NO BREACH OF THE CODE

CASE AUTH/3800/7/23

COMPLAINANT v ASTRAZENECA

Alleged use of medical and educational goods and services (MEGS) to promote Imfinzi

CASE SUMMARY

This case concerned allegations that AstraZeneca used a MEGS to promote Imfinzi and had a poor compliance culture.

The outcome under the 2019 Code was:

No Breach of Clause 2 (x2)	**Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry**
No Breach of Clause 9.1 (x2)	**Requirement to maintain high standards at all times**
No Breach of Clause 12.1	**Requirement that promotional materials and activities must not be disguised**
No Breach of Clause 19.1	**Permits the provision of MEGS which enhance patient care or benefit the NHS and maintain patient care provided they comply with the provisions of Clause 18.1**
No Breach of Clause 19.2	**Requirement that MEGS, among other things, comply with the requirements of Clause 19.1, and do not constitute an inducement to prescribe.**

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

FULL CASE REPORT

A complaint was received from a contactable complainant who described themselves as an AstraZeneca UK Limited employee about AstraZeneca. The complainant later became non-contactable.

COMPLAINT

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

> 'I am an AZ employee, and want to report a very concerning set of breaches of the ABPI code during the recent pandemic. In short, AZ Oncology knowingly (despite compliance advice not to do so), used a MEGs [Medical and Educational Goods and Services] initiative called Auxilium CRT [Chemo Radiation Therapy] to promote an underperforming

product called Imfinzi during Oct 2020 (the second wave of the recent pandemic). I want to make it clear that this order/instruction came from region Europe to [senior leaders]. This instruction is clearly highlighted in the attached slide deck [provided] titled IMFINZI - ideas to boost performance. One of the ideas agreed upon was to launch a MEGs called Auxilium CRT to boost Imfinzi. Imfinzi is the only licensed medicine for unresectable stage III Non Small Cell Lung Cancer but was underperforming in the pandemic as patients need to receive CRT (Chemoradiotherapy), which was not possible in the pandemic due to its immune suppressive nature.

You can also find in the e-mail trail below [provided] how [a senior leader] invited colleagues to a meeting and it was agreed, despite medical affairs/compliance concerns that a MEGs called AUXILIUM CRT would be launched to boost the performance of the AZ medicine Imfinzi.

Before, providing more context on the slides in the slide deck, I want to make it clear that the AUXILIUM CRT MEGs programme was launched and targeted at underperforming centres i.e. centres that are not using enough IMFINZI, and the context of this frustration is summarised in the slide deck on slide 1.

Clauses that have been breached are:

Clause 2 - disguised promotion of an AZ medicine (Imfinzi) using a MEGs, on the back of frustration at AZ Imfinzi sales.
Clause 5.1 - A failure to maintain high standards
Clause 19 breaches of the 2019 code

Context behind Disguised Promotion using MEGs called - Auxilium CRT

Q3 2020 - During a UK country visit by the EU Leadership team the UK was found to be underperforming in terms of sales of Imfinzi, which was reimbursed for unresectable stage III Non Small Cell Lung Cancer. The [senior leader] for the UK was very angry that we were lagging behind our EU counterparts, and asked the cross functional team (medical, marketing, sales [e-mail provided]), to put our heads together, and put together a range of short, medium and long term solutions to boost Imfinzi sales and performance urgently. A marketing colleague [named] was asked to lead this cross functional group, and come up with rapid solutions that can be implemented.

