CASE AUTH/3561/9/21

EX-EMPLOYEE v ASTRAZENECA

Promotion of an unlicensed indication for Enhertu to the public

A complainant who described him/herself as an ex-employee of AstraZeneca UK complained about a LinkedIn post and an article written by a senior employee of AstraZeneca published in The Sunday Times.

LinkedIn post

The complainant stated that the post was clearly promotional in nature and highlighted news around a positive data readout at ESMO (European Society for Medical Oncology) oncology conference. The complainant understood that Enhertu was currently marketed but not in the same setting as in the trial mentioned in the post in question and alleged it was a promotional post to the public and encouraged people to ask their doctors about this medicine. In addition, over 100 people from AstraZeneca UK had liked the promotional post.

The Sunday Times article

The complainant referred to an article published in The Times about the same data. The complainant was astounded that someone from AstraZeneca was discussing a cure for a medicine in a promotional nature in The Times. The complainant assumed that the quotes discussed were outlined in the press releases given to the newspaper. Furthermore, if this was so the complainant did not see how this was not clearly a promotional piece to the public in a pre-licence setting.

The complainant was shocked by the blasé attitude displayed by AstraZeneca in this matter. Both the LinkedIn post and the newspaper article had such a wide audience and reach that the complainant was shocked that they were still live and active.

The detailed response from AstraZeneca is given below.

LinkedIn post

The Panel noted AstraZeneca's submission that the LinkedIn post at issue referred to by the complainant was not the original post made by the named AstraZeneca senior employee. The original post was released on the senior employee's personal LinkedIn feed 4 days earlier and had not been submitted to AstraZeneca's Global Nominated Signatory team for review and approval as per the usual process. This post was brought to the attention of AstraZeneca's global compliance and global nominated signatory team as it included the generic name of the medicine, trastuzumab deruxtecan, within the context of the DESTINY-Breast03 trial in HER2-positive metastatic breast cancer (an unlicensed indication). AstraZeneca submitted that immediate steps were taken to edit

the post, removing any mention of a specific medicine. Whilst the Panel was concerned with regard to AstraZeneca's submission about the original post published, the Panel noted that the complaint did not refer to that post and the Panel therefore made its rulings in relation to the edited LinkedIn post as highlighted by the complainant.

The Panel noted that the LinkedIn post in question began:

> **'Today is a landmark moment at AstraZeneca, with the presentation of results from the DESTINY-Breast03 trial in HER2-positive metastatic breast #cancer. The magnitude of benefit seen in this trial will force us to immediately rewrite the textbooks.'**

The Panel noted that the post also referred, in the context of innovation in breast cancer treatment, to the 'remarkable steps we continue to see today.'

The Panel considered that by referring to the results from the DESTINY-Breast03 trial in HER2-positive metastatic breast cancer as a 'landmark moment' and stating that 'the magnitude of benefit seen in this trial will force us to immediately rewrite the textbooks', the LinkedIn post had indirectly referred to, and thus promoted Enhertu.

The Panel noted that Enhertu had a marketing authorisation at the time that the LinkedIn post at issue was published. The Panel therefore considered that the Clause which stated that a medicine must not be promoted prior to the grant of the marketing authorisation which permits its sale or supply was not relevant and therefore no breach of the Code was ruled.

The Panel, however, noted AstraZeneca's submission that HER2-positive metastatic breast cancer was an unlicensed indication for Enhertu. The Panel noted its finding above that the post in question indirectly referred to, and thus promoted Enhertu. In the Panel's view, therefore, the LinkedIn post which referred to the name of the Enhertu clinical trial (DESTINY-Breast03 trial) and included claims such as 'Today is a landmark moment at AstraZeneca, with the presentation of results from the DESTINY-Breast03 trial in HER2-positive metastatic breast #cancer. The magnitude of benefit seen in this trial will force us to immediately rewrite the textbooks' promoted Enhertu for an unlicensed indication. The Panel ruled a breach of the Code in this regard.

The Panel noted AstraZeneca's explanation that the original LinkedIn post had not been submitted to its global signatory team for review and approval as per its usual process. The Panel noted AstraZeneca's submission that this original post was brought to the attention of AstraZeneca's global compliance and global nominated signatory team and was edited to remove any mention of a specific medicine. The Panel noted AstraZeneca's submission that it did not deem the edited post to be promotional and therefore it did not undergo certification and there was no approval certificate for it. The Panel noted its comments and rulings above that in its view the edited LinkedIn post was promotional. The post had not been certified and therefore a breach of the Code was ruled.

