CASES AUTH/3411/10/20 and AUTH/3412/10/20

COMPLAINANT v DAIICHI-SANKYO AND ASTRAZENECA

Promotion of a phase 3 Trial on LinkedIn

A complainant, who described him/herself as a concerned UK health professional, complained about a post from Daiichi-Sankyo Inc about a Phase 3 trial of a breast cancer therapy which appeared on his/her LinkedIn feed. The post read:

> **'Alongside our collaborators at AstraZeneca, we are pleased to announce that we have initiated our DESTINY-Breast05 Phase 3 Trial of our investigational therapy for HER2+ early breast cancer'.**

The post invited readers to learn more, providing a link to a press release titled 'DESTINY-Breast05 Head-to-Head Phase 3 Trial of ENHERTU Versus T-DM1 Initiated in Patients with HER2 Positive Early Breast Cancer at High Risk After Neo-adjuvant Therapy'.

The complainant submitted that the LinkedIn post at issue had been 'liked' by at least one Daiichi-Sankyo UK based employee. The complainant alleged that it appeared to be promotion to the public as well as promotion prior to gaining a licence.

As the LinkedIn post referred to both Daiichi-Sankyo and AstraZeneca, the complaint was taken up with both companies.

The detailed responses from Daiichi Sankyo and AstraZeneca are given below.

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Two Daiichi-Sankyo UK employees had 'liked' the post and in that regard the Panel considered that their engagement with the post, on the balance of probabilities, would have proactively disseminated the material to their LinkedIn connections in the UK, and therefore brought the LinkedIn post and associated press release within the scope of the UK Code. The Panel noted that the employees complied with a request from Daiichi-Sankyo to remove their 'likes' following receipt of the complaint.

The Panel noted that the press release linked to the LinkedIn post referred to the initiation of DESTINY-Breast05, a global Phase 3, head-to-head trial of Enhertu (fam-trastuzumab deruxtecan-nxki) vs ado-trastuzumab emtansine (T-DM1) as adjuvant therapy in patients with HER2 positive early breast cancer with high risk of disease recurrence who had residual invasive disease in the breast or axillary lymph nodes after receiving neo-adjuvant therapy. The press release stated, 'This research builds on the data from DESTINY-Breast01 which showed durability of response in previously treated HER2 positive metastatic breast cancer'. The Panel noted that, although Enhertu was not available in the UK when the LinkedIn post and associated press release were posted

and 'liked' by the two Daiichi-Sankyo UK employees, the press release contained the US FDA-approved indication for Enhertu and stated that in July 2020, the European Medicines Agency's Committee for Medicinal Products for Human Use granted accelerated assessment for use in the same indication.

The Panel noted that Enhertu was not classified as a prescription only medicine in the UK when the LinkedIn post and associated press release at issue were 'liked' by the two Daiichi-Sankyo UK employees. Clauses 26.1 only applied to prescription only medicines. On that very narrow technical point the Panel ruled no breach of the Code.

However, the Panel considered that the two Daiichi-Sankyo UK employees' 'like' of the LinkedIn post and associated press release, and on the balance of probabilities its subsequent proactive dissemination to all of their connections, promoted an unlicensed medicine and a breach of the Code was ruled.

The Panel noted that Daiichi-Sankyo had a UK Social Media Policy which instructed employees not to share, 'like' or comment on content in connection with Daiichi-Sankyo products, clinical studies, compounds in development or similar on their social media accounts. That instruction also included press releases. Employees were also instructed not to share, 'like', or comment on posts made on any social media accounts owned by Daiichi-Sankyo outside the UK, which related to Daiichi-Sankyo products, clinical studies, compounds in development or similar. The Panel considered that the instructions noted above were clear and unambiguous. It was thus unfortunate that the two individuals who 'liked' the post had let the company down by acting contrary to those company instructions, resulting in a medicine being promoted prior to the grant of its marketing authorisation. In that regard high standards had not been maintained. A breach of the Code was ruled.

