CASE/0563/04/25

COMPLAINANT v ASTRAZENECA

Alleged promotion on LinkedIn

CASE SUMMARY

This case was in relation to a LinkedIn post, posted by a researcher from a cancer institute in the United States, and concerning a number of clinical trials. The complainant alleged that three UK based AstraZeneca employees had engaged with the post thereby promoting four unlicensed indications for two pipeline assets to the public.

The outcome under the 2024 Code was:

Breach of Clause 3.1	**Promoting a medicine prior to the grant of its marketing authorisation**
Breach of Clause 5.1	**Failing to maintain high standards**
Breach of Clause 5.3	**Failing to recognise the special nature of medicines**
Breach of Clause 26.1	**Promoting a prescription only medicine to the public**
Breach of Clause 26.2	**Providing unbalanced information and encouraging members of the public to ask for a specific prescription only medicine**

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 3.1	**Requirement that a medicine must not be promoted prior to the grant of its marketing authorisation**
No Breach of Clause 5.1	**Requirement to maintain high standards**
No Breach of Clause 26.1	**Requirement to not promote prescription only medicines to the public**

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:

> "Dear PMCPA,
>
> I hope this meets you well,
>
> I would like to raise a complaint about AZ who seem to be promoting multiple (total of 4) unlicensed indications in Breast Cancer across two separate ADC [antibody-drug conjugate] assets in its pipeline to the public on LinkedIn.
>
> The two assets are T-Dxd (otherwise known as Enhertu) and Dato- Dxd, which are part of a post on LinkedIn put together by a well known Breast Oncologist. At least three members of the UK AstraZeneca Oncology teams based in UK offices and roles have liked and therefore shared these posts to the public:
>
> The three off license indications for T-Dxd being promoted to the public are for clinical trials named: Destiny Breast 11, Destiny Breast 05, and Destiny Breast 09. Also covered are Tropion Breast 02 for the other ADC asset Dato-Dxd.
>
> Each of these 4 unlicensed indications have been liked by at least 3 senior AZ staff based out of the UK based offices.
>
> I believe we all need to recognize the special nature of medicines and these latest in a series of such breaches show a lack of care for the industry code and promotion of off licensed indications to the public.
>
> Destiny Breast 09 is particularly concerning as the wording refers to how this trial will reshape the first line (1L) treatment landscape, which is raising unfounded hopes for patients, and use of improving OS is also not suitable for use with the public.
>
> The PMCPA should consider the following breaches;
>
> 4 x separate Breaches of Clause 2 for bringing discredit upon & reducing confidence in the Pharma industry
>
> 4 x separate breaches of 26.1 for promoting two medicines in the AZ pipeline and marketed portfolio to the public at large on LinkedIn.
>
> 4 x separate breaches of 3.1 as these are unlicensed indications for two marketed drugs by AZ, and the lack of proven efficacy, safety in these studies is off license promotion on such a large scale
>
> 4 x separate breaches of failing to maintain high standards or even the lowest of standards. This failure to recognize the special nature of medicines must also be considered and relevant clauses applied.
>
> 4 x 26.1 breaches as both T-Dxd which is marketed in a subset of Breast Cancer patients and recently approved by NICE is a POM which should not be promoted to the

public. Separately Dato-Dxd in Tropion Lung 01 is approved for use in this indication and is a POM which has been promoted to the public.

Lastly, the continuous failure to adhere to the code by so many AZ staff, shows the lack of care for compliance within the AZ organisation. This further warrants the PMCPA to seriously consider auditing internal SOPs for compliance training and culture."

FURTHER INFORMATION FROM THE COMPLAINANT

"Please find attached the necessary screenshots linking the likes for the posts in question to the named AZ employees.

Separately I believe two 3.1 clauses should be applied as these two AZ medicines do not have product licenses for the breast cancer indications in the Destiny studies in the post. For example T-Dxd is approved by NICE in a subset of Breast cancer patients but not the indications being researched in the three Destiny studies in the post ie Destiny 9, 5, and 11. These are active clinical trials.

Similarly for Dato-Dxd the indication being studied in Tropion Breast-02 is not yet licensed so 3.1 applies.