The Panel considered that not all the employees' connections on LinkedIn would meet the Code's definition of a health professional and that members of the public were unlikely to make a direct connection between DESTINY-Breast03 trial and Enhertu based

solely on an immediate reading of the post and no links to further information were included within the post. The Panel therefore considered, on the balance of probabilities, that a specific prescription only medicine had not been promoted to the public and no breach of the Code was ruled.

However, in the Panel's view, the strong and unequivocal wording of the LinkedIn post, particularly in relation to the magnitude of the benefit seen with regard to the results of the DESTINY-Breast03 trial in HER2-positive metastatic breast cancer would, on the balance of probabilities, encourage patients to ask their doctors to prescribe the trial medicine and a breach of the Code was ruled.

The Panel noted its comments and rulings above and considered that high standards had not been maintained and a breach of the Code was ruled.

The Panel noted its comments and rulings above and considered that both a very senior employee and AstraZeneca had failed to recognise the promotional nature of the LinkedIn post, dated 21 September and placement of the uncertified post on LinkedIn meant that AstraZeneca had brought discredit upon, and reduced confidence in, the pharmaceutical industry. A breach of Clause 2 was ruled.

In relation to the alleged breach of undertaking, in the Panel's view, the current case, Case AUTH/3561/9/21, was sufficiently different to the previous cases such that there had been no breach of the undertakings given in Cases AUTH/3051/6/18 and AUTH/3163/2/19 as alleged. The Panel therefore considered that AstraZeneca had not failed to maintain high standards in this regard and ruled no breach of the Code.

The Sunday Times article

The Panel noted that the article was titled 'Hopes rise for breast cancer cure' with the opening paragraph stating:

> **'The trial of a new drug to treat an aggressive form of breast cancer has "shattered expectations" raising hopes of a "cure", according to its maker, AstraZeneca.**
>
> **The British pharmaceutical company said three quarters of women in the trial of its new drug, Enhertu, had shown no progression in their disease after 12 months compared with just a third treated with a different medicine.'**

This was followed by a quote from a named very senior AstraZeneca employee saying 'there were tears and cries of surprise when scientists were given the data over a video call last week, Its remarkable to hear the oncology community, as they take the data in, say "Is it possible that we could be offering a cure for some women with advanced disease?"' and 'It's a special moment … to be able to know that as of Monday, it can transform the discussions that physicians are going to have with their patients'. Details of the NHS list price and the statement 'The firm hopes to expand the use of the drug to earlier stages of cancer' were also included.

The Panel noted that the article at issue was based on an interview with the senior AstraZeneca employee quoted in the article and an AstraZeneca press release. The

Panel noted that complaints about articles in the press were judged under the Code on the material provided by the company to the journalist/newspaper, including any interviews, rather than the published article. The Panel noted AstraZeneca's submission that a global press release on the DESTINY-Breast03 results, which was intended for the financial media, was published by AstraZeneca on AstraZeneca.com and a copy was sent to The Sunday Times immediately after it was disseminated to relevant media outlets.

The Panel noted that the press release was titled 'Enhertu reduced the risk of disease progression or death by 72% vs. trastuzumab emtansine (T-DM1) in patients with HER2-positive metatstatic breast cancer'. It went on to state that 'Ground-breaking Phase III head-to-head DESTINY-Breast03 results featured at ESMO Presidential Symposium support Enhertu as the potential new standard of care in previously treated patients'. The press release included a quote from a different senior AstraZeneca employee to that quoted in the article which stated, inter alia, 'Today's results are groundbreaking' and 'These unprecedented data represent a potential paradigm shift in the treatment of HER2-positive metastatic breast cancer and illustrate the potential for Enhertu to transform more patient lives in earlier treatment settings'.

Whilst the Panel had concerns about the strong unqualified claims included in the press release, which, in its view, was promotional, it noted that, contrary to the complainant's assumption, the press release did not include any quotes from the employee quoted in article in question. The Panel noted, however, AstraZeneca's submission that an interview had been arranged with the very senior employee at AstraZeneca at the request of The Sunday Times.

The Panel noted AstraZeneca's submission that whilst it did not have any editorial control over such articles, with hindsight, it accepted that it could and should have done more to brief the employee on the likely lines of questioning and to temper the level of enthusiasm that was subsequently quoted in the article. The Panel noted AstraZeneca's submission that it would have been prudent to make the newspaper aware of the potential implications of such quotes going to print. The Panel further noted AstraZeneca's submission that it understood that any information provided to the media must be in line with the requirements of the Code, and therefore in the spirit of honesty, transparency and willingness to do better, it accepted breaches of the Code.

