CASE AUTH/3729/1/23

COMPLAINANT/S v ASTRAZENECA

Alleged promotional activities

CASE SUMMARY

This case was in relation to six separate complaints, which were amalgamated by the case preparation manager.

Complaint 1 related to a 'Surgical Think Tank' meeting, at which the complainant alleged Iressa (gefitinib) and Tagrisso (osimertinib) were promoted. The outcome of this complaint under the 2021 Code was:

Breach of Clause 5.1 (x3)	**Failing to maintain high standards**
Breach of Clause 6.1 (x2)	**Making a misleading claim**
Breach of Clause 8.1	**Failing to certify promotional material**

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 the marketing authorisation**
No Breach of Clause 5.1	**Requirement to maintain high standards at all times**
No Breach of Clause 5.2	**Requirement that all material and activities must recognise the special nature of medicines and respect the professional standing or otherwise of the audience to which they are directed**
No Breach of Clause 6.1	**Requirement that information, claims and comparisons must not be misleading**
No Breach of Clause 15.6	**Requirement that promotional material and activities must not be disguised**

Complaint 2 related to alleged promotion of Tagrisso (osimertinib) and acalabrutinib to the public via a post on LinkedIn. The outcome of this complaint under the 2019 Code was:

No Breach of Clause 2	**Requirement that activities or materials associated with promotion must not bring discredit upon, or reduce confidence in, the pharmaceutical industry**
No Breach of Clause 9.1	**Requirement to maintain high standards at all times**

No Breach of Clause 12.1	**Requirement that promotional material and activities must not be disguised**
No Breach of Clause 14.1	**Requirement to certify promotional material**
No Breach of Clause 26.1	**Requirement that prescription only medicines must not be advertised to the public**

Complaint 3 related to alleged promotion of capivasertib to the public by liking and reposting a LinkedIn post made by a research institute. The outcome of this complaint under the 2021 Code was:

Breach of Clause 2	**Bringing discredit upon, and reducing confidence in, the pharmaceutical industry**
Breach of Clause 3.1	**Promoting a medicine prior to the grant of the marketing authorisation**
Breach of Clause 5.1	**Failing to maintain high standards**

No Breach of Clause 26.1	**Requirement that prescription only medicines must not be advertised to the public**

Complaint 4 related to alleged promotion of Tagrisso (osimertinib) by a UK-based employee 'liking' a LinkedIn post made by a US-based employee. The outcome of this complaint under the 2021 Code was:

Breach of Clause 5.1	**Failing to maintain high standards**
Breach of Clause 26.1	**Promoting a prescription only medicine to the public**

No Breach of Clause 2	**Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry**

Complaint 5 related to allegations about the pressures that Medical Science Liaisons (MSLs) felt to promote Imfinizi (durvalumab) for an unlicensed indication. The outcome of this complaint under the 2021 Code was:

No Breach of Clause 5.1	**Requirement to maintain high standards at all times**
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 17.9	**Requirement that representatives' briefing material must comply with the relevant requirements of the Code and is subject to certification**

Complaint 6 related to allegations about AstraZeneca's Early Access Programmes (EAPs). The outcome of this complaint under the 2021 Code was:

No Breach of Clause 5.1	**Requirement to maintain high standards at all times**
No Breach of Clause 11.1	**Requirement that a medicine must not be promoted prior to the grant of the marketing authorisation**
No Breach of Clause 17.9	**Requirement that representatives' briefing material must comply with the relevant requirements of the Code and is subject to certification**

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

FULL CASE REPORT

Six separate complaints were received about AstraZeneca UK Limited which the case preparation manager decided to amalgamate.

GENERAL COMMENTS FROM ASTRAZENECA

AstraZeneca stated that the six complaints were as follows:

1. Promotion of gefitinib and Tagrisso at a 'Surgical Think Tank Meeting' in January 2022
2. Promotion of Tagrisso and acalabrutinib to the public by an AstraZeneca Senior Leader
3. Promotion of capivasertib on the LinkedIn platform
4. Promotion of Tagrisso on the LinkedIn platform
5. Encouraging MSLs [Medical Science Liaisons] to promote Imfinzi for an unlicensed indication during a quarterly account review meeting in Q2 2022
6. Encouraging Medical teams to promote the OlympiA EAMS [Early Access to Medicines Scheme] programme

AstraZeneca stated that it took the complainant's allegations very seriously. As an organisation, AstraZeneca subscribed fully to the high ethical and moral spirit of the Code and had internal procedures and SOPs [Standard Operating Procedures] in place to ensure that AstraZeneca maintained these high standards at all times. AstraZeneca operated a culture of 'speak up' and continuous learning and internal procedures in place to ensure that employees were able to voice their concerns confidentially through numerous appropriate channels where their anonymity could be preserved. Through its investigations, AstraZeneca found that its internal procedures had been followed and actions taken were appropriate. AstraZeneca was fully satisfied of its continuing organisational commitment and standards required to operate in the high ethical and moral framework as set out in the Code.

SUMMARY OF ASTRAZENECA'S POSITION

In summary, AstraZeneca stated that it took its obligations under the Code very seriously and had internal SOPs and processes in place to ensure that the company upheld the high ethical

and moral spirit of the Code. As AstraZeneca had set out above, the company vehemently denied bringing the pharmaceutical industry into disrepute and denied being in breach of Clauses 2, 3, 3.1, 3.6, 4, 5.1, 5.2, 7, 8, 8.1, 9.1, 11.1, 15.6, 17.2, 17.9, 26.1 and 26.2.

Furthermore, AstraZeneca had a culture of 'speak up' and continuous learning, with several communication mechanisms in place (including a dedicated AstraZeneca Ethics hotline) to ensure that AstraZeneca employees could express their concerns through various means and channels. As a company, AstraZeneca did not condone any form of bullying and harassment behaviour at the workplace, as indicated in AstraZeneca's global standards of People, Inclusion and Diversity.

In conclusion, AstraZeneca strongly refuted all of the complainant's allegations and categorically denied having brought the pharmaceutical industry into disrepute. AstraZeneca had processes in place to ensure that the company operated consistently to the highest standards and took its obligations under the Code very seriously.

COMPLAINT 1 – Promotion of gefitinib (Iressa) and Tagrisso (osimertinib) at a 'Surgical Think Tank' Meeting in January 2022

COMPLAINT

The complainant stated that they were a member of the [named therapy area] Franchise in the UK MC of AstraZeneca UK.

They complained about the behaviours from members of the [named therapy area] medical team, which could be considered as promotional.

They stated that they had tried to discuss their concerns with UK Compliance and [a senior medical employee], but alleged that the understanding of the Code was very limited in AstraZeneca UK.

The complainant stated that they had attached screenshots of a so-called non-promotional meeting that took place in January 2022, under an educational initiative for surgeons called Surgical Think Tank. The complainant alleged that the [named therapy area] medical team promoted off license gefitinib and also off license Tagrisso (the Tagrisso Adaura indication did not have an MHRA [Medicines and Healthcare products Regulatory Agency] licence at the time). The complainant stated their concerns:

1. The virtual meeting was attended mainly by surgeons, who could not prescribe Tagrisso according to the SPC [summary of product characteristics], so why focus so much of the slides on the Adaura indication and other off license gefitinib data. The complainant alleged that surgeons were not an appropriate group to receive this data which was off license anyway.
2. The Adaura data dominated most of the presentation, and at this time AstraZeneca was running a free of charge access scheme. The complainant alleged that on speaking to marketing colleagues, this virtual meeting aimed to get surgeons to push for Tagrisso prescribing after lung surgery. Free of Charge schemes should not be promoted to non-prescribers like surgeons. The purpose here was to run the numbers up, so that when NICE [National Institute for Health and Care Excellence] and SMC [Scottish Medicines Consortium] reimbursed Tagrisso, then AstraZeneca would benefit

from transfer of patients to commercial stock. The complainant alleged that this was truly a seeding programme.

The complainant stated that they tried to advise both Compliance and [named therapy area] medical team, but they kept insisting that this was a non-promotional meeting as other data was also shared.

The complainant stated that they would like the PMCPA to look into the following clauses in this complaint:

- Clause 2 – Bringing discredit upon, and reducing confidence in, the pharmaceutical industry.

- Clause 3.1 – Promoting a medicine prior to its marketing authorisation. The complainant alleged that this was because both gefitinib (AstraZeneca medicine) & Tagrisso (had no licence for Stage IB to 3A non-small cell lung cancer) at the time of this meeting in January 2022.

- Clause 9.1 – Failing to maintain high standards. The complainant alleged that there was a free of charge scheme in place and all patients were to be transferred to commercial Tagrisso stock upon reimbursement. This Surgical Think Tank was aimed at informing surgeons about the ADAURA trial data, so that they could push MDTs [multidisciplinary teams] to prescribe Tagrisso post surgery. The complainant alleged that AstraZeneca was effectively promoting to surgeons (who did not meet the criterion of prescriber in the Tagrisso SPC).

Further information from the complainant
The complainant stated that as a former [employee] at AstraZeneca, they wanted to report both a disguised promotional activity, and also efforts to cover it up, even though internal discussions between senior compliance leaders, led to the conclusion that the activity was a Clause 2, disguised promotional activity.

On 21 January 2022, [first named medical employee] delivered a meeting under an Early Stage Think Tank initiative, aimed at facilitating surgery discussions between thoracic surgeons and other MDT members. The complainant alleged that despite much advice from team members, [first named medical employee] included AstraZeneca product slides. These products included sharing data on unlicensed use of gefitinib (an unlicensed TKI [tyrosine kinase inhibitor]) in early stage lung cancer post surgery as adjuvant therapy, and also the ADAURA data on Tagrisso in early stage lung cancer post surgery. The complainant alleged that the slide deck was heavily focused on promoting the use of two AstraZeneca products, one in an unlicensed indication, and the other in a licensed indication.

The complainant alleged that [first named medical employee], whilst sharing an update with the wider organisation referred to the Early Stage Think Tank meeting as an ADAURA initiative. ADAURA was the name of the trial for the use of Tagrisso post surgery in Stage 1B to 3A lung cancer; the complainant alleged that this was an acknowledgement that the purpose of the meeting was to promote Tagrisso in the ADAURA indication.

The complainant alleged that internal compliance concerns were raised by [second named employee] but both [first named medical employee] and [third named medical employee],

defended the direct promotion of AstraZeneca medicines to surgeons, who were not even the intended prescriber. Despite these false assurances, [second named employee] felt that the meeting breached the Code under disguised promotion of AstraZeneca medicines, a lack of certification of the meeting slides and content, and the fact that no prescribing information was added. The complainant provided a text message that they alleged showed AstraZeneca's efforts to not report the meeting as a compliance concern.

The complainant provided slides, containing the alleged disguised promotion to the public and words like "cure", which, the complainant alleged, was not a realistic outcome for most Stage III lung cancer patients.

The complainant alleged that in conducting this meeting, AstraZeneca had breached the Code on:

1. 'Disguised promotion, and with a complete disregard for certification, or prescribing information.
2. In the case of gefitinib, it was a direct promotion of an unlicensed indication'

The complainant alleged that these breaches came under Clause 2, as AstraZeneca promoted one licensed indication, and also another unlicensed indication for gefitinib.

The complainant additionally alleged the following breaches of the Code:

- "Clause 2
- Clause 3.1 – for promoting gefitinib (an AstraZeneca medicine) prior to the grant of a marketing authorisation
- Clause 5.1 – for failing to meet high standards
- Clause 5.2
- Clause 7 – use of the words "cure" in [named health professional]'s presentation raised unproven hopes
- Clause 8.1 – for a failure to certify or add prescribing information."

When writing to AstraZeneca regarding the promotion of gefitinib and Tagrisso at a 'Surgical Think Tank' meeting in January 2022, the PMCPA asked it to consider the requirements of Clauses 2, 3.1, and 9.1 of the 2021 Code ,as cited by the complainant, and to bear in mind the requirements of Clause 15.6.

