# CASE AUTH/3900/5/24

# **EX-EMPLOYEE v ASTRAZENECA**

# Allegations about meetings and hospitality

## **CASE SUMMARY**

This case was in relation to allegations about two events. The first event was a conference at which the complainant alleged there had been inappropriate hospitality and inducements to prescribe. The second event was a workshop, which the complainant alleged should have been cancelled due to a lack of attendees and to avoid being a "pseudo advisory board".

## The outcome under the 2021 Code was:

No Breach of Clause 2(x2)	Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry
No Breach of Clause 5.1(x2)	Requirement to maintain high standards at all times
No Breach of Clause 6.7	Requirement that the clinical and scientific opinions of health professionals not be disparaged
No Breach of Clause 10.1	Requirement that companies must not provide inappropriate hospitality
No Breach of Clause 10.2(x2)	Requirement not to pay individuals merely for time spent attending events/meetings
No Breach of Clause 10.7(x2)	Requirement that subsistence must not exceed £75 per person
No Breach of Clause 10.8(x2)	Requirement that payments may not be made to doctors for the rental of room for events/meetings
No Breach of Clause 17.2	Requirement that representatives must maintain high standards of ethical conduct in the discharge of their duties and comply with all relevant requirements of the Code
No Breach of Clause 17.10	Requirement that companies are responsible for representatives even if they are acting contrary to instructions
No Breach of Clause 19.1(x2)	Requirement that gifts etc. may not be provided to health professionals as an inducement to prescribe
No Breach of Clause 24.1	Health professionals may be used as consultants and advisers
No Breach of Clause 24.2	Requirement that consultancy arrangements fulfil set criteria

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 a contactable complainant who described themselves as an ex-employee of AstraZeneca.

## **COMPLAINT**

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

"The Oncology Business Unit at AstraZeneca UK held a company conference for internal employees Tuesday 30th January to Thursday 1st February 2024. This was held in Liverpool. On day 2, Wednesday 31st January, the Oncology Business Unit had a separate meeting where the various business units held their own meetings. Professor [named]. Consultant at [named] NHS Foundation Trust was contracted to provide one service only which involved a presentation on Breast Cancer to the Breast Cancer Franchise members. They were paid for that service. This finished at around 5.30/6pm and then unfortunately instead of leaving, [named marketing employee], [named medical employee] and [named manager] and 2 sales representatives ([named] and another rep) took Professor [named] to the bar and provided them numerous alcoholic drinks. What we witnessed in front of other AstraZeneca employees also at the public bar was a complete disregard of professional behaviour as each of them and two sales colleagues were taking turns to buy [the Professor] drinks. At least 5-6 drinks of scotch/ whiskey were brought, which was paid for by AstraZeneca and over the ABPI limit for hospitality. Whilst this was happening there were discussions about Enhertu and how to increase its prescription and how to help AstraZeneca increase its market share. This is clearly inducement to prescribe and is against Clause 19: Prohibition on Inducements and Inappropriate Payments. It is also against our own SOP: Interaction with HCPs which state subsistence should not be provided in daily activity and that no alcohol should be provided. It is also against our own AstraZeneca values of 'doing the right thing and putting science first'. Also at the bar were [senior employees] for the oncology business unit. They all saw this as well. They also did not intervene and stop this behaviour. All the employees left for dinner at 7pm to go to The Restaurant. [name], [name] and [name] and the 2 sales representatives continued their drinks with Professor [named] and did not join till 7.30pm/7.45pm. I am putting this complaint in as I believe that senior members of the oncology business unit are deliberately and knowingly breaching the code and our own internal policies. I have raised these concerns and they have not been taken seriously. This is why I am raising this with you as plying a healthcare professional with alcohol post a contracted service is not appropriate and bring our whole industry into question. This behaviour breaches clauses 5.1: High standards, Clause 10: Meetings and Hospitality 10.2, 10:7, 10:8, and Clause 2: Upholding Confidence in the Industry. Furthermore, on Friday 22nd March the breast oncology medical team also held a medical education seminar titled 'Acute management of drug-related adverse events in Oncology patients: Cross functional workshop'. Unfortunately, despite sending out numerous invites only 1 HCP turned up at the request of one of the speakers. In this regard the event should either have been cancelled or naturally have been wrapped up quicker than it was. However, the speakers were paid in full for their time there even though they did not fulfil the services outlined in their contract. The event turned into an insights gathering sessions and pseudo advisory board where numerous scenarios

were presented to the speakers to gain their insights on how to manage ILD for Enhertu and how to increase adoption in the second line. AstraZeneca were also slanderous of the NICE process as they had been informed that the Enhertu second line reimbursement had been rejected. Procedure was not followed as no advisory board documents were completed, and the services the HCPs were contracted for and paid in full were actually not completed. This is similar to the scenario above where the AstraZeneca have been paying HCPs for insights and to increase prescriptions despite this not being the initial activity they were contacted for. Again I believe this behaviour breaches clauses 5.1: High standards, Clause 10: Meetings and Hospitality 10.2, 10:7, 10:8, and Clause 2: Upholding Confidence in the Industry."

