CASE/0277/08/24

COMPLAINANT v ASTRAZENECA

Allegations about an interview with a news channel

CASE SUMMARY

This case was in relation to an interview given by an AstraZeneca global senior leader on a mainstream news channel. The complainant alleged that, during the interview, Enhertu (trastuzumab deruxtecan) had been promoted to the public, and that misleading and unsubstantiated claims had been made about Enhertu. Further allegations about the interview included that the global senior leader had disparaged NICE and was not adequately briefed or trained on the Code.

AstraZeneca UK Limited appealed two of the Panel's rulings.

The outcome under the 2021 Code was:

Breach of Clause 5.1 [Panel's breach ruling upheld at appeal]	**Failing to maintain high standards**
Breach of Clause 26.1 [Panel's breach ruling upheld at appeal]	**Promoting a prescription only medicine to the public**

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 5.2	**Requirement that all material and activities must recognise the special nature of medicines and respect the professional standing or otherwise of the audience to which they are directed and must not be likely to cause offence**
No Breach of Clause 5.5	**Requirement to be sufficiently clear as to the company's role and involvement**
No Breach of Clause 6.1	**Requirement that information/claims/comparisons must not be misleading**
No Breach of Clause 6.2	**Requirement that claims/information/comparisons must be capable of substantiation**
No Breach of Clause 6.7	**Requirement that the clinical and scientific opinions of health professionals not be disparaged**
No Breach of Clause 8.1	**Requirement to certify promotional material**
No Breach of Clause 8.3	**Requirement to certify non-promotional material**
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 9.3	**Requirement that representatives must be given adequate training and have sufficient scientific knowledge**
No Breach of Clause 9.4	**Requirement for representatives to pass an appropriate exam**

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

FULL CASE REPORT

A complaint about AstraZeneca UK Limited was received from an anonymous, contactable complainant.

COMPLAINT

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

> "I am a UK Consultant Oncologist and Patient Advocate, and would like to report a serious breach of the ABPI code of practice, perpetrated by AstraZeneca's [named global senior leader] via an interview with [named mainstream news channel] which covered Enhertu access in the UK, with specific references being made to the access situation in Scotland Vs the situation in England and Wales.
>
> Enhertu is an AZ Antibody Drug Conjugate approved for metastatic Breast Cancer, and is being investigated via Phase 3 clinical trials in other indications.
>
> On the 26th July 2024 on [named mainstream news channel], an interview was held with AstraZeneca [named global senior leader] who was sat in one of AZ's UK offices, from where they are normally based. Addressing an audience, which included the UK public, [named global senior leader] made some scathing remarks about the NICE methodology, directly mentioned Enhertu by name and its approved use in Scotland, and compared the England and Wales access situation to multiple countries in Europe. [Named global senior leader] was also being disingenuous and less than truthful, in fact misguiding the public with saying that it had nothing to do with price. A few days later NICE in the press release confirmed that it was disappointed by the fact that AZ were "unwilling to offer a fair price".
>
> My complaint is based on two key elements here. I am not concerned that [named global senior leader] decided to criticize the methodology of NICE. That is their democratic right here in the UK and so I will say no more on this element. What I would like to bring to your attentions are the below items:
>
> 1. In [named global senior leader's] interview they criticize the NICE methodology and approves of the SMC methodology and in doing so actually mentions Enhertu by name and its access in Scotland. They also provided an indication i.e. metastatic breast cancer. I believe [named global senior leader] has breached a number of ABPI code clauses here, including:-

- **Clause 2:** [Named global senior leader] has brought the Pharma industry into disrepute by promoting a POM to the UK public. Moreover referring to a drug by brand name "Enhertu", an indication (metastatic Breast Cancer), and access situation in Scotland, they have promoted to the public there too. What is also mind blowing here is; Where was the briefing by the UK marketing company? Did the UK Marketing company based in London, in the very same offices from where [named global senior leader] addressed the media, not brief them? Did the UK marketing company have any involvement or oversight? I am not an insider of the UK Pharma industry, but I assume there is a press office, legal, ethical and other departments that would brief [named global senior leader] in AZ on what is and isn't appropriate for a UK audience.

Apart from Clause 2, there are additional breaches, such as;

- A failure to maintain any sort of standards by [named global senior leader] and AstraZeneca UK . [Personal information about named global senior leader], and so their behaviour should be exemplary. **The code states in (5.1) High standards must be maintained at all times.** The fact such a huge mishap was allowed to happen indicates a failure of process, care or attention to the ABPI code.
- **Also 5.2 requires that All material and activities must recognise the special nature of medicines and respect the professional standing or otherwise of the audience to which they are directed and must not be likely to cause offence.**

It is very clear from the interview by [named global senior leader] that they did not recognise the special nature of a Breast Cancer medicine, and decided through their specific activity, of promoting to the public that by complaining to the general public, they could add public pressure to the UK NICE process. This is a very old industry tactic, often exerted through patient groups, physicians like myself and other stakeholders. However, this behaviour was extremely poor and AZ breached 5.2.

- **Promotion to the public: Clause 26.1 states that POMs should not be promoted to the public. [Named global senior leader] interview and AZ activity here of allowing [named global senior leader] to promote their Enhertu product to the UK public is a breach of this clause too.**

Additionally, during my 30 years of interactions with AZ [named AZ teams], I noted that these people are fair, balanced, very decent, and qualified people, revalidated and assessed. What [named global senior leader] did in the [named mainstream news channel] interview is act like a sales person, and so although I am not an expert in the ABPI code, I would like to think that [named global senior leader] would need to have had (i) adequate training to promote a POM, all be it incorrectly to the public. So additional breaches of not having done the ABPI sales representative examination, which is often required of sales reps, MSLs, and other people I have met along my career trajectory. Also the fact that [named global senior leader] had no approved or certified materials to substantiate their claims, so there is a massive breach and failure on that part too here that the PMCPA should please consider.

Please see the details of the interview below: [link provided]

2. Misleading information provided by [named global senior leader] & AZ

During the interview, [named global senior leader] is quoted that the current issue with NICE with respect to Enhertu is purely down to NICE's methodology, and not due to price. See link below which contains the following:

"It's not a question of price. The question is the methodology and the decision to score metastatic breast cancer as a moderately severe disease or a severe disease - which we all believe it is."

Only a few days later NICE put the decision by it to issue a negative outcome on access to Enhertu purely down to price. This again demonstrates that [named global senior leader] and AZ acted with ill intent to target the UK public, at a time when there are protests outside the UK parliament by women and breast cancer groups for access to Enhertu. By behaving in this manner of targeting and blaming NICE for a methodology that has so far ensured access to 21 approved Breast Cancer drugs simultaneously, is poor behaviour. In fact, it's misleading, unsubstantiated, and undermines both the Pharmaceutical industry, the professional standing of medicines, and also the relationship between patients and us as treating physicians.
Here Clause 2, 5.1, and all the clauses in the ABPI code under substantiation, NOT MAKING misleading claims, NOT defaming or disparaging other government organs of the state apply.

[The complainant stated that their complaint related to AstraZeneca and not its co-promotion partner]

When writing to AstraZeneca, the PMCPA asked it to consider the requirements of Clauses 2, 5.1, 5.2, 5.5, 6.1, 6.2, 6.7, 8.1, 8.3, 9.1, 9.3, 9.4 and 26.1 of the 2021 Code.

