CASE/0360/11/24

COMPLAINANT v ASTRAZENECA

Allegations about a Trixeo promotional video

CASE SUMMARY

This case was in relation to a promotional video which was hosted on an AstraZeneca website. The video featured a health professional sharing their experience of Trixeo, including how they initially started to prescribe it in 2022, how their confidence had grown over time, the positive patient responses they had received, and the positive impact of Trixeo on one of their patients.

The complainant made several allegations relating to: use of the terms "new" and "best", promotion of Trixeo in a manner that was not in accordance with the terms of its marketing authorisation, a lack of balance, and inadequate briefing and approval of the material.

The outcome under the 2024 Code was:

Breach of Clause 5.1 (x3)	**Failing to maintain high standards**
Breach of Clause 6.1	**Making a misleading claim**
Breach of Clause 14.4	**Not encouraging the rational use of the medicine**

No Breach of Clause 2 (x2)	**Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry**
No Breach of Clause 5.1 (x2)	**Requirement to maintain high standards at all times**
No Breach of Clause 6.5 (x2)	**Requirement for the word 'new' to not be used to describe any product or presentation which has been generally available, or any therapeutic indication which has been promoted, for more than twelve months in the UK**
No Breach of Clause 11.2	**Requirement not to promote a medicine for an unlicensed indication**

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

FULL CASE REPORT

A complaint about AstraZeneca UK Limited was received from an anonymous complainant who described themselves as a health professional and later became non-contactable.

COMPLAINT

The complaint wording is reproduced below with some typographical errors corrected:

> "A video which is promoting Trixeo using a nurse is not compliant. The nurse [named health professional] has completed a video which can be found at; [URL provided] [material identification code and date of preparation]. At 10 seconds, the nurse says that Trixeo is a new therapy. The word "new" cannot be used to describe Trixeo considering Trixeo has been available for more than 12 months. The new inhaler term is repeated again at 1 minute 47 seconds. This is a direct breach of clauses 6.5 and 5.1 At 1 minute 18 seconds, the nurse says that Trixeo was started following a patients recovery from a heart attack. Trixeo is not licensed for this purpose. This is a breach of clauses 11.2 and 5.1 and 2. At 1 minute 33 seconds, the nurse describers Trixeo as the best inhaler. This is an exaggeration and the use of the term best is a superlative. This is a breach of clauses 14.4 and 5.1. Not a single aspect of safety considerations or side effects are discussed in this video. The video is overly positive about Trixeo and is therefore unbalanced without any discussion of safety. This is a breach of clause 6.1 and 5.1 and 2 as the material is sufficiently incomplete and risks patient harm. It is shocking to see that such a video had been approved and released considering the code parameters had been broken. The briefing for the nurse in the video was clearly inadequate, this is a breach of clause 5.1. Astrazeneca have had several breaches around Trixeo in recent times so it is very shocking to see more uncompliant material. This demonstrates lack of respect for self regulation obligations."

When writing to AstraZeneca, the PMCPA asked it to consider the requirements of the following clauses of the 2024 Code:

- Clauses 6.5 and 5.1 in relation to use of the word 'new'.
- Clauses 11.2, 5.1 and 2 in relation to the alleged use of Trixeo for an unlicensed indication.
- Clauses 14.4 and 5.1 in relation to the alleged use of a superlative ('best').
- Clauses 6.1, 5.1 and 2 in relation to the matters of content and balance of the video raised by the complainant.
- Clauses 5.1 in relation to alleged inadequacy of the briefing for the nurse.

ASTRAZENECA'S RESPONSE

The response from AstraZeneca is reproduced below:

> "We are writing to you in response to your letter dated 18 November 2024, concerning a complaint from a healthcare professional (HCP) with respect to a Trixeo promotional video on an AstraZeneca (AZ) owned website.
>
> The complainant's allegations can be broken down as follows:
>
> 1. Video states that Trixeo is a new therapy, but Trixeo has been available for more than 12 months (10s and 1m47s).
> 2. Video states that Trixeo was started following a patient's recovery from a heart attack. Trixeo is not licensed for this purpose.
> 3. Trixeo is described as the best inhaler (1m33s), which is an exaggeration and use of superlative.