When writing to AstraZeneca, the PMCPA asked it to consider the requirements of the following clauses of the 2021 Code:

- 1. In relation to the [named] company conference held in Liverpool:
  - a. Clauses 10.2, 10.7, 10.8, 19.1, 5.1 and 2, as cited by the complainant, and
  - b. Clauses 10.1, 17.2 and 17.10.
- 2. In relation to the medical education workshop:
  - a. Clauses 10.2, 10.7, 10.8, 5.1 and 2, as cited by the complainant, and
  - b. Clauses 6.7, 19.1, 24.1 and 24.2.

## **ASTRAZENECA'S RESPONSE**

The response from AstraZeneca is reproduced below:

"Thank you for your letter dated 13th May 2024, concerning the above from a complainant who described themselves as an AstraZeneca Ex-employee regarding AstraZeneca's company conference held on 30th January – 1st February 2024 and medical education workshop held on 22nd March 2024.

You have asked AstraZeneca to consider the requirements of the following 2021 Code clauses below when responding to this complaint, in relation to:

- Complaint 1 Speaker meeting during the AstraZeneca company conference held in Liverpool: Clauses 10.2, 10.7, 10.8, 19.1, 5.1 and 2. In addition, to bear in mind the requirements of Clauses 10.1, 17.2 and 17.10.
- Complaint 2 Medical education workshop: Clauses 10.2, 10.7, 10.8, 5.1 and 2. In addition, to bear in mind the requirements of Clauses 6.7, 19.1, 24.1 and 24.2.

We will therefore address each of the complainant's allegations in turn according to the above relevant clauses of the ABPI Code of Practice.

# <u>Complaint 1 - Speaker meeting during the AstraZeneca company conference</u> <u>held in Liverpool</u>

Allegation 1

The complaint alleges; 'on 31st January.......Professor [named], Consultant at [named] NHS Foundation Trust was contracted to provide one service only which involved a presentation on Breast Cancer to the Breast Cancer Franchise members. They were paid for that service. This finished at around 5.30/ 6pm and then unfortunately instead of leaving AstraZeneca Marketing [employee], Medical Affairs [employee], Manager and 2 Sales Representatives took Professor [named] to the bar and provided them numerous alcoholic drinks. What we witnessed in front of other AstraZeneca employees also at the public bar was a complete disregard of professional behaviour as each of them and two sales colleagues were taking turns to buy [the Professor] drinks. At least 5-6 drinks of scotch/whiskey were brought, which was paid for by AstraZeneca and over the ABPI limit for hospitality'

## Alleged breach of

- Clause 5.1: High standards
- Clause 10: Meetings and Hospitality
  - 10.2, No payment may be offered or paid to individuals to compensate merely for the time spent in attending events/meetings
  - o 10:7, The cost of any subsistence (food and drink) provided must not exceed £75 per person, excluding VAT and gratuities
  - 10:8, Payments may not be made to doctors, groups of doctors, or to other prescribers, either directly or indirectly, for rental for rooms to be used for events/meetings
- Clause 2: Upholding Confidence in the Industry
- Clause 19.1: No gift, pecuniary advantage or benefit may be supplied, offered, or promised to health professionals or to other relevant decision makers in connection with the promotion of medicines or as an inducement to prescribe, supply, administer, recommend, buy, or sell any medicine,

## AstraZeneca Response

During the AstraZeneca Conference held in Liverpool 30th January – 1st February 2024, the Breast Franchise Team invited a speaker (named Professor) to give a talk to AstraZeneca UK Oncology employees about the history of breast cancer research and the heritage of AstraZeneca in this therapeutic area. This speaker meeting took place on 31st January 2024 between 16:30-18:00. This was a private and AstraZeneca UK only event, and the meeting room was closed-off to members of the public.

The meeting was entirely funded by AZ, and no payment was made for the speaker for the room rental; therefore, AZ refutes any allegation of breach of clause 10.8. AstraZeneca believes this meeting was organised to high standards, whilst maintaining confidence in the industry in line with the ABPI Code of Practice.

The speaker was contracted for 1.5 hours work and paid accordingly. No other payment to the speaker was provided outside of their contract AstraZeneca, therefore, deny breach of clause 10.2 of the Code.