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The Panel noted AstraZeneca's submission that the original LinkedIn post was posted by the Daiichi-Sankyo US marketing company via its US LinkedIn channel with an intended audience of the US general public. The Panel noted that although there was no reference to the availability of the medicine in the UK within the post or associated press release, AstraZeneca had submitted that one of its UK-based employees had 'liked' the post and in that regard the Panel considered that that employee's engagement with the post, on the balance of probabilities, would have proactively disseminated the material to his/her LinkedIn connections within the UK and therefore brought the LinkedIn post and associated press release within the scope of the UK Code.

The Panel noted that although AstraZeneca and Daiichi-Sankyo did not have a co-promotion agreement with regard to Enhertu in the UK at the time of the complaint, they did have a joint development and commercialisation agreement for the compound. In the Panel's view AstraZeneca was therefore responsible under the Code for the activity of its UK-based employee in relation to the post at issue.

The Panel noted that Enhertu was not classified as a prescription only medicine when the LinkedIn post and associated press release at issue were 'liked' by the UK-based AstraZeneca employee. Clauses 26.1 only applied to prescription only medicines. On that very narrow technical point the Panel ruled no breach of the Code.

However, the Panel considered that the UK-based AstraZeneca employee's 'like' of the LinkedIn post and associated press release, and on the balance of probabilities its subsequent proactive dissemination to all of his/her connections, promoted an unlicensed medicine and a breach of the Code was ruled.

The Panel noted that AstraZeneca had a global standard for employee use of personal social media channels for company and work-related content. The document reminded employees that there was special scrutiny from regulatory authorities when content related to company products or was about disease education/awareness. Employees were further reminded that AstraZeneca would be held accountable for company-related content on its employees' personal social media channels. Employees were instructed not to engage with ('like', share, comment on) content that was product-related or was about disease education/awareness topics from third party sources. The Panel considered that that instruction was unambiguous. The Panel noted AstraZeneca's submission that all UK-based employees (global and UK marketing company) had been trained on that policy in 2020; the employee at issue had been reminded of that policy and had immediately withdrawn the 'like' at issue.

The Panel noted its comments above and considered that it was thus unfortunate that AstraZeneca had been let down by one of its UK-based employees not following company guidelines on which he/she had been trained; an action that resulted in a medicine being promoted prior to the grant of its marketing authorisation. In that regard high standards had not been maintained. A breach of the Code was ruled.

A complainant, who described him/herself as a concerned UK health professional, complained about a post from Daiichi-Sankyo Inc about a Phase 3 trial of a breast cancer therapy which appeared on his/her LinkedIn feed. The post read:

> 'Alongside our collaborators at AstraZeneca, we are pleased to announce that we have initiated our DESTINY-Breast05 Phase 3 Trial of our investigational therapy for HER2+ early breast cancer'.

The post invited readers to learn more, providing a link to a press release titled 'DESTINY-Breast05 Head-to-Head Phase 3 Trial of ENHERTU Versus T-DM1 Initiated in Patients with HER2 Positive Early Breast Cancer at High Risk After Neo-adjuvant Therapy'.

The post appeared to include an 8 second video which showed the image of a woman's torso with an animated pulsing image of a tumour on the breast, included Daiichi-Sankyo's logo and stated BREAST CANCER UPDATE.

COMPLAINT

The complainant provided a screenshot of, and a link to, the LinkedIn post at issue and submitted that it had been 'liked' by at least one Daiichi-Sankyo UK based employee (name and job title provided). The complainant alleged that it appeared to be promotion to the general public as well as promotion prior to gaining a licence.

As the LinkedIn post referred to both Daiichi-Sankyo and AstraZeneca, the complaint was taken up with both companies; each were asked to consider the requirements of Clauses 3.1, 9.1 and 26.1.

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RESPONSE

Daiichi-Sankyo submitted that the matter fell outside the scope of the Code. The DESTINY-Breast05 study was a very recently initiated Phase 3 study which was run together with AstraZeneca as part of a joint development and commercialization of trastuzumab deruxtecan – marketed as Enhertu in the US following Food and Drug Administration (FDA) approval on 23 December 2019. Enhertu was indicated for the treatment of adults with unresectable or metastatic HER2-positive breast cancer who had received two or more prior anti-HER2 based regimens in the metastatic setting. The product was currently being reviewed by the European Medicines Agency (EMA) and was not commercially available in the UK. The DESTINY-Breast05 study was in the adjuvant, potentially curative, setting of breast cancer and as such was expected to take several years to fully enrol and report.