When writing to AstraZeneca regarding the further information received from the complainant about promotion of gefitinib and Tagrisso at a 'Surgical Think Tank' meeting in January 2022, the PMCPA asked it to consider the requirements of Clauses 5.1, 5.2, 7 and 8.1 as cited by the complainant.

ASTRAZENECA'S RESPONSE

AstraZeneca stated that in this first complaint, the allegations were that:

(1) The meeting was aimed at surgeons to promote gefitinib and Tagrisso. The virtual 'Surgical Think Tank' meeting was attended primarily by surgeons (who could not prescribe Tagrisso).

(2) This meeting constituted deliberate disguised promotion specifically as a result of allegations 3,4,5,6 and 7 below.
(3) The medical team promoted off-license gefitinib at this meeting.
(4) ADAURA data dominated most of the presentation and the purpose of the meeting was to promote Tagrisso in the ADAURA indication.
(5) The meeting was aimed to 'get surgeons to push for Tagrisso prescribing after lung surgery' and that 'free of charge schemes should not be promoted to non-prescribers like surgeons'. That this was a 'seeding programme' to ensure that patients started on a free-of-charge scheme would be transferred over to commercial stock upon NICE/SMC reimbursement.
(6) Complainant discussed their concerns with compliance, and [a senior medical employee], but they insisted meeting was a non-promotional meeting despite concerns. Concerns about the meeting were flagged by [a named medical employee] but were ignored.
(7) Purpose of the meeting was to promote Tagrisso in the ADAURA indication. That proactive mention of Tagrisso and gefitinib both represented disguised promotion of both a licensed and unlicensed indication (for gefitinib). That the meeting was disguised promotion and required certification, PI [prescribing information], and no unlicensed indications.
(8) [Named health professional]'s presentation raised unfounded hopes of treatment due to use of the word 'cure' in their presentations.

Background information

AstraZeneca stated that gefitinib was a first-generation epidermal growth factor receptor (EGFR) Tyrosine Kinase Inhibitor (EGFR-TKI), now a generic medicine with multiple marketing authorisation holders, of which AstraZeneca was one of them. The licenced indication for AstraZeneca's Iressa (gefitinib) was as monotherapy for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating mutations of EGFR-TKI. In the UK, Iressa was no longer actively promoted by AstraZeneca.

Osimertinib (Tagrisso) was a newer-generation EGFR Tyrosine Kinase Inhibitor, with a licenced indication for use as an adjuvant treatment after complete tumour resection in adult patients with stage IB-IIIA non-small cell lung cancer (NSCLC) whose tumours had epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations. This licenced indication was obtained on the back of the phase 3 ADAURA trial (Wu et al NEJM 2020). The marketing authorisation for Tagrisso in this indication was granted by the MHRA on 7 May 2021. Furthermore, the free-of-change (FOC) Tagrisso scheme agreement that was in place between AstraZeneca, NHS England and NICE between May and December 2021 was already discontinued at the time of this ESTT [Early Stage Think Tank] meeting.

AstraZeneca stated that lung cancer management had evolved significantly over the years, with increasing number of treatment options becoming available for patients at all-stages of their disease. In order to ensure that patients had the best possible treatment choice and outcome, it was important that the wider lung cancer multi-disciplinary team were aware of the evolving management paradigms in this rapidly evolving therapeutic area. In response to this unmet educational need, a non-promotional medical education meeting entitled the 'Early Stage Think Tank' (ESTT) was conducted, aimed at upskilling the general knowledge-base of UK Thoracic surgeons and the extended lung cancer multi-disciplinary team (MDT) professionals involved in the management of early stage lung cancer. The key objectives of the ESTT meeting were to a)

upskill HCPs [healthcare professionals] on how the overall pathway for resectable lung cancer patients could be optimised, exploring screening, prehabilitation and multimodality treatment, b) explore and discuss how patients could be optimised before radical intent treatment and c) provide a platform to discuss neo-adjuvant and adjuvant treatments pre/post-surgical resection, in keeping with the rapidly changing treatment landscape.

Allegations 1 to 3

AstraZeneca noted the complainant's allegation that the meeting was aimed at surgeons to promote gefitinib and Tagrisso. The virtual 'Surgical Think Tank' meeting was attended primarily by surgeons (who could not prescribe Tagrisso). The meeting constituted deliberate disguised promotion as a result of allegations 3, 4, 5, 6 and 7 and the medical team promoted off-license gefitinib.

AstraZeneca stated that the complainant referred to a 'Surgical Think Tank' meeting in the above allegation, however the meeting was titled as Early Stage Think Tank (ESTT) 'Surgery in Lung Cancer: Screen detection to multi-modality care in lung cancer'. The ESTT meeting took place virtually on 21 January 2022 between 14:00-15:45 and was attended by 71 healthcare professionals, over half of which were thoracic surgeons. At the outset of the meeting, the attendees were reminded that this was a non-promotional meeting organised by AstraZeneca, with the objective being to help share best practice and innovative thinking in the management of lung cancer patients, with a particular focus on the role of surgery. The objective of this meeting was clear, addressing an area of significant educational need to help upskill thoracic surgeons and the extended MDT in this rapidly evolving therapy area. The meeting topics were of high educational relevance and importance especially to surgeons, covering topics ranging from the effects of screening and prehabilitation of surgical patients, to techniques of lung-sparing surgery, as well as integrated multi-modality in earlier-stage lung cancer. AstraZeneca's meeting faculty comprised of seven expert HCPs, five of which were thoracic surgeons, one a respiratory physician and another was a medical oncologist. This non-promotional medical education meeting was accredited by the Royal College of Surgeons of England with one Continuous Professional Development (CPD) point awarded for the attendees.

AstraZeneca submitted that it rejected in its entirety the suggestion that this meeting constituted any disguised promotion. AstraZeneca had addressed above the clear and communicated objective of the ESTT and deal with refuting all other suggestions of disguised promotion within its responses to the individual allegations.

AstraZeneca stated that it rejected the suggestion that the medical team promoted off-license gefitinib as gefitinib was licensed at the time the ESTT take place. There was no promotion of gefitinib as further detailed in its response to allegation 4.

Allegation 4

AstraZeneca noted the complainant's allegation that the ADAURA data dominated most of the presentation and purpose of the meeting was to promote Tagrisso in the ADAURA indication.

AstraZeneca stated that a total of 10 slides out of 104 slides for the entire ESTT meeting included information on these two studies, of which 4 slides were on gefitinib and 6 slides were on Tagrisso (ADAURA) data. In total, this section would have amounted to no more than 10 minutes, which was less than 10% of the total ESTT meeting time. AstraZeneca stated that it

therefore strongly refuted the suggestion that the ADAURA data dominated most of the presentation. Furthermore, [named health professional] presented a comprehensive overview of a number of advances that were happening in the neo-adjuvant/adjuvant treatment space that were of importance for thoracic surgeons and the extended MDT to be aware of. Thus, AstraZeneca re-emphasised the objective of this meeting, which was to address an area of significant educational need to help upskill thoracic surgeons and the extended MDT in this rapidly evolving therapy area. AstraZeneca had set out more information on the objective of the meeting in the background paragraph above and AstraZeneca's response to allegations 1 to 3 above and refuted the suggestion that the purpose of the meeting was to promote Tagrisso in the ADAURA indication.

Allegation 5

AstraZeneca noted the complainant's allegation that the meeting was aimed to 'get surgeons to push for Tagrisso prescribing after lung surgery' and that 'free of charge schemes should not be promoted to non-prescribers like surgeons'. This was a 'seeding programme' to ensure that patients started on a free-of-charge scheme would be transferred over to commercial stock upon NICE/SMC reimbursement.

AstraZeneca submitted that the FOC Tagrisso scheme that was in place between May and December 2021 had already been discontinued at the time of this ESTT meeting. The objective of the ESTT meeting was clear, addressing an area of significant educational need to help upskill thoracic surgeons and the extended MDT in this rapidly evolving therapy area. The meeting topics were of significant educational relevance and importance especially to surgeons, covering topics ranging from the effects of screening and prehabilitation of surgical patients, to techniques of lung-sparing surgery, as well as integrated multi-modality in earlier-stage lung cancer. AstraZeneca had a meeting faculty comprising of seven expert HCPs, as detailed above in response to allegations 1-3. This non-promotional medical education meeting was accredited by the Royal College of Surgeons of England with one Continuous Professional Development (CPD) point awarded for the attendees. By the complainant's self-admission surgeons were 'non-prescribers'. In response, AstraZeneca re-emphasised the objective of this meeting, which was to address an area of significant educational need to help upskill thoracic surgeons who, although not prescribing themselves, were involved in treatment discussions pre/post surgery with extended MDT in this rapidly evolving therapy area. AstraZeneca strongly refuted the allegations by the complainant that this meeting was intended to 'get surgeons to push for Tagrisso prescribing after lung surgery' and 'push Tagrisso prescribing through a FOC scheme.

Allegation 6

AstraZeneca noted the complainant's allegation that the complainant had discussed their concerns with compliance and the [senior medical employee], but they insisted the meeting was a non-promotional meeting despite concerns. Concerns about the meeting were flagged by [a named medical employee] but were ignored.

AstraZeneca stated that it took its obligations under the Code very seriously. AstraZeneca had processes in place to ensure that it operated consistently to the highest of standards. As a continuous learning organisation, AstraZeneca conducted prompt and thorough investigations when concerns were brought to its attention. AstraZeneca therefore read with concern that the complainant allegedly had tried to discuss their concerns with UK Compliance and [a senior medical employee] and that concerns were flagged by [a named medical employee] but were

ignored. Following this complaint, AstraZeneca conducted a thorough investigation and ascertained that no member of AstraZeneca's staff recollected any questioning or concerns being raised by anyone prior to the ESTT meeting taking place or during the meeting. AstraZeneca stated that its investigation showed that a retrospective compliance concern was submitted by [a named medical employee] to the AstraZeneca UK compliance reporting platform, following an internal compliance training workshop held by an external agency in the morning of 28 January 2022. During this compliance training, the [named medical employee] raised a question on whether it would be permissible to discuss AstraZeneca data in the context of a balanced presentation on broader management options during a non-promotional meeting. Based on the verbal information given, the external facilitator of the training workshop provided their own opinion that this may be considered promotional. Following this session, the [named medical employee] discussed their concerns with an AstraZeneca medical employee, the [senior medical employee referred to previously] and [named therapy area] medical team prior to reporting their compliance concern via AstraZeneca internal compliance reporting platform in the afternoon of the 28 January 2022, seven days after the ESTT meeting had taken place. As a result, the following actions were taken by AstraZeneca:

- 1/2/22: Briefing of the external agency who had reviewed and approved the ESTT slides
- 11/2/22: Briefing of individual medical team members involved in the ESTT meeting
- 15/2/22: Briefing of the wider UK [named therapy area] and Medical Review/Signatory teams

AstraZeneca stated that it was fully satisfied of the non-promotional nature of this medical education meeting and no further actions in addition to the above were deemed necessary under AstraZeneca's internal guidance detailed in the 'Handling Code of Practice Complaints, AZUK' SOP. The inclusion of the Tagrisso and gefitinib data was required as part of a balanced discussion about the changing treatment landscape in early-stage lung cancer.

AstraZeneca stated that the Panel would note AstraZeneca's thorough and prompt response following the internal compliance concern raised, demonstrating its upmost commitment to high ethical and moral spirit of the Code. AstraZeneca undertook regular compliance and Code training sessions to ensure that all of AstraZeneca's UK-based employees were fully conversant with the Code and took its responsibilities under the Code very seriously. As such, AstraZeneca had internal policies and procedures in place to ensure that employees were able to voice their concerns confidentially and were confident that the right procedures were followed in this case. Concerns were only raised retrospectively by the [named medical employee] seven days after the meeting, which AstraZeneca dealt with swiftly and in an efficient manner. These concerns were in no way ignored, as alleged by the complainant. AstraZeneca's investigation had not revealed any evidence of anyone trying to discuss any concerns prior to, during or after the meeting, save for the retrospective concerns outlined above by the [named medical employee]. AstraZeneca therefore strongly refuted the assertion by the complainant that they discussed any concerns with compliance and the [senior medical employee].