After the meeting finished slightly late at approximately 18:20, 4 AstraZeneca employees and the speaker went to sit at the hotel bar, adjacent to the Main Lobby (which only had two seats), whilst waiting for a taxi to take the speaker home. Unfortunately, due to the inclement weather and distance of the ride back to Manchester - it took time to find an available taxi, which finally arrived at 19.20 to take

the speaker home in Manchester. Of the 4 AstraZeneca employees, the 2 Head Office staff (1 Marketing [employee], 1 Medical Affairs [employee]) were present as they helped organise the day's session and 2 local sales representatives were present as they helped with the speaker engagement. Contrary to the complainant's allegation, there was no Manager present with this group at the time. Whilst waiting with the speaker some drinks were purchased by AstraZeneca total of 5 drinks, all wine/beers. Contrary to the complainant's allegation, there were no numerous alcoholic drinks (i.e., Scotch/Whiskey) ordered. In addition, the total amount for the drinks was £29.90 (excluding VAT and gratuities), which AstraZeneca believes to be reasonable and not excessive. We, therefore, refute the breach of Clause 10.7 of the Code.

During this time at the bar, no inappropriate behaviour took place. Although the bar of the hotel was open to the public, it was predominantly occupied by AstraZeneca employees that were having a drink between the end of the meeting and the Company dinner, with the transfers organised for 19:00 from the hotel lobby. AstraZeneca booked most of the hotel because of the Annual Company Conference taking place in those two days, and the table where the speaker and the 4 AstraZeneca employees sat was away from other AstraZeneca employees to ensure some privacy.

The drinks were bought by the Marketing [employee] following AZ SOP which states that the employee with the highest Global Career Level should pay when in a meeting, to ensure an objective approval process of the expenses. The Marketing [employee] is not a customer-facing role and therefore does not require an ABPI certification. However, the ABPI certificates for the 2 Sales Representatives are provided.

AZ has fulfilled the requirements of Clause 10 for Events and Hospitality. We, therefore, refute a breach of Clause 10.1 of the Code.

In line with ABPI Clauses 17.2 and 17.10, AZ believes its employees (including representatives) behaved professionally and responsibly at the hotel bar with the speaker.

## Allegation 2

The complaint alleges; 'Whilst this was happening there were discussions about Enhertu and how to increase its prescription and how to help AstraZeneca increase its market share. This is clearly inducement to prescribe and is against Clause 19: Prohibition on Inducements and Inappropriate Payments. It is also against our own SOP: Interaction with HCPs which state subsistence should not be provided in daily activity and that no alcohol should be provided.'

## AstraZeneca Response

Contrary to the allegation, there were no discussions about Enhertu (trastuzumab deruxtecan) or helping AZ market share with the speaker at any time (during or after the meeting).

Whilst AZ firmly believes that the company meeting involving the speaker on 31st January 2024 was managed appropriately and to high standards, it is to be noted that the speaker retired from medical practice on 30th September 2023. It would not have been possible for the speaker to prescribe following the meeting as they had already

retired from medical practice. Ultimately, no materials, gift or pecuniary advantage or benefit was supplied, offered, or promised to the speaker in connection with the promotion of medicines as per the above; AstraZeneca therefore refutes the allegation of breaching of Clause 19.1 of the Code.

AstraZeneca believes that its employees conducted themselves professionally and to high standards during and after the meeting involving the speaker. No excessive or extravagant spending on drinks was evident, nor were there any inducement to prescribe directly or indirectly. In addition, the subsistence offered is in line with internal AstraZeneca policy. Therefore, AstraZeneca firmly deny any breach of clause 19.

# Allegation 3

The complaint alleges; 'also at the bar [senior employees] for the oncology business unit. They all saw this as well. They also did not intervene and stop this behaviour.......... I am putting this complaint in as I believe that senior members of the oncology business unit are deliberately and knowingly breaching the code and our own internal policies. I have raised these concerns to my manager, and they have not been taken seriously. This is why I am raising this with you as plying a health professional with alcohol post a contracted service is not appropriate and bring our whole industry into question'

## AstraZeneca Response

As mentioned, the hotel had many AstraZeneca employees including some of the Leadership Team present at the hotel bar (between 18:00 – 19:00) as they awaited transportation to dinner after the meeting had finished for the day. As there was no perceived misbehaviour of any AstraZeneca employee, no intervention by any line manager or Leadership Team was required. After receiving this complaint, relevant line managers (including Medical Ethics Team) were questioned whether any employees had raised any of the alleged concerns, to which there was no recollection or records of such concerns raised. AstraZeneca takes the conduct of all their employees seriously and encourages a 'speak up culture' to allow employees a 'safe space' to raise any compliance concerns to their line manager, Medical Ethics, Compliance, HR, or Senior Leaders. We have training in place to remind employees of the different ways in which they can raise concerns including the anonymous AZEthics platform. Therefore, AstraZeneca refutes this allegation and deny any breaches of clause 2, 5.1, or 10.7.

