CASE/0977/05/26 ***NO BREACH OF THE CODE***

COMPLAINANT v ASTRAZENECA

Allegations about conference materials

CASE SUMMARY

This case was in relation to two promotional materials for Calquence (acalabrutinib) used by AstraZeneca at a UK haematology congress; an advertisement in the congress programme and an invitation to a promotional symposium. The complainant alleged that a claim that appeared in both materials, which was based on an exploratory analysis, was misleading and that one of the materials omitted two of Calquence's licensed indications in mantle cell lymphoma.

The outcome under the 2024 Code was:

No Breach of Clause 2	**Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry**
No Breach of Clause 5.1	**Requirement for companies to maintain high standards at all times**
No Breach of Clause 6.1(x2)	**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 9.1	**Requirement that all relevant personnel concerned with the preparation or approval of material or activities covered by the Code must be fully conversant with the Code and the relevant laws and regulations**
No Breach of Clause 11.2	**Requirement not to promote a medicine inconsistently with its summary of product characteristics**
No Breach of Clause 12.1	**Requirement to include up-to-date prescribing information**

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.

COMPLAINT

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

“Dear PMCPA, I am a UK healthcare professional writing to raise a formal complaint regarding two promotional materials for Calquence (acalabrutinib 100mg tablets), produced and funded by AstraZeneca, which were distributed at the British Society for Haematology (BSH) Annual Scientific Meeting in April 2026. I believe these materials contain breaches of the 2024 ABPI Code of Practice.

MATERIAL 1

BSH Congress Programme Advertisement
Job bag reference: GB-74491 | Date of preparation: March 2026
Alleged breaches: Clauses 2, 6.1, 11.2, 12.1

This full-page advertisement was placed in the BSH congress programme and prominently promotes Calquence with a ‘backbone in 1L CLL & MCL’ headline, stating ‘Visit us at Stand 1 to discuss Calquence (acalabrutinib), including the latest UK RWE in CLL and our two new license updates across 1L CLL and MCL.’ Despite these explicit MCL promotional claims throughout the body of the advertisement, the prescribing information printed at the foot of the piece lists only CLL indications:

- Acalabrutinib monotherapy or in combination with obinutuzumab (previously untreated CLL)
- Acalabrutinib monotherapy (CLL, at least one prior therapy)
- Acalabrutinib in combination with venetoclax with or without obinutuzumab (previously untreated CLL)

No MCL indication appears anywhere in the prescribing information of this piece. I note that the companion material GB-75182, distributed at the same meeting, includes the full MCL licensed indications — including acalabrutinib in combination with bendamustine and rituximab for previously untreated MCL, and acalabrutinib monotherapy for relapsed/refractory MCL not previously treated with a BTK inhibitor.

Both materials share the same date of preparation (March 2026), confirming that the MCL licence was in place and known to AstraZeneca at the time GB-74491 was prepared and distributed. The fact that the MCL indication is present in GB-75182 but entirely absent from GB-74491 — a piece that nonetheless actively promotes Calquence in MCL throughout its body copy — raises serious concern.

This does not appear to be an inadvertent oversight but rather a deliberate editorial decision, whether arising from a failure of the approval and certification process, inadequate training of the personnel responsible for this material, or insufficient standards being applied during the review and sign-off of promotional content.

In any case, the result is that a piece of promotional material was certified and distributed at a national haematology congress that promoted an unlicensed indication without the corresponding prescribing information. This falls significantly below the standards the industry is required to uphold and, in my view, brings the pharmaceutical industry into disrepute.

Alleged breaches:

- Clause 2 — This material fails to maintain the high standards required of the pharmaceutical industry and brings the industry into disrepute. The promotion of MCL throughout a piece that simultaneously omits all MCL prescribing information, at a major national congress, reflects a failure of training, oversight and the certification standards that the Code requires companies to maintain. Whether the omission was deliberate or the result of inadequate internal processes, the outcome is a piece of certified promotional material that is fundamentally misleading to the healthcare professionals who received it.
- Clause 12.1 — The prescribing information accompanying this promotional piece is incomplete. Authorised indications for MCL, which form a central part of the promotional claims made in the body of the advertisement, are entirely absent.
- Clause 11.2 — A healthcare professional reading this advertisement would receive promotional claims about MCL with no supporting licensed indication information, creating a materially misleading picture of the authorised use of the product and rendering this material inconsistent with the Summary of Product Characteristics.
- Clause 6.1 — The omission of the MCL indications from the prescribing information of a piece that actively promotes Calquence in MCL is misleading by omission.