The LinkedIn page on which the post in question was placed was run by Daiichi-Sankyo Inc. which was a Daiichi-Sankyo group affiliate company based in the US. The LinkedIn page was primarily targeted at a US-based audience. The post was approved by Daiichi-Sankyo Inc with an intended US reach with no geo-targeting. The post referred to a clinical trial of a product that was not commercially available in the UK. The post and the article linked to it contained no information about the availability or use of the medicine in the UK.

The Daiichi-Sankyo Inc LinkedIn account had over 100,000 followers, the overwhelming majority being from the US. Daiichi-Sankyo Inc's communications and public affairs office had confirmed that the primary purpose of the LinkedIn page in question was initially driven by human resources for talent acquisition purposes in the US. Daiichi-Sankyo Inc did not use its LinkedIn page or Twitter account as a destination link for events outside of the US.

LinkedIn only provided data based on the 'Top Locations' of page followers. Follower location needed to be equal to, or greater than, ~1% in order to be captured. UK data were not available because the whole of the UK constituted less than 1% of total page followers of the Daiichi-Sankyo Inc LinkedIn account.

Daiichi-Sankyo Inc's LinkedIn page did not currently use geographic targeting and the account settings were based in the US/NY time zone. As such, default targeting would go to that primary location setting, which meant that the intended audience was the US and as such the materials were submitted through the US Product Material Review Process. AstraZeneca in the US was part of that process. A review of the material was not requested by any non-US AstraZeneca reviewer.

Daiichi-Sankyo UK was not aware of the post. There was no prior notification given to the UK organisation. Daiichi-Sankyo UK did not approve the material in question. The material was approved by Daiichi-Sankyo Inc nominated signatory teams. For clarity, Daiichi-Sankyo UK had no involvement in the creation, approval or publication of the post at issue. Daiichi-Sankyo understood that AstraZeneca approval was also through the AstraZeneca US affiliate given the intended US audience.

Daiichi-Sankyo UK-based personnel following Daiichi-Sankyo Inc on LinkedIn would be alerted of any new material posted by the US affiliate. In this case, two individuals 'liked' the posting, and this had been interpreted by the complainant as Daiichi-Sankyo promoting the product to

the public ahead of marketing authorisation. Daiichi-Sankyo UK respectfully disagreed with this interpretation but understood how the complainant could have reached that initial conclusion.

Daiichi-Sankyo acknowledged that, in general, case precedent could be strict on this issue, and so the UK social media policy was written with the specific intent to avoid any possible appearance of improper promotion. Daiichi-Sankyo's social media policy specifically prohibited the liking of product-related articles on LinkedIn, including posts related to clinical trials even where no product was explicitly mentioned.

Upon receiving the complaint, and the UK 'likes' being brought to Daiichi-Sankyo's attention, it immediately checked the post to identify all colleagues who might have interacted with, or 'liked', the post. The two employees responsible for liking the article rapidly complied with a request to remove their 'like'.

The requirements of the social media standard operating procedure (SOP) had been reiterated to the whole oncology business in the UK and all had been instructed to read it again and ensure they understood the requirements. The two individuals who 'liked' the post had been retrained on the UK social media policy and their understanding had been checked by line management.

In terms of case precedent, Daiichi-Sankyo noted Case AUTH/3010/1/18 where it was decided on appeal that tweets placed on the internet outside of the UK, with no involvement from the UK affiliate, containing no information regarding the availability or use of a medicine in the UK were not in scope of the Code.

Daiichi-Sankyo had policies and procedures designed to maintain the highest standards and it had taken steps to train all colleagues in recent weeks and months. Daiichi-Sankyo had reacted quickly and thoroughly when the mistakes of the two individuals had been brought to its attention and would continue to work with those individuals and all of its staff to endeavour to maintain the highest standards in all its activity.