Allegation 7

AstraZeneca noted the complainant's allegation that the purpose of the meeting was to promote Tagrisso in the ADAURA indication. That proactive mention of Tagrisso and gefitinib both represented disguised promotion of both a licensed and unlicensed indication (for gefitinib).

That the meeting was disguised promotion and required certification, PI (prescribing information), and no unlicensed indications.

AstraZeneca submitted that the objective of the meeting was clear, addressing an area of significant educational need to help upskill thoracic surgeons and the extended MDT in this rapidly evolving therapy area. The meeting topics were of significant educational relevance and importance especially to surgeons, covering topics ranging from the effects of screening and prehabilitation of surgical patients, to techniques of lung-sparing surgery, as well as integrated multi-modality in earlier-stage lung cancer. AstraZeneca had a meeting faculty comprised of seven expert HCPs, as stated above in AstraZeneca's response to allegations 1-3. This non-promotional medical education meeting was accredited by the Royal College of Surgeons of England with one Continuous Professional Development (CPD) point awarded for the attendees.

AstraZeneca submitted that this non-promotional educational meeting did not require prescribing information (PI) or certification, meeting content was limited to licensed indications and was examined.

Allegation 8

AstraZeneca noted the complainant's allegation that [named health professional]'s presentation raised unfounded hopes of treatment due to use of the word 'cure' in their presentations.

[Named health professional] presented a comprehensive overview of a number of advances that were happening in the neo-adjuvant/adjuvant treatment space that was of importance for thoracic surgeons with various potential outcomes. Slide 80 titled 'EGFR TKIs instead of chemotherapy' and slide 86 titled 'ADAURA conclusion' presented potential treatment outcomes which may include 'cure', 'delayed recurrence' and 'overtreated'. AstraZeneca submitted that the presentation did not raise unfounded hopes of treatment as slides 80 and 86 did not suggest EGFR TKIs and ADAURA could lead to a 'cure'. The word 'cure' was used in a balanced context of a potential treatment outcome.

Thus, AstraZeneca re-emphasised the objective of this meeting, which was to address an area of significant educational need to help upskill thoracic surgeons and the extended MDT in this rapidly evolving therapy area and strongly refuted the allegation by the complainant that the presentation raised unfounded hopes of treatment due to the use of the word 'cure' in [named health professional]'s presentations.

Summary in relation to Complaint 1

For this complaint 1, AstraZeneca submitted that it had established that the ESTT meeting was a carefully planned and executed non-promotional medical educational meeting and AstraZeneca categorically denied the allegations that the meeting was held to 'push Tagrisso prescribing through a FOC scheme' which had already been discontinued and was not in existence at the time of the meeting. No compliance concerns were raised before or at the time of the meeting. AstraZeneca's investigations did show that a retrospective compliance concern was raised by a member of the [named therapy area] medical team one week after the meeting had taken place. This was investigated promptly and in full accordance with internal policies. AstraZeneca was fully satisfied of the non-promotional nature of this medical educational meeting and no further action in addition to the above was deemed necessary under

AstraZeneca's internal guidance detailed in the 'Handling Code of Practice Complaints, AZUK' SOP. The inclusion of the Tagrisso and gefitinib data was required as part of a broader balanced discussion about the changing treatment landscape in early-stage lung cancer. AstraZeneca submitted that its thorough and prompt response following the internal compliance concern demonstrated its robust internal processes and the upmost organisational commitment to the high ethical standards required of the Code and AstraZeneca therefore denied breaches of Clauses 2, 3, 3.1, 4, 5.1, 5.2, 7, 9.1 and 15.6.

PANEL RULING

General comments

The Panel noted that the complainant/s described themselves as ex-employee/s. A number of different job titles were referred to throughout the six complaints. The Panel's rulings are made on the basis that a complainant has the burden of proving their complaint on the balance of probabilities, therefore the Panel made its rulings based on the information before it. It did not appear to the Panel that the identity of the complainant/s was relevant to the subject matter of these complaints.

The Panel noted that the complainant cited clauses from the 2019 and 2021 Codes. The Panel considered that at the time of the activities at issue in Complaints 1, 3, 4 and 5, the 2021 Code was applicable, and the clauses cited from the 2019 Code were closely similar to the representative clauses in the 2021 Code; the Panel therefore made its rulings under the 2021 Code. The Panel noted that the activities at issue in Complaint 2 took place in early 2021 when the 2019 Code was applicable, therefore made its rulings for Complaint 2 under the 2019 Code. The Panel noted that the activities at issue in Complaint 6 took place between 2020 and 2023, during which both the 2019 and 2021 Codes were applicable and AstraZeneca had been asked to respond to clauses from the 2021 Code, as raised by the case preparation manager. The Panel decided to make its rulings in relation to Complaint 6 under the 2021 Code.

The Panel's general comments above applied to Complaints 1–6.

In relation to Complaint 1 the Panel adopted the allegation numbering system used by AstraZeneca.

Allegations 1 and 2

The Panel noted that the complainant referred to a 'Surgical Think Tank' meeting, which took place virtually in January 2022, and alleged that the meeting was promotional in nature and that the proactive mention of Tagrisso and gefitinib represented disguised promotion of both a licensed and unlicensed indication. The complainant asserted that gefitinib was not licensed, and Tagrisso did not have a licence for Stage IB to 3A non-small cell lung cancer at the time of this meeting in January 2022.

The Panel noted that Iressa (gefitinib) was indicated as monotherapy for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating mutations of EGFR-TK (epidermal growth factor receptor-tyrosine kinase). The Panel noted that the summary of product characteristics (SPC) for gefitinib stated that when considering its use as treatment, it was important that EGFR mutation assessment of the tumour tissue was attempted for all patients.

The Panel noted that Tagrisso (osimertinib) as monotherapy was indicated for:

- the adjuvant treatment after complete tumour resection in adult patients with stage IB-IIIA non-small cell lung cancer (NSCLC) whose tumours have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations.
- the first-line treatment of adult patients with locally advanced or metastatic NSCLC with activating EGFR mutations.
- the treatment of adult patients with locally advanced or metastatic EGFR T790M mutation-positive NSCLC.

The first matter to be determined by the Panel was whether the meeting was promotional or non-promotional. The Panel considered AstraZeneca's submission in this regard and the content of the four presentations that were delivered as part of the meeting.

The Panel noted AstraZeneca's submission that the meeting was titled Early Stage Think Tank (ESTT) 'Surgery in Lung Cancer: Screen detection to multi-modality care in lung cancer'. AstraZeneca submitted that the 71 health professionals who attended the meeting, were reminded at the outset that this was a non-promotional meeting organised by AstraZeneca, aimed at fostering the exchange of best practices and innovative strategies in managing lung cancer patients, with a specific emphasis on surgical interventions.

The Panel also noted that the footer of the title slide for each presentation stated 'This is a non-promotional meeting organised and funded by AstraZeneca'.

The Panel noted that the objectives of the webinar in the 'Background and housekeeping' presentation included, among other things, upskilling health professionals on how the overall pathway for resectable lung cancer patients could be optimised, exploring screening and multi-modality treatment; optimisation of patient health before radical treatment; and providing a platform to discuss neo-adjuvant and adjuvant treatments pre/post-surgical resection.

The Panel noted that the final presentation, titled 'Neo-adjuvant & adjuvant treatments pre/post surgical resection' described the IMPACT and ADJUVANT trials, which involved the use of gefitinib, and the ADAURA trial, involving the use of Tagrisso. Slide headings and/or highlighted boxes referred to the products such as 'There were no treatment-related deaths and gefitinib demonstrated a low incidence of Grade ≥3 AEs in both studies' and 'Who Benefitted from Adjuvant osimertinib?'.

The Panel noted AstraZeneca's submission that less than 10% of the total ESTT meeting time focused on Tagrisso and gefitinib; but was concerned at AstraZeneca's implication that the purpose of the meeting was therefore not promotional. The Panel noted that certain parts of the presentation that did not mention either product might nonetheless be relevant to the products' licensed indications.

The Panel noted the content of what appeared to be part of an internal email sent by a named employee to the wider organisation, sharing a post-webinar report for the Early Stage Think Tank meeting. The email referred to, among other things, the ESTT being an ongoing ADAURA initiative that was UK centric and had surgical impact, developed with the aim of bringing together innovative surgeons to share practice on how to optimise lung cancer surgery services and increase resection rates in early stage NSCLC.

The Panel noted the broad definition of promotion in Clause 1.17. In the Panel's view, noting the content of the presentation slides and their relevance to the products' licensed indications and overall focus on optimising the patient pathway, and that it was an AstraZeneca meeting, the Panel considered that the meeting could not be seen as anything other than promotional, and it was on this basis that the Panel made its rulings.

The second matter to be determined by the Panel was whether the meeting at issue constituted disguised promotion. The Panel noted its view above that the meeting could not be seen as anything other than promotional.

The Panel noted AstraZeneca's submission that the objective of the meeting at issue was clear, addressing an area of significant educational need to help upskill thoracic surgeons and the extended MDT (multidisciplinary team) in this rapidly evolving therapy area. The Panel did not have copies of the meeting invitation or briefing documents for the speakers before it. The impression given by the invitation and any initial documents received by the delegates before the meeting was therefore not known.

The Panel noted that the footer of the title slide for each presentation stated that the meeting was organised and funded by AstraZeneca and that it was a non-promotional meeting. The Panel noted its view above that given the broad definition of promotion the content was such that it was difficult to consider that the meeting was anything other than promotional. That the meeting was organised by AstraZeneca and that the title 'Surgery in Lung Cancer: Screen detection to multi-modality care in lung cancer' related to Tagrisso's licensed indication was also relevant. The Panel considered the immediate and overall impression created; in the Panel's view, delegates would reasonably expect discussion of AstraZeneca products. The Panel did not have sight of the invitation or other material given to attendees prior to the meeting. In the Panel's view the footnotes about the meeting's non-promotional nature were insufficient to negate the clear promotional content of the presentations. The Panel considered that the complainant bore the burden of proof; in the Panel's view, on the limited information before it, the complainant had not established that the promotional nature of the presentation was, on balance, disguised. **No breach of Clause 15.6** was ruled.

The Panel noted that the complainant alleged that the virtual meeting was mainly attended by surgeons who could not prescribe Tagrisso according to the summary of product characteristics (SPC). The Panel noted that Section 4.2 of the SPC, Posology and method of administration, stated that treatment with Tagrisso should be initiated by a physician experienced in the use of anticancer therapies.

The Panel noted AstraZeneca's response, in particular its submission that lung cancer management had evolved significantly over the years, resulting in an expanded array of treatment options. The Panel noted AstraZeneca's submission that it was important that the wider lung cancer multidisciplinary team was aware of the evolving management paradigms in this rapidly evolving therapeutic area, to ensure optimal treatment choices and outcomes for patients. The meeting at issue was therefore conducted, aimed at upskilling the general knowledge base of UK thoracic surgeons and the extended lung cancer multi-disciplinary team professionals involved in the management of early stage lung cancer.

The Panel noted AstraZeneca's submission that the meeting was attended by 71 health professionals, over half of which were thoracic surgeons. The Panel had no information before it

about the attendees who were not thoracic surgeons. Nonetheless, the Panel noted that promotion to health professionals who were not qualified to prescribe or initiate treatment with a specific product was not prohibited under the Code as long as the content of the meeting was appropriate and relevant to the attendees and complied with the Code. In this regard the Panel noted AstraZeneca's submission that [a named health professional] presented a comprehensive overview of a number of advances that were happening in the neo-adjuvant/adjuvant treatment space that were of importance for thoracic surgeons and the extended multi-disciplinary team to be aware of.

The Panel considered that, given the products' licensed indications and the multi-disciplinary approach to treatment, it was not unreasonable for thoracic surgeons to attend the meeting in question.