When writing to AstraZeneca, the PMCPA asked it to consider the requirements of Clauses 2, 3.1, 5.1, 5.3, 26.1 and 26.2 of the 2024 Code."

ASTRAZENECA'S RESPONSE

The response from AstraZeneca is reproduced below:

"Thank you for your letter dated 28 April 2025, concerning a complaint that three AstraZeneca employees have liked a LinkedIn post which contains information about trials relating to antibody-drug-conjugates (ADCs).

The Complainant alleges the following for *Enhertu* (trastuzumab deruxtecan) and datopotamab deruxtecan:

- 'Promoting two medicines in the AstraZeneca pipeline and marketed portfolio to the public at large on LinkedIn'. Complainant states that 'T-Dxd' and 'Dato-Dxd' are prescription only medicines which should not been promoted to the public (alleged breaches of clause 26.1)
- Promoting multiple unlicensed indications in breast cancer across two separate ADC assets, highlighting 'three off license indications for T-Dxd being promoted to the public are for clinical trials named: Destiny Breast 11, Destiny Breast 05 and Destiny Breast 09. Also covered are Tropion Breast 02 for the other ADC asset Dato-Dxd …. As these are unlicensed indications for two marketed drugs by AstraZeneca and the lack of proven efficacy, safety in these studies is off license promotion on such a large scale' (alleged breaches of clause 3.1)
- Raising unfounded hope for patients in relation to DESTINY-Breast09 trial stating that 'Destiny breast 09 is particularly concerning as the wording refers to how this trial will reshape the first line (1L) treatment landscape, which is raising unfounded hopes for patients, and use of improving OS is also not suitable for use with the public' (alleged breach of clause 26.2)

- Failure to recognise the special nature of medicines (alleged breaches of clause 5.3)
- A 'lack of care for compliance within the AZ organisation'
- Failing to maintain high standards 'or even the lowest of standards' (alleged breaches of clause 5.1)
- Bringing discredit upon and reducing confidence in the pharmaceutical industry (alleged breaches Clause 2)

In our response, we will address each of the allegations made by the Complainant as outlined in their emails from 23rd and 26th April focussing on the following clauses of the 2024 Code:
For Dato-DXd: Clauses 3.1 and 26.1.
For T-DXd: Clauses 3.1, 26.1 and 26.2.
Overall: Clauses 5.1, 5.3 and 2.

AstraZeneca's Response

Background

AstraZeneca and Daiichi Sankyo entered into a global collaboration to jointly develop and commercialise *Enhertu* (trastuzumab deruxtecan) in March 2019 and *Datroway* (datopotamab deruxtecan) in July 2020, except in Japan where Daiichi Sankyo maintains exclusive rights for each ADC. Daiichi Sankyo is the UK marketing authorisation holder of E*nhertu* (trastuzumab deruxtecan). AstraZeneca is the marketing authorisation holder of *Imfinzi* (durvalumab).

Our Investigation

AstraZeneca confirms that the three individuals highlighted by the Complainant in the screenshots are AstraZeneca R&D employees, based in the UK. The role titles and employment status of the individuals [provided]. Based on their positions within the organisation, we would not describe these employees as Senior as claimed by the Complainant.

Upon receipt of the complaint, all employees identified by the Complainant were contacted and asked to withdraw their "likes." This was actioned immediately. Employees were also asked to re-familiarise themselves with the Global Standard - Employee Use of Personal Social Media.

We acknowledge that LinkedIn is a professional networking site, and that the PMCPA has previously determined that unless closed groups are used, or the individual can guarantee that their connections are HCPs, then any content being disseminated on LinkedIn is likely to include members of the public. From the individuals LinkedIn profiles, they have 500+ connections, and thus we accept that some of these connections may include members of the public.
AstraZeneca can confirm that the post originated independently of AstraZeneca from an external third-party account [individual initials]. AstraZeneca did not author these posts or influence the content of this post or share this post on global corporate social media channels. Therefore, the post did not require approval by AstraZeneca and so there are no certificates of approval. For the sake of transparency, AstraZeneca has collaborated

with [initials] on other unrelated initiatives. However, this has no connection to their independent social media post which is the subject of the complaint.

