

CASE AUTH/3785/6/23

COMPLAINANT v GSK

Alleged misleading claims about Trelegy on GSK's website

CASE SUMMARY

This case was in relation to the promotion of Trelegy on a GSK website.

The outcome under the 2021 Code was:

Breach of Clause 6.1	Making a misleading claim
Breach of Clause 6.2	Making an unsubstantiated claim
Breach of Clause 5.1	Failing to maintain high standards

No Breach of Clause 6.1	Requirement that claims must not be misleading
No Breach of Clause 6.2	Requirement that claims must be capable of substantiation
No Breach of Clause 2	Requirement that materials must not bring discredit upon, or reduce the confidence in, the pharmaceutical industry

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

FULL CASE REPORT

A complaint was received from an anonymous complainant, who was originally contactable but later became non-contactable about GlaxoSmithKline UK Limited.

COMPLAINT

The complaint wording is reproduced in below:

“A misleading claim was placed at the top of the GSK Trelegy webpage. The claim could be located at: [website link provided]. The claim read Trevor trusts Trelegy*. However, there was no data or evidence around patients trusting Trelegy. Even if the claim was in relation to the dog within the image opposite the claim, this was also misleading as there was no evidence of animals trusting Trelegy especially as the product was for human usage only. Trust was such a strong word to use especially when there were no studies looking at patients trust of Trelegy as a primary endpoint. Further down the page, there was text which asked the reader to meet David & Trevor. Underneath this was a video. At 1 minute 32 seconds, the voiceover stated ‘there is life in this old dog yet’. This was misleading as Trelegy did not extend life expectancy and there was no data to support such a claim. ABPI code clauses 6.1, 6.2, 5.1 and 2 were breached.”

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

GSK'S RESPONSE

The response from GSK is reproduced below:

“GSK was disappointed to receive your letter dated 29th June 2023 in which the PMCPA informed us that a healthcare professional (HCP) has raised concerns about a claim regarding a GSK product (Trelegy) on a page within the GSK promotional website (GSKPro).

The complainant has made multiple allegations about the claim which reads: ‘Trevor trusts Trelegy.’ The claim in question was on the promotional webpage [website link provided]. The complainant alleges that there is no data or evidence presented to support the claim that patients trust Trelegy. They also alleged that, even if the claim relates to the dog in the image accompanying the claim, this was also misleading as there was no data or evidence provided to support animals trusting Trelegy, especially as the product is only licensed for human usage. They have alleged that ‘trust’ is too strong a word to use when no studies exist in which it is an endpoint. Furthermore, the webpage also contained a video on which the voiceover stated (at 1 min 32 secs) that ‘there is life in this old dog yet’ which the complainant alleges is misleading as there was no data to support the claim that Trelegy extended life expectancy. They have therefore alleged breaches of clauses 5.1, 6.1, 6.2 and 2 of the ABPI Code.

GSK is strongly committed to following both the letter and the spirit of the ABPI code of practice and all other relevant regulations. We have reviewed the claim and related materials as well as conducted an urgent internal investigation. It is with regret that GSK acknowledges breaches of clauses 6.1, 6.2 and 5.1 regarding the claim ‘Trevor trusts Trelegy.’ GSK does however deny breaching clauses 6.1, 6.2 and 5.1 with regards to the use of the phrase ‘...there is life in this old dog yet...’ GSK also deny breaching clause 2. We set out our reasons below and explain the robust approach we have taken in response to this complaint.

Background

The webpage referred to is part of a more extensive promotional website called GSKpro which contains promotional information about all the GSK products currently marketed in the UK. It was aimed at UK Health Professionals (HCPs) and HCPs must confirm that they are such before they can access the content. Access by HCPs was only possible by them either searching for it through search engines such as Google, or by directly logging on to the website if they already know about it. They would have to confirm that they are an HCP before accessing the website. Within the website, there is a section dedicated entirely to the product Trelegy. The webpage in question is one of the sections within this.