ASTRAZENECA'S RESPONSE

The response from AstraZeneca is reproduced below:

"Thank you for your letter dated 28 August 2024, regarding a complaint, concerning an online [named mainstream news channel] article based on an interview with [named global senior leader].

In our response, we will address each of the allegations made:

1. [Named global senior leader] has brought the pharmaceutical industry into disrepute by promoting a prescription only medicine to the UK public by referring to Enhertu, an indication (metastatic breast cancer) and the access in Scotland.
2. Failure to maintain high standards
3. The special nature of a breast cancer medicine was not recognised due to promotion to the public and that 'complaining to the general public, [named global senior leader] could put pressure to the UK NICE process'
4. 'Targeting and blaming' NICE methodology is misleading and unsubstantiated

5. [Named global senior leader] acted like a sales representative and so would require training and completion of representative examination
6. [Named global senior leader] has no approved or certified materials to substantiate claims

AZ has been asked to consider Clauses 2, 5.1, 5.2, 5.5, 6.1, 6.2, 6.7, 8.1, 8.3, 9.1, 9.3, 9.4 and 26.1, of the 2021 ABPI Code (the "Code") when responding to each of the allegations. Please find our detailed response below.

AstraZeneca's Response

Background

AZ announced Q2 financial results ("Q2 results") on Thursday 25 July 2024 at 7am (UK time). AZ is one of the largest companies listed on the Financial Times Stock Exchange (FTSE) Index and so our financial updates from the company generate a high level of interest. For this reason, weeks prior to the announcement, business/finance journalists were invited by AZ Media Relations team, to attend a media conference concerning the Q2 results on 25 July 24, at 9am (UK time). In addition, three separate 10-minute recorded interviews, one with [named mainstream news channel] and two with other news outlets, were arranged for the same day. Journalists were invited to attend the media conference and interviews, verbally, by the AstraZeneca Media Relations team. The invitation involved notifying the journalists of the results publication date and offering them an opportunity to interview the AZ [named global senior leader] or [other named global senior leader], to discuss the Q2 results and long-term company ambition.

The purpose of the Q2 results announcement is to keep investors up to date on the company's performance: if any AZ medicine is referred to specifically, this is done solely in the context of current and future revenue. The NICE decision regarding Enhertu (trastuzumab deruxtecan) was not mentioned in the Q2 results published at 7am (UK time).

The NICE decision not to recommend Enhertu for treating HER2-low metastatic or unresectable breast cancer after chemotherapy was made in March 2024: however, the final technology appraisal guidance (TA992) was not published until 29 July 2024. The delay was to allow for extra discussions including campaigning from patient action groups and charities.

To summarise, the timeline of events:
25 July 2024 7am and 9am (UK time), Q2 results and AZ media conference, respectively
25 July 2024 10am (UK time), [named mainstream news channel] interview
26 July 2024, [named mainstream news channel] article published online
29 July 2024, NICE final technology appraisal published

Media conference briefing provided to [named global senior leader]

AZ recognises the care and consideration that must be put into responding to journalists' questions and senior AZ employees are regularly briefed on how to reactively provide appropriate answers to a range of different questions they may get asked by journalists.

The briefing for the Q2 results included key messages and discussion points related to the results, and reactive responses to questions that may be asked by the Media on the day. Since the final NICE technology appraisal guidance (TA992) was expected to be published imminently, AZ anticipated a question related to this and the following was therefore included within the brief for [named global senior leader]:

''Reactive Q&A: Q. Do you have an update on the NICE decision not to recommend Enhertu for HER2-low metastatic or unresectable breast cancer after chemotherapy in England?

- *We look forward to NICE revising their assessment from viewing advanced metastatic breast cancer as only a moderately severe disease. It is vital to recognise that it is a severe disease and this will open up the use of Enhertu as a cost-effective medicine and bring its benefits to patients in England who urgently need it.*
- *NICE issued an exceptional pause to their process and the timeline on their decision is a question for them. We have been clear that NICE mis-classifying HER2-low metastatic breast cancer as 'medium severity' is standing in the way of patient access in England*
- *17 other European countries, including Scotland and most recently Romania, have already delivered routine patient access to trastuzumab deruxtecan for HER2-low breast cancer patients.''*

Interview with [named mainstream news channel] and subsequent published online article

The interview took place on 25 July 24 at 10am (UK time) and then there was a broadcast later that day on the [named mainstream news channel]. A segment of the interview was also published online on 26 July 24. The journalist who interviewed [named global senior leader] is a business journalist. AZ did not record the interview and in line with independent media reporting, AZ had no editorial control or right to review the edited portions of the interview, or the article, that were published. The video embedded in the article is a sequence of several interview snippets.

The AZ Media Relations team confirmed that the journalist was not briefed to ask questions about Enhertu and the NICE decision, nor were any questions solicited on this topic by [named global senior leader], on the day. [Named mainstream news channel] did not inform [named global senior leader] of the questions that would be asked, or topics that would be covered prior to the interview, other than a discussion relating to AZ's Q2 financial performance, which was the focus of the interview.

[Named mainstream news channel] have provided a transcript for the interview. The interview started with questions about the Q2 results, and then the journalist asked questions about the NICE decision on Enhertu. Questions regarding the NICE decision for Enhertu had been raised independently by other journalists during the earlier media conference at 9am (UK time).

Response to the allegations

Allegation 1:

[Named global senior leader] has brought the pharmaceutical industry into disrepute by promoting a POM to the UK public by referring to Enhertu, an indication (metastatic breast cancer) and the access in Scotland.

Allegation 2:

Failure to maintain high standards

Allegation 3:

The special nature of a breast cancer medicine was not recognised due to promotion to the public and that 'complaining to the general public, [named global senior leader] could put pressure to the UK NICE process

Allegation 4:

Targeting and blaming' NICE methodology is misleading and unsubstantiated

The Panel are obliged to make rulings based on what was actually stated, rather than the edited material published by a third party. The questions from the journalist were not included in the published article and [named global senior leader]'s answers published only. Therefore, the article lacks the context of why Enhertu was mentioned.

As demonstrated in the interview transcript, [named global senior leader] only spoke about NICE and Enhertu in response to the following unsolicited questions from the journalist.

"Now, last month, you criticized the National Institute for Health and Care Excellence after they rejected use of Enhertu your breast cancer treatment in the NHS on cost grounds. How worried are you about this access to medicine issue? Is this going to come up again with some of your other products?".

In the transcript of the full interview, [named global senior leader] responded factually, accurately and succinctly to these questions in line with the briefing provided. The topic was not raised by [named global senior leader].

[Named global senior leader]'s response provided reasons why pharmaceutical companies invest in R&D within a country, with one of the considerations being access to medicines.

Regarding NICE, [named global senior leader] describes AZ's view on NICE's methodology to evaluate new technologies, specifically regarding how severity weighting has been applied to metastatic breast cancer. The reference to price is made in the context of the NICE methodology: '*It's not a question of price. The question is the methodology and the decision to score metastatic breast cancer as a moderately severe disease or a severe disease - which we all believe it is.'* This is based on the fact that NICE underwent a major review of its methods and processes for technology appraisal in 2022 and incorporated a QALY weighting multiplier for disease severity for the first time. This modifier enables NICE to effectively make recommendations at variable cost-effectiveness thresholds depending on the severity of the disease. Therefore, the response was not disparaging, targeting, or blaming NICE as alleged by the complaint, but providing AZ's view of the well-known change to NICE's new severity-based, tiered approach to valuing new technologies. [Named global senior leader]'s response also describes how access to the medicine differs to other countries and the impact to patients,

which is factual and responding to the question *'how worried are you about this access to medicine issue'*.