MATERIAL 2
Lunchtime Symposium Invitation
Job bag reference: GB-75182
Date of preparation: March 2026
Alleged breaches: Clauses 6.1, 6.2

This symposium invitation includes the following claim in a highlighted data panel: ‘Calquence reduced the risk of progression or death in high-risk patients by 77% versus OClb at 6 years (exploratory analysis).’ This identical claim also appears in material 1 (GB-74491). Across both materials, at no point is it disclosed that this figure does not derive from the primary endpoint of the ELEVATE-TN trial. The primary endpoint of ELEVATE-TN was progression-free survival comparing acalabrutinib plus obinutuzumab versus chlorambucil plus obinutuzumab, assessed by independent review committee.

The 77% risk reduction figure derives from a 6-year exploratory analysis of the acalabrutinib monotherapy arm versus chlorambucil-obinutuzumab — a non-primary, post hoc comparison involving a different treatment arm to that which the trial was designed and powered to evaluate. While the word ‘exploratory’ appears in brackets in both materials, neither piece discloses that this comparison was not the primary endpoint of the trial, nor that the primary endpoint tested an entirely different treatment arm.

A healthcare professional encountering this claim in either or both materials has no means of understanding that the headline efficacy figure presented to them is derived from an exploratory analysis of a secondary arm, rather than the pivotal finding the trial was designed to demonstrate. The consistent omission of primary endpoint context across two separate certified materials suggests this is not an isolated error but reflects a systematic approach to presenting this data in a way that overstates its evidential weight. Alleged breaches:

- Clause 6.1 — Claims must be accurate, balanced and not misleading. Presenting an exploratory, non-primary analysis result as the headline efficacy claim across two materials, without disclosing that the trial’s primary endpoint was a different

comparison entirely, risks giving a false and unbalanced impression of the strength of evidence underlying this figure.

- Clause 6.2 — Information must not be presented in a way that is likely to mislead by implication. The prominence and framing of the 77% claim across both materials implies it is the principal efficacy finding of ELEVATE-TN. It is not. The repeated omission of primary endpoint context across both pieces compounds this misleading impression.

SUMMARY

GB-74491 (Material 1): Clauses 2, 6.1, 11.2, 12.1
GB-75182 (Material 2): Clauses 6.1, 6.2

I am willing to provide physical copies of these materials to the PMCPA if required. I confirm I am a UK healthcare professional submitting this complaint in good faith."

When writing to AstraZeneca, the PMCPA asked it to consider the requirements of Clauses 2, 5.1, 6.1, 6.2, 9.1, 11.2 and 12.1 of the 2024 Code.

ASTRAZENECA'S RESPONSE

The response from AstraZeneca is reproduced below:

"We are writing to you in response to your letter dated 19 May 2026, concerning a complaint from a healthcare professional with respect to allegations about Calquence conference materials. The complainant's allegations can be broken down as follows:

MATERIAL 1 British Society for Haematology (BSH) Congress Programme Advertisement Job bag reference: GB-74491

- *The Advert only included CLL indications and no MCL indications.*
- *Authorised indications for MCL are absent, and materials are fundamentally misleading to the healthcare professionals and the piece is incomplete.*
- *The material promoted unlicensed indication without the corresponding prescribing information.*

MATERIAL 2 Lunchtime Symposium Invitation Job bag reference: *GB-75182*

- *The claim 'Calquence reduced the risk of progression or death in high-risk patients by 77% versus OClb at 6 years (exploratory analysis)' doesn't disclose that this figure is not derived from the primary endpoint of the ELEVATE-TN trial.*

- *Material 1 and 2 did not disclose that the comparison was not the primary endpoint of the trial, nor that the primary endpoint tested a different treatment arm.*

- *The consistent omission of primary endpoint context across two separate certified materials suggests this is not an isolated error but reflects a systematic approach to presenting this data in a way that overstates its evidential weight.*

- *The prominence and framing of the 77% claim across both materials implies it is the principal efficacy finding of ELEVATE-TN. The repeated omission of primary endpoint context across both pieces compounds this misleading impression.*

AstraZeneca has been asked to consider the requirements of the following clauses 12.1, 11.2, 9.1, 6.2, 6.1, 5.1 and 2 of the 2024 ABPI Code. We will address each of the complainant's allegations according to the relevant clauses.

