

CASE/0392/12/24

COMPLAINANT v SOBI

Allegations about Zynlonta banner advertisements

CASE SUMMARY

This case was in relation to a banner advertisement for Zynlonta (loncastuximab tesirine) that appeared in two journals intended for health professionals. The complainant alleged that the black triangle and the brand name were not adjacent because a brand logo had been placed between them. The complainant also alleged that the advertisement's use of the words "NICE approved" was misleading because NICE 'recommend' rather than approve.

SOBI appealed the Panel's breach ruling.

The outcome under the 2024 Code was:

Breach of Clause 12.7 [Panel's breach ruling upheld at appeal]	Failing to include the black triangle adjacent to the first mention of the product
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	Requirement that information/ claims/ comparisons must not be misleading

**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 Swedish Orphan Biovitrum Ltd ("SOBI") was received from a contactable complainant.

COMPLAINT

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

"I'd like to raise a complaint about Zynlonta banner ads attached.

The black triangle is not adjacent to the name- but is in fact separated by what appears to be a brand logo?

In addition, the strapline is incorrect as its not 'approved' by NICE - NICE gives recommendations. Using the term 'approved' gives a false and misleading impression."

When writing to SOBI, the PMCPA asked it to consider the requirements of Clauses 5.1, 6.1 and 12.7 of the 2024 Code.

SOBI'S RESPONSE

The response from SOBI is reproduced below:

"Thank you for bringing this to our attention and we are happy to provide the following response.

We note from the attachments you have provided that the complaint is in relation to a set of promotional banner advertisements which were provided to [two named journals for health professionals] for display between the dates of 11th November 2024 and 31st January 2025. We enclose a pdf of the images submitted for certification and the certificate approving the material. The signatory who certified this item is [named qualifications].

The target audiences for this item are healthcare professionals and other relevant decision makers, aligned to the audiences accessing the websites on which the banner advertisements are hosted, these being intended for healthcare professionals only.

We note the complainant's allegations that the banner advertisements in question do not display the black triangle adjacent to the brand name and that the statement 'Zynlonta is NICE and SMC approved' is misleading and incorrect and we note your reference to clauses 5.1, 6.1 and 12.7 of the 2024 Code in relation to this complaint.

In relation to the positioning of the black triangle, we are confident that the requirements outlined in Clause 12.7 have been met in terms of the black triangle being located adjacent to the first and most prominent mention of the product and that the size and location are such that it is easily noticed. We do not feel that the positioning of the symbol between the text and the black triangle detracts in any way from how noticeable the black triangle is and therefore we do not feel a breach of Clause 12.7 has occurred.

In relation to the wording 'Zynlonta is NICE and SMC approved as monotherapy for the treatment of adult patients with relapsed or refractory DLBCL and HGBL, after two or more lines of therapy', this statement references the NICE technology appraisal guidance 947 and the Scottish Medicines Consortium Medicines Advice for loncastuximab tesirine, and per your request both references have been enclosed. We are confident that the wording 'Zynlonta is NICE and SMC approved' is neither misleading or incorrect and instead reflects the terminology used by healthcare professionals for outcomes of health technology appraisals, these individuals being the target audience for this item.

In 'The Innovative Medicines Fund Principles', an official document authored by NICE and the NHS, reference is made to 'NICE approved medicines'. In addition, a news article on

the NICE website published in December 2024 carries the title 'New price deal paves way for NICE approval of treatment for rare genetic condition'. A number of NHS Trusts also refer to 'NICE approved medicines' in their online Trust Formularies, and a number of Patient Organisation websites also refer to NICE approval. Given that these are reputable sources of information that the target audience of this item are likely to access on a regular basis, we feel that such terminology is readily understood and does not mislead the audience exposed to this item in any way. We therefore do not feel that a breach of Clause 6.1 has occurred.

We are confident that in the creation, approval and delivery of this item, high standards have been maintained at all times and we therefore do not feel that a breach of Clause 5.1 has occurred."

The Panel requested further information from SOBI, which was provided. This further information did not ultimately form part of the Panel's ruling so is not repeated here.

PANEL RULING

This case was in relation to a banner advertisement for Zynlonta (loncastuximab tesirine) that appeared in two journals intended for health professionals.

The complainant made two allegations about the advertisement:

1. The black triangle and the brand name were not adjacent because a brand logo had been placed between them.
2. The advertisement included the words "*NICE approved*" which was misleading because NICE 'recommend' rather than approve.

Allegation 1 – black triangle not adjacent to name (Clause 12.7)

For the purposes of this complaint, the relevant extracts of Clause 12.7 state:

"When required by the licensing authority, all promotional material must clearly show an inverted black equilateral triangle to denote that additional monitoring is required in relation to adverse reactions.