At the end of a cross functional meeting in October 2020, it was agreed by Marketing that we would use a MEGs called Auxilium CRT to boost Imfinzi sales (see the e-mail by [a senior leader] below [provided]), and although medical pushed that Auxilium CRT was a MEGs and should be used to boost CRT (Chemoradiotherapy rates), [senior leaders] were adamant that we needed to use this MEGs to boost Imfinzi sales. Medical made it clear that this would be a breach of the code but the [senior leader] was insistent that we need to boost the number of patients starting Imfinzi. Medical argued that the MSLs had reported that the low uptake and use of the AZ medicine Imfinzi was due to the fact that it need to be prescribed after CRT and CRT rates were down because of immune suppression, and Lung Oncologists wanted to safeguard patients from becoming acutely unwell. In slide 1 of the slide deck you can see how the Marketing team document that the NHS want to keep patients out of hospital due to the tiered lockdowns, whereas AZ want

patients going into hospital, to receive Imfinzi. So AZ really didn't care about protecting the NHS or patient safety.

As a result the Medical team were pressured into signing off materials for a MEG called Auxilium CRT, which was targeted at underperforming centres, and as clearly articulated by [named] Marketing Colleague below, its aim was to boost Imfinzi sales (see October 2020 email [provided]).

The Auxilium CRT MEGs itself

A website was set up for this and a number of centres/regions which were underperforming in terms of sales of Imfinzi were targeted. Unfortunately, I am not able to share those items as I will be identified. However, from the attached slide deck on slide 3 [provided], you can see under the **title ideal solutions that both Auxilium CRT (MEGs), and Homecare,** where the Imfinzi would be provided to patients at home, which was a Patient Support Programme, underperforming centres were targeted.

I feel that AZ demonstrated clear disguised promotion of Imfinzi and the fact that in their own words, both via e-mail and in the attached slide deck [provided], it is clear that the MEGs was clearly to boost Imfinzi performance, breaching the requirements of MEGs under clause 19 of the 2019 PMCPA Code. Additionally, the blatant and open nature of the non compliant behaviour was done after a clear instruction by the [senior leader], and fully supported by [named] Marketing and Sales colleagues ([named] Sales Manager).

The conduct of disguised promotion has brought the Pharma industry into disrepute, and although I have reported my concerns internally to AZ, no action has been taken since and senior leaders who display non compliant behaviours are fully supported in the AZ UK organisation. I strongly feel that this is a very clear breach of Clause 2.'

When writing to AstraZeneca, the Authority asked it to consider the requirements of Clauses 2, 9.1, 19.1 and 19.2 of the 2019 Code as cited by the complainant and, in addition, Clause 12.1.

RESPONSE

The response from AstraZeneca is reproduced below:

'AstraZeneca has been asked to consider these allegations with respect to Clauses 2, 9.1, 12.1, 19.1 and 19.2 of the 2019 Code.

The complainant's allegations can be broken down as follows:

1. AZ Oncology knowingly used a MEGs initiative called Auxilium Chemo-Radiation (CRT) to promote an underperforming product called Imfinzi during Oct 2020. Auxilium CRT MEGs programme was launched and targeted at underperforming centres i.e., centres that are not using enough Imfinzi.
2. [Senior leader] ignored medical affairs/compliance concerns about Auxilium CRT
3. Cross functional meeting in October 2020, it was agreed by marketing that we would use a MEGs called Auxilium CRT to boost Imfinzi sales. Although medical pushed that Auxilium CRT was a MEGs and should be used to boost

CRT, [senior leader] was insistent that we need to boost the number of patients starting Imfinzi.

4. NHS want to keep patients out of hospital due to the tiered lockdowns, whereas AZ want patients going into hospital, to receive Imfinzi. So, AZ really didn't care about protecting the NHS or patient safety.
5. Medical team were pressured into signing off materials for a MEG called Auxilium CRT which was targeted at underperforming centres.
6. Slide 3, under the title ideal solutions that both Auxilium CRT and Homecare, where Imfinzi would be provided to patients at home, which was a Patient Support Programme, underperforming centres were targeted
7. Blatant and open nature of the non-compliant behaviour, after a clear instruction by [senior leader]
8. I reported my concerns internally to AZ, no action has been taken since and senior leaders who display non-compliant behaviours are fully supported in the AZ UK organisation.