This clearly demonstrates that although [named global senior leader] discussed Enhertu, they did so reactively and their response did not go further than necessary to answer the unsolicited questions raised about the medicine. No information was provided relating to the efficacy or safety of Enhertu. [Named global senior leader]'s response was not promotional in tone or content and was in line with the high standard expected of the pharmaceutical industry.

The complainant alleges a breach of Clause 5.2 because [named global senior leader] 'did not recognise the special nature of medicine by promoting to the public and adding pressure to the UK NICE process.' As described above the questions about Enhertu were unsolicited and the responses did not extend beyond the scope of the questions asked.

In summary, the purpose of the interview with [named mainstream news channel] was to discuss the Q2 financial results, which is reflected in the interview transcript. Whilst the headline and initial focus of the article is on the NICE methodology for Enhertu, the article does proceed to report on investing abroad, AZ's revenue and ambition. [Named mainstream news channel] (independent of AZ) took the editorial decision to present [named global senior leader]'s answers related to the NICE decision on Enhertu. The responses to the questions highlighted above are not promotional (in accordance with clause 1.17 of the Code). All statements made by [named global senior leader] were factual, and information relating to the NICE decision for Enhertu, based solely on the NICE methodology, was provided in response to unsolicited questions.

When properly understood within context, [named global senior leader]'s comments are neither disparaging nor inaccurate and do not constitute promotion to the public. As a result, there can be no suggestion that the interview could be said to have brought the industry into disrepute. Therefore, we **refute a breach of Clauses 26.1, 6.1, 6.2, 6.7, 5.1, 5.2, and 2** in response to this allegation.

Allegation 5:

[Named global senior leader] is acting as a representative, and questions whether [they have] undergone product training and passed the ABPI exam.

The complainant has made an allegation that [named global senior leader] was 'Acting like a sales representative.' The definition of a representative in the ABPI code is 'a representative calling on members of the health professions and other relevant decision makers in relation to the promotion of medicines.' It is unclear why AZ has been asked to respond to clauses related to training of personnel (including representatives) concerned in any way with the preparation or approval of material or activities covered by the ABPI Code (Clause 9.1), training of sales (Clauses 9.3 and 9.4) when the main allegation throughout the complainant's letter is promotion to the public via an online [named mainstream news channel] article.

Nevertheless, as described above, information provided about Enhertu and the NICE decision was made in response to an unsolicited question. All answers were factual and non- promotional. As a result of this, the requirements for training promotional representatives does not apply. We therefore **refute a breach of Clauses 9.1, 9.3, 9.4**.

***Allegation 6*:**

[Named global senior leader] has no approved or certified materials to substantiate claims

AZ has been asked to respond to Clauses 8.1 and 8.3 based on the statement 'the fact that [named global senior leader] had no approved or certified materials to substantiate claims.' However, [named global senior leader] did not use any materials when providing responses to unsolicited questions during the interview and no materials have been provided as evidence by the complainant. Therefore, it is unclear why AZ is required to respond to these clauses of the ABPI code.

If the complainant was referring to approval of the [named mainstream news channel] article, then as established above, AZ had no editorial control or right to review any information that was published by [named mainstream news channel]. Therefore, there was no requirement for AZ to certify the [named mainstream news channel] article, and we **refute a breach of Clauses 8.1 and 8.3**.

AstraZeneca has also been asked to consider Clause 5.5 by the Case Preparation Manager (CPM). The complainant hasn't referred to allegations regarding transparency of AZ's involvement in their complaint, and therefore we are unsure why this clause has been alleged by the CPM. As described above, AZ had no editorial control of the [named mainstream news channel] article, and it is clear that the interview was with AZ's [named global senior leader]. **We refute breach of clause 5.5.**

Summary

It is AstraZeneca's position that:

- AZ had no editorial control of the [named mainstream news channel] article in question
- The mention of Enhertu by [named global senior leader] was factual, accurate, recognised the special nature of the medicine and provided reactively in response to questions from the [named mainstream news channel] journalist. No promotion of AZ medicines to the public took place.
- [Named global senior leader]' comments regarding NICE were provided in response to an unsolicited question. The comments describe AZ's view of the NICE methodology and were appropriate, factual and neither disparaging nor misleading in any way. There is no evidence that the comments failed to recognise the special nature of medicines generally or Enhertu in particular.
- Thorough briefings for this activity mean that AZ has maintained high standards.
- It is entirely appropriate for an individual of [named global senior leader]'s seniority to answer unsolicited questions put to them on a topical question related to AZ in the UK.
- There is no requirement to share materials during an interview nor is there a requirement to certify third-party materials published post interview.
- As we have established that no promotion has occurred, the requirements for training representatives do not apply.

AstraZeneca takes its responsibilities under the ABPI Code very seriously. Based on the above detailed response, we maintain this was a non-promotional activity, and we strongly

refute all allegations of breaches of clauses 2, 5.1, 5.2, 5.5, 6.1, 6.2, 6.7, 8.1, 8.3, 9.1, 9.3, 9.4 and 26.1.

PANEL RULING

This complaint related to an interview given by an AstraZeneca global senior leader on a mainstream news channel. The Panel accepted AstraZeneca's submission that the interview was given on the day that AstraZeneca announced its 2024 Q2 results, and that this was the intended purpose of the interview.

Whilst the complainant referred to the published article, which included an edited video of the interview, the Panel based its ruling on the unedited transcript.

In its response to the PMPCA, AstraZeneca accepted that the interviewer questioned its global senior leader about NICE's consideration of AstraZeneca's medicine Enhertu (trastuzumab deruxtecan), and that the global senior leader answered those questions. AstraZeneca provided a transcript of the interview which the Panel accepted as accurate, whilst acknowledging AstraZeneca's submission that it had been transcribed using audio technology so might contain typographical errors. The Panel acknowledged that the balance of the interview concerned the Q2 results.

It is the following extract of the interview which the Panel considered to be the section to which all of the complainant's allegations related:

Interviewer:

> "*Now, last month, you criticized the National Institute for Health and Care Excellence after they rejected use of Enhertu, your breast cancer treatment, in the NHS on cost grounds. How worried are you about this access to medicine issue? Is this going to come up again with some of your other products?*"

AstraZeneca global senior leader's response:

> "*I think it is an important point. And so let me just back up a little bit and tell you about the industry, not only us as a company, but when the industry looks, looks at when we make decisions to invest. We look at, invest in R&D [Research and Development], I should say we look at do we have good science in the country? And here the answer is a resounding 'yes' for the UK. We have great science in this country. Do we have the right talent pool? The answer is another resounding 'yes'. We have a great talent pool in the UK.*
>
> *Then you look at the financial environment, the tax rate, and finally you look at access. Because if you want to invest in research and development, you have to believe your medicines will be brought to patients. Otherwise you can as well do your R&D efforts elsewhere in other countries where your medicines, where which patients and benefit them. And that's really the area where most efforts, most progress need to be made.*
>
> *And the National Institute for Clinical Excellence, NICE has a methodology that leads to difficult access for innovative medicines. Why? Because they have for scoring a new methodology that is called, severity scoring. And as an example, the decision was that was made that metastatic breast cancer, is only a moderately severe disease. Most*

people would say it's a severe disease. I mean, very much patients, I'm sure would say it's a severe disease, but NICE concluded, it's a moderately severe disease. It looks like a technical detail, but it's very important because it drives willingness to pay.