The Panel noted that the complainant had cited Clause 5.2 which stated, among other things, that all material and activities must recognise the special nature of medicines and respect the professional standing or otherwise of the audience to which they are directed. In the Panel's view, the complainant had not established that the attendance of surgeons at the meeting was inappropriate and meant that AstraZeneca had failed to respect the professional standing of the audience. The Panel ruled **no breach of Clause 5.2** accordingly.

Allegation 3 and part of Allegation 7

The Panel noted the complainant's allegation that the medical team promoted gefitinib which was not licensed at the time of the meeting.

The Panel noted that the complainant made two inconsistent statements regarding this allegation. The complainant stated that at the time of the meeting gefitinib was off-license and the Tagrisso ADAURA indication did not have an MHRA licence. In a later email the complainant alleged that the meeting promoted an unlicensed indication of gefitinib and a licensed indication for Tagrisso. The Panel did not find that there was a consistent allegation.

The Panel noted AstraZeneca's submission that at the time of the meeting gefitinib was licensed. Tagrisso was indicated, amongst other things, for use as an adjuvant treatment after complete tumour resection in adult patients with stage IB-IIIA non-small cell lung cancer (NSCLC) whose tumours had epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations; the marketing authorisation for Tagrisso in this indication was granted by the MHRA in May 2021, obtained following the ADAURA trial, some seven months before the ESTT meeting.

Noting the above, the Panel considered that the complainant had not established that gefitinib and Tagrisso were promoted prior to the grant of their marketing authorisations and ruled **no breach of Clause 3.1** in this regard.

The complainant also alleged that gefitinib was promoted for an unlicensed indication as adjuvant therapy in early-stage lung cancer post-surgery. The Panel noted that the final presentation of the meeting, titled 'Neo-adjuvant & adjuvant treatments pre/post surgical resection' described the IMPACT and ADJUVANT trials, which involved the use of gefitinib in completely resected patients. The Panel did not have the two studies before it, therefore considered the content of the presentation and the SPC for gefitinib.

The Panel noted that gefitinib was indicated as monotherapy for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating mutations of EGFR-TK (epidermal growth factor receptor-tyrosine kinase).

The Panel noted Clause 11.2 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 therefore the Panel considered that element of the complaint under Clause 5.1.

The Panel considered that AstraZeneca had not promoted gefitinib in accordance with the terms of its marketing authorisation; the description of the IMPACT and ADJUVANT trials in the final presentation 'Neo-adjuvant & adjuvant treatments pre/post surgical resection' included the use of gefitinib in completed resected patients. In the Panel's view, AstraZeneca had therefore failed to maintain high standards in this regard, and it ruled **a breach of Clause 5.1**.

Allegation 4

The Panel noted that AstraZeneca had listed what it considered to be the allegations made by the complainant, including that the complainant had stated that ADAURA data dominated most of the presentation and the purpose of the meeting was to promote Tagrisso in the ADAURA indication. Contrary to AstraZeneca, the Panel did not consider that the complainant had made a discrete allegation on this point. In the context of the overall complaint, it appeared to the Panel that such references were made by the complainant in support of their general position that the presentation was promotional and the promotional or non-promotional status of the material was relevant to the allegations made, in particular allegations 1, 2, and 3 above which were the subject of discrete rulings. The Panel therefore made no ruling in relation to these comments.

Allegation 5

The Panel noted the complainant's allegation that at the time of the meeting at issue, in January 2022, AstraZeneca was running a Free of Charge (FOC) access scheme for Tagrisso; the presentation aimed to get surgeons to push for Tagrisso, and that FOC schemes should not be promoted to non-prescribers like surgeons. The complainant alleged that the purpose of the scheme was to inflate prescribing of Tagrisso after lung surgery, allowing AstraZeneca to benefit from patient transfers to commercial stock upon reimbursement by the National Institute for Health and Care Excellence and the Scottish Medicines Consortium.

The Panel noted AstraZeneca’s submission, that the FOC Tagrisso scheme was in place between May and December 2021, such that it had already been discontinued at the time of the meeting. Further, there was no evidence before the Panel to support the complainant’s comments about the nature and use of the FOC scheme.

Noting the above, the Panel considered that the complainant had not established that AstraZeneca had failed to maintain high standards in this regard, and ruled **no breach of Clause 5.1**.

Allegation 6

The Panel noted that AstraZeneca identified as the sixth allegation that the complainant stated that they had discussed their concerns with Compliance and the [senior medical employee], who insisted the meeting was non-promotional, and concerns raised by the [named therapy area] medical team were ignored.

The Panel noted that the complainant raised several internal compliance matters regarding the meeting at issue. It was unclear whether the complainant had intended to make a standalone allegation on this point. In the Panel 's view, that somebody had raised an internal compliance concern did not necessarily fall within the scope of the Code as a discrete allegation but may nonetheless provide relevant evidence for a matter within the scope of the Code. Whether it came within the scope of the Code should be decided on a case-by-case basis. Overall the Panel considered that no clear allegation was made; the Panel therefore made no ruling in this regard.

Allegation 7

The Panel noted the complainant's allegation that AstraZeneca, when holding the meeting, had a complete disregard for certification and prescribing information.

The Panel noted AstraZeneca's submission that this non-promotional medical educational meeting did not require prescribing information or certification. AstraZeneca submitted that the meeting content was limited to licensed indications and was examined.

The Panel noted its comments above, that in its view, the meeting at issue could not be seen as anything other than promotional, and considered that certification of the materials was therefore required. The Panel ruled **a breach of Clause 8.1** accordingly.

The Panel considered that as an allegation was raised regarding prescribing information, Clause 12.1 was relevant. The Panel noted that AstraZeneca had not been asked to respond to Clause 12.1 but had nonetheless responded to the substance of the allegation. The Panel therefore considered this matter under Clause 5.1. The Panel, noting its view set out above that the meeting was promotional, considered that prescribing information for Tagrisso and gefitinib was required and that AstraZeneca had therefore failed to maintain high standards; **a breach of Clause 5.1** was ruled.

Allegation 8

The Panel noted the complainant's allegation that the final presentation of the meeting, titled 'Neo-adjuvant & adjuvant treatments pre/post surgical resection' raised unfounded hopes of treatment due to the word 'cure' being used in some of the presentation slides and the citation of Clause 7 in this regard. The Panel queried whether Clause 7 of the 2021 Code which referred to quotations was applicable, and considered that Clause 6.1 of the 2021 Code, which required, among other things, that information, claims and comparisons must not mislead either directly or by implication, was relevant. The Panel also noted that Clause 6.1 of the 2021 Code was the representative clause for Clause 7.2 in the 2019 Code and its general comments at the outset of its ruling (Complaint 1) regarding the use of representative clauses in the 2021 Code. The Panel noted that AstraZeneca had not been asked to respond to Clause 6.1 but had nonetheless

responded to the substance of the allegation. The Panel therefore decided to rule under Clause 6.1 as the appropriate representative clause in the 2021 Code.

The Panel noted that the word 'cure' was used as part of a traffic light system on three slides to describe three potential treatment outcomes: 'Cure' [green], 'Delay Recurrence' [amber] and 'Overtreated' [red]. The slides covered the use of adjuvant EGFR TKIs instead of chemotherapy, the speaker's thoughts on the conclusions of the ADAURA trial, and the speaker's thoughts on neo-adjuvant immunotherapy.

The Panel noted AstraZeneca's submission that the named health professional presented a comprehensive overview of a number of advancements occurring in the neo-adjuvant/adjuvant treatment space, which held significance for thoracic surgeons with various potential treatment outcomes. AstraZeneca submitted that the word 'cure' was used in a balanced context of a potential treatment outcome.

The Panel considered the content of the presentation; the Panel did not have an accompanying transcript of what the named health professional had said during the presentation. The Panel further considered that material should be capable of standing alone in relation to the requirements of the Code.

In the Panel's view companies should be cautious about using the term 'cure', particularly in areas such as oncology, and should satisfy themselves that use of the term that implied a clinical outcome was capable of substantiation and complied with the Code. The Panel considered that disease free survival and overall survival were terms commonly used in oncology and understood by certain audiences.

The Panel noted the layout of the slides at issue. That headed 'Adjuvant EGFR TKIs: Instead of Chemotherapy' featured a prominent red arrow from an outcome, 'No increase in OS [overall survival]' to 'Delay Recurrence', coloured amber. The term 'Cure' appeared in green, above 'Delay Recurrence'. The Panel noted the content of the preceding slides illustrating an increase in the primary endpoint of disease free survival and no increase in the secondary endpoint of overall survival in the IMPACT and ADJUVANT trials. The Panel further noted AstraZeneca's submission regarding the mixed audience of thoracic surgeons and extended multidisciplinary teams and considered that, in its view, content related to disease free survival and overall survival needed to be sufficiently clear for a mixed audience to form its own opinion of the therapeutic value of a medicine. Overall the Panel noted the outcomes featured on the slide in question: 'Delays, but doesn't prevent recurrence', 'No increase in OS', and 'No reduction in CNS metastases'. Whilst the Panel had some concerns about the use of the term 'cure' it considered that the prominent outcomes listed on the slide were, on balance, sufficient to negate an implication that adjuvant EGFR TKIs could cure the condition or that the word 'cure' would raise unfounded hopes of successful treatment as alleged. **No breach of Clause 6.1** was ruled accordingly.

The slide headed 'My Thoughts: ADAURA Conclusions' featured a prominent red arrow from 'CNS activity' to 'Delay Recurrence', coloured amber. The term 'Cure' appeared above 'Delay Recurrence' in a green box. Beneath the list of three clinical outcomes ('Demonstrated a DFS improvement vs placebo', 'CNS activity', and 'Well tolerated safety profile') was a series of 5 prominent questions in amber coloured boxes including the first question 'Will DFS benefit translate to OS benefit?'. The Panel was concerned about the use of the word 'cure' in the context of a slide that queried whether disease free survival would translate to overall survival

benefit. The Panel did not have a copy of the ADAURA trial but noted the positive DFS data and the percentage of patients with disease recurrence (osimertinib 11% versus placebo 46%) on the preceding slides. The Panel considered that it was important to be clear about such matters particularly when the audience included individuals who were not physicians experienced in the use of anticancer therapies. The Panel noted that the prominent red arrow to which the audience's eye would be drawn pointed to 'Delay Recurrence' rather than 'Cure'. However, and on balance, the Panel considered that the slide at issue, bearing in mind the preceding slides, created a potentially misleading implication that disease free survival benefit might lead to a cure. The term 'cure' was not qualified or otherwise explained and given the multi-disciplinary nature of the audience and its comments above the Panel ruled **a breach of Clause 6.1** accordingly.

In relation to the slide headed 'My Thoughts: (Neo) Adjuvant Immunotherapy', beneath the sub heading Adjuvant Atezolizumab, a prominent red arrow led from the first of three statements 'Are you a DFS believer?' to 'Cure' and beneath a sub heading 'Neo-Adjuvant Chemo-Immunotherapy' a red arrow led from 'Clear pathological beneficial; Not detrimental to surgery' to 'Cure'. The term 'Cure' appeared in a green box. Whilst atezolizumab was not an AstraZeneca product the Panel noted that references to it in an AstraZeneca presentation nonetheless had to comply with relevant requirements in the Code, particularly certain overarching requirements. The Panel noted that the preceding slides compared, among other things, disease free survival of atezolizumab vs best supportive care, noting a difference in favour of atezolizumab (p=0.004). In the Panel's view and on balance, the immediate and unqualified implication of the word 'cure' to which the prominent red arrows pointed in the slide in question, to some delegates, was that a cure might be a real possibility. The Panel noted its comments about the multi-disciplinary nature of the audience above. Whilst the Panel did not have a copy of the study in question from the data in the slides it appeared that the impression was unfounded as alleged and misleading in this regard. The Panel ruled **a breach of Clause 6.1** of the Code.