...

The symbol [the black triangle] should appear at least once and be located adjacent to the most prominent display of the name of the product.

The size and location must be such that it is easily noticed."

The Panel noted that the complainant and SOBI both agreed that there was a logo placed between the name (Zynlonta) and the black triangle. The complainant's allegation was that the requirements of Clause 12.7 had not been met because the black triangle was not adjacent to the product name.

SOBI's submitted that although the logo had been placed between the name and the black triangle, the logo "*did not detract in any way from how noticeable the black triangle is*".

The Panel concluded that, as a matter of fact, inserting a logo between the name and the black triangle meant that it was not adjacent.

In addition, the Panel considered that the nature of the logo in this case was highly relevant. The logo:

- (a) was mostly dark brown in colour (i.e. similar to the colour of a black triangle),
- (b) had three prongs of equal length, sticking out at roughly 60 degrees from each other, to make a triangular shape, and
- (c) had the prongs positioned at what might be described as 10 o'clock, 2 o'clock and 6 o'clock. In other words, they formed an inverted triangle – the same orientation as required of a black triangle under Clause 12.7.

The Panel therefore concluded that it was very likely that the black triangle could be mistaken as being part of the logo, rather than being recognised as an important symbol denoting additional monitoring requirements. In the Panel's view, the relative size and location of the black triangle, compared to the logo, meant that it could not be easily noticed and consequently did not meet the requirements of Clause 12.7.

The Panel ruled a **breach of Clause 12.7**.

Allegation 2 – 'NICE approved' is misleading

The complainant provided screenshots of what appeared to be the third and fourth frames of the banner advertisement at issue as part of their complaint. The Panel noted that all four frames of the advertisement included the prominent brand name (Zynlonta), the generic name, the name of the company and small text at the top of the banner stating "For UK healthcare professionals".

The complainant's second allegation related to the main text of the third frame, the full wording of which was:

"ZYNLONTA is NICE and SMC approved^{2,3} as monotherapy for the treatment of adult patients with relapsed or refractory DLBCL and HGBL, after two or more lines of systemic therapy." (emphasis as it appeared in the advertisement)

The bold text was referenced to the Zynlonta SPC and the NICE technology appraisal guidance, "*Loncastuximab tesirine for treating relapsed or refractory diffuse large B-cell lymphoma and high-grade B-cell lymphoma after 2 or more systemic treatments. (2024) NICE technology appraisal guidance 947*".

The allegation was that, because NICE gives "*recommendations*", using the term "*approved*" gives a false and misleading impression. The Panel made its ruling on this narrow allegation.

SOBI submitted that this banner advertisement had appeared from 11 November 2024 to 31 January 2025 and that the wording 'NICE approved':

“reflects the terminology used by healthcare professionals for outcomes of health technology appraisals, these individuals being the target audience for this item.”

Although the Technology Appraisal Guidance produced by NICE used the term “*recommended*” (rather than “*approved*”), the Panel did not consider that the complainant had established their allegation that using the word “*approved*” gave a false or misleading impression. The Panel’s view was that ‘NICE approved’ is a shorthand that is readily understood by health professionals, who were the target audience for the banner advertisement. The Panel therefore ruled **no breach of Clause 6.1**.

High standards and Clause 2

The Panel did not consider there to be any other allegations that suggested there had been a failure to maintain high standards (under Clause 5.1), or that this case brought discredit upon, or reduced confidence in, the pharmaceutical industry (under Clause 2). The Panel also considered that its ruling of a breach of Clause 12.7 was sufficient in relation to Allegation 1. The Panel therefore ruled **no breaches of Clause 5.1 and Clause 2**.

APPEAL BY SOBI

SOBI’s written basis for appealing is reproduced below:

“Thank you for your letter of 3rd November 2025 stating the Code of Practice Panel outcome of the above case. The Panel ruled the company in breach of Clause 12.7 related to Allegation 1. With respect to Allegation 2, the Panel ruled no breach, and the Panel also ruled no breach of Clause 5.1 or Clause 2.

I write to appeal against the Panel's decision related to Allegation 1 and the ruling of a breach of Clause 12.7. Notice of appeal has been submitted within five working days of notification, and these detailed reasons are lodged within the ten working day deadline of Tuesday, 18 November, in accordance with the PMCPA Constitution and Procedure and Guidance on appeal procedures.

Basis of the Appeal:

We respectfully submit that the Panel has misapplied Clause 12.7 by introducing a requirement of “immediate adjacency” that the Code does not specify for the black triangle symbol, and by overlooking both the textual distinction the Code makes between “adjacent” and “immediately adjacent” and the actual visibility and noticeability features of the advertisement in context. We ask the Appeal Board to set aside the finding of breach under Clause 12.7.