The page consists of the claim with the related image of an elderly gentleman with a dog sitting on his lap. Below this is a video entitled: ‘Meet David and Trevor: Does the impact of David’s COPD remind you of patients you see?’ There are three tabs below the video which provide links for further information about Trelegy including exacerbation, lung

function and safety data. This in turn is followed by information about the ellipta inhaler after which there are three tabs to provide more information on the molecules, sustainability and the ellipta device. Finally on the page, there are tabs to order a demo device and patient resources and prescribing information for GSK's four inhaler products in COPD.

Trevor trusts Trelegy Claim

When considering the campaign and the tag line 'Trevor trust Trelegy,' GSK Trelegy team members were reacting to a highly competitive commercial environment and strategic direction to take a more innovative, patient centric approach to the Trelegy promotional campaign. The concept in this campaign was to use dog-walking as a proxy for normal activities of daily living, to give a more human and engaging way of portraying improvements in health-related quality of life. Trelegy data on QoL was referenced alongside the claim as supporting information.

The Trelegy team had detailed discussions about the suitability of the claim with regards to the ABPI code (including considering previous cases) and logged their discussions, as evidenced in [internal consideration log]. Whilst the team were, with good intent, trying to find a way to portray a patient-focused concept in an engaging way, the decision-making and final execution of this was flawed, and GSK acknowledges that this led to an un-substantiable claim being made. With hindsight, GSK accept that it is not possible to substantiate a claim that an animal trusts a medicine. We acknowledge that the claim is not to the standard we expect and that clauses 6.1, 6.2 and 5.1 have been breached.

It is with disappointment GSK also note that, whilst documenting the team discussions about the ABPI Code considerations in this case, a comment was made that there was 'deliberate ambiguity' with the intent of engaging the HCP. Whilst this statement was made with regards to the use of the name 'Trevor' for the dog and the author justified this with the assertion that there was no intention to confuse how or in whom Trelegy can be used, the perception which remains is that the team were knowingly ambiguous, as to whether Trevor was the dog or the human.

In the final execution of the item, it is very clear that Trevor is the dog. Immediately following, the phrase 'Trevor trusts Trelegy' is clear, emboldened text stating: 'But Trevor is only a dog that wants walkies!' This is within the same white textbox, on a much darker background and although the text is slightly smaller, it is so close as to drive the reader to read it immediately, after reading 'Trevor trusts Trelegy.'

GSK acknowledge that the perception left by the statement concerning ambiguity within the internal document constitutes a failure to maintain high standards and is thus a breach of clause 5.1.

However, GSK would also be clear that this was purely an internal document, and because the execution of the final material makes it explicitly clear that Trevor is a dog, we do not believe that this brings the industry into disrepute and does not warrant a ruling of a breach of clause 2.

Use of the phrase 'There's life in this old dog yet'

The complainant alleges that the phrase 'there is life in this old dog yet' in the accompanying video, was misleading, as Trelegy does not extend life expectancy and that there was no data to support such a claim. GSK disagrees with this aspersion and strongly contends that the use of this phrase does not, in fact, make any claims about mortality. We contend that the phrase is a very well recognised colloquialism used in the English language and GSK believes that English-speaking viewers (to which this webpage and video are directed) will know that no claims are being made about an extension of life expectancy.

The FreeDictionary online defines the phrase as meaning: 'One still has vitality or the ability to perform certain actions, despite one's advanced age' which, we believe, is entirely in keeping with the context of how the phrase was used in the video, in support of a more human and engaging way to portray the impact of health-related quality of life. The phrase is spoken, not written, by an actor who is playing the role of a patient, describing what it means to him to walk his dog. GSK contends that this does not constitute a mortality claim about a medicine, and therefore deny a breach of clause 6.1, 6.2, 5.1 and clause 2 with regards to this phrase.