The Panel noted that Enhertu did have a marketing authorisation at the time the press release was issued and the subsequent interview and publication of the article in question. The Panel therefore considered that the Clauses which stated that a medicine must not be promoted prior to the grant of the marketing authorisation which permits its sale or supply were not relevant and therefore irrespective of AstraZeneca's admission, no breaches of the Code were ruled in this regard.

The Panel, however, noting the definition of promotion in the Code and the strong comments outlined in its ruling above attributable to the very senior AstraZeneca employee within The Times article in question, considered that AstraZeneca had promoted Enhertu for an unlicensed indication. Whilst the Panel did not have a transcript of the interview, it noted that AstraZeneca did not deny that the comments in question were made. The Panel therefore ruled a breach of the Code in this regard, as acknowledged by AstraZeneca.

The Panel considered that the quotes attributable to the very senior AstraZeneca employee such as the trial of a new drug to treat an aggressive form of breast cancer has 'shattered expectations' raising hopes of a 'cure' were strong claims given the ultimate audience and thereby misled by exaggeration and a breach of the Code was ruled as acknowledged by AstraZeneca.

The Panel noted its finding above, however, that the press release was promotional and therefore considered that it required certification which did not appear to have occurred. The Panel therefore ruled a breach of the Code as acknowledged by AstraZeneca.

The Panel considered that the press release and quotes made by the senior AstraZeneca employee during the interview, which were included in the article in question, named and promoted Enhertu, raised unfounded hopes of successful treatment and would, in effect, encourage patients to ask for a specific prescription only medicine, Enhertu, as alleged, in breach of the Code.

The Panel noted its comments and rulings above and considered that AstraZeneca had failed to maintain high standards in breach of the Code.

The Panel considered it was very important that press releases and any other materials including interviews, particularly those that were made available to journalists about sensitive issues such as survival in cancer patients, were fair, factual and not misleading. In addition, the Panel noted that the company accepted that it could and should have done more to brief the very senior employee interviewed on the likely lines of questioning and to temper the level of enthusiasm that was subsequently quoted in the article. Furthermore, AstraZeneca acknowledged that it would have been prudent to make the newspaper aware of the potential implications of such quotes going to print. In the Panel's view, this was a notable omission given the sensitivity of the subject matter. Noting that Clause 2 was used as a sign of particular censure and reserved for such use, the Panel considered that the circumstances warranted such a ruling and a breach of the Code was ruled.

A complainant who described him/herself as an ex-employee of AstraZeneca UK Limited complained about a LinkedIn post and an article published in The Sunday Times about Enhertu which was promoted by AstraZeneca.

The complaint also referred to Daiichi-Sankyo. AstraZeneca confirmed that Daiichi-Sankyo was the UK marketing authorisation holder for Enhertu but that Daiichi-Sankyo had no involvement in either the LinkedIn post or the interview with The Sunday Times. The complaint was therefore only taken up with AstraZeneca.

COMPLAINT

LinkedIn post

The complainant stated that the LinkedIn post was written by a named current senior employee of AstraZeneca and alleged that it was clearly promotional in nature and highlighted news around a positive data readout at ESMO (European Society for Medical Oncology) oncology conference the previous weekend. The complainant understood that this data could have a big impact on breast cancer but did not think it should be spoken about on a public platform where it

had obviously been 'liked' by 2,500 people and had probably been shared much further. The complainant understood this was a medicine which was currently marketed but not in the same setting as mentioned in the trial by the named AstraZeneca employee in his/her post. Surely this was clearly a promotional post to the public and encouraged people to ask their doctors about this medicine. Furthermore, if this was a pre-vetted post then the complainant was shocked at AstraZeneca's standards, in addition over 100 people from AstraZeneca UK had liked this clearly promotional post. The complainant stated that he/she was almost certain that this was a clear breach of the Code. The complainant would be even more shocked if the company had not had previous breaches of a similar manner and had breached undertakings.

The Times

The complainant referred to another article from The Times about the same data. The complainant found it completely astounding that someone from AstraZeneca was discussing a cure for a medicine in a clearly promotional nature to someone like The Times. There were clear quotes which were discussed so the complainant assumed that these quotes were outlined in the press releases given to the newspaper. Furthermore, if this was so the complainant did not see how this was not clearly a promotional piece to the public in a pre-licence setting.

The complainant was shocked by the blasé attitude in both AstraZeneca in the clearly promotional nature in which it had acted. Both the LinkedIn post and the newspaper article had such a wide audience and reach that he/she was shocked that they were still live and active!