# **Complaint 2 Medical Education Workshop**

# Background information

The meeting entitled 'Acute management of drug-related adverse events in Oncology patients: Cross functional workshop' was designed to support regional HCPs to identify the challenges in their local area with regards to adverse event (AE) management in patients prescribed systemic anti-cancer therapies (SACT). The premise of this meeting was to identify areas of need, specific to their locality, whether it be e.g., revision of management protocols, education, new referral pathways etc. We identified HCPs with expertise in managing SACT AEs, set up of acute oncology service (AOS) pathways, patient tolerability and specifically included HCPs who were regional experts. We identified 4 HCPs to steer the agenda, providing input into the content and format of the meeting, audience criteria and outputs and their duties on the day of the

meeting including presentation of cases and facilitation of break out groups. The original meeting concept, discussed with the speakers, was to invite specialist oncology clinical leads from each of the local hospitals (as we wanted to target specialist leaders who may have more impact to implement changes) therefore, originally restricting the group size to 10-15 however, the HCP faculty felt it should be broadened (as they believed that clinical leads would not have the time to attend this type of meeting and that the people who actually have time to conduct projects are the junior staff) so we extended the audience scope to include any HCP with >5yrs oncology speciality experience, at which point the audience limit was set at 25. In addition, the meeting date was moved from December to March due to the doctor's strike. Approved meeting invites were disseminated using the AZ distribution list where HCPs had consented to be invited to such events. In total, 8 registrations had been received in advance of the event.

#### Allegation 1

The complaint alleges; 'Unfortunately, despite sending out numerous invites only 1 HCP turned up at the request of one of the speakers. In this regard the event should either have been cancelled or naturally have been wrapped up quicker than it was. However, the speakers were paid in full for their time there even though they did not fulfil the services outlined in their contract.'

## AstraZeneca Response

On the day of the meeting, we were expecting 7 delegates (out of 8 who had registered to attend), as one cancelled 2 days prior. Two delegates responded to agency outreach, on the day of the meeting, responding that they would not be able to attend, one was logged before the start of the meeting the other after the meeting was due to commence. Therefore, with the expectation of 6 delegates would have allowed us to continue with 2 workshop groups of at least 3 delegates. The objectives of the meeting could still be met in identifying local challenges and potential solutions. One delegate arrived before the start of the meeting and the HCPs were consulted on their thoughts on proceeding with the event, whilst waiting for others to arrive. Given that there were 3 local HCPs speakers, they felt that they could support the objectives of the meeting and start the process of identifying local challenges.

We also considered the fact that delegate and faculty members had taken annual leave and had travelled to be at the meeting. With all this in mind, the consensus was that we continue as planned. In agreement with the HCPs speakers, AZ therefore made the decision to take the pragmatic course of action and proceed with the meeting.

The speaker faculty were chosen based on their experience in managing SACT-related AEs or in managing or implementing acute oncology services and were approved before formal invitation. The faculty consisted of one nurse, one lead pharmacist and two consultant medical oncologists. The role of the speakers was to:

- Support the co-chairs during the introductory presentation on the overarching challenges in acute SACT-AE management. Provide input and answer questions when required
- Moderate discussions in their designated breakout group
- Presentation of a best-practice case study and moderating discussion around this case study

 Facilitate feedback, draw conclusions, and summarise the main outcomes after each breakout activity and at the end of the meeting

The format of the meeting aimed to start with a short case study presentation from each of the speakers followed by break out groups allowing for the sharing and ideation of potential initiatives that the delegates could implement at their local hospital trusts in order to improve the identification and/or management of SACT-related AEs. These break-out discussion groups would be led and facilitated by the speakers.

On the day, the discussion took up the entirety of the time allocated for the meeting. The meeting proceeded with the speakers detailing challenges in identifying and managing SACT-related AEs, including case study examples. The discussions between the HCPS enabled the group to identify key challenges and discuss initiatives that would support best practice. This was illustrated by the speakers with best practice examples such as successful joint working initiatives and other projects that supported service improvements. The aims and objectives of the meeting were met in that initiatives were identified that may improve the way patients with adverse events are managed and ideas for supporting the implementation of these initiatives were discussed. The speakers met the remit of their service in the contract, through meeting prep work and workshop discussion as outlined in the speaker briefs.