4. No safety considerations or side effects are discussed in this video. The video is overly positive about Trixeo and is therefore unbalanced without any discussion of safety. Briefing for the nurse must not be robust given the number of issues with the video.
5. Shocking to see this video has been approved given a number of compliance issues. AZ has lack of respect for self-regulation obligations.

AstraZeneca have been asked to consider clauses 2, 5.1, 6.1, 6.5, 11.2 and 14.4 of the 2024 ABPI Code ('the Code'). We will address each of the complainant's allegations according to the relevant clauses.

Background

This video (Using Trixeo in Clinical Practice with [named health professional], [material identification number]) is hosted on an AZ website. This website hosts several educational resources for nurses, including videos of nurses recounting their experience using Trixeo in practice. This complaint is referring to one of these videos. The title of this video is 'using Trixeo in your clinical practice – [named health professional] experience' and is clearly subtitled '[named health professional] speaks about [their] experience of using TRIXEO in clinical practice and shares a patient case study', ensuring that the purpose of the video is clear from the outset.

HCPs have been directed to this website via an e-mail link sent to delegates following a National Nurse meeting. Each component of this website has been individually reviewed and certified by an experienced Nominated Signatory, including each of the videos. The Nominated Signatory who certified this video is registered with [named regulatory body].

The website includes a single-click, direct link to the Trixeo prescribing information (PI) at the top of the page: [screenshot provided of the webpage where the video was hosted]

AstraZeneca Response to the Allegations

1. *Video states that Trixeo is a new therapy, but Trixeo has been available for more than 12 months (10s and 1m47s).*

   There are 2 instances where 'new' is used in relation to Trixeo in the video.

   Firstly, at 10s, the speaker states '*So I started using Trixeo in about 2022, in quite small quantities at first. Being a new therapy, I think a clinician can be a bit nervous about using something that's different*'. Trixeo was launched in the UK in early 2021 on so it was appropriate to use the term 'new' in relation to Trixeo at the beginning of 2022 (within first 12 months post launch). It is very clear that the HCP is referring to Trixeo being a new therapy in 2022 when [they] starting [sic] using it in this context, versus the time of recording.

   Secondly, at 1m47s, the HCP states '*when the patient attends, and they've had a real positive impact from having a new inhaler*', the HCP is clearly referring to the medicine being new to the patient rather than being new to the market.

Therefore, the word 'new' is used appropriately in this instance, and we do not consider there has been a breach of the Code in relation to this allegation. Therefore, we refute the breach of clauses 6.5 and 5.1.

2. *Video states that Trixeo was started following a patient's recovery from a heart attack. Trixeo is not licensed for this purpose.*

   The HCP states at 0m46s: '*During a routine outpatient review of a COPD patient, a gentleman came in following a hospital discharge, and he'd actually attended with a heart attack. He had a history of COPD that had been poorly managed in the past and he was a current smoker at the time*'. The HCP has mentioned the heart attack to provide further context to the patients' clinical history rather than suggesting that Trixeo has been used to treat the heart attack. To reiterate, the video states '*During a routine outpatient review of a COPD patient*,... *he'd attended [with] a heart attack'.* Therefore, it is clear in the video that Trixeo had been initiated to treat the patient's COPD, and not to treat the heart attack.

   AZ maintains that Trixeo has not been discussed off license in this video and therefore we do not agree that there has been a breach of the Code related to this allegation. We strongly refute a breach of clause 11.2 of the Code and consequently deny a breach of clauses 5.1 and 2.

3. *Trixeo is described as the best inhaler (1m33s), which is an exaggeration and use of superlative.*

   The speaker states: '*…now some of those improvements are multifactorial, but Trixeo has had an impact on his life, and he swears that it's the best inhaler that he's ever experienced*'. The statement that Trixeo is the 'best inhaler' is clearly a reflection of what the HCP has been told about a patient experience with using the medicine. It is clear that this statement is not intended to be a broad factual claim about Trixeo's relative clinical benefit versus any other medicine, but simply a patient's lived experience about using Trixeo.

