CASE/0355/11/24

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 patient experience and the impact of improved quality of life.

The complainant made several allegations relating to: the use of hanging comparisons, misleading claims that were not capable of substantiation, the failure to mention a side effect, lack of safety discussion and balance, and inadequate briefing.

The outcome under the 2024 Code was:

Breach of Clause 5.1 (x2)	**Failing to maintain high standards**
Breach of Clause 6.1 (x3)	**Making a misleading claim**
Breach of Clause 6.2	**Making an unsubstantiated claim**

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 6.1 (x4)	**Requirement that information/claims/ comparisons must not be misleading**
No Breach of Clause 6.2 (x3)	**Requirement that information/claims/comparisons must be capable of substantiation**

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 a contactable 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 promotional Trixeo video [material identification code and date of preparation] titled Using Trixeo in Clinical Practice with [named health professional] who is a respiratory Nurse is in direct breach of the ABPI code. The video can be viewed at – [URL provided]. The issues with the video are as follows:
>
> 1. At 9 to 13 seconds in the video, the nurse refers to the Ethos study data and says the study provides evidence for reduction in exacerbations. However, this is a hanging comparison as there is no reference to what the reduction in exacerbation is against. Secondly, in the Ethos study, the secondary endpoint which looked at reduction vs a LABA/LAMA pMDI in terms of rates of severe exacerbations was NOT significant and therefore what the nurse says is factually incorrect. The nurse has made a broad claim around exacerbations reductions which is misleading and unqualified. There are breaches of clauses 6.1 and 6.2 of the ABPI code.
>
> 2. The Ethos study did not look at mild exacerbations but the video does not mention this anywhere. This is misleading as exacerbations could include mild, moderate or severe. This is a breach of clause 6.1 and 6.2
>
> 3. From 21 seconds to 25 seconds in the video, the nurse discusses patient feedback and claims there is better improved quality of life on Trixeo and a pattern of no further exacerbations. This is misleading as there is no primary endpoint clinical data around Trixeo that confirms improved quality of life or that there would never be any exacerbations as a result of using trixeo. This part of the video is also a breach of clause 6.1, 6.2.
>
> 4. At 52 to 54 seconds, the nurse mentions cardiopulmonary risk. However, [they] fail to mention that Trixeo has a common side effect of palpitations. This is a breach of clause 6.1 as the material is insufficient so a viewer cannot form their own opinion of the therapeutic value of Trixeo.
>
> 5. There is not any discussion about safety data around the product in the video. The entire video is overly positive and is not balanced. This is a patient safety risk. Breach of clauses 6.1 and 5.1.
>
> 6. The briefing provided to the nurse for this video cannot be robust considering the number of issues with the video. This is a breach of clauses 5.1.
>
> 7. In conclusion, the video is not compliant and is unbalanced, does not properly reflect the data. This video should have been challenged by the signatory. As a result of points 1-6 raised above, clauses 5.1 and 2 are also in breach as a HCP has been utilised for producing a misleading video."

When writing to AstraZeneca, the PMCPA asked it to consider the requirements of the following Clauses of the 2024 Code in relation to each of the matters raised by the complainant:

- Clauses 6.1 and 6.2 in relation to each of matters 1, 2, and 3.

- Clause 6.1 in relation to matter 4.
- Clauses 6.1 and 5.1 in relation to matter 5.
- Clause 5.1 in relation to matter 6.
- Clauses 5.1 and 2 in relation to matter 7.

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.
    a. Nurse in the video states that Ethos study reduced exacerbations, however this is a hanging comparison as there is no reference to what the reduction in exacerbations is against (9-13s).
    b. In the Ethos study the secondary endpoint which looked at reduction vs LABA/LAMA pMDI in terms of severe exacerbations was not significant and therefore what is said in the video is factually incorrect.
2. Ethos study did not include mild exacerbations, but this is not mentioned in the video.
3. Nurse claims better quality of life and a pattern of no further exacerbations as a result of using Trixeo. This is misleading as there is no primary endpoint in the clinical data for Trixeo about quality of life, nor does it suggest Trixeo leads to no further exacerbations (21-25s).
4. Cardiopulmonary risk mentioned, but side effect of palpitations for Trixeo not mentioned (52-54s)
5.
    a. No discussion of safety data.
    b. Video is overly positive for Trixeo and unbalanced, which poses a patient safety risk.
6. Briefing for the nurse must not be robust given the number of issues with the video.
7. The video does not properly reflect the data and should have been challenged by the Nominated Signatory.