The Panel was concerned about the failure to classify the meeting as promotional and considered that high standards had not be maintained in this regard. Further the Panel noted that Clause 6.1 applied irrespective of whether the material was promotional or non-promotional, and in addition was concerned about the use of the word 'cure' and noted its rulings of breaches of the Code in that regard. **A breach of Clause 5.1** was ruled.

The Panel was concerned about its comments and rulings of breaches of the Code above, but on balance, considered that these were adequate censure, and did not consider that the circumstances of this case warranted a ruling of a breach of Clause 2 which was a sign of particular censure and was reserved for such use. The Panel, on balance, ruled **no breach of Clause 2**.

The Panel noted that AstraZeneca had in addition referred to Clauses 4 and 9.1 in its response. It did not appear to the Panel that the complaint raised such matters nor that AstraZeneca had been asked to respond to these clauses. This also applied to AstraZeneca's overall reference to Clause 3 (separate and distinct from Clause 3.1). The Panel therefore made no rulings on these matters.

COMPLAINT 2 – Promotion of Tagrisso and acalabrutinib to the public

COMPLAINT

The complainant provided two examples of alleged promotion to the public by a senior UK [named medical employee]. They alleged that these examples were promotion of Tagrisso and acalabrutinib to the public, more specifically on LinkedIn.

The complainant asked that the Panel consider a breach of the following Clauses:

- 'Clause 2
- Clause 26.1 – Promotion to the public
- Clause 3.6 – Disguised Promotion
- Clause 5.1 – High Standards
- Clause 8 – a failure to certify'

When writing to AstraZeneca regarding the promotion of Tagrisso and acalabrutinib to the public by an AstraZeneca Senior Leader, the PMCPA asked it to consider the requirements of Clauses 5.1, 2, 3.6, 8, 8.1 and 26.1 of the 2021 Code, as cited by the complainant.

ASTRAZENECA'S RESPONSE

AstraZeneca stated that in the second complaint, the complainant alleged that a senior UK [named medical employee] had promoted osimertinib (Tagrisso) and acalabrutinib to the public through the LinkedIn platform during 2021.

The [named senior UK medical employee] in question was [description of the employee's previous experience] who joined AstraZeneca in June 2021. Their post around acalabrutinib entitled 'Real-world Evidence Generation with Bruton's tyrosine kinase inhibitors (BTKis)', was published on 14 March 2021. This post on LinkedIn was published almost 2 years ago and was made prior to their employment with AstraZeneca.

The second post in question was done at the time that osimertinib (Tagrisso) had obtained marketing authorisation by the MHRA, as an adjuvant post-surgical treatment for EGFR-mutated early-stage non-small cell lung cancer patients. AstraZeneca noted that the post in question had tagged an article published by [named oncology news website] entitled 'UK's MHRA grants Early Access to AstraZeneca's Tagrisso as Adjuvant NSCLC treatment', published on 7 May 2021. AstraZeneca submitted that its internal investigation also revealed that the post in question was made on 8 May 2021, which also pre-dated the [named senior UK medical employee's] employment with AstraZeneca.

AstraZeneca submitted that it had strict social media policy guidelines in place and regularly updated its employees of these guidelines. AstraZeneca submitted that its investigation had revealed that the two LinkedIn posts made by a Senior UK [named medical employee] were in fact made prior to their employment with AstraZeneca, therefore AstraZeneca could not be held responsible for their actions prior to them joining the organisation. AstraZeneca therefore denied breach of Clauses 2, 3, 3.6, 4, 5.1, 8, 8.1, 26.1 and 26.2.

PANEL RULING

The Panel noted that AstraZeneca was asked to respond to clauses from the 2021 Code, as cited by the complainant. As the posts at issue were made prior to the 2021 Code coming into effect, the Panel decided to make its rulings under the representative clauses in the 2019 Code.

The Panel noted the complainant's allegation that a Senior UK [named medical employee] promoted Tagrisso and acalabrutinib to the public on LinkedIn. The complainant provided copies of two specific posts published on LinkedIn:

- The first post, published on 14 March 2021, regarding acalabrutinib, was titled 'Real-world Evidence Generation with Bruton's tyrosine kinase inhibitors (BTKis)'

- The second post, published on 8 May 2021, stated 'AstraZeneca's Tagrisso approved in the UK for #lungcancer treatment – an [sic] welcoming news for the #cancerpatients and their families. However, evidence generation (#realworlddata) to establish the benefits of early initiation of such therapies, or as first line therapy is of paramount importance' and referred to collaboration between stakeholders to generate real world evidence. The post at issue tagged an article published by [named oncology news website] titled 'UK's MHRA Grants Early Access to AstraZeneca's Tagrisso as Adjuvant NSCLC treatment…'

The Panel noted AstraZeneca's submission that both posts were published before the [named senior UK medical employee's] employment with AstraZeneca UK, which commenced in June 2021.

The Panel noted that the posts at issue were made before the [named senior UK medical employee] became employed at AstraZeneca, however the Panel did not know whether the posts remained live after the employee joined the company and in particular noted with concern the proximity of the posts in question to the date that the [named senior UK medical employee] started at AstraZeneca. Nonetheless, given that the posts at issue were made before the [named senior UK medical employee] commenced employment with AstraZeneca, the Panel considered that the company was, in the particular circumstances of this case, not responsible for the activity in question. The Panel accordingly ruled **no breach of Clauses 12.1, 14.1, 26.1, 9.1 and 2** of the 2019 Code as alleged.

The Panel noted that AstraZeneca had in addition referred to Clauses 4 and 26.2 of the 2021 Code. It did not appear to the Panel that the complaint raised such matters nor that AstraZeneca had been asked to respond to these clauses. This also applied to AstraZeneca's overall reference to Clause 3 (separate and distinct from Clause 3.6). The Panel made no ruling on these matters.

COMPLAINT 3 – Promotion of capivasertib on LinkedIn

COMPLAINT

The complainant stated that they provided two separate examples of alleged direct promotion to the public by AstraZeneca Senior Executives.

The complainant alleged that the behaviour and attitude towards compliance was quite insulting, and despite their best efforts, it seemed that at every major congress, the same behaviour was

repeated. The complainant stated that they had only shared two of a possible half a dozen examples on LinkedIn.

The complainant stated that as a 'senior compliance leader in global', they were part of a dedicated team that had tried very hard to change this behaviour, but to no avail.

The complainant alleged that, with capivasertib being off license, they felt that these two separate cases, one involving 'likes' by [first named employee], and [second named employee], and the other involving reposting of a separate [named research institute] post, were both separate cases for the following clauses:

- 'Clause 2
- Promotion prior to a marketing authorisation
- Promotion to the Public as LinkedIn was a professional platform for people from all works [sic] of life.
- Failing to maintain high standards'

The complainant alleged that there were several other examples on LinkedIn, and they believed this constituted a lack of care or regard, for the Code by UK-based employees.

When writing to AstraZeneca regarding the promotion of capivasertib on LinkedIn, the PMCPA asked it to consider the requirements of Clauses 2, 3.1, 5.1, 26.1 and 26.2 of the 2021 Code.

ASTRAZENECA'S RESPONSE

AstraZeneca stated that the complaint raised was that UK-based members of AstraZeneca had 'liked' or 'reposted' a LinkedIn post by [named research institute], thus promoting the content of the post to the public. The LinkedIn post at hand was published independently of AstraZeneca by [named research institute] which was an independent public research institute based in the UK. The content of the post was based on the latest research findings presented at the San Antonio Breast Cancer Symposium.

AstraZeneca submitted that the LinkedIn post was not posted on any AstraZeneca owned social media corporate channels nor did AstraZeneca instruct, or encourage any UK-based employees to engage or interact with this independent post by [named research institute]. The identified AstraZeneca UK-based employees acted on their own volition to engage/interact with the post by 'liking' and reposting the LinkedIn post. The AstraZeneca UK-based employees did not make any statements or comments related to this post. Inside one business day of receipt of the complaint from the PMCPA, the identified AstraZeneca UK-based employees were asked to withdraw their 'like' and 'repost'. All identified AstraZeneca UK-based employees complied and actioned this request immediately.

AstraZeneca stated that it would like to assure the Panel that it regularly trained and reminded all UK-based (global and UKMC) employees about social media use in relation to work-related content covered by AstraZeneca Global Standard SOP on Social Media Usage version 3.0. As a global organisation, AstraZeneca strove to do the right thing, to regularly engage with its employees and to educate and train them on all aspects of external communication, including social media. AstraZeneca strongly denied bringing the pharmaceutical industry into disrepute because of the actions of a limited number of AstraZeneca UK-based employees who had 'liked' or 'reposted' a single LinkedIn post originated by an independent research organisation with no

instruction/encouragement from AstraZeneca for them to do so. Furthermore, AstraZeneca took the immediate action to rectify and withdraw the 'like' or 'repost' by its employees once the company was notified of this complaint, which they actioned immediately and AstraZeneca therefore denied breach of Clauses 2, 3, 3.1, 4, 5.1, 26.1 and 26.2.

PANEL RULING

The Panel noted that the complainant alleged direct promotion of capivasertib to the public by UK-based AstraZeneca Senior Executives by liking/reposting two separate iterations of a post made by [named research institute].

The Panel noted that first post at issue, which was 'liked' by two AstraZeneca employees, stated, among other things, that capivasertib combined with hormone therapy had shown remarkable benefits for patients with advanced breast cancer in a major phase III clinical trial. The post went on to briefly state positive study results, followed by statements including that the study was sponsored and funded by AstraZeneca. The post then directed its audience to a link to find out more about the trial and the [named research institute]'s involvement in the discovery of capivasertib.

The Panel noted that the second post at issue, which was reposted by an AstraZeneca employee, stated 'NEWS: the new targeted drug, capivasertib combined with hormone therapy has shown 'remarkable' benefits for patients with advanced breast cancer in a …see more', followed by a still image from what appeared to be an embedded video of a named professor from the [named research institute]. An incomplete subtitle at the bottom of this image stated 'Capivasertib is going to be a drug for women who've got secondary breast'.

The Panel noted AstraZeneca's submission that the LinkedIn post was published independently of AstraZeneca by [named research institute] which was an independent public research institute based in the UK and the content of the post was based on the latest research findings. AstraZeneca further submitted that the post was not on any company owned social media corporate channels nor did the company instruct or engage any UK-based employees to engage or interact with this independent post by [named research institute].

The Panel considered that the two original iterations of the post at issue, made by an independent public research institute, independently of AstraZeneca, were not in scope of the Code. In the Panel's view, the 'likes' by two UK-based AstraZeneca employees, and re-post by one employee, brought each iteration within scope.

Noting the content of each iteration of the LinkedIn post as described above, including the name of the product and positive outcomes in relation to the treatment of advanced breast cancer, the reference to 'remarkable' benefits, and a link to find out more about the trial, the Panel considered that in disseminating the post by 'liking' and re-posting the post at issue, AstraZeneca employees had promoted capivasertib prior to the grant of its marketing authorisation. **A breach of Clause 3.1** was ruled accordingly.

The Panel considered that 'liking' and 're-posting' the post would, on the balance of probabilities, have disseminated the post to the employees' followers, which might have included health professionals and members of the public. In the Panel's view, high standards had not been maintained and **a breach of Clause 5.1** was ruled.

The Panel noted that Clause 26.1 prohibited the promotion of prescription only medicines once a marketing authorisation had been granted, and Clause 26.2 stated, among other things, that information about prescription only medicines which is made available to the public must not raise unfounded hopes of successful treatment. On the narrow technical point that capivasertib did not have a UK marketing authorisation and therefore was not a prescription only medicine at the time of the post at issue, the Panel ruled **no breach of Clause 26.1.** Whilst AstraZeneca had been asked to respond to Clause 26.2, and noting that Clause 26.2 applied only to prescription only medicines, the Panel in addition considered that the complainant had not made an allegation about Clause 26.2, and made no ruling in that regard.

The Panel considered that a breach of Clause 2 was a sign of particular censure and reserved for such use.