Training

We can confirm that the three UK-based employees identified by the Complainant have completed training on the interactive module of 'The Use of Social Media – UK,' which included the prior version of the social media policy as a resource. The guiding principles remain consistent between version 3 and current version 4 of the policy.

'Dato-DXd' Content in the LinkedIn Post

The allegations against AstraZeneca are alleged breaches of clause 3.1 and 26.1:

- Clause 3.1 A medicine must not be promoted prior to the grant of the marketing authorisation which permits its sale or supply.
- 26.1 Prescription only medicines must not be advertised to the public. This prohibition does not apply to vaccination and other campaigns carried out by companies and approved by the health ministers.

The external third-party post stated the following in relation to 'Dato-DXd' under a heading 'Triple Negative disease':
"TROPION-Breast02 (NCT05374512) - Dato-DXd is currently approved for HR+ MBC, and has shown promising activity (as monotherapy and with durva) for mTNBC. TROPION-Breast02 compares first-line Dato-DXd vs. chemotherapy in PD-1 ineligible mTNBC, with results expected this year."

Datopotamab deruxtecan (abbreviated to Dato-DXd in the post) is not approved for any indication in the UK. It does not have a UK marketing authorisation and therefore was not a prescription only medicine in the UK at the time of the post at issue, and thus we deny the allegation of promoting datopotamab deruxtecan as a prescription only medicine to the UK public (Clause 26.1).

At the time of the post, there has been no regulatory filing to the MHRA for datopotamab deruxtecan and for this reason we deny breach of clause 3.1.

Imfinzi (durvalumab), (abbreviated to 'durva' in the post),has a marketing authorisation in the UK (see *Imfinzi* UK SmPC). However, it is not licensed in combination with datopotamab deruxtecan. This combination is currently under investigation with no phase III data available in metastatic triple negative breast cancer (mTNBC) at the time of the post. As referenced above, datopotamab deruxtecan does not have a UK marketing authorisation in the UK and at this time, there is no early access programme in the UK for datopotamab deruxtecan. We also note that the post itself does not contain the generic name of datopotamab deruxtecan or brand name of *Datroway,* or the generic name of durvalumab or brand name of *Imfinzi*. The author of the post refers to 'Dato-Dxd'- and 'durva' without further explanation to these abbreviations and does not name the specific breast cancer trial in which datopotamab deruxtecan and durvalumab are being investigated as a combination. Given this context and based on an immediate reading of the post (which contained no links to further information or explanations to the abbreviations used), we deny that a specific prescription only medicine has been promoted to the public (Clause 26.1).

As mentioned above, Imfinzi (durvalumab) had a UK marketing authorisation at the time that the LinkedIn post at issue was published. As such Clause 3.1 which states that a medicine must not be promoted *prior to the grant of the marketing authorisation* which permits its sale or supply is not relevant in this case and on this basis we deny a breach of clause 3.1.

‘T-DXd’ Content in the LinkedIn Post

The allegations against AstraZeneca are alleged breaches of clause 26.1, 26.2 and 3.1:

- Clause 3.1 A medicine must not be promoted prior to the grant of the marketing authorisation which permits its sale or supply.
- 26.1 Prescription only medicines must not be advertised to the public. This prohibition does not apply to vaccination and other campaigns carried out by companies and approved by the health ministers.
- 26.2 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 external third-party post stated the following for T-DXd:

Under heading of HER2-positive disease:
“DESTINY-Breast 09 (NCT04784715) - T-DXd improved OS when used in 2L HER2+ MBC (DB-03). Could it also improve outcomes when used as first-line treatment (vs. THP)? Results are expected by 2025, promising to reshape 1L treatment standards and to raise many open questions in the field.

DESTINY-Breast 05 (NCT04622319) - DB-05 aims at escalating treatment for patients with high-risk, HER2+ residual disease, by comparing adjuvant T-DXd vs T-DM1 after surgery. The trial is fully accrued and results are expected soon.