# Allegation 2

The complaint alleges; 'The event turned into an insights gathering sessions and pseudo advisory board where numerous scenarios were presented to the speakers to gain their insights on how to manage ILD for Enhertu and how to increase adoption in the second line. AstraZeneca were also slanderous of the NICE process as they had been informed that the Enhertu second line reimbursement had been rejected. Procedure was not followed as no advisory board documents were completed, and the services the HCPs were contracted for and paid in full were actually not completed.'

## AstraZeneca Response

This meeting was not an advice seeking activity, or 'pseudo-ad board', as outlined by the complainant. Indeed, the meeting was designed to support regional HCPs to identify the challenges in their local area with regards to adverse event (AE) management in patients prescribed systemic anti-cancer therapies (SACT). The premise of this meeting was to identify areas of need, specific to their locality, whether it be e.g., revision of management protocols, education, new referral pathways etc. We identified HCPs with expertise in managing SACT AEs, set up of acute oncology service (AOS) pathways, patient tolerability and specifically included HCPs who were regional experts. Furthermore, there were no discussions regarding Enhertu, ILD or NICE. In fact, trastuzumab deruxtecan (Enhertu) was recommended for treating HER2-positive unresectable or metastatic breast cancer after 1 or more anti-HER2 treatments on 1st February 2023. This is the only indication for Enhertu which has been discussed with NICE in the 'second line setting', so we are unsure as to the basis of this allegation. No healthcare bodies or HCP opinions were disparaged during the course of this meeting.

No advisory board documents were completed, as this activity was not an advisory board. The HCP speakers were paid for the pre-work, briefing calls, and the meeting

discussion. The meeting and facilitation of the discussion lasted for the entirety of the planned meeting duration. HCPs were not paid for the time spent in attendance at the meeting, each speaker had a defined role, participated, and shared their expertise throughout the duration of the meeting. Therefore, they were paid for the service they were contracted for which was delivered in its entirety. The meeting report, written by the agency erroneously utilises the term 'advisor' rather than speaker, given that the initial premise of the meeting was for the expert speakers to support the delegates providing expert guidance to identify the challenges in their local area with regards to adverse event (AE) management in patients prescribed systemic anti-cancer therapies (SACT), this may be where the confusion lay. The concept of the meeting has always been an HCP-led workshop with expert HCPs presenting cases following by workshop facilitation.

Subsistence was provided as part of the venue arrangements. This was paid for in advance of the meeting in line with our internal policy and ABPI Code of Practice. All venue arrangements were organised and paid for via the contracted agency to the venue for the purpose of hosting the meeting. No payments were made to any HCP for venue rental or any other meeting arrangement purposes.

As alleged by the complainant, AZ does not accept that it breached any aspects of Clause 10, specifically clauses 10.2, 10.7 and 10.8 as the event was a medical education workshop aimed at identifying a number of potential initiatives that could assist in improving patient outcomes, in relation to the identification and management across SACT-related AEs.

Based on the above, we also deny breach of clauses 5.1 and 2, we organised and conducted the 'Acute management of drug-related adverse events in Oncology patients: Cross functional workshop' fully in accordance with ABPI Code of Practice and AZ policies and procedures.

We have also been asked to consider requirements of clauses 6.7, 19.1, 24.1 and 24.2. With regards to clause 6.7 and the disparagement of HCPs. We assume this is linked to the comment claiming we were disparaging towards a NICE recommendation on the 'Enhertu second line reimbursement'. Trastuzumab deruxtecan (Enhertu) was recommended for treating HER2-positive unresectable or metastatic breast cancer after 1 or more anti-HER2 treatments on 1st February 2023. This is the only indication for Enhertu which has been discussed by NICE in the 'second line setting', so we are unsure as to the basis of this allegation. No HCPs or any individuals and their opinions were disparaged at the meeting.

Furthermore, this was not an advice seeking activity as outlined by the complainant. Indeed, the premise of this meeting was to support regional HCPs to identify the challenges in their local area with regards to adverse event (AE) management in patients prescribed systemic anti-cancer therapies (SACT) as outlined above and was not an advisory board. The meeting objectives clearly defined the scope of the meeting, the venue, subsistence, and selection of the faculty was fully in accordance with ABPI Code of Practice and AZ policies and procedures. Therefore, requirements of clauses 19.1, 24.1 and 24.2 have been fulfilled.

# Allegation 3

**The complaint alleges;** 'This is similar to the scenario above [complaint 1] where AstraZeneca have been paying HCPs for insights and to increase prescriptions despite this not being the initial activity they were contacted for. Again, I believe this behaviour breaches clauses 5.1: High standards, Clause 10: Meetings and Hospitality 10.2, 10:7, 10:8, and Clause 2: Upholding Confidence in the Industry'.