The Panel noted that the AstraZeneca Global Standard - Employee use of personal social media channels for AstraZeneca and work-related content SOP, which was applicable to all global employees, stated in bold under the heading 'Sharing AstraZeneca-related content on your personal channels from 3rd party sources': 'You are not permitted to engage with (liking, sharing, commenting on) content that is product-related or is about disease education/awareness topics from 3rd party sources. This is because there has been no internal check to verify the information in the post is accurate (we have a special responsibility as a life sciences company to be accurate) and that the content does not amount to product promotion'.

In that regard, it appeared to the Panel that the three UK-based employees had breached the company's global standard policy.

The Panel noted that two of the three UK-based employees had very senior global job titles, including a [global job title] and a [global job title]. The job title of the third employee was unknown. The Panel considered that it appeared that two very senior employees had acted contrary to company policy and had failed to note the promotional nature of the post such that by 'liking' the post in question they had promoted capivasertib prior to the grant of its marketing authorisation, including a reference to its 'remarkable benefits', to their LinkedIn connections which would, on the balance of probabilities, be a predominantly UK audience, including health professionals and members of the public.

The Panel noted that a previous case AUTH/3707/11/22 in relation to a LinkedIn post made by a senior AstraZeneca employee working for the US affiliate, about a new lung cancer treatment combination, which was 'liked' by 14 UK-based employees, was found to be in breach of the Code for, among other things, promotion to the public. In that case, the Panel noted the job titles of twelve of the UK-based employees and was concerned that they all appeared to be senior employees. However, following a successful appeal of the Panel's ruling of a breach of Clause 2 the Appeal Board ruling was silent on the issue of the relevance of the seniority of the AstraZeneca UK employees in relation to the Clause 2 matter.

The Panel noted that it had been long-established in case precedent that seniority was a relevant factor in deciding whether such activity amounted to a breach of Clause 2. The impression given by very senior staff was important. The Panel further noted with concern that the engagement of UK-based AstraZeneca employees with social media posts, in breach of company policy and the Code, did not appear to be an isolated occurrence.

The Panel further noted that in addition the Supplementary Information to Clause 2 referred to promotion prior to the grant of a marketing authorisation as an example of an activity likely to be in breach of that clause. Taking all the circumstances into account, including the seniority of the AstraZeneca employees, two of whom apparently had global roles, the impression created by very senior staff acting contrary to the company's global social media policy, the supplementary information to Clause 2 and in addition that the iterations of the original post at issue contained the strong phrase 'remarkable benefits' the Panel considered that, on balance, AstraZeneca had brought discredit upon and reduced confidence in the pharmaceutical industry. **A breach of Clause 2** was ruled.

The Panel noted that AstraZeneca had in addition referred to Clause 4 in its response. It did not appear to the Panel that the complaint raised such matters nor that AstraZeneca had been asked to respond to this clause. This also applied to AstraZeneca's overall reference to Clause 3 (separate and distinct from Clause 3.1). The Panel made no ruling on these matters.

COMPLAINT 4 – Promotion of Tagrisso on LinkedIn

COMPLAINT

The complainant stated that they were a former AstraZeneca employee and wanted to expose the "complete lack of regard for basic compliance" at AstraZeneca, in the [named therapy area] team based in the UK and Global.

The complainant provided screenshots of a global medic posting updated efficacy results for Tagrisso on LinkedIn and a member of the AstraZeneca UK sales force 'liking' it.

The complainant alleged that despite their best efforts to raise compliance issues with [named global team], around posting to the public, certifying travel for UK HCP attendance at global meetings abroad, they were bullied and harassed into silence both by their line manager and the wider commercial organisation in the UK.

The complainant alleged that in their view the number of AstraZeneca LinkedIn posts with 'likes' and 'shares' not only warranted a Clause 2, but an audit into AstraZeneca.

The complainant alleged that in this example, Clause 2, and clauses around a failure to meeting high standards, and promotion to the public were a minimum.

When writing to AstraZeneca regarding the promotion of Tagrisso on LinkedIn, the PMCPA asked it to consider the requirements of Clauses 2, 5.1 and 26.1 of the 2021 Code.

ASTRAZENECA'S RESPONSE

AstraZeneca stated that this fourth complaint centred around a LinkedIn post made by a former Global AstraZeneca employee who was US-based who had shared an academic article independently published by [named medical journal], which was in turn, inadvertently 'liked' by a single UK-based AstraZeneca employee.

AstraZeneca submitted that the LinkedIn post was not posted on any AstraZeneca owned social media corporate channels nor did AstraZeneca instruct, or encourage any UK-based employees to engage or interact with this post. The identified AstraZeneca UK-based employee acted on

their own volition to ‘like’ the post. The AstraZeneca UK-based employee did not make any statements or comments related to this post. Inside one business day of receipt of the complaint from the PMCPA, the one AstraZeneca UK-based employee identified was asked to withdraw their ‘like’ immediately, which was actioned promptly.

AstraZeneca stated that it would like to assure the Panel that it regularly trained and reminded all UK-based (global and UKMC) employees about social media use in relation to work-related content covered by the AstraZeneca Global Standard SOP on Social Media Usage version 3.0. As a global organisation, AstraZeneca strove to do the right thing, to regularly engage with its employees and to educate and train them on all aspects of external communication, including social media. AstraZeneca stated that it was also planning to conduct a dedicated training session soon to ensure that the expectations laid out in the newly published PMCPA Social Media Guidance were well understood and applied within the organisation.

AstraZeneca submitted that it did not believe that it had brought the pharmaceutical industry into disrepute because the UK-based employee had ‘liked’ a post originated by a former US-based AstraZeneca employee, with no instruction or encouragement from AstraZeneca for them to do so. Furthermore, the ‘like’ was withdrawn immediately once AstraZeneca was notified of this complaint and it therefore denied a breach of Clauses 2, 3, 4, 5.1, 9.1 and 26.1.

PANEL RULING

The Panel noted the complainant’s allegation that a post made on LinkedIn by a global US based employee and ‘liked’ by a UK employee, promoted Tagrisso (osimertinib) to the public.

The Panel noted that the screenshot of the post at issue, provided by the complainant, displayed the name and job title of the AstraZeneca global employee, beneath which was a graph illustrating the probability of overall survival following treatment with osimertinib versus a Comparator. The title of the [named medical journal] article that was shared within the post appeared below the graph and stated ‘Overall Survival with Osimertinib in Untreated, EGFR-Mutated Advanced NSCLC | [named medical journal]’.

The Panel considered AstraZeneca’s submission that a former Global AstraZeneca employee who was US-based had shared on LinkedIn an academic article independently published by [named medical journal], which was in turn, inadvertently ‘liked’ by a single UK-based AstraZeneca employee. The LinkedIn post was not posted on any AstraZeneca owned social media corporate channels nor did AstraZeneca instruct or encourage any UK-based employees to engage or interact with this post.

The Panel did not have any information about when the global employee ceased their employment with AstraZeneca; AstraZeneca did not make an explicit submission in this regard, although given the nature of the complaint and AstraZeneca’s description of the employee as an ex-employee there was an implication on the part of AstraZeneca that the employee in question had left its employment at the relevant time. It was unclear to the Panel if the employee in question was employed at the time of the post. The Panel noted that the screenshot provided by the complainant stated ‘3w’ beneath the name and job title of the global employee who had made the post, indicating that the sharing of the article might have been done 3 weeks prior to when the screenshot provided by the complainant was taken. The Panel noted that the complainant bore the burden of proof. However the Panel further noted that on the screenshot

provided by the complainant the global employee's job title indicated that they were at that point an AstraZeneca employee. The position was unclear.

The Panel considered, in general terms, that whether the activities of global employees came within the scope of the UK Code, would be decided on a case-by-case basis bearing in mind, amongst other things, the UK nexus and, if relevant, the requirements of Clause 1.2. The Panel, noting that the complainant bore the burden of proof, and noting the above, considered that the complainant had not established, on the balance of probabilities, whether AstraZeneca was responsible for the post. The content of the post as provided by the complainant did not appear to have a UK nexus. The Panel did not have a copy of the linked article.

The Panel considered however that it was the interaction with the post by a UK-based employee that brought it within the scope of the Code, and it was well established that 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 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. The Panel noted that the proactive dissemination of material, which directly or indirectly referred to a particular medicine on social media, was likely to be considered promotion of that medicine.

The Panel considered, noting the content of the post at issue, and, on the balance of probabilities, its proactive dissemination to the UK-based AstraZeneca employee's connections as a result of them engaging with it, constituted promotion of Tagrisso.

The Panel considered that, on the balance of probabilities, not all of the employees' connections on LinkedIn would meet the Code's definition of a health professional or other relevant decision maker. It therefore followed that by 'liking' the promotional LinkedIn post it had likely been proactively disseminated to members of the public and constituted promotion of Tagrisso, a prescription only medicine, to the public, and **a breach of Clause 26.1** was ruled.

The Panel noted its comments and ruling above and considered the dissemination to the UK employee's followers was such that high standards had not been maintained and **a breach of Clause 5.1** was ruled.

The Panel considered that promotion to the public was an important matter; whether it amounted to a breach of Clause 2, however, was considered on a case-by-case basis. The Panel noted that the UK-based employee was not a senior employee. The Panel considered that Clause 2 was a sign of particular censure and should be reserved for such use; in the particular circumstances of this case, the Panel considered that a ruling of a breach of Clause 2 was not warranted. The matter was adequately covered by its ruling of a breach of Clause 5.1 above. The Panel accordingly ruled **no breach of Clause 2**.

The Panel noted that AstraZeneca had in addition referred to Clauses 3, 4 and 9.1. It did not appear to the Panel that the complaint raised such matters nor that AstraZeneca had been asked to respond to these clauses and the Panel made no ruling on these matters.

COMPLAINT 5 – Medical Science Liaisons [MSLs] and the promotion of Imfinzi

COMPLAINT

The complainant alleged that [named senior oncology employee] would make non-compliant suggestions to MSLs (including the complainant and [named MSL]). The complainant stated that Imfinzi was licensed and reimbursed in unresectable Stage 3 NSCLC, whereas [named senior oncology employee] would suggest that even patients that were deemed resectable i.e. the cancer could be operated on (patients fit for surgery) should receive Imfinzi. This was still an unlicensed indication and was covered by the AEGEAN trial. [Named senior oncology employee] wanted the MSLs to promote off license and many of them would just dial out of these Quarterly Account Review meetings. The complainant provided a copy of a message, which allegedly showed how [named sales representative] for [a named region] wanted to include MSL activity in their Local Business Plan. The complainant stated that they warned them on the Teams chat on one occasion that they could verbalise this but that they should not include MSL activity, and their influence over it in their local plan. The complainant alleged that [a senior commercial employee] would pressurise [named senior oncology employee] to increase the number of new patient starts on Imfinzi, no matter how, even if it meant promoting off license. They would argue chemoradiotherapy and Imfinzi should mean no need for surgery in these patients. The complainant alleged that this was clinically dangerous and non-compliant. The complainant stated that having left the organisation, they had limited access to the Quarterly Review minutes/action plans but provided two attached messages which, they alleged, were typical non-compliant behaviours that [named senior oncology employee] would promote, condoned by [named senior medical employee], who would shrug their shoulders when the MSLs sought their support, and alleged that the [second named senior medical employee] did not understand compliance at all. The complainant alleged that the Regional Business Managers would also encourage the MSLs to be more proactive, effectively speak to surgeons and promote the Imfinzi data, even though they were non prescribers.

The complainant provided further information, an email from [named senior oncology employee], containing the purpose of the Key Account Reviews (sales meetings), where, the complainant alleged, MSLs would be forced to attend and provide an update on their interactions/details of discussions and be directed or dictated to by the [named therapy area] commercial leaders.

When writing to AstraZeneca regarding the promotion of Imfinzi for an unlicensed indication during quarterly account review meetings, the PMCPA asked it to consider the requirements of Clauses 5.1, 17.2 and 17.9 of the 2021 Code.