DESTINY-Breast 11 (NCT05113251) - DB-11 compares neoadjuvant T-DXd to T-DXd-THP and AC-THP for high-risk HER2+ breast cancer. The trial is expected to report by the end of this year, and may lead to an alternative, anthracycline-sparing regimen for a high-risk population.”

In the external post under heading of HR+/HER2- disease, together with information about a non-AZ trial (ASCENT-07), there is a reference to T-DXd and DB-06 trial:
“ASCENT-07 (NCT05840211) - DB-06 has positioned T-DXd as 1L cytotoxic option for patients with ET-refractory, HR+/HER2- MBC. ASCENT-07, with results expected soon, compares SG to chemo in a similar 1L cytotoxic setting, potentially providing an additional option for chemo-naive patients.”

In the UK, *Enhertu* (trastuzumab deruxtecan) has the following licensed indications in the breast cancer setting:

- *HER2-positive breast cancer: Enhertu* as monotherapy is indicated for the treatment of adult patients with unresectable or metastatic HER2-positive breast cancer who have received one or more prior anti-HER2-based regimens.

- *HER2-low breast cancer: Enhertu* as monotherapy is indicated for the treatment of adult patients with unresectable or metastatic HER2-low breast cancer who have received prior chemotherapy in the metastatic setting or developed disease recurrence during or within 6 months of completing adjuvant chemotherapy.

Other UK indications for *Enhertu* can be viewed on the UK SmPC.
Enhertu had a UK marketing authorisation at the time that the LinkedIn post at issue was published. As such Clause 3.1 which states that a medicine must not be promoted *prior to the grant of the marketing authorisation* which permits its sale or supply is not relevant in this case and on this basis we deny a breach of clause 3.1.

The post does not contain the generic name of trastuzumab deruxtecan or brand name of *Enhertu.* Instead, it refers to 'T-DXd'. There are no explanations as to this abbreviation of 'T-DXd' used in the post and no links to further information. Whilst we acknowledge trial names have been included (DESTINY-Breast09, DESTINY-Breast05, DESTINY-Breast11 and the abbreviations DB-03 and DB-06), it has not been directly connected to the brand name '*Enhertu*' or generic name 'trastuzumab deruxtecan'. Based on an immediate reading of the post and given that no links to further information were included, and no explanations to the abbreviation of 'T-DXd' is provided which link it to '*Enhertu*' or 'trastuzumab deruxtecan'', we deny that a specific prescription only medicine has been promoted to the public (Clause 26.1).

Regarding the allegation of 26.2, the Complainant has stated that '*Destiny breast 09 is particularly concerning as the wording refers to how this trial will reshape the first line (1L) treatment landscape, which is raising unfounded hopes for patients, and use of improving OS is also not suitable for use with the public'.*

The actual wording in the third-party post was *'DESTINY-Breast 09 (NCT04784715) -T-DXd improved OS when used in 2L HER2+ MBC (DB-03). Could it also improve outcomes when used as first-line treatment (vs. THP)? Results are expected by 2025, promising to reshape 1L treatment standards and to raise many open questions in the field.'*

As highlighted, there are no explanations as to what the different abbreviations refer to in this post (including for 'T-DXd', 'OS', '2L', 'HER2+ MBC', 'DB-03', 'THP' and '1L') and there are no links to further information. The brand name '*Enhertu*' or generic name 'trastuzumab deruxtecan' has not been specifically cited in the post. Thus based on an immediate reading of this post, we question whether these statements would typically be comprehensible to a wider audience lacking in-depth knowledge of the breast cancer field. Specifically, whether the audience could recognise the context as specific to a particular breast cancer setting, understand "OS" as referring to overall survival, and associate the post with *Enhertu*. Furthermore, regarding DESTINY-Breast09 specifically, the author of the post poses a question 'Could it also improve outcomes when used as first-line treatment (vs. THP)?' and acknowledges results are yet to read out. As such for all these reasons the post is unlikely to raise unfounded hope of the general public or encourage members of the public to ask their health professional to prescribe a specific prescription only medicine. Therefore, we deny breaches of clause 26.2.

Additional Information

The Complainant has alleged that there is 'a lack of care for compliance within the AZ organisation' without any evidence. We are unable to investigate non-specific allegations, therefore we have not addressed this in our response.