# AstraZeneca Response

As detailed above, AZ have genuinely contracted and paid HCP for the medical education workshop as intended in line with the contract and did not pay HCPs for insights to increase prescription of any AZ medicines. AZ believes that its employees conducted themselves professionally acting pragmatically and empathetically whilst upholding ABPI Code of Practice requirements for this medical education workshop. The meeting objectives were met.

## SUMMARY OF ASTRAZENECA'S POSITION

In summary, AstraZeneca takes its obligations under the ABPI Code of Practice very seriously and have internal SOPs and processes in place to ensure that we uphold high ethical standards and in line with the letter and spirit of the ABPI code. As we have set out above, we vehemently deny bringing the pharmaceutical industry into disrepute and deny being in breach of clauses 2, 5.1, 10.2, 10.7, 10.8, 19.1. In addition, the requirements of clauses 6.7, 10.1, 17.2, 17.10, 19.1, 24.1 and 24.2 have been fulfilled.

Furthermore, AstraZeneca has a culture of 'speak up' and continuous learning, with several communication mechanisms in place (including our dedicated anonymous AZ Ethics hotline) to ensure that our employees may express their concerns through various means and channels.

In conclusion, AstraZeneca strongly refutes all of the complainant's allegations and categorically denies having brought the pharmaceutical industry into disrepute. We have processes in place to ensure that we operate consistently to the highest standards and take our obligations under the ABPI Code of Practice very seriously."

## **PANEL RULING**

This complaint was in relation to an ex-employee of AstraZeneca who made allegations about:

- 1. Excessive hospitality and inducements to prescribe, provided to the speaker at a conference on 31 January 2024.
- 2. A medical education workshop on 22 March 2024, which was poorly attended and, as a result, was turned into insight gathering sessions and a pseudo advisory board.

## The conference allegations

The complainant alleged that, from around 17.30-19.30 on 31 January 2024, at the end of a conference hosted by AstraZeneca, the speaker was given "numerous alcoholic drinks" and "at least 5/6 drinks of scotch/whiskey were brought". The complainant also alleged that, during these drinks, there were discussions about AstraZeneca's product, Enhertu (Trastuzumab

deruxtecan) and "how to increase its prescription and how to help AstraZeneca increase its market share."

AstraZeneca's response to this complaint confirmed that there had been a conference on 31 January 2024. It provided evidence of the invitation and the agenda (showing the sessions lasting from 13.00-18.00).

In response to the allegations, AstraZeneca's position was that, at the end of the conference (which finished late; at 18.20), the taxi to collect the speaker also took longer than expected to arrive, due to inclement weather. While waiting, one round of five drinks was bought by the Marketing [employee]. AstraZeneca submitted that this was compliant with its SOP, given the Marketing [employee] was the most senior employee present. The five drinks were shared between five people: the Marketing [employee], the Medical Affairs [employee], two sales representatives and the speaker.

AstraZeneca provided the following documentary evidence in support of its position:

- A receipt for a round of drinks purchased at 18.52. It showed five drinks were purchased (two pints, one half pint, one large glass of wine and one small glass of wine) for £29.90, excluding VAT.
- 2. The receipt for the speaker's taxi which showed that it left at 19.22.
- 3. Email correspondence from the speaker confirming that they ceased practising as a physician on 30 September 2023.
- 4. The General Medical Council register showing that the speaker's registration lapsed in February 2024.
- 5. A copy of the speaker's contract and confirmation of payment details. These showed that payment was made to the speaker for their services: a thirty minute presentation and a one hour panel discussion, plus their travel arrangements.

The Panel considered the allegations and the evidence provided. It then ruled on each of the clauses on which AstraZeneca had been asked to respond.

#### <u>Clause 10.1 – prohibition on inappropriate hospitality</u>

This clause provided that companies must not provide hospitality to health professionals except in association with scientific meetings etc. Specifically in relation to subsistence (food and drink), this clause states that it must be "strictly limited to the main purpose of the event/meeting, must be of secondary consideration and must be appropriate and not out of proportion to the occasion."

The Panel accepted the documentary evidence provided by AstraZeneca, which showed that five drinks were bought (none of which were scotch/whiskey, as alleged by the complainant). On the balance of probabilities, the Panel considered it was likely that only one of the five drinks purchased was for the speaker and it was consumed in the thirty minute window between the purchase of the drinks at 18.52 and their taxi journey starting at 19.22. The Panel was satisfied that the drink was a secondary consideration to main purpose of the conference, for the purposes of Clause 10.1. The Panel also took account of the fact that the drink was not preplanned (given it was not foreseeable that the taxi would be delayed by bad weather). Taking account of the time of day, and the overall impression, the Panel did not consider the

subsistence in this case to be excessive or out of proportion to the occasion. The Panel therefore ruled **no breach of Clause 10.1**.