Background information

Chemo-Radiation Therapy (CRT) was given to patients, in the UK, as standard of care for curative intent in Stage III Non-Small Cell Lung Cancer (NSCLC). Auxilium was a MEGs, a fully tailored and bespoke support and education programme to both patients and their treating clinicians. The programme provided patients with easy access to information and support to help prepare them for their forthcoming CRT treatment, and throughout their CRT treatment to help improve patient care and experience as an outcome. Whether to offer further treatment after completion of CRT was a clinical decision to be made by the treating HCP. Subsequent treatment could include both pharmacological and non-pharmacological treatment options. The objective of Auxilium CRT MEGs was to improve the patient's opportunity to successfully complete curative intent treatment with CRT. The program was approved by our internal compliance governance forum [copy provided] to ensure the Auxilium CRT MEGs service was appropriate and delivered in line with the ABPI Code. The programme was approved in March 2020, some months prior to the meeting and slide presentation provided by the complainant (October 2020). Conditions for provision of the service as a MEGs were reflected in all briefing documents to the field force [copies provided]. The Auxilium CRT MEGs service [copy provided] was provided to centres where patients had already been diagnosed with stage III NCSLC, who:

- have planned CRT treatment
- are already undergoing their CRT treatment

A series of educational modules, which can be tailored to fulfil centre-specific needs, was also offered to clinics across the UK. The service provided HCPs, patients, and carers with easy-to-access information and support in order to help prepare for forthcoming CRT treatment.

It is important to note that, the concept of Auxilium CRT MEGs was identified before the pandemic – COVID impact in 2020 (and the potential impact on lung cancer patient diagnosis and treatment) further reinforced the need to support the NHS in optimising patient care in stage III NSCLC.

Regarding the slide- *"IMFINZI Ideas to boost performance – UK"*

The slides were created as the key output from an idea-generating meeting, where the objective was to identify potential ways in which AZ could support the NHS to address declining lung cancer patient diagnosis rates in the UK. [A senior leader] had asked us to consider possible AZ support solutions, and the cross functional team was convened to consider different commercial and medical initiatives. There was no pressure from the [senior leader] to implement any specific solution. The slide was not intended as a briefing of any kind. Rather, ideas that were agreed on (by both medical and commercial team members) were worked up in more detail, considering feasibility in line with Code of Practice and all relevant AZ SOPs. Auxilium CRT MEGs was already approved and available before this idea-generating meeting related to the slides. This meeting was not initiated to "drive a MEGS."

The statement "NHS want to keep patients OUT of hospital, and we want to encourage more in!" in the current situation section – refers to increasing diagnosis rates for lung cancer (which were declining both prior to, and within the context of the COVID pandemic)– not a disregard for patient safety. Patients were instructed to stay away from hospital if they had symptoms of COVID-usually a persistent cough. This is also one of the main symptoms of lung cancer, which can only be diagnosed with a proper investigation. It is well known that if lung cancer is diagnosed early, patients are more likely to be eligible for curative intent treatment, therefore achieve better outcomes.

Short term ideas: These were generated by the team to focus on sharing best practice through virtual means, and bringing together how some centres were still managing to increase diagnosis rates in uncertain times.

Mid-term ideas: This was generated with the situation of "no contact" in mind -providing support via an app which could help with patient support and questions, i.e., avoiding putting further strain into the NHS system for patients undergoing CRT.

Long Term ideas: Get It Right First Time (GIRFT) – was an NHS initiative looking to improve patient pathways across many disease areas. At the time GIRFT were auditing Lung Cancer services and care across many centres. The GIRFT report had identified gaps in care, and one of the ideas was to engage with centres (regardless of how they were performing with Imfinzi) and work together on how AZ could assist. AstraZeneca had the MEGs, to help and support CRT if there was a specific need raised by the physician, but this was never linked to Imfinzi. There was a separate Imfinzi support (homecare) program that was only available for patients already initiated on Imfinzi – this was in no way linked to Auxilium CRT MEGs.