AstraZeneca have been asked to consider clauses 2, 5.1, 6.1 and 6.2 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 clinician], [material identification number]) is hosted on an AZ website [URL provided]. This website hosts several educational resources for nurses, including videos of nurses recounting their experience of 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. The purpose of the video was not to discuss the details of ETHOS study.

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 approved this video is registered with the [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 promotional AstraZeneca website on which the video in question was hosted].

AstraZeneca Response to the Allegations

1.

a. Nurse in the video states that Ethos study reduced exacerbations, however this is a hanging comparison as there is no reference to what the reduction in exacerbations is against (9-13s).

When the HCP mentions that the ETHOS study '*shows that there is support in reduction of exacerbation rates*', there is a statement in top left-hand corner of the screen '*Triple therapy may be considered for patients inadequately controlled on dual therapy*' . [screenshot showing the statement in top left-hand corner of the video]

This clearly shows that triple therapy is initiated after the patient has been on dual therapy, and therefore the reduction in exacerbation rate seen after initiation of triple therapy will be in comparison to their past dual therapy treatment. In addition, the nurse has used the language *'support with reduction'*, which is not comparing Trixeo to another product.

We do not accept, therefore, that this is a hanging comparison and deny a breach of clauses 6.1 and 6.2 of the Code in relation to this allegation.

b. In the Ethos study the secondary endpoint which looked at reduction vs LABA/LAMA pMDI in terms of severe exacerbations was not significant and therefore what is said in the video is factually incorrect.

The only reference to the ETHOS study in the video is '...from the ETHOS study that shows that there is support with reduction in exacerbation rates'. As the nurse has used the language '*support with the reduction'*, there is no indication that all endpoints met statistical significance in relation to reduction of exacerbation rates. The ETHOS study met its primary endpoint of reduction in moderate to severe exacerbations and therefore the statement used by the HCP is correct and substantial. We therefore refute a breach of clauses 6.1 and 6.2 of the Code in relation to this allegation.

2. *Ethos study did not include mild exacerbations, but this is not mentioned in the video.*

   As mentioned above, the only reference to the ETHOS study is *'...from the ETHOS study that shows that there is support with reduction in exacerbation rates*'. The HCP doesn't talk in detail of the ETHOS study, and only summarises the key outcome to highlight why [they] choose Trixeo for [their] patients. We therefore deny breach of clauses 6.1 or 6.2 of the code in relation to this allegation.

3. *Nurse claims better quality of life and a pattern of no further exacerbations as a result of using Trixeo. This is misleading as there is no primary endpoint in the clinical data for Trixeo about quality of life, nor does it suggest Trixeo leads to no further exacerbations (21-25s).*

   At the beginning of the video, the HCP states: "*Trixeo is my first-choice triple therapy based on the evidence-based trial data from the ETHOS study that shows that there is support with reduction in exacerbation rates. Also, down to the patient feedback that I receive on improvement on symptom control, better quality of life, and what I've observed in that pattern of no further exacerbations*".

   It is clear that the nurse is referring to patient feedback when referring to quality of life, rather than discussing results of the ETHOS study. At 1m14s in the video the HCP states "*for a patient, improved quality of life can mean a number of things. This could be more time with family, more ability to complete things that they expected as their normal daily activities that they were limited to completing before. They are able to do day to day activities that they took for granted. This could mean that they're going to the supermarket, going to collect their prescriptions, not relying on friends and family to do things that they can do themselves. Spending more time with loved ones, and getting out in the community*'. It is clear from this statement that the speaker is talking specifically about the patient experience rather than quality of life as measured in clinical trials.

   With regards to '*...a pattern of no further exacerbations*', in this context the nurse is specifically referring to [their] own personal experience in using Trixeo rather than the ETHOS trial results. This statement is prefaced with '*down to the patient feedback that I receive*' to emphasize this point.

   We therefore deny a breach of clauses 6.1 and 6.2 of the Code in relation to these allegations.