   AstraZeneca understands the specific issue around the use of superlatives, but as this is being used in the context of one patient's own experience, we do not consider this to be a breach of the Code. Therefore, we refute the breach of clauses 14.4 and 5.1 of the Code.

4. *No safety considerations or side effects are discussed in this video. The video is overly positive about Trixeo and is therefore unbalanced without any discussion of safety*.

   The title of this video is 'using Trixeo in your clinical practice – [named health professional] experience' and is clearly subtitled '[named health professional] speaks about [their] experience of using TRIXEO in clinical practice and shares a patient case study'. It is clear to the viewer, therefore, that Trixeo would be discussed in the context of their experience with using Trixeo. It is not accurate that the video is 'overly positive' or unbalanced for Trixeo. The HCP is reflecting on their own experience of using this medicine for their patients.

We maintain that safety information was not relevant for this video as it is simply reflecting on HCP experience with Trixeo. HCPs treating COPD patients are aware that they would need to determine whether Trixeo is right for their patients by seeking further information before prescribing via the Prescribing Information (PI) and the Summary of Product Characteristics (SmPC). There is a clear statement at the beginning of the video alerting the viewer to location of the Trixeo PI, which is located at the top of the webpage as a single click link where the video is hosted. The PI has a prominent statement at the top **'Consult Summary of Product Characteristics before prescribing'**.

Based on this, we ascertain that there has been no breach of clause 6.1 of the Code regarding this statement.

5. *Briefing for the nurse must not be robust given the number of issues with the video.*

   The speaker was briefed properly on the purpose and content of the video. The background, objective, discussion points and special considerations are clearly laid out and thus is a robust briefing. In addition, the final recorded video was reviewed and certified by a Nominated Signatory before it made available to HCPs to view.

   AstraZeneca has maintained high standards by ensuring that an appropriate briefing was approved for this activity, and therefore deny that there has been a breach 5.1 of the Code.

6. *Shocking to see more uncompliant material. This demonstrates lack of respect for self-regulation.*

   Given the explanation provided above, we do not agree that this is an uncompliant material. It is an HCP sharing their experience of using Trixeo which is entirely appropriate and valuable for other HCPs to hear.

   AZ takes it's responsibilities under the Code very seriously and values the importance of self-regulation. We do not believe this video demonstrates that AZ has lack of respect for self-regulation obligations.

Summary of AstraZeneca's position

In summary:

- The word 'new' is used appropriately in relation to Trixeo.
- Trixeo has been promoted in accordance with the license.
- Use of the phrase 'best inhaler' is used in the context of one patient's feedback.
- This video is complete for its intended purpose and does not pose any risk to patient safety.
- HCP had been appropriately briefed and the video certified by a Nominated Signatory before being made available to HCPs.

AstraZeneca takes its responsibilities under the Code very seriously. Based on the above detailed response, we maintain that the video is appropriately reflecting on HCP

experience using Trixeo, **we refute breach of clauses 2, 5.1, 6.1, 6.5, 11.2 and 14.4 of the Code.**"

PANEL RULING

This case was in relation to a short promotional video (2m16s) titled "Using Trixeo In Your Clinical Practice", which was hosted on an AstraZeneca website among other similar resources featuring health professionals sharing their experiences of Trixeo. The video was subtitled "[named health professional] speaks about their experience of using TRIXEO in clinical practice and shares a patient case study". The health professional described their experience of using Trixeo, including how they initially started to prescribe it in 2022, how their confidence had grown over time, the positive patient response received, and the positive impact of Trixeo on one of their patients.

The Panel noted that the video was a Trixeo promotional item for which AstraZeneca was responsible under the Code. It was well-established that if companies' materials, within the scope of the Code, contained interviews with patients or health professionals, such published interviews should comply with the Code and the pharmaceutical company would be responsible for their content. To permit otherwise would allow companies to circumvent the requirements. The Panel noted that AstraZeneca had complete editorial control over the content of the video.

The complainant made several allegations which the Panel considered in order:

1) Use of the term "new"

The complainant alleged that the health professional's references to Trixeo as a "new therapy" and "new inhaler" were misleading, given that Trixeo had been available for more than 12 months.