Background to BSH 2026

The BSH 66th annual scientific meeting took place in April 2026 in [the UK] and is a major UK congress attended by haematology specialists with strong familiarity with CLL, MCL and general BTKi therapy. The meeting is a scientific forum intended to provide specialist haematology HCPs with a platform for clinical data exchange, including both independent research and industry sponsored sessions.

Calquence (Acalabrutinib) Licensed Indications (in line with SmPC):
Monotherapy or in combination with obinutuzumab is indicated for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL).

Monotherapy is indicated for the treatment of adult patients with chronic lymphocytic leukaemia (CLL) who have received at least one prior therapy.

Combination with venetoclax with or without obinutuzumab is indicated for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL).

Combination with bendamustine and rituximab (BR) is indicated for the treatment of adult patients with previously untreated mantle cell lymphoma (MCL) who are not eligible for autologous stem cell transplant (ASCT).

Monotherapy is indicated for the treatment of adult patients with relapsed or refractory MCL not previously treated with a BTK inhibitor.

Allegations 1

MATERIAL 1 BSH Congress Programme Advertisement Job bag reference: GB-74491

Prominently promotes Calquence with a 'backbone in 1L CLL & MCL' headline, stating 'Visit us at Stand 9 to discuss Calquence (acalabrutinib), including the latest UK RWE in CLL and our two new license updates across 1L CLL and MCL.' The PI at the foot of the piece lists only CLL indications and no MCL indication. The lunch time symposium invitation GB-75182 includes the full MCL licensed indications. A deliberate editorial decision, whether arising from a failure of the approval and certification process, inadequate training of the personnel responsible for this material, or insufficient standards being applied during the review and sign-off of promotional content. A piece of promotional material was certified, distributed and promoted an unlicensed indication without the corresponding PI. This falls significantly below the standards the industry is required to uphold and brings the pharmaceutical industry into disrepute Clause 2. The promotion of MCL omits all MCL indications on the PI, reflects a failure of training,

oversight and the certification standards that the Code requires companies to maintain. A piece of certified promotional material is fundamentally misleading to the healthcare professionals who received it, Clause 12.1 the PI piece is incomplete. Authorised indications for MCL are absent, Clause 11.2, a healthcare professional reading this advertisement would receive promotional claims about MCL with no supporting licensed indication information, creating a materially misleading picture of the authorised use of the product and rendering this material inconsistent with the SmPC Clause 6.1. the omission of the MCL indications from the PI of a piece that actively promotes Calquence in MCL is misleading by omission.

AstraZeneca Response

Directly beneath Calquence claims boxes is a list of CLL indications, footnote, safety information and a clear and prominent QR code with a clear statement to *'scan here for UK PI and AE reporting'.* We acknowledge that MCL indications were not included in the main body of the material but this does not render the PI incomplete or misleading as the full PI (including the MCL indications) was accessible via a clear and prominent QR code with a statement to '*scan here for UK PI and AE reporting'* as required by Clause 12.1.

The material also included a statement *'Visit us at Stand 9 to discuss Calquence (acalabrutinib), including the latest UK RWE in CLL and our two new license updates across 1L CLL and MCL'* advising readers to visit the stand for more information about the new licenses therefore, the material is not inconsistent with the SmPC.

In addition, the accompanied material (*GB-75182*) has all the indications including MCL as below. Therefore, the reader would be aware that Calquence is indicated in MCL.

The material was developed, reviewed and approved following our internal policy and procedure and in accordance with requirements of the ABPI Code. We, therefore, deny a breach of clauses 12.1, 11.2, 5.1 and 2 of the ABPI Code.