4. *Cardiopulmonary risk mentioned, but side effect of palpitations for Trixeo not mentioned (52-54s).*

   The HCP states that '*we recognise that assessing the cardiopulmonary risk is important for these patients, factoring in the triple therapy, while making sure that we reduce the deterioration of their lung function, we address the*

exacerbating features of other comorbidities that can develop if remaining untreated' .

There is no mention of cardiopulmonary risk in relation to Trixeo specifically. The speaker is highlighting cardiopulmonary risk in the context of co-morbidities in COPD, and as such, it is an important consideration during consultation. We therefore do not deem it necessary for the speaker to highlight the potential adverse events of Trixeo, specifically palpitations in this instance. In any case, there is a clear statement at the beginning of the video alerting the viewer to location of the Trixeo Prescribing Information (PI), which is also a single click link at the top of the webpage where the video is hosted. The PI has a prominent statement at the top **'Consult Summary of Product Characteristics before prescribing'** and includes palpitations as a possible side effect within the PI itself (within the subsection of **undesirable events)**. [screenshots of Trixeo prescribing information provided]

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

5.

a. No discussion of safety data.

This video is based on the speaker's opinion and clinical experience with Trixeo, which as previously described is clear from the outset. Safety information was not relevant for their experience with Trixeo. As detailed above there is a clear statement referring the reader to PI with safety information, and it is one single click link away at the top of the webpage where the video is hosted. The PI has a prominent statement at the top **'Consult Summary of Product Characteristics before prescribing'.** Due to the nature of the video, we do not agree that safety information is required and deny any breach of clauses 6.1 or 5.1 of the Code in relation to this.

b. Video is overly positive for Trixeo and unbalanced, which poses a patient safety risk.

The title of this video is 'Using Trixeo in your clinical practice – [named health professionals] experience' and is clearly subtitled '[named health professionals] 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. HCPs treating COPD patients are aware that they would need to determine of Trixeo is right for their patients and upon consulting the PI and the SmPC. It is not accurate to state that the video is 'overly positive' for Trixeo. We therefore deny that there has been breach of clauses 6.1 or 5.1 of the Code in relation to this allegation.

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

The speaker was briefed on the purpose and content of the video. The background, objective, intended methods of distribution and other key details

including special considerations are clearly laid out here and thus should be considered a robust briefing. In addition, the video was certified by a Nominated Signatory before it made available externally for HCPs to view.

We ascertain that an appropriate briefing was in place for this activity, and therefore deny that there has been a breach of clause 5.1 of the Code in relation to this.

7. *The video does not properly reflect the data and should have been challenged by the Nominated Signatory.*

As previously discussed, the ETHOS data is not discussed in detail in this video and the purpose is for the HCP to share their own experiences using Trixeo in practice. This is made apparent to the viewer from the outset; this was a resource to support nurses. We ascertain that the brief mention to ETHOS study is accurate and reflects the main objective of the study. We therefore do not agree with this allegation and deny that we have breached clause 5.1 or 2 of the Code.

Summary of AstraZeneca's position

In summary:

- The intention of the video is to share HCP experience using Trixeo. It is valuable for HCPs to hear about others experiences using medicines in addition to considering all of the relevant efficacy/safety/dosing information before prescribing Trixeo.
- ETHOS data is mentioned appropriately but not discussed in detail, as was not the purpose of the video. The purpose of the video was clear to the viewer from the outset.
- Cardiopulmonary risk is mentioned as an important consideration when reviewing COPD patients, not in relation specifically to Trixeo.
- The video is not overly positive and the HCP was appropriately briefed before filming the video.

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 and therefore, **we refute breach of clause 6.1, 6.2 of the Code.** We strongly deny that this video jeopardises patient safety in any way, and therefore also refute **5.1 and 2 of the Code.**"

PANEL RULING

This case was in relation to a short promotional video (1m53s) titled "Using Trixeo In Your Clinical Practice", which was hosted on an AstraZeneca promotional 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:

1. Trixeo as their *"first choice triple therapy based on the evidenced-based trial data from the ETHOS study that shows that there is support with reduction in exacerbation rates",*

2. how patient feedback had influenced their decision to use Trixeo,

3. a patient's experience with the medication, and

4. what improved quality of life meant.

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.

1A) Reference to reduction in exacerbations being a hanging comparison

The complainant alleged that the health professional's statement that the ETHOS study showed *"there is support with **reduction in exacerbation rates**"* (emphasis added by Panel) was a hanging comparison, as there was no reference to what the reduction in exacerbations was being compared against.