For the reasons stated above, Daiichi-Sankyo denied breaches of Clauses 3.1, 9.1 and 26.1.

PANEL RULING

Firstly, the Panel had to decide whether the LinkedIn post in question and associated press release which was inextricably linked to it, were subject to the Code.

The Panel noted Daiichi-Sankyo's submission that in its view the post did not fall within the scope of the Code; the original post was approved and placed by Daiichi-Sankyo Inc based in the US on its LinkedIn page with no involvement of the UK; it had an intended US reach and there was no reference to the availability of the medicine in the UK within the post or associated press release. The Panel noted, however, Daiichi-Sankyo's submission that its UK-based personnel who followed Daiichi-Sankyo Inc on LinkedIn would be alerted to any new material posted by the US affiliate. In this case, two Daiichi-Sankyo UK employees had 'liked' the post and in that regard the Panel considered that their engagement with the post, on the balance of probabilities, would have proactively disseminated the material to their LinkedIn connections in the UK, and therefore brought the LinkedIn post and associated press release within the scope of the UK Code. The Panel noted that the two employees responsible for liking the article had

rapidly complied with a request from Daiichi-Sankyo to remove their 'likes' following receipt of this complaint.

The Panel noted that LinkedIn was different to some other social media platforms in that it was a business and employment-orientated network and was primarily, although not exclusively, associated with an individual's professional heritage and current employment and interests; its application was not limited to the pharmaceutical industry or to health care. In the Panel's view, it was of course not unacceptable for company employees to use personal LinkedIn accounts; the Code would not automatically apply to all activity on a personal account. The Panel noted that compliance challenges arose when the personal use of social media by pharmaceutical company employees overlapped with their professional responsibilities or the interests of the company. The Panel noted that material could be disseminated or highlighted by an individual on LinkedIn in a number of ways, by posting, sharing, commenting or liking. The Panel understood that if an individual 'liked' a post it increased the likelihood that the post would appear in his/her connections' LinkedIn feeds, appearing as '[name] likes this'. In the Panel's view, activity conducted on social media that could potentially alert one's connections to the activity might be considered proactive dissemination of material. In addition, an individual's activity and associated content might appear in the individual's list of activities on his/her LinkedIn profile page which was visible to his/her connections; an individual's profile page was also potentially visible to others outside his/her network depending on the individual's security settings. Company employees should assume that such activity would, therefore, potentially be visible to both those who were health professionals or other relevant decision makers and those who were members of the public. In that regard it was imperative that they acted with extreme caution when using all social media platforms, including LinkedIn, to discuss or highlight issues which impinged on their professional role or the commercial/research interests of their company. Whether the Code applied would be determined on a case-by-case basis, taking into account all of the circumstances including, among other things, content and distribution of the material. If an employee's personal use of social media was found to be in scope of the Code, the company would be held responsible. The Panel considered that companies should assume that the Code would apply to all work-related, personal LinkedIn posts/activity by their employees unless, for very clear reasons, it could be shown otherwise. Any material associated with a social media post, for example a link within a post, would be regarded as being part of that post. Companies must have comprehensive and up to date social media policies that provide clear and unequivocal guidance on what was, and what was not, acceptable and it was extremely important that employees were trained upon them and followed them.

The Panel noted that the press release linked to the LinkedIn post referred to the initiation of DESTINY-Breast05, a global Phase 3, head-to-head trial of Enhertu (fam-trastuzumab deruxtecan-nxki) vs ado-trastuzumab emtansine (T-DM1) as adjuvant therapy in patients with HER2 positive early breast cancer with high risk of disease recurrence who had residual invasive disease in the breast or axillary lymph nodes after receiving neo-adjuvant therapy. The Panel noted that the press release stated, 'This research builds on the data from DESTINY-Breast01 which showed durability of response in previously treated HER2 positive metastatic breast cancer'. The Panel noted that, although Enhertu was not available in the UK when the LinkedIn post and associated press release were posted and 'liked' by the two Daiichi-Sankyo UK employees, the press release contained the US FDA-approved indication for Enhertu, ie for the treatment of adults with unresectable or metastatic HER2-positive breast cancer who had received two or more prior anti-HER2-based regimens, and stated that in July 2020, the European Medicines Agency's Committee for Medicinal Products for Human Use granted accelerated assessment for use in the same indication.