The health professional's first reference to "new" in the video was: "*So I started using Trixeo in about 2022, in quite small quantities at first. Being a **new therapy*** (emphasis added by Panel*), I think a clinician can be a bit nervous about using something that's different"*.

AstraZeneca submitted that Trixeo was launched in the UK in early 2021 and it was therefore appropriate to use the word "new" at the beginning of 2022, within 12 months of the product being launched.

The health professional's second reference to "new" followed a brief COPD patient case study and was: *"when the patient attends, and they've had a real positive impact from having a **new inhaler**"* (emphasis added by Panel).

AstraZeneca submitted that the health professional was referring to the medicine being new to the patient rather than being new to the market.

The Panel considered, in both instances, that the word "new" was not being used to suggest Trixeo was newly available at the time the video was recorded or published. The Panel considered it clear that:

1. the first reference related to Trixeo being new to the clinician when they first used it in 2022, and
2. the second quote related to Trixeo being new to a patient.

The Panel ruled **no breach of Clause 6.5** in relation to each mention of the term "new". It therefore followed the complainant had not established that AstraZeneca had failed to maintain high standards in this regard and **no breach of Clause 5.1** was ruled.

2) Reference that Trixeo was started following a patient's recovery from a heart attack

The complainant alleged that Trixeo was not licensed as described by the health professional, following a patient's recovery from a heart attack:

> "*During a routine outpatient review of a COPD patient, a gentleman came in following a hospital discharge, and he'd actually attended with a heart attack. He had a history of COPD that had been poorly managed in the past and he was a current smoker at the time. The gentleman was very, very unwell during the admission, and made a remarkable recovery. He managed to stop smoking, and his cardiologist, recognising the cardiopulmonary risk, put him on Trixeo*".

The Panel took account of Section 4.4 of Trixeo's summary of product characteristics (Special warnings and precautions for use (Cardiovascular effects)), which included a caution for use in patients with clinically significant uncontrolled and severe cardiovascular disease, including acute myocardial infarction. The Panel queried whether the case study was sufficiently qualified in this regard.

Nonetheless, the Panel considered the video described a patient with a history of a heart attack that was initiated on Trixeo by a cardiologist in view of their poorly managed COPD and cardiopulmonary risk. In the broader context of the video, it was clear that Trixeo was being promoted for COPD. The Panel concluded it had not been established that Trixeo was promoted in a manner that was not in accordance with the terms of its marketing authorisation or inconsistent with the particulars listed in its summary of product characteristics. The Panel therefore, on the narrow allegation before it, ruled **no breach of Clause 11.2.** In the absence of any other allegations in this regard, it followed that the Panel ruled **no breach of Clauses 5.1 and 2**.

3) Use of the term "best"

The complainant alleged that the health professional's description of Trixeo as "the best inhaler" was an exaggeration and constituted the use of a superlative, in breach of the Code.

The health professional continued to discuss the patient from Allegation 2 and stated:

> "*And I can only describe him as bouncing into clinic. He was delighted. Now, some of those improvements are multifactorial but Trixeo has had an impact on his life and he swears that it's the best inhaler he's ever experienced*".

AstraZeneca's submitted the statement clearly reflected a patient's own feedback and was not intended to be a broad factual claim about Trixeo's relative clinical benefit versus any other medicine; it was a patient's lived experience about using Trixeo.

Clause 14.4 required:

> "*Promotion must encourage the rational use of a medicine by presenting it objectively and without exaggerating its properties. Exaggerated or all-embracing claims must not*

be made and superlatives must not be used except for those limited circumstances where they relate to a clear fact about a medicine. Claims should not imply that a medicine or an active ingredient has some special merit, quality or property unless this can be substantiated."

While the Panel acknowledged reference to Trixeo as "the best inhaler" was made in relation to one patient's experience, it nonetheless appeared within promotional material for Trixeo, which was the only medicine mentioned.

It was an established principle that individual patient cases in promotional material must not be misleading or exaggerate a medicine's properties.

The Panel concluded that the statement "*Trixeo has had an impact on his life and he swears that it's the best inhaler he's ever experienced"* included a superlative ("best"), exaggerated Trixeo's properties and implied some special merit or superiority over other inhalers without substantiation. The Panel ruled a **breach of Clause 14.4**.