Adjacency:

With regard to the black triangle specifically, clause 12.7 requires “adjacent,” not “immediately adjacent.” The Code explicitly distinguishes these terms. Clause 12.7 provides that the black triangle “should appear at least once and be located adjacent to the most prominent display of the name of the product,” and that “the size and location must be such that it is easily noticed.” Elsewhere in the Code (for example in Clauses 12.4, 13.5 and Clause 12.1 Supplementary Information, in relation to the non-proprietary

name), the wording “immediately adjacent” is used. In the Supplementary information for Clause 12.4, “immediately adjacent” is further defined as “means immediately before, after, above or below”. This deliberate drafting contrast demonstrates that “adjacent” in Clause 12.7 is a different, less stringent spatial requirement than “immediately adjacent.”

In our advertisement, the black triangle is adjacent to the most prominent display of “Zynlonta.” The presence of a small brand logo between the product name and the symbol does not negate adjacency. The Cambridge English dictionary definition of adjacent is “very near, next to or touching”. The relevant requirement is not contiguity without any intervening element, but proximity sufficient for clear association. The Panel’s reasoning effectively imports an “immediately adjacent” threshold into Clause 12.7, thereby elevating the requirement beyond what the Code stipulates.

Noticeability:

The Code’s requirement of “easily noticed” guards against designs that could obscure the triangle. Our layout ensures the triangle is conspicuous. Noticeability in Frame 1: a prominent safety box and adverse event statement enhance visibility.

In Frame 1 of the banner sequence, a large, visually dominant box captures the black triangle and the adverse event reporting statement and related safety messaging. This box is the principal graphical feature of the frame and is designed expressly to draw the eye to the triangle and the associated safety information.

This presentation directly engages the Clause 12.7 requirement that “the size and location must be such that [the triangle] is easily noticed.” The safety box’s prominence, the use of contrasting colour and whitespace, and the proximity to the product name together make the triangle highly salient. The Panel’s assertion that the triangle “could be mistaken as part of the logo” overlooks the way the triangle is functionally embedded within a safety-signalling construct, which is visually and semantically distinct from branding.

The Panel observes the logo’s dark hue and pronged, triangular motif, suggesting potential confusion. In our design:

The logo is a multi-pronged, non-solid, stylised shape with negative space, distinct from the standard solid equilateral black triangle.

The triangle appears within a safety messaging construct (the adverse event notice box), giving it a clear safety signification context, further differentiating it from branding or decorative elements.

The relative sizing, positioning, and contrast in Frame 1 are deliberately chosen to satisfy the “easily noticed” requirement of Clause 12.7. The logo does not diminish the triangle’s salience in that frame.

MHRA vetting: no concerns about the black triangle/logo arrangement were raised. The advertising materials were provided to the MHRA as part of vetting which completed at the end of June 2024. The advertising assessor at the Advertising Standard Unit did not raise concerns about the logo/triangle arrangement and did not indicate that the placement minimised noticeability or rendered the triangle part of the logo.

We fully acknowledge PMCPA’s independence; however, MHRA’s lack of comment on adjacency or noticeability is persuasive contextual evidence that, within regulatory

practice, the arrangement did not frustrate the triangle's purpose or visibility. It supports the view that Clause 12.7's adjacency and noticeability tests were met in the materials as certified and deployed.

Relief sought

That the Appeal Board allows the appeal and overturns the Panel's ruling of breach of Clause 12.7 with respect to Allegation 1. That, in the case of the appeal being allowed, no sanction be applied in respect of Clause 12.7 in this case.

We appreciate the Appeal Board's consideration and remain available to clarify any aspect of this submission."

RESPONSE FROM THE COMPLAINANT

The complainant did not respond to the appeal.

APPEAL BOARD RULING

The Appeal Board considered the black triangle to be an important safety symbol. Clause 12.7 of the Code required the black triangle symbol to be adjacent to the name of the product and that the size and location of the black triangle must be such that it is easily noticed. The Appeal Board considered that 'adjacent' meant 'next to'.

The Appeal Board concluded that the black triangle symbol in the banner advertisement at issue was not 'next to' the product name because there was a brand logo in between the name of the medicine and the black triangle. Furthermore, the black triangle symbol appeared much smaller than the brand logo, and the two partially overlapped. The Appeal Board concluded that the size and location of the black triangle meant that it could be mistaken as part of the brand logo and therefore it could not be easily noticed. A potential consequence of the layout of this banner advertisement was that adverse events may not be reported, which the Appeal Board considered to be a patient safety issue. The Appeal Board upheld the Panel's ruling of a **breach of Clause 12.7**. The appeal was unsuccessful.

Complaint received **10 December 2024**

Case completed **13 January 2026**