The Panel noted Clause 3.1 prohibited the promotion of a medicine prior to the grant of its marketing authorisation. Once the marketing authorisation had been granted Clause 26.1 prohibited the promotion of prescription only medicines to the public.

The Panel noted that Enhertu was not classified as a prescription only medicine in the UK when the LinkedIn post and associated press release at issue were 'liked' by the two Daiichi-Sankyo UK employees. Clauses 26.1 only applied to prescription only medicines. On that very narrow technical point the Panel ruled no breach of Clause 26.1 of the Code.

However, the Panel considered that the two Daiichi-Sankyo UK employees' 'like' of the LinkedIn post and associated press release, and on the balance of probabilities its subsequent proactive dissemination to all of their connections, promoted an unlicensed medicine and a breach of Clause 3.1 was ruled.

The Panel understood that employees might feel inclined to endorse articles related to their senior colleagues on LinkedIn or their company's corporate social media posts but noted that depending on the content such activity might or might not fall within the scope of the Code; companies would be well advised to cover the possibility of that activity in their social media policies. This was particularly important if UK employees were likely to follow the social media accounts of overseas affiliates which might have Codes, laws and regulations that differed to the UK.

The Panel noted that Daiichi-Sankyo had a UK Social Media Policy which instructed employees not to share, 'like' or comment on content in connection with Daiichi-Sankyo products, clinical studies, compounds in development or similar on their social media accounts. That instruction also included press releases. Employees were also instructed not to share, 'like', or comment on posts made on any social media accounts owned by Daiichi-Sankyo outside the UK, which related to Daiichi-Sankyo products, clinical studies, compounds in development or similar. The Panel considered that the instructions noted above were clear and unambiguous. It was thus unfortunate that the two individuals who 'liked' the post had let the company down by acting contrary to those company instructions, resulting in a medicine being promoted prior to the grant of its marketing authorisation. In that regard high standards had not been maintained. A breach of Clause 9.1 was ruled.

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RESPONSE

AstraZeneca strongly refuted a breach of Clauses 3.1, 9.1 or 26.1 and contended that the UK Code did not apply as the post in question was posted by Daiichi-Sankyo's US marketing company, on a US LinkedIn channel and was intended for a US-only audience. AstraZeneca (global and UK marketing company) could not be held liable for such a post being viewed by members of the public in the UK.

By way of background, AstraZeneca submitted that the DESTINY-Breast 05 trial was being conducted by both Daiichi-Sankyo and AstraZeneca as part of a joint development and commercialisation agreement for trastuzumab deruxtecan, marketed as Enhertu in the US. AstraZeneca submitted that Enhertu was approved by the FDA on 23 December 2019 for the treatment of adults with unresectable or metastatic HER2-positive breast cancer who had received two or more prior anti-HER2-based regimens in the metastatic setting. Enhertu was

currently being reviewed by the European Medicines Agency (EMA) and therefore was not commercially available for use in the UK.

The LinkedIn post in question (DESTINY-Breast 05 trial, 5 November 2020) was posted by the Daiichi-Sankyo US marketing company (based in New Jersey) via its US LinkedIn channel with an intended audience of the US general public – indeed, such posts were deemed permissible in the US. Given that it was a US-specific channel, Daiichi-Sankyo US made efforts to ensure the post was not directed towards audiences outside of the US – to that end, the 'geo-targeting' and 'comments' features were disabled. Only the 'like' function was enabled for the post. Given the US-focused nature of the post, it was reviewed and approved by an experienced nominated signatory in the AstraZeneca US marketing company only. Neither AstraZeneca global, nor AstraZeneca UK were informed of the intended posting because it was not intended for audiences outside of the US. Following the matter being brought to AstraZeneca's attention and upon investigation by the UK team, it was found that one AstraZeneca employee in the UK (part of the global organisation based in Cambridge) had 'liked' the post – the individual was reminded of AstraZeneca's social media policy (copy provided) and immediately withdrew the 'like'. AstraZeneca noted that all UK-based employees (global and UK marketing company) had been trained on that policy in 2020.