The complainant cited a breach of Clause 5.1 in relation to the exaggerated claim. The Panel considered that AstraZeneca had complete editorial control over the final video prior to certification and publication, and was responsible for its content. The Panel therefore concluded that the failure to identify and address the claim at issue in the video meant that AstraZeneca had failed to maintain high standards. The Panel ruled a **breach of Clause 5.1**.

4) Lack of safety considerations or side effects

The complainant alleged that the video was overly positive about Trixeo and unbalanced, as it did not include any safety considerations or side effects.

AstraZeneca submitted that the title and subtitle to the video made clear to the viewer that Trixeo would be discussed in the context of their own clinical experience. AstraZeneca further submitted that safety information was not relevant and that the video, along with the webpage, included a prominent statement referring to the prescribing information.

Clause 6.1 required information and claims to be balanced and fair, and that material must also be sufficiently complete to enable recipients to form their own opinion of the therapeutic value of the medicine. It was a well-established principle of the Code that promotional material must stand alone and not rely on qualification in the prescribing information.

The Panel considered the video was promotional material for Trixeo, directed at health professionals, and only described the positive patient outcomes and merits of Trixeo, without reference to its safety profile. In the Panel's view, the video was not sufficiently balanced nor complete to enable recipients to form their own opinion of the therapeutic value of the medicine. The Panel therefore ruled a **breach of Clause 6.1**.

The Panel observed that the video presented only favourable outcomes with Trixeo and that it lacked a balance of safety information. In particular, the Panel noted its comments above (Allegation 2) that the promotional video endorsed the use of Trixeo in a patient with a previous heart attack, without sufficient qualification that acute myocardial infarction might be a caution, as per the "Special warnings and precautions for use" section of its summary of product characteristics. The Panel concluded that the undue emphasis on the positive response with Trixeo, without sufficient qualification and balance, was such that high standards had not been maintained and a **breach of Clause 5.1** was ruled in this regard.

The Panel recognised that Clause 2 was a sign of particular censure for cases where a company had brought discredit upon, or reduced confidence in, the pharmaceutical industry. While the Panel considered it essential that health professionals be able to rely on materials produced by companies to be complete, the Panel concluded that its ruling of a breach of Clause 5.1 adequately covered the matter and that the circumstances of this allegation did not warrant an additional breach ruling. The Panel therefore ruled **no breach of Clause 2**.

5) Approval of the video and inadequate briefing

The complainant stated it was "shocking" that the video had been approved and published, and that the briefing for the health professional "was clearly inadequate".

The Panel reviewed the briefing document which set out the objectives, discussion points and special considerations, along with filming and technical guidance. AstraZeneca submitted that the final video was certified prior to publication. The briefing instructed the health professional to not mention side effects for any specific product and to not criticise other company's medicines.

The Panel noted the briefing document provided broad sample interview questions, such as those exploring rationale for the health professional's clinical decision making and patient experience. While these questions would guide the health professional on expected topics, the Panel noted that the briefing document contained no information on the requirements and principles of the Code, such as the need for information to be balanced or to avoid the use of superlatives and exaggerated claims. Of particular concern, there was no inclusion of safety considerations, such as ensuring information presented was well qualified and not inconsistent with Trixeo's summary of product characteristics.

In particular, one of the listed questions invited the health professional to discuss the role cardiopulmonary risk plays when managing COPD patients. The Panel queried whether this warranted additional guidance to ensure that any such discussion was appropriately qualified in line with the cardiovascular considerations set out in Trixeo's summary of product characteristics.

The Panel considered that it was particularly important to be clear about the quality standards in the Code if a health professional was invited to discuss their personal experience. The Panel did not consider that the written briefing overall was sufficiently clear and detailed such that the health professional would understand the relevant requirements of the Code. The health professional had subsequently made a number of strong statements that were not qualified.

In relation to the briefing provided to the health professional, and taking into account that AstraZeneca had editorial control prior to publishing the promotional video, the Panel considered that in the circumstances of this case, AstraZeneca had failed to maintain high standards. The Panel therefore **ruled a breach of Clause 5.1**.

Complaint received **14 November 2024**

Case completed **4 November 2025**