When writing to AstraZeneca, the Authority asked it to consider the requirements of Clauses 2, 3.1, 5.1, 8.1, 26.1 and 26.2 of the 2021 Code with regard to the LinkedIn article and Clauses 2, 3.1, 5.1, 6.1, 8.1, 11.1, 11.2, 26.1 and 26.2 of the 2021 Code with regard to The Times article.

In response to a request for further information from the case preparation manager, the complainant referred to Cases AUTH/3051/6/18 and AUTH/3163/2/19 which involved Alexion which the complainant submitted had recently become an AstraZeneca company.

RESPONSE

LinkedIn post:

AstraZeneca submitted that the LinkedIn post at issue was posted by a senior executive team (SET) employee at AstraZeneca on their personal LinkedIn feed. The post made mention of recent results from the DESTINY-Breast03 trial in HER2-positive metastatic breast cancer, in the context of discussing the level of innovation that had occurred in the breast cancer treatment landscape over the last few decades. The LinkedIn post was intended for the employee's professional network, recognising ground-breaking advancements in the field of scientific research and discovery. The post also paid tribute to a late named employee, who was the driving force behind the development programme at AstraZeneca.

AstraZeneca stated that it did not believe that the post promoted a medicine prior to the grant of a marketing authorisation which permitted its sale or supply (Clause 3.1) as it did not provide any mention of a specific medicine. For that same reason, the post did not advertise a prescription-only medicine to the public (Clause 26.1), and thus did not encourage members of

the public to ask their health professional to prescribe such a prescription-only medicine (Clause 26.2).

For the purpose of full transparency to the Panel and as a measure of AstraZeneca's commitment to upholding high standards, the company wished to make it transparent that the LinkedIn post in question was not the original post made by the SET member. The original post was released on the SET member's personal LinkedIn feed on 18 September. This original post was brought to the attention of AstraZeneca's Global Compliance and Global Nominated Signatory team on 21 September, as it included the generic name of the medicine, trastuzumab deruxtecan within the context of the DESTINY-Breast03 trial in HER2-positive metastatic breast cancer (an unlicensed indication).

AstraZeneca submitted that immediate steps were taken to edit the post, removing any mention of a specific medicine, and thereby bringing the content in line with the requirements of the Code. It should be noted that the post was amended the same day that it was brought to the attention of AstraZeneca's Global Compliance and Global Nominated Signatory team, the 21 September 2021.

AstraZeneca initiated its own investigation regarding how the post was made in its original form; said investigation was well underway when the company received the first letter of complaint on 29 September 2021. During AstraZeneca's investigation the company found that the original post was authored on 18 September and had not been submitted to AstraZeneca's Global Nominated Signatory team for review and approval, per the usual process. Despite having undergone training, the individuals in question had not fully understood the process for approval of such posts, in accordance with AstraZeneca's standard operating procedure.

The original post was not in accordance with the requirements of the Code. AstraZeneca stated that it was disappointed that the correct process for review was not followed in this instance, and the company therefore accepted that on this occasion high standards were not maintained (Clause 5.1). By way of remedial action, following completion of the investigation, AstraZeneca had clarified the correct procedure to all of the individuals involved and were providing additional training to employees that might be involved in external corporate communications in the future to prevent recurrence. In addition, AstraZeneca had reviewed and updated the relevant new starter training materials to ensure that this topic was covered in depth.

Article in The Sunday Times

A global press release on the DESTINY-Breast03 results, which was intended for the financial media, was published by AstraZeneca on 18 September 2021 on AstraZeneca.com. This press release discussed the results of the DESTINY-Breast03 trial, which were presented at the European Society for Medical Oncology Congress (ESMO) 2021, one of the largest international oncology congresses in the world. The press release was newsworthy, and an accurate, fair and balanced representation of the data presented at ESMO. A copy of this press release was sent to the senior business correspondent at The Sunday Times on 18 September immediately after it was disseminated to relevant media outlets.

An interview had been arranged with a named very senior AstraZeneca employee at the request of The Sunday Times. The very senior employee was asked about the data to be released and was specifically questioned about the AstraZeneca development team's reaction to the data, as well as the reaction to the data from members of the scientific community. He/she was also

asked to provide comment on the potential impact of this data, given the extremely high level of unmet need and the public's awareness on this issue. The very senior employee answered the journalist's questions openly, honestly, and thoroughly based on the trial results.

The Sunday Times covered newsworthy events for the service of the public and had full editorial control over its own content. The senior business correspondent distilled the interview conducted with the AstraZeneca executive at his/her own discretion and at the discretion of his/her editors.

