**CASE/0579/05/25 AND CASE/0580/05/25**

# ROCHE v ASTRAZENECA AND DAIICHI SANKYO

## Allegations regarding a misleading comparison and claim in promotional materials

### CASE SUMMARY

**This case related to an intercompany complaint and concerned a claim and a cross-trial comparison made by AstraZeneca and Daiichi-Sankyo in promotional materials. Further allegations were not progressed by the case preparation manager. The Panel made no rulings in relation to the allegations relating to the cross-trial comparison as it concluded this matter had been successfully resolved during intercompany dialogue.**

**The outcome under the 2024 Code was:**

| | |
|---|---|
| **Breach of Clause 5.1** | **Failing to maintain high standards** |
| **Breach of Clause 6.1** | **Making a misleading claim** |
| **Breach of Clause 6.2** | **Making a claim that was not capable of substantiation** |
| **Breach of Clause 14.4** | **Making an all-embracing claim and implying special merit** |

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

### FULL CASE REPORT

An intercompany complaint was received from Roche Products Ltd about AstraZeneca UK Limited and Daiichi Sankyo UK Ltd.

AstraZeneca and Daiichi-Sankyo provided a joint response to the complaint, and both companies subsequently provided an undertaking in relation to the Panel's rulings of the breaches of the Code. Accordingly, a single report has been published encompassing both cases.

### COMPLAINT

The complaint wording is reproduced below with some typographical errors corrected. Allegations made by Roche that were not progressed to the Panel by the case preparation manager have been redacted:

> "Following unsuccessful inter-company dialogue (ICD) between Roche Products Limited (Roche) and AstraZeneca/Daiichi Sankyo, Roche is seeking PMCPA adjudication to

address ongoing concerns regarding the promotion of Enhertu (trastuzumab deruxtecan) in the HER2-positive metastatic breast cancer (MBC) setting. These concerns relate specifically to the accuracy, clarity, and appropriateness of promotional materials and associated messaging disseminated by AstraZeneca and Daiichi Sankyo (AZ/DS) [redacted].

Although AZ/DS made a modest attempt to engage in inter-company dialogue, Roche remains concerned by the lack of meaningful commitment to resolve the matters raised [redacted]. Given the unresolved nature of these issues, Roche respectfully refers the matter to the PMCPA for formal adjudication.

**Background**

Roche holds the marketing authorisations for Perjeta (pertuzumab), Herceptin (trastuzumab), and Phesgo (pertuzumab/trastuzumab), which are authorised and routinely used in the UK as first-line treatment for HER2-positive mBC. In particular, Phesgo is indicated in combination with docetaxel for patients who have not previously received anti-HER2 therapy or chemotherapy in the metastatic setting.

Enhertu is licensed for use in adult patients with HER2-positive unresectable or metastatic breast cancer who have received one or more prior anti-HER2-based regimens, based on the results of DESTINY-Breast03 study, which evaluated Enhertu predominantly in the second line setting following prior anti-HER2 therapy. This is the primary clinical evidence underpinning the promotional activities and materials at issue.

Whilst AstraZeneca and Daiichi Sankyo are conducting a clinical trial programme (DESTINY-Breast09) investigating Enhertu in the first-line metastatic breast cancer setting, its use in this population remains outside the current marketing authorisation.

Following unsuccessful inter-company dialogue, Roche remains concerned that materials and communications issued by AZ/DS inappropriately promote Enhertu, which Roche believes is in breach of the ABPI Code of Practice.

**Summary of InterCompany Dialogue**

Below is a summary of the outstanding issues raised during two separate Inter-Company Discussions (ICDs) that remain unresolved. For your reference, we have also attached copies of all related correspondence exchanged regarding the two complaints between Roche and AstraZeneca/Daiichi Sankyo.

**Complaint 1: Symposium at [named third party] Breast Cancer Congress on [date] January 2025**

On [date] January 2025, Roche colleagues attended the [named third party] Breast Cancer Congress, where AstraZeneca and Daiichi Sankyo (AZ/DS) hosted a promotional symposium for their product, Enhertu. During this session, [named speaker] delivered a presentation titled ‘ESMO Guidelines Review and Treatment Decisions for HER2-positive (HER2+) Metastatic Breast Cancer (mBC).’

Roche identified several issues during the presentation that warranted further scrutiny. While some of these were clarified through subsequent intercompany dialogue, Roche continues to question the accuracy and appropriateness of certain materials and statements presented by AZ/DS. Particular points of contention include the use of cross-trial comparison slides and the visual representation of safety data, which Roche considers potentially misleading.