ASTRAZENECA'S RESPONSE

AstraZeneca stated that in this fifth complaint, the allegations raised were that:

(1) At quarterly account review meetings (sales meetings) MSLs were forced to attend and update on their interactions/details of discussions and directed or dictated to by the [named therapy area] commercial leaders.
(2) [Senior oncology employee] made non-compliant suggestions to MSLs. Imfinzi was licensed in unresectable Stage Non Small Cell Lung Cancer (NSCLC), [senior oncology employee] would suggest resectable patients i.e., the cancer could be operated on (patients

fit for surgery) should receive Imfinzi. Unlicensed indication was covered by the AEGEAN trial. The [senior oncology employee] wanted the MSLs to promote off license.

(3) Sales wanted to include MSL activity in local business plan. [Senior commercial employee] would pressure [senior oncology employee] to increase the number of new patient starts on Imfinzi even if off-license. The [senior oncology employee] would argue that with chemoradiotherapy & Imfinzi there was no need for surgery in these patients. This was clinically dangerous & non-compliant.
(4) Non-compliant behaviours by [senior oncology employee] condoned by the [senior medical employee], and that the [second senior medical employee] did not understand compliance at all.
(5) The [managers] encouraged MSLs to be more proactive, to speak to surgeons and promote the Imfinzi data, even though they were non-prescribers.

Background information relating to Imfinzi (durvalumab) 50 mg/mL concentrate for solution for Infusion.

AstraZeneca stated that monotherapy was indicated for the treatment of locally advanced, unresectable non-small cell lung cancer (NSCLC) in adults whose tumours express PD-L1 on ≥ 1% of tumour cells and whose disease had not progressed following platinum-based chemoradiation therapy. In combination with etoposide and either carboplatin or cisplatin was indicated for the first-line treatment of adults with extensive-stage small cell lung cancer (ES-SCLC). In combination with gemcitabine and cisplatin was indicated for the first line treatment of adults with locally advanced, unresectable, or metastatic biliary tract cancer (BTC).

Response to complainant's allegations

Allegation 1
<u>At quarterly account review meetings (sales meeting) MSLs were forced to attend and update on their interactions/details of discussions and directed or dictated to by the [named therapy area] commercial leaders</u>

AstraZeneca submitted that the quarterly account review meetings were cross-functional team alignment meetings and they were not sales meetings. Discussions were limited to ongoing business to help the cross-functional team work together. There were no off-label or pre-launch discussions during these meetings. Attendance at these quarterly account review meetings was by Medical (if applicable to the discussion), Sales, Marketing and Diagnostics. The quarterly account review meetings were held for the cross-functional teams to share appropriate insights about patient care provision/pathway in accounts and limited to licensed and approved medicines. There were three regions and quarterly account review meetings took place in each region. A quarterly account review meeting would focus on Tagrisso brand and while another quarterly account review meeting would focus on Imfinzi brand. The [medical employee] and MSL Lead in [named therapy area] encouraged and championed Medical team involvement in the cross-functional quarterly account review meetings as part of cross-functional collaborative working. MSLs were not compelled or forced to attend any of these quarterly account review meetings.

AstraZeneca submitted that the Medical team contributed appropriate insights during the meeting to help AstraZeneca personalise its approach in a customer account and environment. Insights provided by Medical might include updates on early identification, diagnosis, treatment pathway optimisation not specific to a particular medicine, whether there was early stage

multidisciplinary team (MDT) in place, the place of molecular testing, the decision to treat before or after surgery, if there was proper molecular work-up to understand whether patients were being treated appropriately in terms of patient pathway optimisation. The [medical employee] and MSL lead would also share what their key priorities were as part of cross-functional/collaborative working. There was no requirement or expectation for Medical or MSLs to discuss interactions with individual customers whether on or off-label.

Allegation 2
[Senior oncology employee] made non-compliant suggestions to MSLs. Imfinzi was licensed in unresectable Stage 3 Non Small Cell Lung Cancer (NSCLC), [senior oncology employee] would suggest resectable patients i.e., the cancer could be operated on (patients fit for surgery) should receive Imfinzi. Unlicensed indication was covered by the AEGEAN trial. The [senior oncology employee] wanted the MSLs to promote off license.

AstraZeneca submitted that Imfinzi was only licensed and promoted in unresectable stage 3 NSCLC. AstraZeneca's investigations had not revealed any evidence to suggest the [senior oncology employee] made any non-compliant suggestions to MSLs or that they encouraged or suggested Imfinzi use in resectable lung cancer. AstraZeneca's investigations had not revealed any evidence that the [senior oncology employee] wanted MSLs to promote off license.

AstraZeneca stated that its investigations had also not revealed any evidence of compliance concerns or issues being raised by MSLs about non-compliant suggestions by [senior oncology employee] either via MSL leads/manager, Medical Lead, via the quarterly account review meetings or AstraZeneca's internal compliance reporting routes.

Allegation 3
Sales wanted to include MSL activity in local business plan. [Senior commercial employee] would pressure [senior oncology employee] to increase the number of new patients starts on Imfinzi even if off-license. The [senior oncology employee] would argue that with chemoradiotherapy & Imfinzi there was no need for surgery in these patients. This was clinically dangerous & non-compliant.

AstraZeneca stated that its account plans included local business plans and were living documents updated before and after quarterly account review meetings and they also acted as debrief of the meetings. Medical did not have access to this document and there were no directions given to Medical including MSLs. Medical (including MSLs or any MSL activity) were not captured in local business plans or included in general discussions. AstraZeneca internal policy was clear that marketing/commercial and medical could not direct each other's work/activities but may work together as part of a cross-functional team. AstraZeneca's investigations had not revealed any evidence to suggest the [senior oncology employee] encouraged, directed, or instructed MSLs to proactively discuss or promote Imfinzi outside of its licensed indication. Any discussions about chemoradiotherapy and Imfinzi were limited to understanding care provision and patient pathway optimisation in an account.

AstraZeneca stated that its investigations had revealed that at the Q2 2022 quarterly review meeting in May 2022, there was discussion about possible reasons as to why there had been a decline in the number of patients on Imfinzi at a named hospital. There had not been any new challenges to the patient pathway identified and the oncology consultant and nurse team had remained constant. One discussion point was that there could be patients that were eligible to start on Imfinzi but were being enrolled onto clinical trials. The ongoing clinical trial sites in

[named therapy area] were in the public domain with the estimated number of patients that the trial was looking to recruit. No specific trials were discussed during the meeting. During this meeting, an MSL volunteered to look online to get an idea of the numbers of stage III unresectable NSCLC patients (if any) that were being recruited nationally/regionally. This would have been part of insight sharing only and would not have changed the account plan in any way. AstraZeneca's investigations also revealed that following the Q2 2022 quarterly account review meeting in May 2022, the sales [employee] sent an email with a summary and agreed actions from the meeting which included an action for Medical in error. This was the first and only time that an agreed action from Medical was captured in the notes and account plan. At a later time on the same day, the MSL who volunteered to provide ongoing clinical trial insight sent the sales [employee] a Teams message to advise that their name should be removed from the notes and account plan. The sales [employee] agreed and immediately removed the MSL's name from the notes and live account plan in Teams. The standard practice of capturing actions from the meeting did not permit directions to Medical/MSLs in account plan however, investigation revealed this one isolated incident where this had been done in error by the sales lead, which was immediately rectified.

Allegation 4
Non-compliant behaviours by [senior oncology employee] condoned by the [senior medical employee], and that the [second senior medical employee] did not understand compliance at all.

AstraZeneca stated that its investigations had not revealed evidence of any compliance concerns or issues being raised about the conduct or behaviour of the [senior oncology employee] either via MSL leads/manager, Medical Leads, via the quarterly account review meetings or AstraZeneca's compliance reporting routes. There was therefore no condonement of any non-compliant behaviour by the [senior oncology employee] by the [senior medical employee]. AstraZeneca strongly refuted the suggestion that the [senior medical employee] 'did not understand compliance at all'.

Allegation 5
The [managers] encouraged MSLs to be more proactive, to speak to surgeons and promote the Imfinzi data, even though they were non-prescribers.

AstraZeneca submitted that its investigations had not revealed any evidence to suggest Regional Business Managers encouraged, instructed, or directed MSLs to proactively speak to surgeons to promote Imfinzi data. MSLs did not promote medicines, nor did they have any goals or incentives aligned to the sale of medicines.

Summary in relation to complaint 5

For this complaint 5, AstraZeneca submitted that its investigations had revealed that quarterly account review meetings were cross-functional team meetings with attendance from sales, marketing, diagnostic and medical (if appropriate to discussions) to share appropriate insight about patient care provision/pathway in accounts and that discussions were limited to licensed and approved medicines. The quarterly account review meetings helped AstraZeneca to personalise the company's approach in a customer account and environment. MSLs were not directed or dictated to in any way by the [named therapy area] commercial leaders. There was no evidence to suggest the [senior oncology employee] made non-compliant suggestions to MSLs or directed or instructed MSLs to promote off license. MSL roles were non-promotional, and they did not promote medicines, nor did they have any goals or incentives aligned to sales

of medicines. The Medical team was not included in account plans with the exception of one incident where an action for Medical was captured in error by the sales lead in an account plan following the account review meeting in Q2 2022. This error was immediately rectified. Discussions on chemoradiotherapy and Imfinzi were limited to understanding care provision and patient pathway optimisation in an account. Therefore, AstraZeneca refuted all the allegations in complaint 5 and denied a breach of Clauses 5.1, 17.2 and 17.9.

PANEL RULING

The Panel noted that the complainant made several allegations about the pressures that MSLs felt to promote Imfinzi for an unlicensed indication during quarterly account review meetings. The complainant provided a copy of a message which they alleged showed a Sales Representative wanting to include MSL activity in their local business plan. The complainant further alleged that the [senior commercial employee] would pressure [named senior oncology employee] to increase the number of new patient starts on Imfinzi including off license. The complainant alleged that the Regional Business Managers would also encourage MSLs to be more proactive by effectively speaking to surgeons and promoting Imfinzi data, even though they were non-prescribers.

The complainant provided material, namely an email from [named senior oncology employee], which referred to the purpose of the sales meetings. The complainant alleged that MSLs would be forced to attend and provide an update on their interactions/details of discussions and be directed by the [named therapy area] commercial leaders.

The Panel noted that AstraZeneca had identified five distinct allegations to which it responded separately. The Panel noted the common themes across the allegations and decided it was more appropriate to consider the allegations as set out below.

The Panel noted AstraZeneca's submission, that the quarterly account review meetings were cross-functional alignment meetings, and they were not sales meetings. The meetings were held for the cross-functional teams to share appropriate insights about patient case provision/pathway in accounts and limited to licensed and approved medicines. AstraZeneca submitted that the medical team contributed appropriate insights during the meeting to help the company personalise its approach in a customer account and environment. It further submitted that there was no requirement or expectation for MSLs to discuss interactions with individual customers.

The Panel noted AstraZeneca's submission that MSL roles were non-promotional, and they did not promote medicines, nor did they have any goals or incentives aligned to sales of medicines. The Panel did not have a copy of their contract and standard objectives or similar. AstraZeneca further submitted that internal investigations revealed that the Medical Team was not included in account plans with the exception of one incident where an action for Medical was captured in error by the sales lead in an account plan following the account review meeting in Q2 2022. This error was immediately rectified. Discussions on chemoradiotherapy and Imfinzi were limited to understanding care provision and patient pathway optimisation in an account.

The Panel noted that AstraZeneca was asked to respond to Clause 17.2, which stated, among other things, that representatives must maintain a high standard of ethical conduct, and Clause 17.9 which stated, among other things, that representatives' briefing material must comply with the relevant requirements of the Code.

The Panel noted AstraZeneca's submission above that the MSL roles were non-promotional. The Panel considered that Clauses 17.2 and 17.9 would only apply if the role of the MSLs was promotional. Insofar as the complainant was alleging that the subject matter of the complaint rendered the MSLs promotional, the Panel did not consider that the complainant had established, on the balance of probabilities, that either such matters occurred, or that they rendered the MSLs' role promotional. The Panel, noting AstraZeneca's comment about the removal of an MSL's name from a live account plan, whilst of concern, given its immediate removal, did not consider that this rendered the role promotional. The MSLs' role appeared to be limited to insight sharing. The Panel therefore noting that the complainant bore the burden of proof ruled **no breach of Clauses 17.2 and 17.9**.