<u>Clauses 10.2 – prohibition on payments to individuals merely for attending events/meetings</u> Clause 10.8 – prohibition on payments to doctors for renting rooms for events/meetings

In its response to this complaint, AstraZeneca provided a copy of the contract details and payment confirmation. These made it clear to the Panel that payment was for those services only. In the absence of any evidence that payment had been made to the speaker merely for attending the conference, or in relation to the rental of the room, the Panel ruled **no breach of Clauses 10.2 and 10.8**.

## Clause 10.7 – cost of subsistence must not exceed £75 per person

This clause stated that "the cost of any subsistence (food and drink) provided must not exceed £75 per person, excluding VAT and gratuities".

The Panel accepted AstraZeneca's evidence that the total amount spent after the conference was £29.90 (excluding VAT and gratuities) and that not all of that amount was spent on the speaker. The Panel therefore ruled **no breach of Clause 10.7**.

# <u>Clause 17.2 – representatives must maintain a high standard of ethical conduct</u> Clause 17.10 – companies are responsible for their representatives

Part of this complainant was also an allegation that, whilst in the bar after the conference, AstraZeneca's employees and the speaker discussed Enhertu, how to increase its prescription and how to help AstraZeneca increase its market share.

AstraZeneca's response to these allegations was that there was no such discussion. It believed that its employees had behaved professionally and responsibly in relation to the period between the conference ending and the speaker's taxi arriving.

The Panel considered that complaints based on one party's word against the other's were difficult to adjudicate upon. Given the information before it, the Panel decided it was not possible to determine precisely what had been said verbally by AstraZeneca employees during their drink with the speaker. The Panel considered that the complainant had not, on the balance of probabilities, proven their allegation. The Panel therefore concluded that it had not been established that AstraZeneca employees had failed to maintain a high standard of ethical conduct in the discharge of their duties. The Panel ruled **no breach of Clauses 17.2 and 17.10**.

# Clause 19.1 – prohibition on gifts etc. to health professionals as an inducement to prescribe

The complainant alleged that the discussions about Enhertu were also an inducement to prescribe, which is prohibited by Clause 19.1.

AstraZeneca provided evidence, which the Panel accepted, that showed that the speaker retired from medical practice on 30 September 2023. In other words, at the time of the conference, they were not authorised to prescribe.

The Panel noted that Clause 19.1 did go further than just inducements to prescribe; it also included inducements to "supply, administer, recommend, buy or sell any medicine." However, given the Panel's conclusion above that:

- 1. the complainant had failed to prove their allegation that there had been a discussion about Enhertu.
- 2. the speaker was retired from practice and had no authorisation to prescribe, and
- 3. only one drink had been bought for the speaker while they waited for their taxi,

the Panel did not consider that the circumstances of this case gave rise to any inducement in breach of this clause. The Panel ruled **no breach of Clause 19.1**.

<u>Clause 5.1 – requirement to maintain high standards</u> <u>Clause 2 – requirement not to discredit the pharmaceutical industry</u>

Given its conclusions above and, in the absence of any additional evidence to establish that there had been a failure to maintain high standards by AstraZeneca at this conference, the Panel ruled **no breach of Clause 5.1**. For the same reasons the Panel ruled **no breach of Clause 2**.

# The medical education workshop allegations

The second part of this complaint related to a medical education workshop that took place on 22 March 2024. It was titled: "Acute management of drug-related adverse events in Oncology patients: Cross functional workshop". The complaint alleged that the workshop only had one health professional as an attendee, yet the speakers were paid in full and that the event amounted to insight gathering sessions and a pseudo advisory board.

In essence, AstraZeneca's response to this complaint was that:

- 1. Four health professionals were contracted as speakers at this non-promotional workshop. AstraZeneca provided copies of the contracts which showed that fees were paid for:
  - a. eight hours of planning meeting and slide preparation, plus
  - b. six hours¹ for setting-up and attending the workshop.
- 2. Although it had intended to have an audience of up to twenty-five people, only eight had registered. Of those eight, one of the registered attendees cancelled with two days' notice while two others cancelled on the day. Ultimately, only one attendee arrived at the workshop.
- 3. Given that the delegate and faculty members had taken annual leave to attend, AstraZeneca decided to proceed with the workshop.
- 4. The workshop lasted the full duration of its scheduled time of five hours.
- 5. The workshop did ultimately achieve its purpose of identifying challenges in managing drug-related adverse events in oncology patients (as set out in the meeting report, a copy of which AstraZeneca provided).