Comment on Complainant Conduct and Intent

As the Complainant is anonymous, we cannot verify the Complainant's stated neutrality and find that it is difficult to reconcile the Complainant's claim of being a "concerned healthcare professional, and have no attachment to Pharma" with the level of effort involved in this complaint.

The individual would have had to manually review hundreds of social media interactions (circa 775) on an external independently written post, to identify three individuals from AstraZeneca based in the UK. It is our view that this level of analysis is not consistent with nature of concern from a healthcare professional, particularly when the content in question relates to information written in an abbreviated terminology and is not promotional messaging. Furthermore, only AstraZeneca is highlighted in the Complainant's letter despite interactions by members of other pharmaceutical companies. It is our view that this level of scrutiny and specificity suggests a deliberate attempt to monitor and target AstraZeneca, rather than a good-faith concern about compliance from a 'concerned healthcare professional'.

Summary

AstraZeneca did not author the post or share this post on global corporate channels. The post originated independently from an external third-party account, of which the Complainant has highlighted three UK-based AstraZeneca employees who have liked the post from their personal social media accounts. This was not a co-ordinated activity nor one initiated or encouraged by AstraZeneca. There was no effort and no intent to influence prescribing or use of an AstraZeneca medicine. The post included abbreviations and did not directly identify the following by brand or generic name: *Datroway* (datopotamab deruxtecan), *Enhertu* (trastuzumab deruxtecan) or *Imfinzi* (durvalumab).

AstraZeneca has approximately 10,000 employees in the UK and we believe that in the dynamic and fast paced environment of social media, three UK-based employees 'liking' a LinkedIn post of this nature does not mean the individual, or the AstraZeneca organisation as a whole, is misunderstanding the special nature of medicines, failing to maintain high standards or bringing disrepute upon the pharmaceutical industry. Thus, we refute being in breach of respecting the special nature of medicines (Clause 5.3), lack of high standards (Clause 5.1) or bringing the pharmaceutical industry into disrepute (Clause 2).

Based on the above detailed response, we respectfully refute all allegations of breaches of clauses 2, 3.1, 5.1, 5.3, 26.1 and 26.2."

PANEL RULING

This complaint concerned a LinkedIn post which had been posted by a researcher from a renowned cancer institute in the United States; it was alleged that three UK based AstraZeneca employees had engaged with the post thereby promoting four unlicensed indications for two pipeline assets to the public.

The post stated that 2025 was expected to be the year with the highest number of Phase 3 ADC (antibody-drug conjugates) trials read outs in breast oncology, with impact for all breast cancer subtypes and provided a summary of eight clinical trials 'expected to reshape practice in 2025'. An outlined box headed 'ADC Phase 3 trials that may change practice in 2025' listed Phase 3 trials within sections headed: HER2 positive disease; Triple Negative disease; and HR+/HER2- disease.

The DESTINY-Breast trials were listed under an orange banner headed 'HER2-positive disease' in bold text and stated:

1. "DESTINY-Breast 09 (NCT04784715) → T-DXd improved OS when used in 2L HER2+ MBC (DB-03). Could it also improve outcomes when used as first line treatment (vs THP)? Results are expected by 2025, promising to reshape 1L treatment standards and to raise many open questions in the field.
2. DESTINY-Breast 05 (NCT04622319) → DB-05 aims at escalating treatment for patients with high-risk HER2+ residual disease, by comparing adjuvant T=DXd vs T-DM1 after surgery. The trial is fully accrued and results are expected soon.
3. DESTINY-Breast 11 (NCT05113251)→ DB-11 compares neoadjuvant T-DXd to T-DXd-THP and AC-THP for high-risk HER2+ breast cancer. The trial is expected to report by the end of this year, and may lead to an alternative, anthracycline-sparing regimen for a high-risk population."

The TROPION-Breast 02 trial was set out under a green highlighted banner headed 'Triple Negative disease' in bold text and stated:

4. "TROPION-Breast02 (NCT05374512)→ Dato-DXd is currently approved for HR+MBC, and has shown promising activity (as monotherapy and with durva) for mTNBC. TROPION-Breast02 compares first-line DAT-DXd vs chemotherapy in PD1 ineligible mTNBC, with results expected this year."