Actions taken by GSK

This complaint was received very soon after another (case AUTH 3781/6/23), which also related to a Trelegy claim on the GSKPro website (a different claim). A separate response will be provided to the PMCPA on that case, however, a senior team were already engaged in significant activity to respond to that complaint and understand how the ABPI Code was being applied to promotional material in the Trelegy team, and had already taken the step of withdrawing material containing the claim at issue in Case Auth/3781/6/23. When the complaint concerning the 'Trevor trusts Trelegy' claim was received, the website page which contained the 'Trevor trusts Trelegy' claim was taken down by the end of the day, and an urgent meeting was convened with [senior leader and senior medical, commercial, compliance and legal employees]. In this meeting, the claim at issue, was immediately acknowledged as being in breach, and the seriousness of this alongside Case AUTH/3781/6/23 was realised. Whilst both are different complaints with specific nuances in operational detail, it is important to note that it was the same team, working on the same product, that were involved in the impacted claims, and from this point on, GSK managed both cases together (rather than maintaining an artificial separation by nature of PMCPA case number). Whilst there are some differences in how key decisions were made, in the activity that resulted in each complaint, the overarching root cause and remediation requirements are the same, and so we will cross reference to actions taken in response to Case/AUTH/3781 in this response.

Given the gravity of the two cases taken together, a decision was made to immediately suspend **all** promotional pages on the GSKPro HCP Trelegy website, regardless of whether it contained the claims at issue or not, and this was actioned and confirmed by the close of the same day, preventing any further potential for HCPs to be exposed to the claims at issue, and to allow GSK time to look for any further potential, but as yet unidentified, issues.

Acknowledging the seriousness of the wider issue in hand, a decision was made to form what GSK call an Incident Management Team, to manage the further investigation, corrective actions and preventive measures in both cases and ensure senior management

leadership and oversight. The IMT were convened at 09:00h on Friday 30th June. The IMT consisted of [senior leader and senior medical, commercial, compliance and legal employees]. The IMT further required the withdrawal of all promotional material, beyond the GSKPro website, which contained the additional claims at issue and appointed [a senior medical employee] , as an independent lead for the IMT investigation and actions. The IMT asked [this senior medical employee] to form a team to ensure the following:

1. Assess any remaining Trelegy materials that had not yet been identified as being at issue, to reassure the IMT that this was an isolated issue and that there were no further claims to cause concern.
2. Conduct a thorough root cause analysis and identify Corrective and Preventive Actions.
3. Manage the responses to the PMCPA.
4. Consider if any action was required, to confirm that this issue does not extend into teams outside of the Trelegy team.
5. Consider how to approach business continuity and provide signatory resource, to allow some business continuity, without relying on the signatories who approved the claims at issue, until investigation and remediation is in place.

On Monday, 3rd July, the [senior medical employee] initiated and briefed the following workstreams:

1. Management of Immediate Response:
 - A senior GSK employed signatory from outside of the business unit and who was not involved in the complaints, to review remaining materials in circulation and confirm no additional risk / misleading claims were in circulation.
2. Root Cause Analysis: Review of the Internal Control Framework (ICF):
 - Thorough review of the ICF that governs promotional materials
 - Assess the effectiveness of the ICF across the business:
 - confirm that training and validation of signatories had been conducted as required in the ICF
 - review core promotional campaign for each priority product in all other business units, (for speed, this was limited to a review of claims, not a review of technical aspects of code compliance or materials execution), specifically to identify any similarly misleading or un-substantiable claims and in their absence, reassure GSK that the issue was limited to the Trelegy team.
3. Root Cause Analysis: Deep Dive on Judgement and Decision Making in the Trelegy Team
 - Understand decision making and judgement – conducting a deep dive on timelines for decision making and judgement in both cases: to understand

who made what decision, who else was involved, identify any disagreement and how it was dealt with, and understand any escalations made / not made.