[Statements regarding an allegation not progressed to the Panel]

To support these concerns, images of the presentation slides and the briefing document received from AZ/DS are provided, with further details outlined below

Cross-trial Comparison Slide:

Roche Complaint: A presentation slide titled 'Summary of other trials in HER2+ MBC' included cross-trial comparisons of multiple studies. This comparison considered studies that were in multiple different lines of therapy, included trials with varying patient populations and one set of study results that looked at a different subtype of breast cancer.

The cross-trial comparison slide did not adequately reference the significant differences between the studies, as mentioned previously, which may have resulted in attendees leaving with misleading interpretations and significance of the data presented.

Additionally, some of the data presented relates to studies in the HER2+ metastatic first line setting, an area of breast cancer that Enhertu is not currently licensed, but a treatment area that Enhertu is currently being studied as part of the Destiny Breast-09 clinical trial. The use of data related to lines of therapy that Enhertu cannot currently be used in, the heavy reliance on the use of small footnotes to attempt to contextualise the studies, and the use of cross-trial comparisons to focus solely on efficacy outcomes for the respective studies, has the overt risk of leading clinicians to misinterpret the data being presented, and where Enhertu could fit in the current treatment landscape.

Cross-trial comparisons require rigorous methodological considerations to ensure the validity and reliability of conclusions drawn from such analyses. Roche does not believe footnotes in significantly smaller text than the title, particularly when discussing multiple, complex studies and in a large auditorium where it may be difficult to read, are sufficient explanations of these cross-trial comparisons.

Roche also has concerns regarding a slide focused purely on efficacy results for studies, with no further discussion about the safety impact of these studies, provides a clear, fair and balanced view of the studies presented. While Roche accepts that this cross-trial comparison slide does not refer to Enhertu, given that it is part of a promotional slide presentation for this product, it is inevitable that comparisons will be made between these studies and the Enhertu studies subsequently referred to.

AZ/DS Response: AZ/DS agreed to discontinue the slide in its current format and to take Roche's feedback into consideration. This, and subsequent responses, did not provide adequate assurances to prevent similar issues in future presentations with respect to the use of cross trial comparisons. Specifically, AZ/DS did not commit to ensure that cross

trial comparisons are not used when comparing trials of different populations, but rather stated that they would ensure that data presented was in full adherence to Clause 6.1.

Outcome: The lack of assurance to prevent similar issues, and a commitment to not use cross trial comparisons when comparing different populations in the future leaves this concern unresolved.

Roche asserts that use of cross trial comparisons in this manner breaches clauses 5.1, 6.1, 6.3 and 14.1 of the ABPI Code of Practice 2024.
[Additional allegations regarding the promotional symposium that were not progressed to the Panel]

**Complaint 2: Promotional Leave piece 'Push the Paradigm'**

On 27 March 2025, Roche raised significant concerns regarding a promotional leave piece titled *'Push the Paradigm'*, produced by AstraZeneca and Daiichi Sankyo for Enhertu. The material was found to contain multiple inaccuracies and misrepresentations, particularly in its use of misleading graphics and text, and [statements about allegations not progressed to the Panel]. Although some progress was made through intercompany dialogue, key issues remain unresolved. These include the implication that Enhertu is appropriate for use in treatment settings where it is not currently licensed, as well as the failure to appropriately contextualise its indication in relation to prior anti-HER2 therapy. Roche maintains that these deficiencies breach Clauses 5.1, 6.1, 6.3, and 14.1 of the ABPI Code of Practice 2024. Supporting materials, including the leavepiece and briefing document provided by AZ/DS, are included as [enclosures provided].

Roche Complaint:

1. Misleading Graphic and Text:

Roche Complaint: The leavepiece included a sub-heading claiming 'Enhertu: The recommended 2nd-line standard of care for the majority of HER2+ mBC patients' without the claim clarifying where the recommendation has come from or the patient criteria that would form the majority of patients referred to, other than by following the superscript reference alongside the claim (which relates to ESMO guidelines). This was particularly concerning as the leavepiece does not provide further detail as to the patients that would be ineligible for treatment, most notably patients with active brain metastases.

In addition, the leavepiece used a stamp graphic directly underneath this claim stating, 'Recommendation NICE TA 862' and it is Roche's belief this would be seen by a reader as implying that NICE has recommended Enhertu as the preferred option rather than as one possible option amongst others. This again is misleading as readers are likely to believe that a stamp of approval has been provided for Enhertu to be used as the only option in 2L HER2+ mBC patients.