The Panel noted that T-DXd was licensed in the UK as Enhertu, and that in April 2025 Dato-DXd was licensed in the EU as Datroway however it was not licensed in the UK. The marketing authorisation holder for both products was Daiichi Sankyo but Astra Zeneca had a global collaboration agreement with Daiichi Sankyo to jointly develop and commercialise both products. The Panel noted neither the names of the active ingredients nor brand names of the trial medicines were mentioned in the post, however, 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 noted Astra Zeneca's detailed submission about Imfinzi but considered that there was no complaint about Imfinzi per se, the complaint concerned only T-DXd and Dato-DXd. The Panel restricted its consideration to these two products.

The Panel noted that although the complainant had raised some clauses multiple times AstraZeneca had been asked to respond in relation to Clauses 3.1, 26.1 and 26.2 for T-DXd, Clauses 3.1 and 26.1 for Dato-DXd and in relation to Clauses 5.1, 5.3 and 2 overall.

T-DXd

The Panel noted T-DXd (Enhertu) was licensed, among other things, for the treatment of adult patients with metastatic HER2-positive breast cancer (HER2+ MBC) who had received one or more prior anti-HER2-based regimens.

The complainant had cited 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. In this regard, the Panel noted that Enhertu already had a marketing authorisation, albeit for different indications to those being explored in the various trials mentioned in the LinkedIn post, and on this narrow technical point, the Panel ruled **no breach of Clause 3.1** of the 2024 Code.

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 may therefore have viewed the post as a result of the employees' engagement with the post. In the Panel's view developments in breast cancer treatments were sensitive matters that were likely to attract a high level of public interest. It noted that T-DXd (Enhertu) had been studied in a number of DESTINY trials. The Panel accepted that neither the brand nor the non-proprietary name appeared in the post but further noted that, as stated above, it was possible for material to be promotional in the absence of such references. In the Panel's view T-DXd was a specific prescription only medicine which, when considered in combination with the positive references to breast cancer treatment and clinical trials expected to reshape practice, had been promoted to the public. The fact that members of the public might not know that the abbreviated term referred to Enhurtu was not in the Panel's view necessarily relevant, not all recipients of the 'liked' post would have previously heard of Enhurtu; the important point was that the abbreviated term was a reference to a specific prescription only medicine. In the Panel's view to take a different approach might allow companies to circumvent the requirements of the Code. Further in the Panel's view it was possible that some members of the public and patients reading the post would make a direct connection between the various DESTINY-Breast trials and Enhertu.

For the above reasons the Panel concluded, on the balance of probabilities, that by 'liking' and thereby disseminating the post a specific prescription only medicine had been promoted to the public and ruled a **breach of Clause 26.1.**

The Panel noted the complainant specifically referred to off licence indications being promoted to the public in relation to each of the three T-DXd clinical trials named in the post.

Clause 11.2 of the Code required that the promotion of a medicine must be in accordance with the terms of its marketing authorisation and must not be inconsistent with the particulars listed in its summary of product characteristics. The Panel noted that AstraZeneca had not been asked to respond to Clause 11.2 which only applied to promotion to health professionals and other relevant decision makers and it had not provided any comments specifically relating to this clause. The Panel decided to consider the alleged promotion to the public of unlicensed indications for T-DXd as part of its consideration of Clause 5.1.

The Panel considered that in discussing ongoing clinical trials researching new uses for T-DXd the post referred to unlicensed indications and given its ruling of a breach of Clause 26.1 above these unlicensed indications had been promoted to the public as alleged. In this regard high standards had not been maintained and the Panel ruled a **breach of Clause 5.1**.

Clause 26.2 requires, among other things, that information about prescription only medicines which is made available to the public must not raise unfounded hopes of successful treatment or be made for the purpose of encouraging members of the public to ask their health professional to prescribe a prescription only medicine. Given the high level of public interest in developments in the treatment of breast cancer and compounded by the reference to the Phase 3 trials being' expected to reshape practice in 2025' the Panel considered the positivity expressed in the statement 'Results are expected by 2025, promising to reshape 1L treatment standards ..' made in relation to the DESTINY-Breast 09 clinical trial was likely to encourage patients to ask their health professional about T-DXd. The Panel ruled a **breach of Clause 26.2**.