In the video, the health professional stated: *"TRIXEO is my first choice triple therapy based on the evidenced-based trial data from the ETHOS study that shows that there is support with reduction in exacerbation rates".* For approximately eight seconds while this statement was made, small on-screen text appeared in the top left-hand corner reading *"Triple therapy may be considered for patients inadequately controlled on dual therapy".*

AstraZeneca submitted this statement showed that triple therapy was initiated after the patient had been on dual therapy, and therefore the reduction in exacerbation rate seen after initiation of triple therapy would be in comparison to their past dual therapy treatment. AstraZeneca further submitted use of "*support with reduction*" was not comparing Trixeo to another medicine.

The Panel noted that the ETHOS study:

- was a randomised controlled trial with four arms, comparing two doses of triple therapy with two different dual therapy combinations over 52 weeks in patients with moderate-to-severe COPD,

- included eligible patients receiving at least two inhaler therapies and the primary endpoint was the annual rate of moderate or severe exacerbations (the estimated mean number per patient per year), and

- showed that the two Trixeo dose arms had a statistically significant reduction compared to each dual therapy.

Clause 6.1 required among other things, comparative statements to be balanced, fair, objective, unambiguous and not misleading. The supplementary information to Clause 6.1 stated that "*hanging comparisons whereby a medicine is described as being better or stronger or suchlike without stating that with which it is compared, must not be made*".

In the Panel's view, the statement that the ETHOS study showed a "*reduction in exacerbation rates*" was ambiguous as to whether the reduction was an absolute improvement in time or a comparison against an alternative treatment regimen. The statement which appeared on-screen, in small font and for a brief period of time, did not sufficiently clarify that the reduction was observed versus dual therapy as submitted by AstraZeneca.

The Panel took into account that the statement *"…ETHOS study that shows that there is support with reduction in exacerbation rates"* failed to mention what the reduction was in comparison to. In the Panel's view, the claim was not sufficiently complete to enable recipients to form their own opinion of the therapeutic value of the medicine and, in the absence of an explicit comparator or appropriate qualification, constituted a hanging comparison. The Panel therefore ruled a **breach of Clause 6.1**.

1B) Reference to reduction in exacerbations in relation to severe exacerbations

The Panel understood the complainant's allegation to be that the statement, as detailed in Allegation 1A, was a broad claim around exacerbation reduction which was misleading and unqualified. In this regard, the complainant appeared to refer to the secondary endpoint of the ETHOS study that assessed the annual rate of severe COPD exacerbations, for which the reduction compared to LABA/LAMA dual therapy was not statistically significant. The complainant alleged the statement was therefore factually incorrect.

AstraZeneca submitted that the language "*support with the reduction",* in the context of reduction in exacerbation rates, did not indicate that all endpoints met statistical significance. The ETHOS study met its primary endpoint of reduction in moderate to severe exacerbations and therefore the statement used by the HCP was correct, according to AstraZeneca.

The Panel observed the primary endpoint of the ETHOS study was the annual rate of moderate or severe COPD exacerbations (estimated mean number per patient per year). Both Trixeo triple therapy doses demonstrated a statistically significant reduction in moderate or severe exacerbations compared with each dual therapy regimen ($p < 0.01$ for all comparisons).

The relevant secondary endpoint assessed the annual rate of severe COPD exacerbations for each arm. The rate ratio of severe exacerbations over 52 weeks in the 320-µg–budesonide triple-therapy Trixeo group was 16% lower than in the LAMA/LABA glycopyrrolate–formoterol group (0.84; 95% CI, 0.69 to 1.03; P = 0.09) and 20% lower than in the ICS/LABA budesonide–formoterol group (0.80; 95% CI, 0.66 to 0.97; P = 0.02). The Panel observed that the former reduction in exacerbations did not meet statistical significance ($p < 0.05$), as highlighted by the complainant.

The Panel considered the health professional's reference to the ETHOS study was in the context of providing *"support with reduction in exacerbation rates"* and that the statement was not inconsistent with the outcomes of the primary endpoint. While the Panel considered it would have been helpful to provided further context regarding the ETHOS study when referencing it (e.g. the study design and endpoints), the health professional did not specify the severity of exacerbations, nor imply that any or all endpoints were statistically significant.

