy is a maintenance treatment for COPD patients not adequately treated by ICS/LABA or a LABA/LAMA. The Trelegy sales aid 2023 promoted Trelegy for use in COPD patients not adequately treated on multiple (open) triple therapy. As an example this would include patients who were on ICS/LABA inhaler and a LAMA inhaler separately. This was off-label promotion as Trelegy was not indicated for COPD patients on multiple inhalers but only Dual therapy (ICS/LABA

or LABA/LAMA). Off-label promotion was in breach of clause 11.2 and 5.1. Clause 2 is also breached."

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. 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. GSK notes that the complainant failed to provide precise evidence to corroborate their allegation, instead citing the promotion of Trelegy within sales aids used over a 12-month period (2023). Notwithstanding that the complainant bears of burden of proof, GSK will address this case in full due to our ongoing commitment to self-regulation.

Sales aids

During the course of 2023 GSK sales representatives used four separate electronic sales aids – two primary care detail aids (Anoro/Trelegy e-detail aid and the UK effectiveness and device deck), a secondary care Trelegy detail aid; and a single combined sales aid for use across both primary and secondary from Oct/Nov 2023. These materials were updated and reapproved several times during 2023, meaning there are multiple versions of each. Since the complaint did not specify a particular claim or material, but rather the Trelegy promotional strategy, this response will focus on the overarching rationale GSK applied when deciding to promote Trelegy in COPD patients not adequately treated on multiple inhaler triple therapy. Thereafter, should the PMCPA wish to examine specific material, GSK has enclosed a version of each sales aid. The versions enclosed are reflective of the longest duration of use during 2023 by the sales representatives. We hope this approach is satisfactory to the PMCPA.

Allegation and PMCPA Clauses for consideration

The complainant has alleged off label promotion of Trelegy in *'COPD patients not adequately treated on multiple (open) triple therapy'.* GSK was asked to consider Clauses 11.2, 5.1 and 2. Clause 11.2 states 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'...

Triple inhaler therapy

Triple inhaler therapy in 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. This differs from SITTs which all have the same indication.

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.

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 was 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 Indication

'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. One of the most prescribed MITT in the UK is Fostair 100/6 pMDI (beclomethasone dipropionate/formoterol; ICS/LABA) and Braltus (tiotropium, LAMA). Fostair, one puff twice daily through a 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, one puff once daily through a dry powdered inhaler, is indicated as '*a maintenance bronchodilator treatment to relieve symptoms in patients with chronic obstructive pulmonary disease (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 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.

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 and prescribers. 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. The daily routine for patients requiring MITT combinations must incorporate different dosing regimens (one or two puffs either once or twice daily) and/or different inhalation techniques for each separate inhaler.

There is consistent evidence, including UK data, that MITT is associated with low adherence and persistence. Sansbury at 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 a 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). These COPD patients may clinically need a LAMA, LABA and an ICS, but may 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. Such patients should have the option to consider receiving the same classes of medicine in one single inhaler. This example is representative of the most commonly prescribed MITT regimens in the UK (e.g Fostair MDI and Braltus (Tiotropium), or Fostair NEXThaler (DPI) + Spiriva Respimat (Soft Mist 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 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.

In summary, GSK considers that the phrase 'not adequately treated' allows clinicians to prescribe Trelegy for patient 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 LABA/LAMA and ICS/LAMA, 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.

2023 Trelegy sales aids

As noted earlier, GSK has enclosed four examples of the 2023 sales aids.

- Primary care Anoro/Trelegy combined eDA (V4), in use 29/3/2023 to 26/6/2023
- Primary care Trelegy Real-World Effectiveness and Device deck (V2), in use 14/9/2023 – 11/11/2023
- Secondary care Trelegy sales aid (V3), in use from 29/3/2023-26/6/2023.
- Combined primary and secondary Trelegy sales aid (V2), in use 11/11/2023.

Given the size of these materials, GSK would like to draw the PMCPA's attention to some standard governance features which can be found within each of the electronic sales aid.