So the end result is 17 countries around Europe have, decided to reimburse and Enhertu for metastatic breast cancer. More recently, Romania, reimbursed it in the UK. Scotland, which is using a different methodology decided to reimburse unhealthful for metastatic breast cancer. So we end up with this difference where Scotland reimburses it. Many countries in Europe do.

And England and Wales patients don't have access because of this NICE methodology. So it really has to change. It's affecting on health too, but it will affect many innovative new medicines that are brought to patients who are dealing with severe disease."

Interviewer:

"*Have you had an opportunity to raise this with the new government yet?*"

AstraZeneca global senior leader's response:

"*We are raising it, every opportunity we have. We have raised it before. We have raised this now too, with the new government. And I understand they are looking at it.*

So we are hopeful that, the methodology can be changed because if you look at it now too, in metastatic breast cancer as an example, it's quite sad because patients, they need it and they're waiting for it. And in fact, if the methodology was to score metastatic breast cancer as a severe disease automatically, instantaneously, the methodology NICE users would recommend, we're going to ombudsman. So it's not a question of price. The question of the methodology and the decision to score metastatic breast cancer as moderately disease moderately with moderately severe disease.
Apologies or a severe disease which we all believe, it is."

The complainant made several allegations about the global senior leader's answers to these two questions, which fell under different clauses of the Code. The Panel considered each in turn.

Clause 26.1 – promotion of a prescription only medicine to the public

The complainant alleged that the global senior leader had promoted Enhertu to the public in breach of Clause 26.1. The Panel considered the context in which the interview had been given:

(a) It was with a mainstream news channel and was therefore likely to reach a wide audience of the general public.
(b) The Panel considered that the subject of Enhertu approval was likely to be relevant to AstraZeneca's financial performance in Q2.
(c) The interview took place shortly after comments that the global senior leader had made about NICE's methodology in the context of Enhertu.

The Panel concluded that it was a reasonably foreseeable that an interview on this day would likely include questions on this topic and indeed it appeared that this had been anticipated by

AstraZeneca. AstraZeneca provided an extract from the briefing material it had used to prepare the global senior leader for these interviews. The Panel noted that the pre-prepared answers within the briefing materials referred to Enhertu being a cost-effective medicine and bringing its benefits to patients in England who urgently need it.

The Panel also took account of the emotive language and phrasing used in the interview. For example:

- the reference to patients in the phrase "*patients, I'm sure would say it [metastatic breast cancer] is a severe disease, but NICE concluded, it's a moderately severe disease."*

- *"17 countries around Europe have, decided to reimburse and Enhertu for metastatic breast cancer."*

- "*it's quite sad because patients, they need it and they're waiting for it."*

The Panel accepted that the global senior leader's comments were in response to a foreseeable question and further it could be argued that the question was about a newsworthy matter. However, in the Panel's view, and on balance, the global senior leader's answers went beyond a limited factual response to the question, particularly given the ultimate audience and the sensitive nature of the therapy area. Given the fact that the global senior leader referred to the patient demand and urgent need for this medicine, how it was available in other countries including Scotland, and described the lack of availability as "sad", the Panel considered this to be promotional of a prescription only medicine to the public and ruled a **breach of Clause 26.1**.

Clause 5.1 – failure to maintain high standards

The complainant alleged that the answers to these questions also amounted to a failure to maintain high standards. The Panel agreed, because it considered that extra care was needed in relation to interviews being given on national television and that high standards were particularly important in this context. In addition, the Panel took account of the promotional nature of the briefing that AstraZeneca had provided its global senior leader which the Panel interpreted as being a potentially contributing factor to the answer that they gave in relation to this foreseeable line of questioning.

In addition to the failures of process by AstraZeneca in its briefing for the interview, the Panel also factored in the subject matter being access to breast cancer medication, where there was likely to be heightened public interest. For all of these reasons, the Panel concluded that AstraZeneca had failed to maintain high standards and ruled a **breach of Clause 5.1**.

Clause 2 – bring discredit upon, or reduce confidence in, the pharmaceutical industry

Clause 2 was a sign of particular censure and was reserved for such use. In the circumstances of this case, the Panel did not consider that the overall content and context of the extract of the interview in question met the threshold for bringing discredit upon, or reducing confidence in, the pharmaceutical industry. The Panel was satisfied that it rulings of a breach of Clauses 26.1 and 5.1 were sufficient in relation to this matter and therefore ruled **no breach of Clause 2**.

Clause 5.2 – not recognising the special nature of medicines

The Panel concluded that the complainant's allegation in relation to this clause was unfounded. Based on the transcript above, the Panel considered that the global senior leader had not failed to recognise the special nature of breast cancer medicine; they had simply explained why AstraZeneca disagreed with the classification of the medicine by NICE. In the absence of any supporting evidence, the Panel did not interpret that as AstraZeneca seeking to "*add public pressure to the NICE process*" as alleged.

The Panel therefore concluded that the complainant had not established their case in relation to this clause and ruled **no breach of Clause 5.2**.

Clause 5.5 - material sponsored by company must make clear the role of that company

The Panel did not consider that the complainant had made out any allegation in relation to this clause and ruled **no breach of Clause 5.5**.

Clause 6.1 and Clause 6.2 – misleading claims that were not capable of substantiation

The Panel interpreted the complainant's allegation to be that the global senior leader made a misleading claim (in breach of Clause 6.1) that was also not capable of substantiation (in breach of Clause 6.2) by suggesting that NICE's consideration of Enhertu was based on NICE's methodology, as opposed to price. The complainant referred to a NICE publication shortly after the interview in question, in which it stated that its decision was based on price rather than methodology.

The Panel took account of the fact that, based on the evidence before it, the complainant was alleging that the global senior leader's claim in the interview had been *subsequently* contradicted by NICE. The Panel noted that the conclusion paragraph of the NICE guidance stated:

> "*With the severity weight of 1.2 applied, the committee's preferred ICERs were above £30,000 per QALY gained. Even after accounting for innovation and uncaptured benefits, the committee concluded that the most likely cost-effectiveness estimates were above what it considered to be a cost-effective use of NHS resources. So, trastuzumab deruxtecan could not be recommended for treating HER2-low metastatic or unresectable breast cancer in adults*" (Panel's emphasis).

The Panel considered that it was likely that AstraZeneca was aware of the NICE recommendation at the date of the interview but did not know whether it would have been given prior notice of the NICE press release. The Panel also considered that the global senior leader had given a reasonable amount of context in their answer. For example, they stated "*you look at the financial environment, the tax rate, and finally you look at access".* In other words, the Panel accepted that the global senior leader did not *only* refer to price in their answer and had explained their concerns about the severity classification. The Panel considered that there was an inherent interconnection between NICE methodology and price in that one would impact the other. On that basis, the Panel was not satisfied that the complainant had established their case that the reference to NICE methodology, given by the global senior leader in the interview, was misleading. The Panel therefore ruled **no breach of Clauses 6.1 and 6.2**.

Clause 6.7 – disparaging the clinical and scientific opinions of health professionals

This part of the complaint related to the complainant's allegation that, in the interview, the global senior leader was "*defaming or disparaging other government organs of the state*". The Panel interpreted this to be an allegation that the health professionals that worked at NICE were being disparaged.