The Panel considered the allegations and the evidence provided. It then ruled on each of the clauses on which AstraZeneca had been asked to respond.

<sup>&</sup>lt;sup>1</sup> One of the contracts provided a slightly less amount of time (4.5 hours) for setting up and attending the workshop.

## Clause 6.7 – health professionals and their opinions must not be disparaged

The Panel considered that AstraZeneca had been asked by the PMCPA case preparation manager to consider this clause because of the allegation that "AstraZeneca were also slanderous of the NICE process as they had been informed that the Enhertu second line reimbursement had been rejected."

The Panel noted that the meeting report provided by AstraZeneca did not mention NICE, let alone make any disparaging remarks. In the absence of any evidence or additional clarification from the complainant, the Panel concluded that this allegation had not been established. The Panel ruled **no breach of Clause 6.7**.

Clause 10.2 – prohibition on payments to individuals merely for attending events/meetings

Clause 10.7 – cost of subsistence must not exceed £75 per person

Clause 10.8 – prohibition on payments to doctors for renting rooms for events/meetings

Clause 19.1 – prohibition on gifts etc. to health professionals as an inducement to prescribe

The complainant had provided no evidence that the one delegate had been paid to attend the workshop or had received any subsistence or gifts etc.

The Panel accepted the documentary evidence from AstraZeneca which demonstrated that the four speakers were paid solely to prepare for, and deliver, the workshop. There was no evidence that the four speakers had been:

- 1. paid for a greater number of hours than those which were set out in their contracts,
- 2. provided with subsistence greater than £75 per person (AstraZeneca provided evidence that the hotel delegate day rate was £33 per person, which the Panel considered was in line with Code requirements).
- 3. paid for the rental of the room, nor
- 4. given any gift, pecuniary advantage or benefit as an inducement to prescribe.

On that basis, the complainant had not established these aspects of their complaint. The Panel ruled **no breach of Clauses 10.2, 10.7, 10.8 and 19.1**.

<u>Clauses 24.1 and 24.2 – where health professional are used as consultants or advisers, they</u> must fulfil certain criteria

These two clauses were added to the complaint by the PMCPA case preparation manger, rather than by the complainant.

The Panel noted that the complainant had made no allegation that the four speakers were not qualified to deliver the workshop. From the documentary evidence provided, it was clear to the Panel that this was a contracted service, which the four speakers had fulfilled. The Panel did not consider the contracts provided by AstraZeneca included anything that was inconsistent with the requirements of, and the criteria set out in, these clauses.

The Panel noted the requirement of the fourth bullet point of Clause 24.2 which stated that the number of contracted individuals must not be greater than the number "reasonably necessary to achieve the identified need".

However, the Panel accepted AstraZeneca's submission that the original plan for the workshop was to have up to twenty-five attendees and that, on the day, they were expecting seven attendees. The Panel did not consider that AstraZeneca had acted unreasonably in:

- 1. originally contracting four speakers for this workshop when the intended number of attendees was up to twenty-five,
- 2. not cancelling the workshop in the days leading up to it, when the expected number of attendees was seven, and
- 3. deciding to proceed with the workshop on the day, notwithstanding the very low turn-out.

The Panel did note that it was highly unusual for four delegates, who had accepted the invitation to join this (relatively small) workshop, to have failed to attend on the day without giving any notice. Nevertheless, in the Panel's view, a workshop of four speakers and eight attendees would not have been incompatible with Clause 24.1 or 24.2. There was therefore no reason why AstraZeneca should have cancelled the event in the days leading up to it.

Given the identified need of the workshop was to support regional health professionals to identify the challenges in their local area with regards to adverse event management in patients prescribed systemic anti-cancer therapies, the Panel concluded that ultimately AstraZeneca could still likely have achieved those objectives, albeit with a narrower perspective than it had intended.

In relation to the complainant's suggestion that it should have been cancelled on the day, the Panel accepted that this would have resulted in wasted time for the contracted health professionals and may have deterred them from speaking at future events.

It was also clear to the Panel that this workshop was never intended to be an insights gathering session or an advisory board and the complainant had not established why they considered this to be a "pseudo advisory board". The Panel therefore ruled **no breach of Clauses 24.1 and 24.2**.

<u>Clause 5.1 – requirement to maintain high standards</u> <u>Clause 2 – requirement not to discredit the pharmaceutical industry</u>

Given its conclusions above and, in the absence of any additional evidence to establish that there had been a failure to maintain high standards by AstraZeneca in proceeding with this workshop despite the low attendance, the Panel ruled **no breach of Clause 5.1**. For the same reasons the Panel ruled **no breach of Clause 2**.

Complaint received 8 May 2024

Case completed 30 June 2025