The output of these workstreams is detailed below. However, it is of note that a further complaint, Case AUTH/3792/7/23, was received by GSK on 5th July at 10:32h concerning a GSK Trelegy payor / commissioner promotional website (value.gsk) and at 14:30h, the review of remaining Trelegy promotional materials flagged a further use of a misleading claim ‘...vs an ICS/LABA...’ that was inappropriate and should not be in use. Whilst Case/AUTH/3792/7/23 was not concerning similarly misleading or un-substantiated claims, taken together with the finding of further claims of concern in remaining materials, [a senior commercial employee] made an immediate decision to require the suspension of the value.gsk website (this was actioned and confirmed by the close of the same day) and to discuss next steps with the [senior leader]. By 09:30h on Thursday 6th July, the [senior commercial employee] and [senior leader] had concluded that GSK no longer had confidence in the full set of respiratory promotional materials, and so requested the recall of **all** active materials utilised throughout the wider respiratory team, recognising the significant business impact of such a severe action, but also recognising the need to ensure control of our promotional compliance with the Code. Whilst Case AUTH/3792/7/23 will be the subject of a separate response, it is important to note that all further actions taken by GSK take account of the broader impact of that case, case AUTH/3781/6/23 and case AUTH/3785/6/23.

On Friday 7th July, the findings of the work-streams were reported back and these were then discussed at a further meeting of the IMT on Monday 10th July, to agree further remediation activities and how to respond to the PMCPA. The findings of the root cause analysis and the agreed remediation activities are detailed below.

GSK root cause analysis – Framework of Controls

As mentioned above, GSK has worked urgently and diligently to thoroughly review all relevant existing procedures and controls that are in place: the ICF. GSK believes the ICF to be robust and industry leading in its comprehensive approach. We also attach the GSK UK copy approval SOP, (a part of the ICF), in which all signatories must follow. The copy approval SOP has been updated several times and incorporates findings of breaches from previous complaints where possible. GSK do recognise that Copy Approval Management Monitoring (CA MM) was reduced in the time leading up to certification and release of the materials at issue. The decisions relating to the reduced CA MM, as discussed in [the ICF], were made based on no findings for some time, and so GSK believe that at the time, this was a reasonable use of resource. GSK acknowledge that CA MM may have caught the claims at issue in this complaint, however we also recognise that they may not have (only a percentage of work is ever reviewed in any management monitoring). GSK also recognise that MM is not a requirement of the Code, but a step over and above usual requirements, and so do not believe that the temporary reduction in CA MM detracts from the comprehensive nature of our ICF nor constitutes a breach of the ABPI Code.

GSK was also reassured to find that our review of leading campaign materials from other business units, whilst highlighting some areas for improvement, did not identify any claims of a similarly misleading or un-substantiable nature. We were also reassured to find that the medical signatories who certified the promotional material that was subject to the

complaint, had undertaken all required training, validation, and continuing development through attendance at the required ABPI Code update forums.

GSK believe that the findings of our thorough review of the existence and operation of the ICF provides reassurance that the ICF is working as intended and that the issues that have led to the current complaints are isolated within a particular team, in the presence of a set of unique circumstances, as explained below.

Understand decision making and judgement

GSK acknowledges that the decision to allow the use of this claim was misguided, in the face of a competitive commercial environment and an attempt to make the Trelegy promotional campaign more patient-focussed. We believe that the team made a genuine attempt to deliver a patient-focussed and engaging campaign, however they were let down by their judgement. In our analysis, GSK has identified a few reasons for this:

- The Business Unit (BU) Leadership team (LT) had set a tone for a new ambition of innovation and for a rapid turnaround of content. The team was not optimally resourced in terms of ABPI Code signatories to be able to do this, with an over-reliance on short-term contractors.
- There were varied levels of experience among signatories. None of the line managers of the medical signatory team were signatories, nor were they experienced with the ABPI Code.
- The signatories responsible for the material sought input from a variety of individuals with more Code experience, however the formal route of escalation was not followed and therefore those giving advice, did so informally and without necessarily having all the operational and background details available
- The team did consider various available sources of information, including for example the copy approval and animal welfare policies etc when making their decisions. However, they took these individual, separate components of information and wrongly concluded that they were okay to proceed, without formal escalation.
- The team captured their understanding of the risks involved, and mitigations for those risks in a document [internal consideration log], and they believed that the nature of the proposed claim was widely known, risks understood and potential defence against complaints was established.
- There was pressure to deliver on time, and to step up and be innovative, but there was no pressure to cut corners. The medical signatory for the claim is clear they did not feel pressured into approving it.