1. The Prescribing Information for Trelegy is accessible from every page.
2. The licenced indication always appears in the opening pages.
3. The use of real-world evidence is always prefaced by the Phase III randomised controlled trial data, either the complete data set or reference to IMPACT and FULFIL and the hierarchy of evidence which exists within Trelegy data pack.
4. When referring to MITT real world data, GSK uses the following boxed disclaimer.

   GSK does not advocate switch programmes. A clinical therapy review should occur before any change of medication.
   This RWE expands upon the evidence from the FULFIL and IMPACT trials on the efficacy of using Trelegy to treat moderate to severe COPD.

All material has been certified by a ABPI qualified signatory and certificates are enclosed.

Conclusion

Based on the factors described above, GSK remains confident that the promotion of Trelegy for patients inadequately 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 describing the clinical 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."

PANEL RULING

The complainant alleged that "the Trelegy sales aid used by GSK COPD sales representatives throughout 2023" was off-label promotion of Trelegy as it promoted Trelegy for use in COPD patients not adequately treated on multiple (open) triple therapy. As an example, the complainant referred to patients who were on an ICS/LABA inhaler and a LAMA inhaler separately. The complainant alleged that this was off-label promotion as Trelegy was indicated for COPD patients on dual therapy (ICS/LABA or LABA/LAMA), not patients on multiple inhalers.

The complainant did not provide a copy of the sales aid at issue as part of their complaint.

GSK stated that during 2023 its sales representatives used four separate electronic sales aids – two primary care detail aids (Anoro/Trelegy e-detail aid and the UK effectiveness and device deck), a secondary care Trelegy detail aid; and a single combined sales aid for use across both primary and secondary from Oct/Nov 2023. GSK submitted that these materials were updated and reapproved several times during 2023, meaning there were multiple versions of each.

GSK provided the Panel with four examples of the 2023 sales aids, which it submitted were reflective of the longest duration of use during 2023:

- Primary care Anoro/Trelegy combined eDA (V4), in use 29/3/2023 to 26/6/2023
- Primary care Trelegy Real-World Effectiveness and Device deck (V2), in use 14/9/2023 to 11/11/2023
- Secondary care Trelegy sales aid (V3), in use from 29/3/2023 to 26/6/2023
- Combined primary and secondary Trelegy sales aid (V2), in use 11/11/2023.

The Panel noted that the complaint referred to the general principle of promoting a switch from multiple inhaler triple therapy (MITT) to Trelegy, a single inhaler triple therapy (SITT) and gave promoting a switch from ICS/LABA and LAMA as an example of this. The complaint referred to a Trelegy sales aid but, bearing in mind GSK's response, the Panel noted that the complainant did not identify a specific document.

The Panel noted that each of the four sales aids referred to by GSK promoted Trelegy and a switch from MITT to SITT.

The Panel noted that the complainant was now non-contactable and so it was not possible to obtain clarification about which specific claims and which sales aid the complaint related to. The Panel therefore ruled on the general principle, making reference to the complainant's example of how promoting a switch from ICS/LABA and LAMA to Trelegy Ellipta would be promoting a switch from MITT to Trelegy.

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 that had transferred to Trelegy Ellipta from MITT.

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 noted that the primary issue to consider was whether promoting a switch from patients not adequately treated by MITT to Trelegy Ellipta 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 considered in principle that it was not necessarily unacceptable to promote a switch from MITT to Trelegy Ellipta including a switch from ICS/LABA and LAMA. Whether such a claim was acceptable would depend on the circumstances of each case; context was important. The Panel noted that the complainant bore the burden of proof. The complainant had not specified which sales aid their complaint referred to, nor provided any examples of specific wording or content within the sales aid that they considered was promotion outside the terms of Trelegy’s marketing authorisation. The context of potentially relevant claims varied; it was not for the Panel to infer reasons on the complainant’s behalf. 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 **9 June 2024**

Case completed **17 July 2025**