Finally, AstraZeneca noted that guidelines to the Code specified that 'Where companies jointly promote the same product and the promotional material bears both company names, the companies concerned will be held jointly responsible for it under the Code' and the guidance to Clause 14.1 which stated that 'Under co-promotion arrangements or other arrangements where companies work together, such as joint working projects, the companies concerned can agree to have only one final signatory to certify on behalf of all the companies. This must all be agreed beforehand and the Medicines and Healthcare products Regulatory Agency and the Prescription Medicines Code of Practice Authority must be informed in advance who the signatory will be. In the event of a complaint about material certified in this way each company involved in the project/activity would be responsible under the Code'. For clarification, AstraZeneca and Daiichi-Sankyo had not entered into a co-promotional agreement in the UK as the product was not approved for use in the UK. As such, there had been no joint activity in the UK regarding the post in question or any other promotional material and therefore the case could not be a co-promotional activity. On that basis, even if Daiichi-Sankyo was responsible for the post under the UK Code, there were no provisions in the Code that would allow AstraZeneca UK to be held jointly liable for it.

In summary, AstraZeneca contended that the Code did not apply in this case. Despite LinkedIn being a global platform, the post in question was distributed by Daiichi-Sankyo US, on its US channel and was specifically intended for US audiences, which was permissible in the US. AstraZeneca UK could not be held liable for such a post being viewed by members of the public in the UK and therefore it strongly refuted breaches of Clauses 3.1, 9.1 and 26.1.

PANEL RULING

Firstly, the Panel had to decide whether the LinkedIn post in question and associated press release which was inextricably linked to it, were subject to the Code.

The Panel noted AstraZeneca's submission that the original LinkedIn post was posted by the Daiichi-Sankyo US marketing company via its US LinkedIn channel with an intended audience of the US general public. The Panel noted that although there was no reference to the

availability of the medicine in the UK within the post or associated press release, AstraZeneca had submitted that one of its UK-based employees had 'liked' the post and in that regard the Panel considered that that employee's engagement with the post, on the balance of probabilities, would have proactively disseminated the material to his/her LinkedIn connections within the UK and therefore brought the LinkedIn post and associated press release within the scope of the UK Code.

The Panel noted that LinkedIn was different to some other social media platforms in that it was a business and employment-orientated network and was primarily, although not exclusively, associated with an individual's professional heritage and current employment and interests; its application was not limited to the pharmaceutical industry or to health care. In the Panel's view, it was of course not unacceptable for company employees to use personal LinkedIn accounts; the Code would not automatically apply to all activity on a personal account. The Panel noted that compliance challenges arose when the personal use of social media by pharmaceutical company employees overlapped with their professional responsibilities or the interests of the company. The Panel noted that material could be disseminated or highlighted by an individual on LinkedIn in a number of ways, by posting, sharing, commenting or liking. The Panel understood that if an individual 'liked' a post it increased the likelihood that the post would appear in his/her connections' LinkedIn feeds, appearing as '[name] likes this'. In the Panel's view, activity conducted on social media that could potentially alert one's connections to the activity might be considered proactive dissemination of material. In addition, an individual's activity and associated content might appear in the individual's list of activities on his/her LinkedIn profile page which was visible to his/her connections; an individual's profile page was also potentially visible to others outside his/her network depending on the individual's security settings. Company employees should assume that such activity would therefore, potentially, be visible to both those who were health professionals or other relevant decision makers and those who were members of the public. In that regard it was imperative that they acted with extreme caution when using all social media platforms, including LinkedIn, to discuss or highlight issues which impinged on their professional role or the commercial/research interests of their company. Whether the Code applied would be determined on a case-by-case basis, taking into account all of the circumstances including, among other things, content and distribution of the material. If an employee's personal use of social media was found to be in scope of the Code, the company would be held responsible. The Panel considered that companies should assume that the Code would apply to all work-related, personal LinkedIn posts/activity by their employees unless, for very clear reasons, it could be shown otherwise. Any material associated with a social media post, for example a link within a post, would be regarded as being part of that post. Companies must have comprehensive and up to date social media policies that provide clear and unequivocal guidance on what was, and what was not, acceptable and it was extremely important that employees were trained upon them and followed them.