Corrective and Preventative Actions

[GSK provided detailed corrective and preventative actions, which have been removed from the case report]

Summary

With regards to the claim 'Trevor trusts Trelegy' GSK acknowledge that it could not be substantiated that an animal trusts a medicine and thus, acknowledge breaches of clause

6.1 and 6.2 of the Code. We also acknowledge that this is not of the standard that we would expect of a claim and acknowledge a breach of clause 5.1 of the Code.

With regards to the use of the spoken phrase, 'there is life in this old dog yet...' within the video, GSK do not believe that the phrase, as used, constitutes a mortality claim about a medicine, but that it supports a patient-centred and engaging way to refer to the impact of quality of life. GSK denies any breach of clause 6.1, 6.2, 5.1 and 2 of the Code with regards to the use of this phrase.

Following the robust actions GSK has taken, that are detailed above, GSK is confident that the issues concerning judgement and execution of the concept, that is the basis of the claim in the complaint, is isolated within a specific team (the General Medicines respiratory team) due to a specific set of circumstances, rather than a widespread occurrence across the UK affiliate. The team in question has had inadequate full-time GSK employee signatory support, leading to a forced reliance on multiple short-term contractors for sign off.

The commercial team has also had recent personnel changes, adding further to the disruption. While GSK acknowledges that this does not absolve it of blame and that it is responsible for the actions of all its staff, we believe that the overall standard of materials across the rest GSK, is of as high a standard as can be expected. Despite this, GSK takes its responsibility extremely seriously when we are made aware of any issues and have acted urgently, proactively, and ethically, to remove the claims at issue, investigate and rectifying them. We believe our actions as described above demonstrate this.

We are also confident that the processes and internal structure within GSK are robust enough to maintain a high standard of compliance and governance, with respect to the ABPI Code of Practice, UK regulations and the law, as evidenced by the actions we have undertaken.

GSK believes that a breach of clause 2 is, and should be, reserved for special sanction when fundamental flaws in the inner workings of a company, including deliberately deceptive behaviour or actions are identified or, crucially, when there is a significant risk to patient safety, which we strongly do not believe to be the case here. While acknowledging that the claim in the complaint is not up to what we would consider a high enough standard, GSK firmly believes that we do not have a fundamental issue with our processes and controls. We therefore deny a breach of clause 2.

Additional Information

The signatory who certified the webpage at issue in Case AUTH 3785/6/23 is [details provided]."

PANEL RULING

The Panel noted the promotional page at issue appeared to be the homepage of the Trelegy Ellipta (Fluticasone furoate, umeclidinium, vilanterol) section of the GSK Pro website.

The Panel considered the layout of the page and noted that the Trelegy Ellipta section contained subsections accessed by tabs at the top of the webpage which were labelled "Home",

“Clinical Data”, “Trelegy Patient”, “Molecules”, “Dosing and Device”, “Cost”, and “Safety Data”. At the top was an image of a male COPD patient with a dog sitting on his lap. Inside the image, in a box and in large prominent font was the claim “Trevor trusts Trelegy*”. Immediately below, in a smaller font, was the statement “*But Trevor is only a dog that wants walkies! Consult our data to see why ^{1,2}” followed by a tab linking to the health-related quality of life (HRQOL) data. Beneath this was a section titled “Meet David and Trevor. Does the impact of David’s COPD remind you of patients you see?” followed by the indication for Trelegy.