Allegations 2

MATERIAL 2 Lunchtime Symposium Invitation Job bag reference: GB-75182

Includes claim 'Calquence reduced the risk of progression or death in high-risk patients by 77% versus OClb at 6 years (exploratory analysis)' which also appears in Material 1 (GB-74491). At no point is it disclosed that this figure does not derive from the primary endpoint of the ELEVATE-TN trial. The primary endpoint of ELEVATE-TN was progression-free survival comparing acalabrutinib plus obinutuzumab versus chlorambucil plus obinutuzumab. The 77% risk reduction figure derives from a 6-year exploratory analysis of the acalabrutinib monotherapy arm versus chlorambucil-obinutuzumab — a non-primary, post hoc comparison involving a different treatment arm to that which the trial was designed and powered to evaluate. While the word 'exploratory' appears in brackets in both materials, neither piece discloses that this comparison was not the primary endpoint of the trial, nor that the primary endpoint tested an entirely different treatment arm. A healthcare professional seeing this claim in either or both materials would not know that the headline efficacy figure presented is derived from an exploratory analysis of a secondary arm, rather than the pivotal finding the trial was designed to demonstrate. The consistent omission of primary endpoint context across two separate certified materials

suggests this is not an isolated error but reflects a systematic approach to presenting this data in a way that overstates its evidential weight. Alleged breach clause 6.1 claims must be accurate, balanced and not misleading. Presenting an exploratory, non-primary analysis result as the headline efficacy claim across two materials, without disclosing that the trial's primary endpoint was a different comparison entirely, risks giving a false and unbalanced impression of the strength of evidence underlying this figure. Clause 6.2, information must not be presented in a way that is likely to mislead by implication. The prominence and framing of the 77% claim across both materials implies it is the principal efficacy finding of ELEVATE-TN. It is not. The repeated omission of primary endpoint context across both pieces compounds this misleading impression.

AstraZeneca Response

After the claim "Calquence reduced the risk of progression or death in high-risk patients by 77% versus OClb at 6 years follow-up'', *'exploratory analysis'* followed immediately after in brackets indicating this is not a primary endpoint for ELEVATE TN Trial. The claim also included a symbol (^) related to a footnote which states *'high-risk groups are del(17p) and/or TP53 mutation'.* The claim explicitly included "high-risk patients," and the footnote defined the 'high risk patients,' highlighting a specific sub-group analysis.

Additionally, directly beneath the claim panel is a list of all Calquence indications, exploratory analysis information, ELEVATE TN study information with study design and primary end point, high-risk patient definition, safety summary and references.

Therefore, the absence of a primary end point reference in the body of this claim, but the inclusion of an exploratory analysis reference, denoting its status as such by use of a symbol next to the specific claim box is clear and not misleading, as alleged by the complainant. In addition, this is in line with previous PMCPA case precedents regarding the inclusion of primary endpoint.

This is the detail of the information in the footnote of the above material:
*'*Based on an exploratory analysis of 6-year follow-up data from ELEVATE-TN (n=179)5; † EPIC (n=170, 95% CI: 82, 92%, interim analysis); Non-randomised RWE; subject to selection and confounding; ELEVATE-TN (n=179, 95% CI: 81, 92%, primary analysis)5; ‡ UK local audit data was collected by HCPs. ELEVATE-TN was a global, phase 3, multicentre, open-label study comparing in patients with treatment-naive CLL (N=535). The primary endpoint of PFS with acalabrutinib-obinutuzumab vs chlorambucil-obinutuzumab was met (p<0.0001). EPIC is an ongoing observational multi-centre cohort study (N=350). The primary endpoint is rwPFS 5, 6. Obinutuzumab + chlorambucil (Obi+Clb). ^High-risk 'groups are del(17p) and/or TP53 mutation.'*

Given the above, we do not believe the claim was misleading and we therefore deny breaches of clauses 6.1 and 6.2 of the ABPI Code.

Summary of AstraZeneca's position

- Although the Calquence advert in the congress programme GB-74491 did not include MCL indications, this advert made prominent reference to MCL as a new licensed indication.

- A clear and prominent QR code with the statement *'scan here for UK PI and AE reporting'* where all Calquence indications are listed was included and as such, we do not believe the material was misleading or advertised Calquence outside of its licensed indication or in a manner inconsistent with the SmPC.
- The symposium invitation GB-75182 efficacy claims in the first box included reference to 'high-risk' patients and in brackets 'exploratory analysis.' Therefore, readers would be aware that the data is not the primary end point of ELEVATE TN. Additionally, the symbol next to the claim included definition of a high-risk patient and the footnote included details of ELEVATE TN trial design and that the primary endpoint was met.
- Therefore, AstraZeneca deny the breach of clauses 12.1, 11.2, 9.1, 6.2 and 6.1.