In the Panel's view, the health professional's statement would have been reasonably understood as a broad reflection of the evidence supporting reduced exacerbations in patients eligible for triple therapy, rather than a specific claim about severe exacerbations. The Panel, therefore, considered the complainant had not established their allegation that the claim was

misleading, unqualified, inaccurate or incapable of substantiation. The Panel ruled **no breaches of Clauses 6.1 and 6.2**.

2. Reference to exacerbations without mentioning that ETHOS did not include mild exacerbations

The complainant referred to the health professional's mention of exacerbations, as described in Allegation 1 above, which could include mild, moderate or severe, and alleged that the video was misleading because it did not make clear that the ETHOS study did not analyse mild exacerbations. AstraZeneca submitted the health professional did not detail the ETHOS study and only summarised the key outcome to highlight why they choose Trixeo for their patients.

The Panel observed that eligible patients in the ETHOS study, among other criteria, had a history of moderate or severe COPD exacerbations and that the primary endpoint was the annual rate of such exacerbations.

The Panel considered that it would have been helpful if the video provided further context regarding the ETHOS study when referencing it, or included Trixeo's licensed indication, either of which would have clarified the population for whom the findings were relevant. Nonetheless, the Panel noted that the reference to the study was brief and did not imply the reduction in exacerbations applied for mild exacerbations.

In the Panel's view, health professionals for whom the video was intended would have reasonably understood that the statement about reductions in exacerbations with triple therapy referred to moderate to severe exacerbations rather than mild exacerbations. While the video did not specify that the *"ETHOS study did not look at mild exacerbations",* it had not been established that this omission rendered the statement misleading and/or incapable of substantiation. The Panel ruled **no breaches of Clauses 6.1 and 6.2**.

3. Claims regarding quality of life and no further exacerbations

The complainant stated that during the health professional's discussion of patient feedback, they claimed *"better quality of life"* and *"a pattern of no further exacerbations"* with Trixeo. This was alleged to be misleading as there was no primary endpoint in the clinical data for Trixeo about quality of life, nor did it suggest that Trixeo leads to no further exacerbations.

The Panel noted the broader context in which the claims were made, whereby the health professional stated:

> *"Trixeo is my first-choice triple therapy based on the evidence-based trial data from the ETHOS study that shows that there is support with reduction in exacerbation rates. Also down to the patient feedback that I receive on improvement on symptom control, better quality of life, and what I've observed in that pattern of no further exacerbations."*

Clause 6.1 included a requirement for material to be sufficiently complete to enable recipients to form their own opinion of the therapeutic value of the medicine.

3A) Better quality of life

The Panel noted that quality of life was not a primary endpoint of the ETHOS study but appeared to have been a secondary endpoint, measured using the St George's Respiratory Questionnaire.

While the health professional's reference to better quality of life followed reference to the ETHOS study having shown a reduction in exacerbations, the Panel acknowledged AstraZeneca's submission that it was clear that the health professional was referring to patient feedback when referring to quality of life. The health professional later listed what quality of life meant to them in holistic terms, such as "*more time with loved ones, and getting out in the community"*.

In any instance, quality of life was nonetheless measured as a secondary endpoint of the ETHOS study with trends in favour of Trixeo. In the Panel's view, the complainant had not established that the claim in question relied upon the ETHOS study nor that reference to quality of life in this context would be misleading or incapable of substantiation solely because it was not measured as a primary endpoint. Based on the narrow allegation in this part of Allegation 3, and the evidence before it, the Panel ruled **no breaches of Clauses 6.1 and 6.2**.

3B) Pattern of no further exacerbations

The Panel acknowledged reference to a "*pattern of no further exacerbations*" was made in relation to patient feedback the health professional had received. However, the Panel considered 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 did not consider that the data before it was consistent with the health professional's claim that there was "*a pattern of no further exacerbations*". For example, in the ETHOS study, it appeared 48% (n=1026) of patients on 320-µg–budesonide triple therapy and 47.8% (n=1013) patients on 160-µg–budesonide triple therapy (Trixeo) experienced at least one moderate or severe COPD exacerbation over 52 weeks.

Without any further qualification or context, the Panel concluded that the singular case study was insufficient to satisfy the requirements of Clause 6.1. There would likely be examples of patients to whom the claim did not apply and, as a balance of information was not provided, the claim could be considered as all-embracing and unrepresentative.