Underneath was an embedded promotional video one minute, 53 seconds long, and tabs linking to exacerbation data, lung function data and safety data. The video was about David and his life with his dog, Trevor. David described the impact using Trelegy had on his quality of life. Towards the end of the video David states “we may be older and greyer than we used to be, but there’s life in this old dog yet”. A disclaimer on the screen stated “results may vary”. The video ended with an image of Trevor sitting on David’s lap next to the “Trevor trusts Trelegy Ellipta” claim and information:

“Trevor trusts Trelegy Ellipta*

fluticasone furoate/umeclidinium/vilanterol

*But Trevor is only a dog that wants walkies! Consult our data to see why.1.2

1. Lipson DA et al. AM J Crit Care Med 2017 ; 196:438-446
2. Lipson DA et al. N Engl J Med 2018; 378:1671-1680”

The Panel accepted GSK’s submission that the concept behind the campaign was to use dog-walking as a proxy for normal activities of daily living, to give a more human and engaging way of portraying improvements in health-related quality of life. While the Panel understood the attraction of creating a patient-focused and memorable campaign it was important that companies did not lose sight of the requirements of the Code for claims to be balanced, fair, objective, unambiguous and not misleading, and be capable of substantiation.

“Trevor trusts Trelegy”

The complainant alleged that the claim was misleading and not capable of substantiation as there was no data or evidence to support that patients trusted Trelegy as “trust” had not been a primary endpoint in any studies and that if the claim related to use of Trelegy in the dog it was also misleading as, similarly, there was no evidence to support animals trusting Trelegy and the product was only licensed for human use.

The Panel considered the immediate and overall impression created by the webpage to a busy health professional. The Panel noted the claim at issue and its qualifying statement appeared in large prominent font at the top of the homepage. GSK submitted that internal discussions, prior to the approval of the materials, had commented on the ambiguity of the claim in order to engage health professionals and make them question whether Trevor was the human or the dog. The Panel noted that in the final execution of the material it was clear that Trevor was the dog, but nonetheless, it was not clear from the webpage as a whole why Trevor trusted the medicine. On balance, the Panel considered the claim was ambiguous and thus was misleading and not capable of substantiation. The Panel therefore ruled **breaches of Clauses 6.1 and 6.2** as acknowledged by GSK.

“There’s life in this old dog yet”

The complainant alleged that use of the phrase “there’s life in this old dog yet” in the video was misleading as Trelegy did not extend life expectancy and that there was no data to support such

a claim. In the video an actor portrayed the role of a COPD patient, describing what it meant to him to walk his dog. The Panel noted the full statement included in the video “We may be older and greyer than we used to be but there’s life in this old dog yet”. The video illustrated how David’s COPD symptoms impacted his daily life and his ability to undertake activities like walking his dog. David was then shown using Trelegy after having a discussion with his nurse about how he was feeling. The video ended with shots of David walking his dog, Trevor, with the claim as a voiceover. The final frame showed David in an armchair with Trevor on his lap and the claim “Trevor trusts Trelegy to keep his walkies on track”. The Panel agreed with GSK that the phrase was an established colloquialism in common usage. The Panel considered that how the phrase had been used in the video was highly unlikely to be misinterpreted as a claim that Trelegy could extend life expectancy as alleged. The Panel did not consider that the phrase constituted a claim about a medicine and therefore ruled **no breaches of Clauses 6.1 and 6.2**.

The Panel noted its comments above regarding GSK’s submission that an internal document indicated there was deliberate ambiguity with regards to whether Trevor was the dog or human. The Panel was concerned that despite the suitability of the “Trevor trusts Trelegy” claim being called into question it appeared that, beyond making it clear in the final execution that Trevor was a dog, there were no further discussions about whether the claim was misleading or could be substantiated. In this regard the Panel considered that GSK had failed to maintain high standards and ruled **a breach of Clause 5.1**, as acknowledged by GSK.

Clause 2 was a sign of particular censure and was reserved for such use, The Panel recognised that GSK had conducted a thorough investigation in response to this complaint and had put corrective and preventative measures in place. The Panel considered that the matters raised in this complaint were adequately covered by its rulings of breaches of the Code above therefore that a breach of Clause 2 was not warranted. The Panel ruled **no breach of Clause 2**.

Complaint received **27 June 2023**

Case completed **22 October 2024**