Both materials 1 and 2 were developed, reviewed and approved following our internal policy and procedure and in accordance with requirements of the ABPI Code. We, therefore, believe high standards have been maintained and we have not discredited or reduced confidence in the pharmaceutical industry and refute a breach of clauses 5.1 and 2.

AstraZeneca is fully committed to the ABPI Code of Practice and takes its responsibilities under the Code very seriously."

PANEL RULING

This case was in relation to two promotional conference materials for Calquence (acalabrutinib) used by AstraZeneca at a UK haematology congress. The complainant alleged that a claim that appeared in both materials, and was based on an exploratory analysis, was misleading and that one of the materials omitted two of Calquence's licensed indications in mantle cell lymphoma.

At the time of the congress and complaint, Calquence was licensed as a monotherapy, or as part of a combination, for chronic lymphocytic leukaemia (CLL) as well as mantle cell lymphoma (MCL).

The Panel divided its ruling into two parts to deal with each of the two materials separately, and to match the structure of the complaint.

The congress programme advertisement (Material 1)

AstraZeneca submitted that the material had been placed as a full-page advertisement in the printed congress programme. The headline read "For eligible patients START STRONG with a CALQUENCE backbone in 1L CLL & MCL". Beneath the headline appeared the claim "The only licensed 2nd Generation BTKi [Bruton tyrosine kinase inhibitor] offering both continuous or fixed-duration treatment options in 1L CLL", and a coloured bar stating, "Visit us at Stand 1 to discuss Calquence (acalabrutinib), including the latest UK RWE in CLL and our two new license updates across 1L CLL and MCL". Although the complainant's photograph and allegation referred to "Stand 1", rather than "Stand 9" as provided by AstraZeneca, the Panel considered the versions to otherwise be substantively the same.

Lower down, under the tab heading "CLL: Calquence continuous monotherapy", appeared three panels with the following claims (with the emphasis as it appeared in the advertisement):

1. “Calquence reduced the risk of progression or death in **high-risk patients by 77%** versus OClb at 6 years (exploratory analysis).”

2. “Low incidence of grade ≥ 3 **atrial fibrillation (1.7%), bleeding (4.5%)** and **hypertension (5%)** with acalabrutinib monotherapy in the front-line setting at 6-year follow-up.”

3. “UK local audit data reinforces real world outcomes seen in EPIC: **87% of UK patients** receiving first-line CALQUENCE monotherapy in EPIC continued to be **progression-free at 2 years.**”

The bottom of the advertisement included, in smaller font: “Licensed indications in CLL:” followed by Calquence’s three CLL indications, footnotes, a safety summary and references. At the bottom right was a QR code accompanied by “Scan here for UK PI and AE reporting”.

The complainant raised concerns that although Material 1 promoted Calquence in MCL, the MCL indications were absent from what the complainant described as the prescribing information at the foot of the advertisement and that only CLL indications were present. The complainant alleged that:

1. the prescribing information was incomplete,

2. the material “promoted an unlicensed indication without the corresponding prescribing information” and was inconsistent with the summary of product characteristics (SPC), and

3. the omission of the MCL indications was misleading.

Prescribing information (Clause 12.1)

Clause 12.1 required, among other things, that the prescribing information listed in Clause 12.2 be provided in all promotional material and in printed material, either:

- by inclusion as text, or

- through a clear and prominent QR code with instructions to scan it for the prescribing information.

The Panel interpreted the complainant’s allegation to be that the information towards the bottom of the advertisement constituted incomplete prescribing information because it only listed the CLL indications for Calquence and omitted its MCL indications.

The Panel considered that the complainant appeared to have regarded the bottom section of the advertisement as the prescribing information. However, this section started with “Licensed indications in CLL” and listed Calquence’s three CLL indications. Separately, the Panel observed that the bottom right of the advertisement included a clear and prominent QR code with the instruction to “Scan here for UK PI and AE reporting”.

AstraZeneca provided the full Calquence prescribing information available via the QR code as part of its response and this included all five licensed indications as per its SPC across CLL and MCL.

The Panel therefore concluded that the complainant had not established that the prescribing information was incomplete and the Panel ruled **no breach of Clause 12.1**.