AZ/DS Response: AZ/DS contended that the recommendation was clear to oncologists, backed by ESMO guidelines, that the clinician could refer to the prescribing information (PI) for further information related to eligibility criteria using the QR code provided, and that the NICE stamp graphic was used appropriately.

Outcome: Given the unsatisfactory response, particularly regarding the qualification of the recommendation, that the clinician should refer to the PI, provided as a QR code, as the primary source of information related to eligibility for treatment with Enhertu and the misleading nature of the NICE graphic, ICD remains unresolved.

Roche asserts that use of these misleading graphics and text breaches clauses 5.1, 6.1, 6.2 and 14.4 of the ABPI Code of Practice 2024.

[Information about allegations not progressed to the Panel]

Request for PMCPA adjudication

We request the PMCPA to investigate these matters and facilitate an appropriate resolution. Roche acknowledges the importance of responsible promotional activities in the pharmaceutical industry and appreciates the PMCPA's role in maintaining and enforcing these standards in the absence of resolution between the companies involved.

Roche appreciates your attention to this complaint and welcomes a prompt response."

When writing to AstraZeneca and Daiichi Sankyo, the PMCPA asked both companies to consider the requirements of the following clauses of the 2024 Code:

Part 1: Symposium at [named third party] Breast Cancer Congress on [date] January 2025
- Cross-comparison slide: Clauses 5.1, 6.1, 6.3 and 14.1
- [Allegation not progressed to the Panel]

Part 2: Promotional leavepiece 'Push the Paradigm'
- [Allegation not progressed to the Panel]
- Alleged misleading graphic and text: Clauses 5.1, 6.1, 6.2 and 14.4
- [Allegation not progressed to the Panel]

**ASTRAZENECA AND DAIICHI-SANKYO'S JOINT RESPONSE**

The joint response from AstraZeneca and Daiichi Sankyo is reproduced below:

"In 2019, Daiichi Sankyo UK Ltd and AstraZeneca UK Ltd entered into a global alliance to jointly develop and commercialise certain assets, including trastuzumab deruxtecan (Enhertu). The intercompany dialogue with Roche has been managed collaboratively through the Daiichi Sankyo and AstraZeneca Alliance. Given that identical correspondence has been received from the PMCPA by both companies, this response is being provided as agreed with the PMCPA jointly on behalf of Daiichi Sankyo and AstraZeneca (DS/AZ).

DS/AZ take their obligations under the ABPI Code of Practice very seriously and strives to maintain high standards and to always behave responsibly and ethically.

DS/AZ are very disappointed that Roche believes the Intercompany Dialogue (ICD) process has not yielded a satisfactory resolution. DS/AZ believe they have actively and constructively engaged with the ICD, offering concessions and withdrawing materials where appropriate. DS/AZ is concerned this may undermine the purpose and

effectiveness of ICD. We respectfully submit that initiating a formal complaint after resolutions through ICD risks creating a precedent for duplicative actions and may disincentivise early resolution efforts.

DS/AZ remain of the view that ICD is a valuable mechanism to resolve concerns efficiently and proportionately upholding standards in line with self-regulation without the need for escalation to the PMCPA as far as is possible.

DS/AZ understands that the PMCPA exists to uphold the ABPI Code through both its spirit and its letter, rather than to serve as a forum for adjudication as Roche is requesting. We respectfully suggest that this foundational principle remains central to the matter at hand.

DS/AZ also note Roche's suggestion that the PMCPA investigate DS/AZ more broadly. However, as the PMCPA is aware under current procedures, the burden of proof rests with the complainant. The PMCPA does not act as an investigatory body. DS/AZ is concerned that Roche's approach resembles in parts a speculative enquiry rather than a full and complete substantiated complaint.

Expanding the PMCPA's remit in this way could fundamentally alter the principles of self-regulation and fairness within the industry.

**Part 1 Symposium at [named third party] Breast Cancer Congress on [date] January 2025**

**a) Cross-Trial Comparisons: Clauses 5.1, 6.1, 6.3 and 14.1**

Roche raised a concern regarding a slide which was shared during the DS/AZ promotional symposium at [named breast cancer conference]on [date] January 2025.