The Panel noted that the complainant bore the burden of proving their complaint, on the balance of probabilities. The Panel considered that the complainant had not provided enough information with regard to the allegations, and had not discharged their burden of proving the allegations to show that a breach of the Code had occurred. Therefore, the Panel ruled **no breach of Clause 5.1** in this regard.

COMPLAINT 6 – Encouraging Medical teams to promote the OlympiA EAP [Early Access Programme]

COMPLAINT

The complainant referred to a number of Early Access Programs that AstraZeneca UK [named therapy area team] was undertaking, all under the disguise of providing access to life changing medicines, but alleged that they were actual seeding programmes with commercial franchise heads, including the [senior commercial employee] providing regular updates, and pushing the medical teams to ensure proactive uptake by health professionals.

The complainant alleged that the communication from the [senior commercial employee] was clear that the patients in the OlympiA EAP were to be 'leveraged at reimbursement and launch' i.e. they already expected each patient to be converted onto commercial stock. The complainant further alleged that some of the colleagues included in the post, such as [four named employees] were members of the medical affairs team, so by making their intent that each patient was regarded as a sale, i.e. they would be leveraged at reimbursement, and converted to commercial stock, this EAP was not reactive, it did not put patients first, but was a clear example of disguised promotion, and a seeding programme.

The complainant alleged that several other EAPs in AstraZeneca [named therapy area team] had been designed with this intention, including the Calquence EAP in 2020, where hundreds of patients were converted to commercial stock, and AstraZeneca commercial heads planned and executed that EAP too with sales in mind, and effectively the EAP served as disguised promotion.

The complainant alleged that for further context NICE was currently reviewing the below indication for Lynparza, directly related to the OlympiA EAP and a decision was expected in the next few weeks, so the numbers in the EAP might be past 100 now.

The complainant provided a screenshot with the following information:

> 'Olaparib for adjuvant treatment of high-risk HER2-negative, BRCA-positive early breast cancer after chemotherapy [ID3893]. In development [GID-TA10903] Expected publication date: 29 March 2023'.

When writing to AstraZeneca regarding the allegation: Encouraging Medical teams to promote the OlympiA Early Access Programme, the PMCPA asked it to consider the requirements of Clauses 5.1, 11.1 and 17.9 of the 2021 Code.

ASTRAZENECA'S RESPONSE

AstraZeneca stated that the allegations raised were:

(1) [Senior employee] medical plan encouraged MSLs to proactively communicate about the OlympiA EAP, with a view to boosting patient starts, which were 'leveraged and commercialized on reimbursement'.
(2) [Named therapy area team] early access programs (EAP) were actual 'seeding programmes' with commercial franchise heads, including the [senior commercial employee] providing regular updates, and pushing medical teams to ensure proactive uptake by health professionals.
(3) Communication by [senior commercial employee] that patients in OlympiA EAP were to be 'leveraged at reimbursement and launch e.g., patients converted on to commercial stocks' communication included medical affairs team, the EAP was not reactive, it did not put patients first, but was a clear example of disguised promotion, and a 'seeding programme'.
(4) Several other EAPS in [named therapy area] including Calquence EAP in 2020 with hundreds of patients were converted to commercial stock, and AstraZeneca commercial heads planned and executed EAP with sales in mind, and effectively the EAP served as disguised promotion.

Allegation 1
<u>Senior employee] medical plan encouraged MSLs to proactively communicate about the OlympiA EAP, with a view to boosting patient starts, which were 'leveraged and commercialized on reimbursement'</u>

AstraZeneca stated that it had an open Olaparib Early Access Programme (OlympiA EAP) between January 2020 – April 2023 for adult patients with germline BRCA1/2 mutations (gBRCAm), who had human epidermal growth factor receptor 2 (HER2)-negative high-risk early breast cancer previously treated with neoadjuvant or adjuvant chemotherapy. The marketing authorisation was approved by the MHRA on 2 September 2022.

The EAP continued to enrol eligible patients until reimbursement was granted on 6 April 2023.

The MSL Training/briefing was clear in setting out that EAPs were to be provided reactively only by Medical following unsolicited request. EAPs were documented and recorded as part of evidence gathering/collection to support reimbursement. When reimbursement was granted and the EAP ended, patients who continued to meet reimbursement criteria were transitioned to NHS stock to continue their treatment.

Allegation 2
[Named therapy area team] early access programmes (EAP) were actual 'seeding programmes' with commercial franchise heads, including the [senior commercial employee] providing regular updates, and pushing medical teams to ensure proactive uptake by health professionals

AstraZeneca submitted that it had an open Olaparib Early Access Programme (OlympiA EAP) between January 2020 to 11 April 2023 for adult patients with germline BRCA1/2 mutations (gBRCAm), who had human epidermal growth factor receptor 2 (HER2)-negative high-risk early breast cancer previously treated with neoadjuvant or adjuvant chemotherapy. The early access programme (EAP) in adjuvant early breast cancer treatment (OlympiA EAP) was provided reactively by [named third party], MSLs and UK medical team prior to MHRA license and reimbursement between Jan 2022 – 11 April 2023 and had 120 patients.

EAPs were non-promotional and were provided upon unsolicited request by medical in area of high unmet clinical need and were not used as a 'seeding programme' and not proactively provided by the medical teams. As set out within the briefing to [named therapy area] Account Managers they were instructed to direct any HCP enquiries about OlympiA EAP without discussion to the appropriate MSL for further information.

Allegation 3
Communication by [senior commercial employee] that patients in OlympiA EAP were to be 'leveraged at reimbursement and launch e.g., patients converted on to commercial stocks' communication included medical affairs team, the EAP was not reactive, it did not put patients first, but was a clear example of disguised promotion, and a 'seeding programme'

AstraZeneca submitted that the internal communication by the [senior commercial employee] was an update on the Medical team's work with regards to the OlympiA EAP and this acknowledged that once OlympiA EAP reimbursement was granted and where eligible patients that continued to meet reimbursement criteria, patients would be transitioned to NHS stock. The post did not encourage, instruct, or direct Medical or MSLs to discuss OlympiA EAPs proactively.

The early access programme (EAP) in adjuvant early breast cancer treatment (OlympiA EAP) was provided reactively prior to MHRA license and reimbursement between Jan 2022–11 April 2023.

As set out in AstraZeneca's response to allegation 1 above, the MSL Training/briefing as stated was clear in setting out that EAPs are reactive only by Medical following unsolicited request.

Allegation 4
Several other EAPS in [named therapy area] including Calquence EAP in 2020 with hundreds of patients were converted to commercial stock, and AstraZeneca commercial heads planned and executed EAP with sales in mind, and effectively the EAP served as disguised promotion

AstraZeneca stated that the complainant made reference in the above allegation of 'several other EAPS in oncology including Calquence EAP in 2020', to provide context, and in the interest of transparency, AstraZeneca had included all the UK [named therapy area] EAPs between 2020–present. [A table detailing that there were two EAPs in total from 2020 to April 2023 was provided].

AstraZeneca submitted that EAPs were non-promotional and were provided upon unsolicited request by the medical team in area of high unmet clinical need and they were not disguised promotion.

EAPs were documented and recorded as part of evidence gathering/collection to support reimbursement. When reimbursement was granted and EAP ended, patients who continued to meet reimbursement criteria were transitioned to NHS stock to continue their treatment.

Summary

For this complaint 6, AstraZeneca investigations had revealed that early access programmes were set up and provided in areas of high unmet clinical needs prior to MHRA license and/or reimbursement. The OlympiA EAP was provided via the [named third party] and all liaison activities and arrangements with health professionals was done by the AstraZeneca MSLs and their UK medical team. Additionally, briefing to [named therapy area] Account Managers instructed them to direct any health professional enquires about OlympiA EAP early access enquires without discussion to the appropriate MSL for further information. The early access programme in adjuvant early breast cancer treatment (OlympiA EAP) was provided reactively prior to MHRA license and reimbursement between Jan 2022 – 11 April 2023. The MHRA license was granted in September 2022. The OlympiA EAP continued to enrol eligible patients until reimbursement was granted on 6 April 2023. Therefore, AstraZeneca refuted all allegations set out within complaint 6 and AstraZeneca therefore denied a breach of Clauses 5.1, 11.1 and 17.9.

PANEL RULING

The Panel noted that the complainant made several allegations regarding AstraZeneca UK [named therapy area team]'s Early Access Programmes (EAPs), including that these programmes, ostensibly aimed at providing access to life-changing medicine, were in reality serving as a guise for seeding activities and that commercial heads were providing regular updates and pressuring medical teams to ensure proactive adoption by health professionals.

The complainant alleged that several other EAPs in AstraZeneca [named therapy area team] were designed with the intention of commercial stock sales in mind. The complainant alleged this was present in the Calquence EAP in 2020 and OlympiA EAP.

The Panel noted the complainant's allegation that a communication by the business unit head stated that patients in the OlympiA EAP were to be 'leveraged at reimbursement and launch'. The Panel did not have a copy of this communication before it.

The Panel noted AstraZeneca's submission that it had an open Olaparib Early Access Programme (OlympiA EAP) between January 2020 and April 2023 for adult patients; the EAP continued to enrol eligible patients until reimbursement was granted on 6 April 2023.

The Panel noted AstraZeneca's submission that the MSL training and briefing document concerning the OlympiA EAP was clear in setting out that the EAPs were to be offered reactively by Medical only upon receiving unsolicited requests. AstraZeneca submitted that the EAPs were documented and recorded to gather evidence in support of reimbursement. Upon receiving reimbursement approval and the conclusion of the EAP, patients who still met the reimbursement criteria were transitioned to NHS stock to continue their treatment.

The Panel noted that the internal briefing communication email regarding the Olaparib EAP, sent to [named therapy area] Account Managers, Channel Account Managers and Diagnostic Managers and Liaison stated 'AstraZeneca runs the programme via the [named third party] and all liaison activities and arrangements with HCPs will be done by the AstraZeneca MSLs and their UK medical team. If an HCP enquires about early access to olaparib prior to reimbursement of olaparib, the enquiry must be directed without discussion to the appropriate MSL for further information'.

The Panel noted that Clause 11.1 required that a medicine must not be promoted prior to the grant of its marketing authorisation.

The Panel noted the complainant's concerns about the communication by the business unit head and AstraZeneca's response on the communication including that once reimbursement was granted and the EAP had ended, eligible patients would be transferred to NHS stock, and that the post did not encourage, instruct or direct medical staff or MSLs to discuss OlympiA EAPs proactively.

The Panel considered AstraZeneca's submissions in relation to the nature of the programme supported its position that the OlympiA EAP was offered reactively. The Panel noted that the complainant bore the burden of proving their complaint, on the balance of probabilities. The Panel considered that the complainant had not provided sufficient information with regard to the allegations, and had not discharged their burden of proving the allegations to show that a breach of the Code had occurred. Therefore, the Panel ruled **no breach of Clause 11.1** accordingly.

The Panel noted that AstraZeneca was asked to respond to Clause 17.9 which stated, among other things, that representatives' briefing material must comply with the relevant requirements of the Code.

The Panel noted AstraZeneca's submission that the MSL roles were non-promotional and they did not promote medicines, nor did they have any goals or incentives aligned to sales of medicines. The Panel noted its ruling of no breach of Clause 11.1 above. The Panel did not consider that the complainant had established that the MSLs had been instructed to act promotionally such that their role was promotional and therefore Clause 17.9 did not apply. The Panel accordingly ruled **no breach of Clause 17.9**.

Noting its rulings of no breach of the Code above, the Panel did not consider that the complainant had established that AstraZeneca had failed to maintain high standards. The Panel ruled **no breach of Clause 5.1** accordingly.

Complaint received **14 December 2022**

Case completed **22 July 2024**