For these reasons, the Panel considered the claim to be misleading, insufficiently complete to enable recipients to form their own opinion of the therapeutic value of the medicine and incapable of substantiation. The Panel ruled **breaches of Clauses 6.1 and 6.2**.

4. The mention of cardiopulmonary risk without the mention of palpitations as a common side effect of Trixeo

The complainant stated that the nurse referred to cardiopulmonary risk but failed to mention palpitations were a common side effect of Trixeo, which meant the material was allegedly insufficient to allow a viewer to form their own opinion on the medicine's therapeutic value.

During the video, the health professional stated:

"We recognise that assessing the cardiopulmonary risk is important for these patients, factoring into the triple therapy, while making sure that we reduce the deterioration of their lung function, we address the exacerbating features of other comorbidities that can develop if remaining untreated".

Whether a common adverse event needed to be highlighted within promotional material, depended on a consideration of all the circumstances. The Panel noted that palpitations was the only common side effect that appeared under cardiac disorders but was unsure why the complainant alleged palpitations needed to be mentioned specifically, and in isolation from other cardiovascular adverse events and cautions.

It was clear to the Panel that the reference to cardiopulmonary risk was in the context of co-morbidities in COPD, rather than a statement regarding the safety profile of Trixeo. The complainant therefore had not established why specific reference to palpitations was required in this context and, on the narrow allegation, the Panel ruled **no breach of Clause 6.1**.

5. Lack of safety discussion and balance

The complainant alleged there was no discussion about the safety of Trixeo and that the video was overly positive, unbalanced and that this was a patient safety risk.

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 experience. AstraZeneca further submitted 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 standalone and not rely on qualification in the prescribing information.

The Panel considered the video was promotional material for Trixeo, directed at health professionals, which 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**.

In relation to this Allegation 5, the Panel considered that the complainant's reference to Clause 5.1 (a failure to maintain high standards) overlapped with their broader concerns dealt with under Allegation 7 below. In the Panel's view, these matters were not sufficiently distinct to warrant a separate ruling, and an additional ruling of a breach of Clause 5.1 under Allegation 5 would be duplicative as well as disproportionate.

While the Panel had concerns about the overall balance and absence of safety information in the video, this had already been ruled upon under Clause 6.1 above and was considered further when assessing the overall concerns below under Allegation 7. In relation to Allegation 5, the Panel ruled **no breach of Clause 5.1**.

6. Inadequate briefing

The complainant alleged the briefing provided to the health professional for the video was not robust considering the number of alleged issues with the video.

The Panel reviewed the briefing document, which set out the objectives, discussion points and special considerations, along with filming and technical guidance. 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. The Panel was concerned that 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 that cardiopulmonary risk plays when managing COPD patients. The Panel queried whether this warranted additional guidance regarding the cardiovascular considerations as 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.

Given this lack of robustness and omission of key information, which the Panel concluded had likely contributed to the breaches ruled above, the Panel considered that AstraZeneca had not maintained high standards in respect of the briefing. The Panel ruled a **breach of Clause 5.1**.

7. Overall lack of balance and failure to properly reflect data

The complainant alleged that the video should have been challenged during the certification process because it was not compliant, it was unbalanced and it did not properly reflect the data.

The Panel took account of its rulings of breaches of Clauses 6.1 and 6.2 above. Taken in its entirety, the promotional video presented only favourable outcomes for Trixeo, lacked sufficient qualification or balance, and omitted safety considerations. This resulted in the Panel's findings that claims in the video were misleading, unqualified, insufficiently complete and/or incapable of substantiation. The Panel also took account of its conclusion that the health professional briefing had been inadequate and that AstraZeneca had complete editorial control over the final video prior to certification and publication.

In the Panel's view, the cumulative effect of these shortcomings meant that high standards had not been maintained. The Panel therefore ruled a **breach of Clause 5.1**.

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. The Panel considered it essential that health professionals are able to rely on materials produced by companies to be complete. However, the Panel concluded that its ruling of

breaches of the clauses above adequately covered the allegations and that the circumstances of this case did not warrant any additional breach rulings. The Panel therefore ruled **no breach of Clause 2**.

Complaint received **13 November 2024**

Case completed **4 November 2025**