Dato-DXd

The Panel noted the content of the post in relation to TROPION-Breast 02 trial and Dato-DXd, and particularly the reference to the product being approved for HR+ MBC and that it had shown promising activity as monotherapy and in combination with durva for metastatic triple negative disease. The Panel considered the style and content of the post noting the absence of the name of the medicine or a clear description of the indication. The Panel considered that its comments above in relation to T-DXd and the absence of the brand name and non-proprietary name and use of the abbreviation applied equally here. For similar reasons the Panel considered that the reference to Dato-DXd and the Tropion 02 trial was promotional. The Panel noted that Dato-DXd was licensed in other jurisdictions and that an application for a marketing authorisation had not been submitted in the UK. That an application for a UK marketing authorisation had not been submitted did not, in the Panel's view, and as inferred by AstraZeneca, preclude a ruling under this clause. The Panel did not consider that Dato-DXd was in such an early stage of its development that it could not be considered a medicine for the purposes of Clause 3.1. Noting its comments above and on the basis that the employees' engagement with the post constituted the promotion of Dato-DXd, a medicine that was not licensed in the UK had been promoted and accordingly the Panel ruled a **breach of Clause 3.1.**

On the basis that Clause 26.1 concerned prescription only medicines and that datopotamab deruxtecan (Dato-DXd) was not licensed in the UK and therefore not a prescription only medicine the Panel ruled **no breach of Clause 26.1**.

Clause 5.3

The Panel noted that the complainant had alleged a failure to recognise the special nature of medicines and had cited Clause 5.3. It considered the post created the impression that 2025 would see positive developments in the treatment of different sub-types of breast cancer which together with statements such as 'promising to reshape 1L treatment standards', 'aims at escalating treatment for patients with high-risk HER2+ residual disease', 'may lead to an alternative, anthracycline-sparing regimen for a high-risk population', and 'promising activity (as monotherapy and with durva for mTNBC' would likely provoke interest from readers such that they might be encouraged to ask their health professional to prescribe a specific prescription only medicine. In this regard the Panel considered, on balance, that the dissemination of the

post was such that AstraZeneca had failed to recognise the special nature of medicines and ruled a **breach of Clause 5.3**.

Clause 5.1

The Panel noted its comments and rulings of breaches above and determined to limit its consideration of Clause 5.1 to the complainant's broad allegation that "the continuous failure to adhere to the code by so many AZ staff, shows the lack of care for compliance within the AstraZeneca organisation" and their suggestion of failures in the company's standard operating procedures for compliance training and culture.

The Panel noted that AstraZeneca did not provide any UK specific social media guidance. Instead, it provided two global standard social media documents, on employee use of personal social media channels and work-related content, and on employee use of personal social media; both of which appeared to apply to all countries. Having considered the documents the Panel concluded that overall, AstraZeneca discouraged employees from engaging with product-related posts and referred readers to country specific rules. According to AstraZeneca the three UK based employees had completed an interactive training module 'The Use of Social Media – UK' which was based on these documents. However, the Panel had not seen the training provided to the individuals nor did it know when or how frequently the training was provided and thus it was unclear whether any training on UK specific rules had been provided.

Whilst the Panel was concerned that, despite social media training the three UK-based employees had received, they had engaged with the LinkedIn post and it further noted that AstraZeneca did not consider the employees to be in senior roles. Noting that the complainant bore the burden of proof, and on balance, the Panel did not consider there was sufficient evidence before it in relation to training to establish that AstraZeneca had failed to maintain high standards and **no breach of Clause 5.1** was ruled.

Clause 2

The Panel noted that Clause 2 was used as a sign of particular censure and was reserved for such use. It considered that the particular circumstances of this case did not warrant a ruling of breach of Clause 2 and accordingly it ruled **no breach of Clause 2**.

Complaint received **23 April 2025**

Case completed **17 October 2025**