The Panel considered the ordinary dictionary definition of the word "*disparage*": "*to criticise someone or something in a way that shows you do not respect or value him, her, or it*". It is therefore clear that it means more than to simply disagree. The Panel did not interpret the comments of the global senior leader to meet the definition of disparage. Although they could be seen as critical of NICE, they did not demonstrate a lack of respect. The Panel therefore ruled **no breach of Clause 6.7**.

Clauses 8.1 and 8.3 – certification of materials

The complainant alleged that the global senior leader had no approved or certified materials to substantiate claims. The Panel considered that the allegation was not sufficiently clear. The complainant had provided a copy of the NICE press release which included a link to the NICE guidance. AstraZeneca had explained why it disagreed with the NICE guidance. Given Clauses 8.1 and 8.3 both relate to "*materials*", the Panel did not consider the complainant had identified which materials they considered ought to have been certified, nor had they clearly identified the claims at issue. Therefore the Panel ruled **no breach of Clauses 8.1 and 8.3**.

Clause 9.1 – all relevant personnel must be fully conversant with the Code

Although the Panel had ruled breaches of the Code above in relation to the global senior leader's interview answers, the Panel did not consider that the complainant had satisfied the burden of proof in their allegation that the senior leader was not conversant with the Code. The Panel therefore ruled **no breach of Clause 9.1**.

Clause 9.3 – Representatives must be given adequate training
Clause 9.4 – Representative must take an appropriate examination

Both these clauses apply to "*representatives*"; a term defined in Clause 1.19 of the Code as:

> "*a representative calling on members of the health professions and other relevant decision makers in relation to the promotion of medicines.*"

The Panel did not consider that the global senior leader met the definition of a "*representative*" for the purposes of the Code. In the absence of any evidence provided by the complainant to the contrary, the Panel ruled **no breaches of Clause 9.3 and 9.4**.

APPEAL BY ASTRAZENECA

AstraZeneca's written basis for appealing is reproduced below.

> "Following consideration of the Complaint, the Panel ruled breaches of Clauses 26.1 and 5.1 of the ABPI Code of Practice ("the Code") by AstraZeneca. We strongly disagree with the Panel's rulings in this respect. We set out our reasons for our appeal below, consistent with paragraph 8.3 of the PMCPA Constitution and Procedure.

Background

The Complaint was communicated to PMCPA on 23 August 2024, by an anonymous but contactable complainant, who described themselves as a UK Consultant Oncologist and Patient Advocate ("Complainant") and notified to AstraZeneca by letter from the PMCPA dated 28 August 2024. It arose from an interview provided to [named mainstream news channel] on 25 July 2024 by AstraZeneca's [named global senior leader] ("the Interview").

The Complaint alleged in summary that, by referring to the recent appraisal of medicinal product Enhertu by the National Institute for Health and Care Excellence ("NICE"), the Interview promoted a prescription only medicine to members of the public, in breach of the Code.

The Interview

The Interview took place immediately following the announcement of AstraZeneca's Q2 2024 Financial Results, on 25 July 2024.

As one of the largest companies listed on the Financial Times Stock Exchange (FTSE) Index, AstraZeneca is obliged to announce its financial results publicly in order to inform investors; as a result, they generate substantial interest. Various business and finance journalists were contacted by AstraZeneca's Media Relations team prior to 25 July 2024 and invited to attend a media conference shortly after the Q2 results were announced. They were also offered an opportunity to conduct an interview with AstraZeneca's [named global senior leader] specifically relating to the Q2 Financial Results. As a result of these invitations, a number of journalists attended the media conference and three separate 10 minute interviews were given by the AstraZeneca [named global senior leader], one with [named mainstream news channel] (the Interview) and two with other news outlets.

The Interview with [named mainstream news channel] took place at 10am on 25 July 2024 and a version was broadcast later that day on [named mainstream news channel]. A segment of the Interview was also published online on 26 July 24. The journalist who conducted the Interview was [named journalist], a business journalist. AstraZeneca was not given advance notice of the questions that would be asked or the topics that would be covered during the Interview, other than the focus was AstraZeneca's financial results. [Named journalist] was not briefed by AstraZeneca to ask questions about Enhertu or NICE's guidance following appraisal and no questions regarding this issue were solicited by the AstraZeneca Media Team or the [named global senior leader].

The Interview started with questions about the Q2 results, and then [named journalist] asked about the NICE decision on Enhertu referring in his question to the name of the product and the fact that it was indicated for the treatment of breast cancer. In response to [named journalist]'s questions, the [named global senior leader] expressed concern regarding the NICE process and methodology, referring to the clinical need of patients with metastatic breast cancer as the example raised by the journalist. [Their] references to Enhertu were factual and limited to the information required to respond to [named journalist]'s questions in the context of NICE assessment. A full transcript of the Interview was provided with our initial response to the complaint. AstraZeneca was given no opportunity for advance review and, consistent with independent media reporting, had no

editorial control over the article and its embedded video that was subsequently published.

Media briefing provided to the AstraZeneca [named global senior leader] prior to the Interview

Senior AstraZeneca employees are regularly briefed on how to provide appropriate answers in response to a range of different questions they may get asked by journalists. In advance of the announcement of all quarterly results, AstraZeneca prepares reactive responses for likely questions that may be put to the [named global senior leader] by journalists during the associated media conference. This preparation includes consideration of current topics and questions journalists have recently asked. A briefing document is then prepared which is discussed with the [named global senior leader]. This approach is typical for all listed companies to ensure that helpful and informed responses can be provided if likely questions arise. Such a briefing was provided to the AstraZeneca [named global senior leader] in advance of the media conference and interviews on 25 July 2024.

The briefing prepared by the AstraZeneca Media Team included key messages and discussion points related to the Q2 Financial Results and reactive responses to questions that might be asked by journalists on the day across a range of topics. The media conference and interviews were not focused on NICE appraisals or discussion on Enhertu. However, in view of the fact that final draft guidance for Enhertu ("trastuzumab deruxtecan for treating HER2-low metastatic or unresectable breast cancer after chemotherapy" (TA992)) had been issued by NICE in March 2024 and final guidance was expected to be published imminently, the AstraZeneca Media Team anticipated that the appraisal might be raised in questions. Therefore, the briefing included the following:

> "Reactive Q&A: Q. Do you have an update on the NICE decision not to recommend Enhertu for HER2-low metastatic or unresectable breast cancer after chemotherapy in England?
>
> • We look forward to NICE revising their assessment from viewing advanced metastatic breast cancer as only a moderately severe disease. It is vital to recognise that it is a severe disease and this will open up the use of Enhertu as a cost-effective medicine and bring its benefits to patients in England who urgently need it.
>
> • NICE issued an exceptional pause to their process and the timeline on their decision is a question for them. We have been clear that NICE mis-classifying HER2-low metastatic breast cancer as 'medium severity' is standing in the way of patient access in England
>
> • 17 other European countries, including Scotland and most recently Romania, have already delivered routine patient access to trastuzumab deruxtecan for HER2-low breast cancer patients.''

The Complaint and the Panel's ruling

The Complainant, who referenced only the published article, which included an edited version of the Interview, considered that the statements by the AstraZeneca [named global senior leader] promoted Enhertu. As a result of this conclusion, the Complainant alleged

breaches of Clauses 2, 5.1, 5.2 and 26.1 of the 2021 Code. The letter from PMCPA dated 28 August 2024, notifying AstraZeneca of the Complaint, additionally asked us to bear in mind the requirements of Clauses 5.5, 6.1, 6.2, 6.7, 8.1, 8.3, 9.1, 9.3 and 9.4 of the 2021 Code in our response.