Consistency with the marketing authorisation and SPC (Clause 11.2)

Clause 11.2 required that the promotion of a medicine be in accordance with the terms of its marketing authorisation and not be inconsistent with the particulars listed in its SPC.

The complainant alleged that the advertisement "promoted an unlicensed indication" and was inconsistent with the SPC because promotional claims about MCL were made with no supporting licensed indication information.

At the date the advertisement was used, Calquence had two licensed indications for use in MCL:

1. in combination with bendamustine and rituximab for the treatment of adult patients with previously untreated MCL who were not eligible for autologous stem cell transplant, and

2. as monotherapy for the treatment of adult patients with relapsed or refractory MCL not previously treated with a BTK inhibitor.

Calquence therefore had licensed indications for use in MCL at the relevant time and the complainant had not identified any particular reference to Calquence in MCL which fell outside the terms of its marketing authorisation. The Panel also took account of the complainant's acknowledgement in their complaint that the "MCL licence was in place" when Material 1 had been prepared and that Material 2 included "the full MCL licensed indications".

The Panel understood the complainant's concern to arise from the fact that, although Material 1 referred to Calquence in MCL, the corresponding MCL indications were not reproduced as text within the advertisement.

The Panel did not consider that the absence of the MCL indications, in itself, meant that references to Calquence in MCL were outside the terms of its marketing authorisation or inconsistent with its SPC. The prescribing information, which was made available via a QR code, included the two licensed MCL indications.

The Panel considered that the complainant had failed to establish that the references to Calquence in MCL, without the full MCL licensed indications being reproduced in the advertisement itself, meant that Calquence had been promoted outside the terms of the marketing authorisation, or in a manner that was inconsistent with the particulars listed in its SPC. The Panel therefore ruled **no breach of Clause 11.2**.

Whether the advertisement was misleading (Clause 6.1)

Clause 6.1 stated:

> "Information, claims and comparisons must be accurate, balanced, fair, objective and unambiguous and must be based on an up-to-date evaluation of all the evidence and reflect that evidence clearly. They must not mislead either directly or by implication, by distortion, exaggeration or undue emphasis.
>
> Material must be sufficiently complete to enable recipients to form their own opinion of the therapeutic value of the medicine."

The complainant alleged that the omission of the MCL indications from an advertisement that actively promoted Calquence in MCL was misleading.

Material 1 referred to Calquence in both CLL and MCL. It also included the prominent statement "START STRONG with a CALQUENCE backbone in 1L CLL & MCL" and an invitation to visit AstraZeneca's stand to discuss "two new license updates across 1L CLL and MCL". The indications reproduced towards the bottom of the advertisement were limited to CLL and were introduced with the words "Licensed Indications in CLL".

The Panel acknowledged that it might have been helpful for the MCL indications for Calquence to also have been reproduced, given the references to MCL in the advertisement. However, the Panel considered that:

- the indications listed were expressly identified as "Licensed Indications in CLL", rather than being presented as the complete licensed indications for Calquence,
- the advertisement invited readers to the stand to learn about the licence updates across 1L CLL and MCL, and
- the prescribing information included the licensed indications for MCL.

Taking all of the above into account, the Panel considered that the complainant had not established that the omission of the MCL indications from the material itself rendered the advertisement misleading or insufficiently complete to enable recipients to form their own opinion of the therapeutic value of Calquence. The Panel ruled **no breach of Clause 6.1**.

Bringing discredit upon, or reducing confidence in, the pharmaceutical industry (Clause 2)

The complainant had raised Clause 2 specifically in relation to Material 1. Clause 2 required that activities or materials associated with a company must never be such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry.

A ruling of a breach of Clause 2 is a sign of particular censure and is reserved for such use. Having ruled no breach of Clauses 12.1, 11.2 and 6.1 as set out above, the Panel considered that there were no other allegations or evidence in this case which gave rise to a ruling of a breach of Clause 2 and the Panel therefore ruled **no breach of Clause 2**.

The 77% risk reduction claim (Materials 1 and 2)

The second aspect of the complaint concerned the claim "Calquence reduced the risk of progression or death in **high-risk patients by 77%** versus OClb at 6 years (exploratory analysis)" (emphasis as it appeared).