Roche allege that the slide entitled 'Summary of other trials in HER2+ MBC' did not provide sufficient clarity and context

DS/AZ are disappointed that Roche have escalated this particular matter to the PMCPA despite commitment through ICD to an undertaking that DS/AZ would immediately recall the slide and no longer use it in its current format, and a further commitment to take Roche's feedback into consideration and to ensure that all data presented going forward would be in full adherence with Clause 6.1.

Given the immediate actions taken and commitments made by DS/AZ; DS/AZ believe this matter was successfully resolved through ICD. However, Roche are requesting an undertaking that cross-trial comparisons are not used when comparing trials of different population.

In specialist therapeutic areas like oncology, cross-trial comparisons are commonly used with appropriate clear and unambiguous context to assist clinical understanding. A recent example of such a cross-trial comparison of different populations was in fact used by Roche themselves recently and can be seen in the attached**.** In addition, there is nothing in the Code that precludes the use of cross-trial comparisons as long as the information is clear from the outset and HCPs can make their own informed clinical decision.

[Information related to an allegation not proceeded to the Panel]

**Part 2 – Promotional Leave piece: 'Push the Paradigm'**

Roche raised concerns regarding 'inaccuracies and misrepresentations, on a promotional leave piece entitled "Push the Paradigm" namely the use of misleading graphics and text, and [statement related to allegation not progressed to the Panel].'

It is important to note that the material in question had been recalled for continuous improvement and therefore was not in use prior to receiving Roche's complaint, this was made clear to Roche through ICD.

**A. Misleading Graphic and Text: Clauses 5.1, 6.1, 6.2 and 14.4**

Roche alleges that the headline on the front page of the leave piece is misleading:

*'Enhertu: The recommended 2nd-line standard of care for the majority of HER2+ mBC patients'*.

DS/AZ do not believe that the above headline is misleading for the following reasons:

- The ESMO (European Society for Medical Oncology) guideline provided as a reference to support the headline statement state: 'Based on the strength of these efficacy and safety data, it is reasonable to consider trastuzumab deruxtecan (TDXd) the new standard second-line therapy in regions where this drug is available [I, A (European Society for Medical Oncology – Magnitude of Clinical Benefit Scale, Grade A: Highest magnitude of clinical benefit)], moving T-DM1 to a later-line setting.'
- The ESMO guidelines reference recommends trastuzumab deruxtecan (TDXd) for patients with 'no, unknown or stable BMs.' (brain metastases)
- Patients with HER2+ metastatic breast cancer have a prevalence of brain metastases (active or stable) between 18.6-32.4% at second line of therapy. Of these, only a small proportion will have active brain metastases**,** therefore, active brain metastases form a small minority of patients, who should not be treated with TDXd. It follows that the majority of HER2+ MBC 2$^{nd}$ line fall into the category 'no, unknown or stable BMs' as stated on the leave piece.
- Patients with active brain metastases are not only a minority, but clinically distinct and pragmatically managed differently by oncologists. They are conventionally excluded from clinical trials, much the same way as pregnant women, and as such a busy HCP would not automatically prescribe systemic treatment for active/unstable brain metastases, which requires localised management with surgery/radiotherapy.
- Furthermore, in UK clinical practice, all patients with metastatic breast cancer are discussed at a multidisciplinary team (MDT) meeting where the MDT discuss the patient holistically. Treatment decisions are not made by one HCP in isolation.
- The headline statement used the word 'majority' of HER2+ mBC patients not '**all'** HER2+ mBC patients, which does not suggest that all patients would be eligible for Trastuzumab deruxtecan (Enhertu) as a second-line treatment based on the above.

- Moreover, the licensed indication for Trastuzumab deruxtecan (Enhertu) is stated prominently on the same page as the above statement. There is clear direction to the SmPC for further information *'**Please see the SmPC for full details.'***
- There is clear direction to prescribing information.

Based on the above DS/AZ do not believe that it is misleading to state *'Enhertu: The recommended 2nd-line standard of care for the majority of HER2+ mBC patients'*.

Roche further alleges that the leave piece is also misleading due to the use of a NICE stamp graphic*:*

'Recommendation NICE TA 862' as this would be seen by a reader as implying that NICE has recommended Enhertu as the preferred option rather than as one possible option amongst others.

DS/AZ do not believe that the NICE stamp would be interpreted in the way Roche alleged. In seeing the stamp, the expert audience would not believe that NICE have recommended Enhertu as the only recommended standard of care product in this line of therapy but rather that NICE has carried out its technology appraisal within Enhertu's licence and provided guidance for its use. DS/AZ believe that the remit of NICE is well understood by HCPs.