AstraZeneca responded to the Complaint by letter dated 12 September 2024. We addressed all the points raised by the Complainant and expressed our firm view that the Interview, subsequent broadcast and article were not promotional and that the references to Enhertu constituted appropriate, factual responses to unsolicited questions. All allegations of breach of the Code were denied.

The Panel's decision, communicated to AstraZeneca by letter dated 21 August 2025, found breaches of Clauses 5.1 and 26.1 of the Code. The Panel based these findings on the unedited transcript of the Interview, rather than the published article and edited video of the interview over which AstraZeneca had no editorial control. AstraZeneca strongly disagrees with the finding that the statements by its [named global senior leader] were promotional or that they breached the Code. Our reasons are set out below.

The other matters raised by the Complainant and the remaining findings of the Panel are not addressed in this letter.

AstraZeneca's Appeal

1) Finding of breach of Clause 26.1 – promotion of a prescription only medicine to the public

The Panel's findings

The Panel considered the context in which the Interview was given, specifically referencing:

• That it was given to [named mainstream news channel] and was therefore likely to reach a wide audience of the general public;

• Its view that the subject of Enhertu approval was likely to be relevant to AstraZeneca's financial performance in Q2; and

• That the interview took place shortly after comments that AstraZeneca's [named global senior leader] had made about NICE's methodology in the context of Enhertu.

The Panel concluded that it was reasonably foreseeable that an interview on this day would be likely to include questions regarding NICE's appraisal of Enhertu and referenced the briefing materials prepared in advance of the Interview, which referred to Enhertu being a cost-effective medicine and bringing its benefits to patients in England who urgently need it.

The Panel also suggested that language and phrasing used in the Interview were "emotive", specifically:

• the reference to patients in the phrase "patients, I'm sure would say it [metastatic

breast cancer] is a severe disease, but NICE concluded, it's a moderately severe disease."

• "17 countries around Europe have, decided to reimburse and [sic] Enhertu for metastatic breast cancer."

• "it's quite sad because patients, they need it and they're waiting for it."

In the circumstances, the Panel stated that it "accepted that the senior leader's comments were in response to a foreseeable question and further it could be argued that the question was about a newsworthy matter". However, it concluded that "on balance, the global senior leader's answers went beyond a limited factual response to the question". In reaching this conclusion, the Panel referred to:

• "the ultimate audience"

• "the sensitive nature of the therapy area"

• the fact that the Interview referenced "the patient demand and urgent need for this medicine"

• that AstraZeneca's [named global senior leader] had stated that the product "was available in other countries including Scotland" and described the lack of availability as "sad".

The Panel considered these statements to be promotional of a prescription only medicine to the public and, therefore, ruled a breach of clause 26.1

Appeal by AstraZeneca

The application of the 2021 ABPI Code is defined at Clause 1.1:

"This Code applies to the promotion of medicines to members of the United Kingdom (UK) health professions and to other relevant decision makers….. The Code also applies to a number of areas which are non-promotional, including information made available to the public about prescription only medicines".

"Promotion" is defined at Clause 1.17, which states explicitly that this does not include certain activities including:

"replies made in response to unsolicited individual enquiries from members of the health professions or other relevant decision makers or in response to specific communications from them whether of enquiry or comment, including letters published in professional journals, but only if they relate solely to the subject matter of the letter or enquiry, are accurate and do not mislead and are not promotional in nature"
…
"factual, accurate, informative announcements and reference material concerning licensed medicines and relating, for example, to pack changes, adverse reaction warnings, trade catalogues and price lists, provided they include no product

claims."

Clause 26.1 states:

> "Prescription only medicines must not be advertised to the public".

Clause 26.2 provides:

> "Information about prescription only medicines which is made available to the public either directly or indirectly must be factual and presented in a balanced way. It must not raise unfounded hopes of successful treatment or be misleading with respect to the safety of the product.
>
> Statements must not be made for the purpose of encouraging members of the public to ask their health professional to prescribe a specific prescription only medicine".

The supplementary information to Clause 26.2 provides further information regarding its interpretation:

> "This clause allows for the provision of non-promotional information about prescription only medicines to the public either in response to a direct enquiry from an individual, including enquiries from journalists, or by dissemination of such information via press conferences, press announcements, television and radio reports, public relations activities, etc.
> …
> Any information so provided must observe the principles set out in this clause; that is, it should be factual, balanced and must not encourage members of the public to ask their doctors or other prescribers to prescribe a specific prescription only medicine. It must not constitute the advertising of prescription only medicines to the public prohibited under Clause 26.1".
> And additionally:
>
> "Companies may supply information to relevant patient organisations, the public or patients in relation to forthcoming health technology assessments by public national organisations such as NICE, AWMSG or SMC, provided the information is accurate, not misleading, not promotional in nature and otherwise complies with Clause 26.2".

Information provided in accordance with Clause 26 is categorised as Proactive Information, Reference Information or Reactive Information. The supplementary information to Clause 26.1 states:

> "Reactive information is supplied to the public in response to a direct request and must be limited to that information necessary to respond to the request"

In responding to the decision of the Panel, we refer to the unedited transcript of the Interview consistent with the approach set out in the PMCPA's letter of 21 August 2025.

AstraZeneca does not agree that the statements by its [named global senior leader] "went beyond a limited factual response to the question". The Panel accepted AstraZeneca's submission that the Interview was given on the day that AstraZeneca announced its 2024

Q2 results, and that this was the intended purpose of the Interview. While AstraZeneca recognised that the outcome of the NICE appraisal of Enhertu was, as accepted by the Panel, “newsworthy” and that questions might be asked on this topic, we do not understand the comments by the Panel regarding “context” to have any other significance. The questions put to the AstraZeneca’s [named global senior leader] regarding the NICE appraisal of Enhertu during the Interview were wholly unsolicited.

The unsolicited question put to the AstraZeneca’s [named global senior leader] during the Interview, which resulted in the statements regarding Enhertu, was:

> “Now, last month, you criticized the National Institute for Health and Care Excellence after they rejected use of Enhertu your breast cancer treatment in the NHS on cost grounds. How worried are you about this access to medicine issue? Is this going to come up again with some of your other products?”.

This question referenced the brand name “Enhertu” and the use of this product to treat breast cancer (albeit imprecisely). The AstraZeneca [named global senior leader] was specifically asked to comment on the outcome of the NICE appraisal of Enhertu on cost grounds and implications for access to medicines. [They] answered the question in the following way:

- [They] referred to the factors that affect investment decisions by the pharmaceutical industry, including that, if patients do not get access to medicines in the UK, this will result in research and development being directed to countries where patients will benefit.

- [They] expressed the view that NICE’s methodology, which scores different diseases by severity is limiting access to innovative medicines in England. [They] illustrated this concern by the experience with Enhertu, consistent with the journalist’s question, which inevitably required reference to the severity of breast cancer and how therapies are affected by NICE’s methods.

- The impact of NICE’s methodology to access of the medicine was illustrated by the fact that 17 countries around Europe, which do not use such methods, have decided to reimburse Enhertu. Scotland was also mentioned specifically in the context of having a different methodology to NICE and the decision to reimburse. The AstraZeneca [named global senior leader] commented that the use of NICE’s methodology would affect many innovative new medicines intended for patients with severe diseases.