While AstraZeneca did not have any editorial control over such articles, with hindsight, the company accepted that it could and should have done more to brief the very senior employee on the likely lines of questioning and to temper the level of enthusiasm that was subsequently quoted in the article. Furthermore, it would have been prudent to make the newspaper aware of the potential implications of such quotes going to print. Moving forwards, AstraZeneca would ensure that written briefing instructions were provided for employees involved with such interviews regarding promotional regulations, when speaking to the media.
AstraZeneca stated that it understood that any information provided to the media must be in line with the requirements of the Code, and therefore in the spirit of honesty, transparency and willingness to do better, AstraZeneca accepted a breach of Clauses 3.1, 5.1, 6.1, 8.1, 11.1, 11.2, 26.1 and 26.2.

Additional Response to PMCPA Letter of 1 October

With regard to the additional information provided in relation to the undertakings provided by Alexion (Case AUTH/3051/6/18 and Case AUTH/3163/2/19), AstraZeneca could confirm that AstraZeneca completed the acquisition of Alexion Pharmaceuticals, Inc. on 21 July 2021. As such, AstraZeneca did not believe that the undertakings from 2018 and 2019 were relevant to this complaint, as AstraZeneca was not affiliated with Alexion during this period and had no knowledge of these undertakings until very recently.

Clause 2

AstraZeneca stated that it was committed to maintaining high standards in everything it did. Upon being notified of the original LinkedIn post in question, AstraZeneca worked immediately to rectify the situation by bringing the post in line with the Code, investigating the root cause for why the company's SOPs had not been followed in this instance, and proactively implementing numerous actions to prevent recurrence, including extensive training and re-training for all employees that might be involved with external communications (copy provided). Additionally, AstraZeneca recognised that it should have made more effort to brief its media spokespeople about the relevant medicines promotion regulations when placed in 1:1 interview situations, and AstraZeneca was putting measures in place to ensure that this happened each and every time (copy provided). AstraZeneca submitted it was striving to ensure that the materials it shared with media and investors were accurate, balanced and up-to-date and AstraZeneca also worked hard to ensure its spokespeople were fully transparent with the risks and benefits of AstraZeneca's medicines to ensure patient safety. AstraZeneca stated that it was committed to upholding the reputation of the pharmaceutical industry.

In response to a request for further information, AstraZeneca submitted that the amended post of 21 September 2021, which was the subject of the complaint, was not deemed to be

promotional and therefore, did not undergo certification and there was no approval certificate for it.

PANEL RULING

LinkedIn post

The Panel noted AstraZeneca's submission that the 21 September LinkedIn post at issue referred to by the complainant was not the original post made by the named AstraZeneca senior employee. The original post was released on the senior employee's personal LinkedIn feed 4 days earlier on 18 September and had not been submitted to AstraZeneca's Global Nominated Signatory team for review and approval as per the usual process. This post was brought to the attention of AstraZeneca's global compliance and global nominated signatory team on 21 September, as it included the generic name of the medicine, trastuzumab deruxtecan, within the context of the DESTINY-Breast03 trial in HER2-positive metastatic breast cancer (an unlicensed indication). AstraZeneca submitted that immediate steps were taken to edit the post, removing any mention of a specific medicine. Whilst the Panel was concerned with regard to AstraZeneca's submission about the post published on 18 September, the Panel noted that the complaint did not refer to the post-dated 18 September and the Panel therefore made its rulings in relation to the 21 September LinkedIn post as highlighted by the complainant.

The Panel noted that the LinkedIn post of 21 September on the senior AstraZeneca employee's profile which was the subject of this complaint began:

> 'Today is a landmark moment at AstraZeneca, with the presentation of results from the DESTINY-Breast03 trial in HER2-positive metastatic breast #cancer. The magnitude of benefit seen in this trial will force us to immediately rewrite the textbooks.'

The Panel noted that the post also referred, in the context of innovation in breast cancer treatment, to the 'remarkable steps we continue to see today.'

The Panel noted that, contrary to AstraZeneca's submission, it was an accepted principle under the Code that it was possible for material to promote a medicine without mentioning that medicine by name.

The Panel considered that by referring to the results from the DESTINY-Breast03 trial in HER2-positive metastatic breast cancer as a 'landmark moment' and stating that 'the magnitude of benefit seen in this trial will force us to immediately rewrite the textbooks', the LinkedIn post had indirectly referred to, and thus promoted Enhertu.

The Panel noted that Enhertu had a marketing authorisation at the time that the LinkedIn post at issue was published on 21 September 2021. The Panel therefore considered that Clause 3.1 which stated that a medicine must not be promoted prior to the grant of the marketing authorisation which permits its sale or supply was not relevant and therefore no breach of Clause 3.1 was ruled.