Additionally, the stamps for SMC and NICE clearly state within them 'SEE ADVICE FOR DETAILS'/SEE GUIDANCE FOR DETAILS' respectively, which clarifies the remit of NICE recommendation.

The wording in the NICE stamp was prominent and no HCP would be misled by this accurate information.

[Information related to allegations not progressed to the Panel]

**In summary:**

- Cross-trial comparisons are common in specialist areas like oncology and are permitted under the Code if the context is clear and HCPs can make informed decisions.

- [Information related to allegation not progressed to the Panel]

- We do not believe that it is misleading to state *'Enhertu: The recommended 2nd-line standard of care for the majority of HER2+ mBC patients'* based on the substantiation within the references provided.

- We do not agree with Roche's interpretation of the NICE stamp, as the expert oncology audience understands that NICE's guidance relates only to the appraised use within Enhertu's license, not as the only recommended standard of care. The NICE stamp directs readers to *see specific advice/guidance for details*, and no HCP would be misled.

- DS/AZ committed to making the reference to 'previous' in the claims and graphics clearer going forward in our materials. The front-page clearly states Enhertu's licensed indication. There is no reference nor intent to the displacement of any therapies in any subsequent line of treatment.

- DS/AZ have acted in good faith, addressed concerns promptly, withdrawn materials as needed, and believed Roche's concerns were resolved.

**Conclusion**

DS/AZ takes its obligations under the ABPI Code of Practice very seriously and strives to maintain high standards. Based on the above detailed response, DS/AZ has maintained high standards in its activities and strongly believe we have not brought the pharmaceutical industry into disrepute and has not jeopardised patient safety in this regard.

We have processes in place to ensure that we operate consistently to the highest standards and take our obligations under the ABPI Code of Practice very seriously."

## PANEL RULING

This intercompany complaint related to promotional activities for Enhertu (trastuzumab deruxtecan) conducted by AstraZeneca and Daiichi Sankyo, specifically a cross-trial comparison presented at a promotional meeting and a leave piece which claimed Enhertu was the recommended 2nd-line standard of care. Roche alleged that the cross-trial comparison did not adequately reference the significant differences between the studies presented and may have resulted with attendees leaving the symposium with misleading interpretations of the data and its significance. Roche further alleged that a promotional leave piece included graphics and text which made a misleading claim regarding the recommendation status of trastuzumab deuxtecan. Roche made additional allegations about both the symposium content and the leave piece however, following receipt of AstraZeneca & Daiichi Sankyo's response, the case preparation manager determined that there was no prima facie case in relation to the allegations and these matters were not referred to the Panel.

Allegation 1: A cross-trial comparison at a promotional symposium

The Panel noted that the cross-trial comparison slide at issue was displayed at an AstraZeneca & Daiichi Sankyo promotional symposium. The title of the symposium was '*ESMO Guidelines Review and Treatment Considerations in HER2-postiive (HER2+) metastatic Breast Cancer (mBC)'*. The cross-trial comparison slide in question was slide 20 of 24 and was headed '*SUMMARY OF OTHER TRIALS IN HER2+ MBC'*. The slide contained a bar graph displaying the results of six clinical trials. The X axis of the bar graph was labelled 'mPFS (months)' and the Y axis was labelled 1L, 2L and 3L referring to first to third line treatment options.

Beneath the bar graph, the statement *'Slide intended to succinctly summarise data from several trials and is not intended to be a cross-trial comparison; cross-trial comparisons are limited by different study designs and patient populations'* was included. The remainder of the content of the slide consisted of the citations for the studies presented in addition to a number of footnotes providing qualification for three of the studies.

The Panel noted that during intercompany dialogue, AstraZeneca and Daiichi Sankyo had agreed to recall the cross-trial comparison slide, that the slide would no longer be used in its current format and that going forward, all data presented would be in full adherence with Clause 6.1 of the Code. AstraZeneca and Daiichi Sankyo submitted that Roche were requesting an undertaking that cross-trial comparisons would not be used when comparing trials with different patient populations, which was not acceptable to AstraZeneca and Daiichi Sankyo as they stated cross-trial comparisons are frequently used in specialist therapy areas such as oncology and such comparisons were not prohibited provided they comply with the requirements of the Code. The Panel considered that the cross-trial comparison slide at issue had been withdrawn and noted the AstraZeneca and Daiichi Sankyo had agreed that the slide would not be used again in its current format. In the Panel's view, companies could not use the inter-company dialogue process to request an undertaking for material or activity which had not taken place and which was not prohibited by the Code. On this basis, in addition to the fact that the cross-trial comparison slide had been withdrawn, the Panel concluded that this issue had been successfully resolved during intercompany dialogue and made no ruling on this matter.