- Finally, [they] said that [they] hoped NICE would change its methodology and referred back to the example of Enhertu in the question by the journalist, noting the clinical need of patients (as recognised by NICE) and the moderate conclusion that it was “sad” that patients were being denied access to treatment as a result of NICE’s current methods.

This response was therefore directed solely to the issues raised by the journalist in the question and provided in a factual way. The response spoke to the financial environment, reimbursement and access to innovative new medicines in the UK, including the impact of the particular methodology used by NICE and its general impact on R&D investment. To

the extent that it referred to NICE's appraisal of Enhertu this reflected the journalist's question, and the content was consistent with the supplementary information to Clause 26.2, as quoted above, in relation to forthcoming appraisals.

In reaching its decision, the Panel appears to have construed particular words and phrases used in the Interview in isolation. However, if these are considered in the context of the question posed by the journalist in the Interview and the overall response by AstraZeneca's [named global senior leader], as set out above, it is clear that the language and phrasing used in the Interview was necessary in order to respond to the question and were neither inappropriately "emotive" nor promotional. AstraZeneca's responses to the specific words identified by the Panel are set out below:

(a) The Panel's statement that certain language and phrasing used in the Interview were "emotive":

We respectfully suggest that the Panel's decision for what constitutes "emotive" language incorrectly conflates "emotive language" with "language that expresses emotions." AstraZeneca rejects the suggestion that any of the language and phrasing referenced by the Panel was "emotive". It is clear that the AstraZeneca [named global senior leader] was responding to the question asked by the journalist. [They were] not using language designed to inflame or encourage an emotional response in others. As a result, when such language is considered in the context of the question by the journalist and the overall response, the description is factual and appropriate.

• The reference to patients in the phrase "patients, I'm sure would say it [metastatic breast cancer] is a severe disease, but NICE concluded, it's a moderately severe disease."

To the extent that the severity of breast cancer is viewed as "emotive", it was a necessary part of any response to the journalist's question because the question of "severity" is an inherent part of the methodology applied by NICE to review and compare treatments for different patients and different conditions.

• "17 countries around Europe have, decided to reimburse and [sic] Enhertu for metastatic breast cancer."

Again, this statement directly responded to the journalist's question regarding the implications of NICE's methodology in the context of access to medicines. The question referred to experience with Enhertu as an example and the statement, therefore, indicated the number of countries which have decided to reimburse Enhertu using a different methodology. The statement identified by the Panel was simply a factual account of the consequences of NICE's methodology, rather being inappropriately "emotive". As [named global senior leader] of a global organisation, during an interview pertaining to financial results, it was appropriate to consider/comment on access to medicines not just in the UK but also in other countries.

• "it's quite sad because patients, they need it and they're waiting for it."

This statement, which was not reflected in the broadcast video or published article, was made in relation to discussions between AstraZeneca and the UK Government, and was

intended to communicate concerns regarding NICE's methods in order to address issues relating to access to medicines. In context, the statement stated:

> "So we are hopeful that, the methodology can be changed because if you look at it now too, in metastatic breast cancer as an example, it's quite sad because patients, they need it and they're waiting for it".

By referring to patient need for medicines, the statement directly addressed the journalist's question regarding the "access to medicines issue", by reference to metastatic breast cancer, the example [they] had specifically identified. It does not follow that, just because the language referenced an emotion, this means that such language must be emotive; the statement by the AstraZeneca [named global senior leader] did not go beyond what was necessary to answer the question put to him.

(b) The Panel's reasons for concluding that "the senior leader's answers went beyond a limited factual response to the question"

• "the ultimate audience" for the Interview

We understand that, by "ultimate audience", the Panel is referring back to its earlier observation that the Interview "was with [named mainstream news channel] and was therefore likely to reach a wide audience of the general public". However, it is unclear how the Panel took this factor into account in its decision making.

The Panel has accepted that the NICE appraisal of Enhertu was "newsworthy" and we have explained that statements by the AstraZeneca [named global senior leader] simply responded to the unsolicited questions from the [named mainstream news channel] journalist in a factual non-promotional way. In these circumstances, the fact that the Interview would potentially reach a wide audience of the general public does not convert a non-promotional response to an unsolicited question, to promotion of Enhertu to the public.

Furthermore, at the time the article was published, it was in the 'Business' section of [named mainstream news channel] website and therefore directed towards a financial audience, rather than a "wide audience of the general public".

• "the sensitive nature of the therapy area"

The unsolicited question by the journalist specifically asked the AstraZeneca [named global senior leader] to comment on NICE methodology and access to medicines in the context of Enhertu for breast cancer. In circumstances where AstraZeneca's concerns in relation to NICE's methodology involved the use of NICE's severity modifier, it was necessary for the response to consider the severity of breast cancer, as explained above. This is in line with Clause 1.17 which allows for factual information or reference about a medicine provided they include no product claims. Therefore, we do not agree that any references to breast cancer during the Interview converted this to promotion of Enhertu to the public.

• the fact that the Interview referenced "the patient demand and urgent need for this medicine"

We refer to the response under (a) third bullet above. The Interview was not intended to encourage members of the public to ask their health professional to prescribe Enhertu and there were no claims and no statement which would suggest otherwise.

Furthermore, the Interview did not refer to “urgent need”. This wording was used in the Media Briefing, but not in the Interview itself. The Complaint did not relate to the Media Briefing.

> • That AstraZeneca’s [named global senior leader] had stated that the product “was available in other countries including Scotland” and described the lack of availability as “sad”

We refer to the responses under (a) second and third bullets above.

In summary, it is AstraZeneca’s firm view that the statements made by its [named global senior leader] during the Interview in relation to NICE’s methodology and its implications for access to medicines, in the context of the guidance for Enhertu for HER2-low metastatic or unresectable breast cancer after chemotherapy, responded directly to the unsolicited questions from the journalist in relation to a “newsworthy” issue. The response provided did not go beyond the scope of the questions, which addressed legitimate queries regarding the procedures adopted by a public health technology assessment body. It was balanced, accurate, factual, non-promotional and entirely appropriate.

As a consequence, we respectfully submit that the Interview did not amount to a breach of Clause 26.1.

2) Finding of breach of Clause 5.1 – high standards

The Panel’s findings

The Panel accepted the Complainant’s view that there had been a failure to maintain high standards. The Panel’s reasons for this conclusion were:

> • it considered that extra care was needed in relation to interviews being given on national television and that high standards were particularly important in this context;
>
> • it took into account what it described as “the promotional nature” of the briefing that AstraZeneca had provided to its [named global senior leader], which the Panel interpreted as being a potentially contributing factor to the answer that the [named global senior leader] gave during the Interview to a foreseeable line of questioning.
>
> • it took into account the subject matter being access to breast cancer medication, where there was likely to be heightened public interest.

Appeal by AstraZeneca

We respond below to the reasons given by the Panel for its finding of breach of Clause 5.1.

a) The need for extra care in relation to interviews being given on national

television and the particular importance of high standards in this context.

The Code does not address the “extra care” required in the context of interviews given on national television and the letter from the Panel dated 21 August 2025 provides no detail in this respect and does not explain what it concludes AstraZeneca should have done differently.