The Panel, however, noted AstraZeneca's submission that HER2-positive metastatic breast cancer was an unlicensed indication for Enhertu. The Panel noted its finding above that the post in question indirectly referred to, and thus promoted Enhertu. In the Panel's view, therefore, the LinkedIn post which referred to the name of the Enhertu clinical trial (DESTINY-

Breast03 trial) and included claims such as 'Today is a landmark moment at AstraZeneca, with the presentation of results from the DESTINY-Breast03 trial in HER2-positive metastatic breast #cancer. The magnitude of benefit seen in this trial will force us to immediately rewrite the textbooks' promoted Enhertu for an unlicensed indication. The Panel noted that Clause 11.2 had not been raised in relation to the LinkedIn post and the Panel therefore ruled a breach of Clause 5.1 in this regard.

The Panel noted AstraZeneca's explanation that the original LinkedIn post of 18 September had not been submitted to its global signatory team for review and approval as per its usual process. The Panel noted AstraZeneca's submission that this original post was brought to the attention of AstraZeneca's global compliance and global nominated signatory team on 21 September and was edited to remove any mention of a specific medicine. It appeared that it was this edited post that was published on 21 September. The Panel noted AstraZeneca's submission that it did not deem the post of 21 September to be promotional and therefore it did not undergo certification and there was no approval certificate for it. The Panel noted its comments and rulings above that in its view the 21 September LinkedIn post was promotional. The post had not been certified and therefore a breach of Clause 8.1 was ruled.

The Panel considered that not all the employees' connections on LinkedIn would meet the Code's definition of a health professional and that members of the public were unlikely to make a direct connection between DESTINY-Breast03 trial and Enhertu based solely on an immediate reading of the post and no links to further information were included within the post. The Panel therefore considered, on the balance of probabilities, that a specific prescription only medicine had not been promoted to the public and no breach of Clause 26.1 was ruled.

However, in the Panel's view, the strong and unequivocal wording of the LinkedIn post, particularly in relation to the magnitude of the benefit seen with regard to the results of the DESTINY-Breast03 trial in HER2-positive metastatic breast cancer would, on the balance of probabilities, encourage patients to ask their doctors to prescribe the trial medicine, contrary to the requirements of Clause 26.2. A breach of Clause 26.2 was ruled.

The Panel noted its comments and rulings above and considered that high standards had not been maintained and a breach of Clause 5.1 was ruled.

The Panel noted its comments and rulings above and considered that both a very senior employee and AstraZeneca had failed to recognise the promotional nature of the LinkedIn post, dated 21 September and placement of the uncertified post on LinkedIn meant that AstraZeneca had brought discredit upon, and reduced confidence in, the pharmaceutical industry. A breach of Clause 2 was ruled.

The Panel noted that Clause 3.3 of the 2021 Code stated that when an undertaking had been given in relation to a ruling under the Code, the company concerned must ensure that it complied with that undertaking. The Panel noted that the undertakings for Cases AUTH/3051/6/18 and Case AUTH/3163/2/19 had been provided by Alexion. The Panel noted AstraZeneca's submission that it completed the acquisition of Alexion Pharmaceuticals, Inc. on 21 July 2021. The Panel noted that, in its view, when acquiring a company or product, in relation to the Code and in the absence of unambiguous evidence to the contrary, the new company, in addition to its general responsibility for complying with the Code, would likely have a responsibility to ensure that similar breaches of the Code, in relation to the company or product it acquired, were avoided and undertakings were thereby complied with. Each case

would be decided on its individual circumstances. It was important that the new company had systems in place to ensure, in particular, that claims etc, previously ruled in breach of the Code, were not repeated.

The Panel noted that AstraZeneca had not commented on its responsibility for compliance with an undertaking given by Alexion which it had subsequently acquired. The Panel noted that Clause 3.3 of the 2021 had not been raised but AstraZeneca had, nonetheless, responded to the matter at issue. The Panel considered this matter under Clause 5.1 of the 2021 Code.

The Panel noted that Case AUTH/3051/6/18 concerned a LinkedIn post which had been 'liked' by an Alexion employee and informed readers that Alexion had submitted an application for approval of ALXN1210 as a treatment for patients with paroxysmal nocturnal haemoglobinuria (PNH) in the European Union (EU). The post included a link to a press release which provided more detail; it described the results of two large Phase 3 studies and included statements such as 'We are excited about this next important step towards our goal of establishing ALXN1210 as the new standard of care for patients with PNH…'. The Panel noted that the product, ALXN1210, was not classified as a prescription only medicine when the LinkedIn post and associated press release at issue were liked by the UK employee. Clauses 26.1 and 26.2 only applied to prescription only medicines. On this very narrow technical point the Panel ruled no breach of Clauses 26.1 and 26.2 of the Code. However, the Panel considered that the Alexion UK employees' like of the LinkedIn post and associated press release regarding an unlicensed medicine and the potential subsequent dissemination to all of their connections meant that Alexion had failed to maintain high standards and a breach of Clause 9.1 was ruled.