Material 1 was the congress programme advertisement as described above. Material 2 was a two-sided invitation to an AstraZeneca-sponsored promotional symposium and a “Meet the Experts” session at the company's stand.

The second page of the invitation was very similar to the advertisement in Material 1. Under the heading “CLL: Calquence continuous monotherapy”, it included the same three claim panels including the 77% claim in question. Beneath the panels were five licensed indications for Calquence, together with a footnote, safety summary, references and QR code to prescribing information and adverse event reporting. The Panel observed that, unlike Material 1, Material 2 listed all licensed indications, for CLL and MCL.

Whether the claim was misleading or incapable of substantiation (Clauses 6.1 and 6.2)

The complainant stated that the primary endpoint was progression-free survival comparing acalabrutinib plus obinutuzumab with chlorambucil plus obinutuzumab (OClb), whereas the 77% risk reduction claim figure was derived from a six-year exploratory analysis comparing acalabrutinib monotherapy with OClb.

While the complainant acknowledged the words “exploratory analysis” appeared in brackets immediately after the claim, the complainant alleged that neither material disclosed that the comparison underlying the 77% claim was not the primary endpoint of the trial, nor that the primary endpoint concerned a different treatment arm. The complainant alleged that the way the claim was presented therefore gave a misleading and unbalanced impression of the strength of the evidence underlying the figure and implied that it was the principal efficacy finding of ELEVATE-TN.

The Panel noted that both materials included “exploratory analysis” in brackets at the end of the claim and in the same size font. The footnote, which appeared in smaller font, stated it was “Based on an exploratory analysis of 6-year follow-up data from ELEVATE-TN” and that “ELEVATE-TN was a global, phase 3, multicentre, open-label study comparing in patients with treatment-naive CLL”. The footnote went on to state that the primary endpoint of progression-free survival with acalabrutinib-obinutuzumab versus chlorambucil-obinutuzumab had been met.

It was an established principle of the Code that claims should be capable of standing alone. The Panel also took into account that the supplementary information to Clause 6.1 stated that, in general, claims should not be qualified by the use of footnotes.

The Panel considered the context in which the claim appeared: in materials that invited health professionals at a haematology congress to attend a symposium and visit AstraZeneca's stand. In both materials, the claim appeared under the heading “CLL: Calquence continuous monotherapy”.

While the Panel considered that it would have been helpful for the relationship between the exploratory analysis and primary endpoint to have been made clearer, the Panel noted that it was stated expressly in brackets, immediately after the claim, that it was derived from an exploratory analysis. The accompanying information in the footnote additionally identified the primary endpoint and treatment arms, from which the differences could be identified.

In the particular circumstances, the Panel concluded that the complainant had not established their allegation that the manner in which the 77% claim in high-risk patients was presented

implied that it represented the principal efficacy finding of ELEVATE-TN, or otherwise gave a misleading or unbalanced impression of the evidence behind it. Nor, on the evidence provided to the Panel, had the complainant established that the claim was incapable of substantiation. The Panel therefore ruled **no breaches of Clause 6.1 and Clause 6.2**.

High standards and knowledge of the Code (Clause 5.1 and Clause 9.1)

The complainant questioned whether the omission of the MCL indications from Material 1 resulted from "inadequate training of the personnel responsible for this material" or "a failure of the approval and certification process" and that the materials failed to "maintain the high standards". The complainant further alleged that the omission of primary endpoint context in both materials, in relation to the 77% claim, demonstrated a systematic approach rather than an isolated error.

Clause 5.1 required that companies maintain high standards at all times. Clause 9.1 required that all relevant personnel concerned in any way with the preparation or approval of material or activities covered by the Code be fully conversant with the Code and the relevant laws and regulations.

The Panel considered its rulings of no breach in relation to the two materials, based on the allegations before it. The Panel also noted that both materials had been certified.

The Panel considered that the complainant had not provided any evidence to establish a failure in AstraZeneca's approval or certification process. Nor had the complainant provided evidence regarding whether the relevant personnel involved in the preparation or approval of materials were fully conversant with the Code. The Panel therefore considered that the complainant had not established that AstraZeneca had failed to maintain high standards or had failed to comply with the requirements of Clause 9.1 in this case. The Panel ruled **no breaches of Clause 5.1 and Clause 9.1**.

Complaint received **16 May 2026**

Case completed **14 October 2026**