Allegation 2: Graphic and text in a promotional leave piece

In addition to the above, Roche made allegations that graphics and text included in a promotional leave piece for Enhertu misleadingly represented the recommendation status of Enhertu. The leave piece consisted of seven pages, the first of which was titled '*Push the Paradigm'* and directly below featured the claim:

*'ENHERTU®: The recommended 2nd-line standard of care for the majority of HER2+ mBC patients[1,2]'*

Beneath the claim were two stamps which included the statements *'accepted'* and *'recommendation'* for the Scottish Medicines Consortium (SMC) and National Institute for Health and Care Excellence (NICE) respectively. The stamps contained the reference number of the specific SMC and NICE advice and guidance and referred readers to see the full documents for details. The remainder of the front page of the leave piece included a statement that the marketing authorisation for Enhertu was conditional, signposting to prescribing information, an adverse event reporting statement and the licenced indication for Enhertu.

The Panel noted that in addition to the front page, a claim that Enhertu is the recommended standard of care at 2L+ for the majority of HER2+ mBC was made on the penultimate page of the leave piece. A box at the bottom of this page stated that Enhertu is reimbursed for NHS use across the UK in patients with HER2-positive metastatic breast cancer who have received one or more prior anti-HER2 therapies. The NICE and SMC guidance were again referred to with an asterisk next to the NICE guidance which related to a qualifying statement that '*ENHERTU is recommend by NICE only if the conditions of the managed access agreement are followed'*.

The Panel noted that Roche's concerns were specifically that the recommendation claim did not clarify where the recommendation had come from or the patient criteria that would form the 'majority' of patients referred to. Additionally, in Roche's opinion, the inclusion of the NICE and SMC stamps implied that these bodies had recommended Enhertu as the preferred option rather than a possible option amongst others which was again misleading.

Neither party provided the Panel with copies of the NICE or SMC guidance.

The Panel noted two references were cited in support of the recommendation claim, and these were listed on page 7 of the leave piece. One reference was the 2023 European Society for Medical Oncology (ESMO) Guidelines. The Panel noted that the ESMO guidelines included a decision tree which ended with Enhertu as the recommended 2nd line treatment for patients with no, unknown or stable brain metastases.

The Panel noted AstraZeneca & Daiichi-Sankyo's submission that the expert audience would not believe, on seeing the NICE stamp, that NICE had recommended Enhertu as the only recommended standard of care product but rather that NICE had carried out a technology assessment within Enhertu's licence and provided guidance on its use. The Panel noted that the claim and graphics appeared on the front page of the leave piece and that this prominent placement suggested that they were intended to be the key messages. The Panel considered that the statement '***the** recommended 2nd-line standard of care…'* (emphasis added by the Panel) without explicitly mentioning ESMO or its guidelines implied some kind of special merit and that the overall wording of the claim, implied a general, all-embracing recommendation for Enhertu. Furthermore, in the Panel's view, the proximity of the claim to the NICE and SMC stamps, together with the lack of reference to the ESMO guidelines within the claim itself, could lead the reader to interpret the recommendation as being, at least in part, derived from the NICE and SMC guidance. As presented in the leave piece it would not have been clear to the reader that the recommendation came from the ESMO guidelines alone. The Panel concluded that readers of the leave piece may be misled by the claim. **Breaches of Clauses 6.1 and 14.4** were ruled.

The Panel noted that the recommendation in question did not make it clear that it had been from the ESMO guidelines. Coupled with the close proximity of both the NICE and SMC stamps, it created the impression that such recommendation was endorsed by both NICE and SMC which was not so. The Panel therefore concluded that the claim as it was presented was not capable of substantiation and ruled a **breach of Clause 6.2**.

In the Panel's view, the cumulation of factors including the omission of the specific reference to the recommendation being derived from ESMO guidelines, the use of the definitive article and the proximity to the NICE and SMC stamps led to a misleading impression being created and demonstrated that in this instance AstraZeneca and Daiichi Sankyo had failed to maintain high standards. Therefore, the Panel **ruled a breach of Clause 5.1**.

**Complaint received** **13 August 2025**

**Case completed** **27 February 2026**