However, as explained above, it is AstraZeneca’s position that the statements made by AstraZeneca’s [named global senior leader] properly reflected the context. His response to the unsolicited questions from the journalist in relation to a topic that was accepted to be “newsworthy” was accurate, factual and limited to the information necessary to address the issues raised by the journalist. The response was not promotional in tone or content and was, in our view, in line with the high standards expected of the industry.

b) The allegedly “promotional nature” of the briefing that AstraZeneca had provided to its [named global senior leader], which the Panel interpreted as being a potentially contributing factor to the answer that AstraZeneca’s [named global senior leader] gave during the Interview to a foreseeable line of questioning.

The Panel has not explained why it considers the Media Briefing provided by AstraZeneca (which is not the subject of the Complaint) to be “promotional” or how this results in ‘’failures of process by AstraZeneca’’. This inevitably prejudices AstraZeneca in its ability to respond. However, it is our view that the Media Briefing was not promotional.

• The text was not intended to be used proactively but only reactively in the context of unsolicited questions relating to the appraisal of Enhertu by NICE, in circumstances where AstraZeneca recognised that the appraisal was a matter of public interest.

• The Media Briefing referenced AstraZeneca’s concerns regarding the methodology used by NICE, including in particular the severity modifier which, we believe was the reason for the negative guidance issued by NICE for Enhertu in TA992 and its conclusion regarding the cost effectiveness of the product. It is legitimate for AstraZeneca to express such concerns in a non-promotional way.

• We have explained above why the reference to the reimbursement of Enhertu in other countries is factual rather than promotional and a necessary part of any discussion of the impact of NICE’s methodology and the severity modifier.

• The references to the NICE appraisal of Enhertu reflected the supplementary information to Clause 26.2 of the Code in relation to forthcoming appraisals by NICE.

• In addition, "the Panel accepted that the senior leader did not only refer to price in their answer and had explained their concerns about the severity classification. The Panel considered that there was an inherent interconnection between NICE methodology and price in that one would impact the other"

We have explained in the response to the finding of breach of Clause 26.1 above, that the responses provided by the [named global senior leader] to the unsolicited questions from the journalist were not promotional, but provided appropriate information in relation to a

query from a journalist. To the extent that the Media Briefing contributed to the non-promotional responses given during the Interview, we do not consider that this reflects a failure to meet high standards.

c) The subject matter being access to breast cancer medication, where there was likely to be heightened public interest.

As explained above, the questions from the journalist related to NICE's appraisal of Enhertu for breast cancer and the response by AstraZeneca's [named global senior leader] necessarily addressed the question in that context.

It is unclear why the Panel considers that the response to the journalist's questions in relation to a matter of public interest breached high standards. As a result of the reasons set out above, we consider that the response provided by AstraZeneca's [named global senior leader] addressed the questions appropriately, factually and in a non-promotional way.

Summary

In summary, AstraZeneca does not believe that the findings of breach of Clause 26.1 and Clause 5.1 were appropriate in the context of the applicable facts:

- The [named global senior leader] was responding to a journalist's specific unsolicited questions in relation to the NICE appraisal of Enhertu during a live interview.
- Of the matters raised by the Panel, two were not reflected in the interview or did not appear in the published article and video.
- Overall, the statements provided by the [named global senior leader] were a legitimate response limited to the matters raised and were not promotional in tone or content.

Conclusion

Both findings appear to reflect the conclusion of the Panel that the responses to unsolicited questions by a journalist regarding NICE's appraisal of Enhertu for HER2-low metastatic or unresectable breast cancer were promotional. AstraZeneca firmly believes that this was not the position. The responses to the questions by the journalist were limited to the specific queries raised, namely NICE's methodology incorporating a severity modifier and the implications of this for patient access to medicines, by reference to the appraisal of Enhertu as an example of the broader topic. Such responses were non-promotional in tone, factually accurate and balanced. In addition, "the Panel acknowledged that the balance of the interview concerned the Q2 results".

We respectfully submit that the Panel has misconstrued a necessary factual response to an unsolicited question as "promotion" as a result of, amongst other things, conflating the use of language that describes an emotion with language intended to be emotive and inflame the reactions of the audience.

AstraZeneca respectfully maintains that nothing in either the interview by or the briefing for the [named global senior leader] constituted promotion of a prescription only medicine and

rejects any suggestion that it failed to uphold high standards. The interview was conducted as a corporate business update and responses provided were wholly appropriate for a [named global senior leader] of a global organisation. Thus, there was no breach of Clauses 26.1 or 5.1 or any other requirements of the Code.

We would be pleased to provide any further information if this would assist the Appeal Board.

RESPONSE FROM THE COMPLAINANT

The complainant did not respond to the appeal.

APPEAL BOARD RULING

The Appeal Board interpreted the subject matter of this complaint to be the article that was published on the [named mainstream news channel] website on 26 July 2024 and the video embedded within that article (which included three extracts from the interview with the AstraZeneca global senior leader). This was accepted by AstraZeneca's representatives at the appeal.

Although part of the Panel's ruling was based on the senior leader's emotive language that NICE's decision was "sad" for patients (which was part of the full interview transcript), this wording did not appear in the relevant materials in this case and the Appeal Board therefore did not base its ruling on that particular statement.

The Appeal Board considered the broad definition of "promotion" in Clause 1.17 of the Code, alongside the wording of Clause 26.1. The Appeal Board recognised that it was permissible for pharmaceutical companies to answer unsolicited questions from journalists provided that answers were not promotional and were factual and balanced.

The Appeal Board based its ruling on the language used by the global senior leader which referred to the brand name (Enhertu) and the indication (metastatic breast cancer). There were references to metastatic breast cancer being a severe disease, the availability of Enhertu in Scotland and other European countries, and how Enhertu could benefit patients. The Appeal Board concluded that the global senior leader's language was likely to result in the public, and particularly breast cancer patients, concluding that Enhertu could benefit them. That amounted to activity which promoted the administration, consumption, prescription, purchase, recommendation, sale, supply or use of the company's medicines.

None of the exceptions in Clause 1.17 applied: for example, this was not a response to an unsolicited individual enquiry from a member of the health professions or other relevant decision maker. It followed that the Appeal Board concluded that the relevant material was promotional, and the Appeal Board upheld the Panel's ruling of a **breach of Clause 26.1**. The appeal on this point was unsuccessful.

The Appeal Board considered how the promotional interview had come about, and in particular considered the briefing given to the senior leader. The Appeal Board took account of the context of this case: it was an interview with a global senior leader, on national television, and in relation to a therapy area and medicine where there was high public interest; in that context it was particularly important that there was a robust briefing. The Appeal Board did not have the whole

briefing, but had an extract from the briefing, and a description of the remainder from the representatives of the company at the Appeal Board hearing. The company representatives said that the briefing did not include express reminders about the principles of the ABPI Code. The Appeal Board was concerned about the following statement from the briefing: “it’s vital to recognise that it [metastatic breast cancer] is a severe disease and this [potential NICE approval] will open up the use of Enhertu as a cost-effective medicine and bring its benefits in England who urgently need it”. The Appeal Board considered this part of the briefing encouraged the use of promotional language in the interview.

The Appeal Board concluded that failings in relation to the briefing contributed to the promotional language used by the global senior leader which had resulted in the breach of Clause 26.1. The Appeal Board therefore concluded that there had also been a failure to maintain high standards by AstraZeneca and upheld the Panel’s ruling of a **breach of Clause 5.1**. The appeal on this point was unsuccessful.

Complaint received **23 August 2024**

Case completed **2 December 2025**