The Panel noted that Case AUTH/3163/2/19 concerned the same LinkedIn post as above. In Case AUTH/3051/6/18, the complainant was concerned that the material would be seen by a variety of people including those who were not health professionals. The complainant stated that he/she had read the outcome for Case AUTH/3051/6/18 and noted that it appeared that the case had focused on promotion to the general public but noted that the LinkedIn post also promoted an unlicensed medicine (ALXN1210) to health professionals. The complainant alleged that the associated press release's reference to Soliris was promotion of a medicine to the public. The Panel considered that, on the balance of probabilities, the Alexion UK employees' connections on LinkedIn would include health professionals as well as members of the public. In the Panel's view, the disseminated LinkedIn post and associated press release promoted ALXN1210 prior to the grant of its marketing authorisation and a breach of Clause 3.1 was ruled. The Panel further noted that the press release referred to Soliris, which was a prescription only medicine available in the UK. The Panel noted the statements made with regard to Soliris and considered that the disseminated press release promoted a prescription only medicine to members of the public who might be encouraged to ask for it and breaches of Clauses 26.1 and 26.2 were ruled.

Turning to the current case (Case AUTH/3561/9/21), the Panel noted that it concerned a LinkedIn post by AstraZeneca which referred to the name of the Enhertu clinical trial (DESTINY-Breast03 trial) and included claims such as 'Today is a landmark moment at AstraZeneca, with the presentation of results from the DESTINY-Breast03 trial in HER2-positive metastatic breast #cancer. The magnitude of benefit seen in this trial will force us to immediately rewrite the textbooks' which, in the Panel's view, promoted Enhertu for an unlicensed indication. The Panel noted that Clause 11.2 had not been raised in relation to the LinkedIn post and the Panel had therefore ruled a breach of Clause 5.1 in this regard.

In relation to the alleged breach of undertaking, in the Panel's view, the current case, Case AUTH/3561/9/21, was sufficiently different to the previous cases such that there had been no breach of the undertakings given in Cases AUTH/3051/6/18 and AUTH/3163/2/19 as alleged. The Panel therefore considered that AstraZeneca had not failed to maintain high standards in this regard and ruled no breach of Clause 5.1.

Sunday Times article

The Panel noted that the article was titled 'Hopes rise for breast cancer cure' with the opening paragraph stating:

> 'The trial of a new drug to treat an aggressive form of breast cancer has "shattered expectations" raising hopes of a "cure", according to its maker, AstraZeneca.
>
> The British pharmaceutical company said three quarters of women in the trial of its new drug, Enhertu, had shown no progression in their disease after 12 months compared with just a third treated with a different medicine.'

This was followed by a quote from a named very senior AstraZeneca employee saying 'there were tears and cries of surprise when scientists were given the data over a video call last week, Its remarkable to hear the oncology community, as they take the data in, say "Is it possible that we could be offering a cure for some women with advanced disease?"' and 'It's a special moment … to be able to know that as of Monday, it can transform the discussions that physicians are going to have with their patients'. Details of the NHS list price and the statement 'The firm hopes to expand the use of the drug to earlier stages of cancer' were also included.

The Panel noted that the article at issue was based on an interview with the senior AstraZeneca employee quoted in the article and an AstraZeneca press release. The Panel noted that complaints about articles in the press were judged under the Code on the material provided by the company to the journalist/newspaper, including any interviews, rather than the published article. The Panel noted AstraZeneca's submission that a global press release on the DESTINY-Breast03 results, which was intended for the financial media, was published by AstraZeneca on 18 September 2021 on AstraZeneca.com and a copy was sent to the senior business correspondent at The Sunday Times on 18 September immediately after it was disseminated to relevant media outlets.

The Panel noted that the press release was titled 'Enhertu reduced the risk of disease progression or death by 72% vs. trastuzumab emtansine (T-DM1) in patients with HER2-positive metatstatic breast cancer'. It went on to state that 'Ground-breaking Phase III head-to-head DESTINY-Breast03 results featured at ESMO Presidential Symposium support Enhertu as the potential new standard of care in previously treated patients'. The press release included a quote from a different senior AstraZeneca employee to that quoted in the article which stated, *inter alia*, 'Today's results are groundbreaking' and 'These unprecedented data represent a potential paradigm shift in the treatment of HER2-positive metastatic breast cancer and illustrate the potential for Enhertu to transform more patient lives in earlier treatment settings'.