The Panel noted that although AstraZeneca and Daiichi-Sankyo did not have a co-promotion agreement with regard to Enhertu in the UK at the time of the complaint, they did have a joint development and commercialisation agreement for the compound. In the Panel's view AstraZeneca was therefore responsible under the Code for the activity of its UK-based employee in relation to the post at issue.

The Panel noted that the press release linked to the LinkedIn post referred to the initiation of DESTINY-Breast05, a global Phase 3, head-to-head trial of Enhertu vs ado-trastuzumab emtansine (T-DM1) as adjuvant therapy in patients with HER2 positive early breast cancer with high risk of disease recurrence who had residual invasive disease in the breast or axillary lymph

nodes after receiving neo-adjuvant therapy. The Panel noted that the press release stated, 'This research builds on the data from DESTINY-Breast01 which showed durability of response in previously treated HER2 positive metastatic breast cancer'. The Panel noted that, although Enhertu was not available in the UK when the LinkedIn post and associated press release were posted and 'liked' by the AstraZeneca employee, the press release contained the US FDA-approved indication for Enhertu, ie for the treatment of adults with unresectable or metastatic HER2-positive breast cancer who had received two or more prior anti-HER2-based regimens, and stated that in July 2020, the European Medicines Agency's Committee for Medicinal Products for Human Use granted accelerated assessment for use in the same indication.

The Panel noted Clause 3.1 prohibited the promotion of a medicine prior to the grant of its marketing authorisation. Once the marketing authorisation had been granted Clause 26.1 prohibited the promotion of prescription only medicines to the public.

The Panel noted that Enhertu was not classified as a prescription only medicine when the LinkedIn post and associated press release at issue were 'liked' by the UK-based AstraZeneca employee. Clauses 26.1 only applied to prescription only medicines. On that very narrow technical point the Panel ruled no breach of Clause 26.1 of the Code.

However, the Panel considered that the UK-based AstraZeneca employee's 'like' of the LinkedIn post and associated press release, and on the balance of probabilities its subsequent proactive dissemination to all of his/her connections, promoted an unlicensed medicine and a breach of Clause 3.1 was ruled.

While the Panel understood that employees might feel inclined to endorse third-party posts which related to their company, they had to be mindful that, depending on the content, such activity might or might not fall within the scope of the Code; companies would be well advised to cover the possibility of this activity in their social media policies. This was particularly important if UK employees were likely to follow the social media accounts of overseas companies/affiliates which might have Codes, laws and regulations that differed to the UK.

The Panel noted that AstraZeneca had a global standard for employee use of personal social media channels for company and work-related content. The document reminded employees that there was special scrutiny from regulatory authorities when content related to company products or was about disease education/awareness. Employees were further reminded that AstraZeneca would be held accountable for company-related content on its employees' personal social media channels. Employees were instructed not to engage with ('like', share, comment on) content that was product-related or was about disease education/awareness topics from third party sources. The Panel considered that that instruction was unambiguous. The Panel noted AstraZeneca's submission that all UK-based employees (global and UK marketing company) had been trained on that policy in 2020; the employee at issue had been reminded of that policy and had immediately withdrawn the 'like' at issue.

The Panel noted its comments above and considered that it was thus unfortunate that AstraZeneca had been let down by one of its UK-based employees not following company guidelines on which he/she had been trained; an action that resulted in a medicine being promoted prior to the grant of its marketing authorisation. In that regard high standards had not been maintained. A breach of Clause 9.1 was ruled.

Complaint received	**2 November 2020**	
Cases completed	**Case AUTH/3411/10/20**	**4 June 2021**
	Case AUTH/3412/10/20	**14 December 2021**