Whilst the Panel had concerns about the strong unqualified claims included in the press release, which, in its view, was promotional, it noted that, contrary to the complainant's assumption, the press release did not include any quotes from the employee quoted in the article in question. The Panel noted, however, AstraZeneca's submission that an interview had been arranged with

the very senior employee at AstraZeneca at the request of The Times' senior business correspondent. The employee was asked about the data to be released and was specifically questioned about the AstraZeneca development team's reaction to the data, as well as the reaction to the data from members of the scientific community. He was also asked to provide comment on the potential impact of this data, given what was described as the extremely high level of unmet need and the public's awareness on this issue.

The Panel noted AstraZeneca's submission that whilst it did not have any editorial control over such articles, with hindsight, it accepted that it could and should have done more to brief the employee on the likely lines of questioning and to temper the level of enthusiasm that was subsequently quoted in the article. The Panel noted AstraZeneca's submission that it would have been prudent to make the newspaper aware of the potential implications of such quotes going to print. The Panel further noted AstraZeneca's submission that it understood that any information provided to the media must be in line with the requirements of the Code, and therefore in the spirit of honesty, transparency and willingness to do better, it accepted a breach of Clauses 3.1, 5.1, 6.1, 8.1, 11.1, 11.2, 26.1 and 26.2.

The Panel noted that Enhertu did have a marketing authorisation at the time the press release was issued on 18 September 2021 and the subsequent interview and publication of The Times article. The Panel therefore considered that Clauses 3.1 and 11.1 which stated that a medicine must not be promoted prior to the grant of the marketing authorisation which permits its sale or supply were not relevant and therefore irrespective of AstraZeneca's admission, no breach of Clauses 3.1 and 11.1 was ruled in this regard.

The Panel, however, noting the definition of promotion at Clause 1.17 of the Code and the strong comments outlined in its ruling above attributable to the very senior AstraZeneca employee within the article in question, considered that AstraZeneca had promoted Enhertu for an unlicensed indication. Whilst the Panel did not have a transcript of the interview, it noted that AstraZeneca did not deny that the comments in question were made. The Panel therefore ruled a breach of Clause 11.2 in this regard, as acknowledged by AstraZeneca.

The Panel considered that the quotes attributable to the very senior AstraZeneca employee such as the trial of a new drug to treat an aggressive form of breast cancer has 'shattered expectations' raising hopes of a 'cure' were strong claims given the ultimate audience and thereby misled by exaggeration in breach of Clause 6.1 and a breach was ruled as acknowledged by AstraZeneca.

The Panel noted that the supplementary information to Clause 8.3 required press releases to be examined. The Panel noted its finding above, however, that the press release was promotional and therefore considered that it required certification which did not appear to have occurred. The Panel therefore ruled a breach of Clause 8.1 as acknowledged by AstraZeneca.

The Panel noted that Clause 26.1 prohibited the promotion of prescription only medicines to the public. Clause 26.2 stated that information about prescription only medicines which was made available either directly or indirectly to the public must be factual, presented in a balanced way, must not raise unfounded hopes of successful treatment and must not encourage members of the public to ask their health professional to prescribe a specific prescription only medicine.

The Panel considered that the press release and quotes made by the senior AstraZeneca employee during the interview, which were included in The Sunday Times article, named and

promoted Enhertu, raised unfounded hopes of successful treatment and would, in effect, encourage patients to ask for a specific prescription only medicine, Enhertu, as alleged. A breach of Clauses 26.1 and 26.2 was ruled as acknowledged by AstraZeneca.

The Panel noted its comments and rulings above and considered that AstraZeneca had failed to maintain high standards. A breach of Clause 5.1 was ruled as acknowledged by AstraZeneca.

In relation to the alleged breach of Clause 2, the Panel considered it was very important that press releases and any other materials including interviews, particularly those that were made available to journalists about sensitive issues such as survival in cancer patients, were fair, factual and not misleading. In addition, the Panel noted that the company accepted that it could and should have done more to brief the very senior employee interviewed on the likely lines of questioning and to temper the level of enthusiasm that was subsequently quoted in the article. Furthermore, AstraZeneca acknowledged that it would have been prudent to make the newspaper aware of the potential implications of such quotes going to print. In the Panel's view, this was a notable omission given the sensitivity of the subject matter. Noting that Clause 2 was used as a sign of particular censure and reserved for such use, the Panel considered that the circumstances warranted such a ruling and a breach of Clause 2 was ruled.

Complaint received **24 September 2021**

Case completed **19 August 2022**