The "website" that the complainant letter referred to was a simple website that had no performance data attached, but rather, enabled correct process for directing HCPs to the relevant 3rd party provider supplying Auxilium CRT MEGs on behalf of AZ [copy provided].

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

Allegation 1

AZ Oncology knowingly used a MEGs initiative called Auxilium CRT to promote an underperforming product called Imfinzi during Oct 2020. AUXILIUM CRT MEGs programme was launched and targeted at underperforming centres i.e., centres that are not using enough IMFINZI

As stated above, the objective of Auxilium CRT MEGs was to improve the support that centres provide to patients going through CRT -see Statement of work with [named provider] for CRT nurse service [copy provided], Auxilium CRT MEGs flowchart website [copy provided] and phone request to AZ Exchange team [copy provided]. Decisions on further treatment which may include both pharmacological and non-pharmacological options post CRT were the sole responsibility of the treating clinician. Auxilium CRT MEGs provided an opportunity for patients to have the best chance of starting and completing curative intent treatment with CRT. The program fulfilled all compliance requirements of both the ABPI Code of Practice and AZ SOPs.

Conditions for provision as a MEGs were reflected in the Auxilium HCP FAQ Document [copy provided] for promotional and non-promotional roles which clearly states: this MEGs is a non-promotional activity:

"*This is a non-promotional offering linked to the provision of a service to medicine. It should not be discussed with customers alongside a conversation about Imfinzi. It can only be discussed at the end of an interaction and should never be linked to brand. It must be discussed in a separate call. You cannot leave the room and come back in."* The non-promotional intent is also explicitly stated in the briefing document to the AZ exchange team [copy provided].

We strongly refute the suggestion that Auxilium CRT MEGs was used to promote Imfinzi in underperforming centres and therefore deny alleged breach of clauses 12.1, 19.1 and 19.2.

Allegation 2

Marketing lead ignored medical affairs/compliance concerns about AUXILIUM CRT

Our investigations have not revealed any evidence to this allegation and the complainant has not provided any evidence of this nature to suggest that the [senior leader] ignored medical/compliance concerns about Auxilium CRT MEGs.

We strongly refute the suggestion that the [senior leader] ignored medical affairs/compliance concerns about Auxilium CRT MEGs and deny all alleged Code breaches.

Allegation 3

Cross functional meeting in October 2020, it was agreed by Marketing that we would use a MEGs called Auxilium CRT to boost Imfinzi sales. Although medical pushed that Auxilium CRT was a MEGs and should be used to boost CRT, [senior leader] was insistent that we need to boost the number of patients starting Imfinzi

The above meeting was not linked to a MEGs. Auxilium CRT MEGs had already launched prior to this meeting. Email sent by [senior leader] in October 2020 (as provided by the complainant), states, “in addition to maximising implementation and up take of great initiatives like AUXILIUM CRT and HOMECARE.”

Our investigations have not revealed that the [senior leader] insisted that we needed to boost the number of patients starting on Imfinzi.

As stated in allegation 1, there is no evidence to suggest that Auxilium CRT MEGs was used to boost the number of patients starting Imfinzi.

We strongly refute the suggestion that at the cross-functional meeting in October 2020, it was agreed by marketing to use Auxilium CRT MEGs to boost Imfinzi sales and the [senior leader] insisted that we need to boost the number of patients starting Imfinzi. We, therefore, deny alleged breach of clauses 12.1, 19.1 and 19.2.

Allegation 4

NHS want to keep patients out of hospital due to the tiered lockdowns, whereas AZ want patients going into hospital, to receive Imfinzi. So, AZ really didn’t care about protecting the NHS or patient safety

As previously stated, this statement refers to increasing diagnosis rates for lung cancer – and not a disregard for patient safety. The diagnosis rates for lung cancer were declining both before and as a result of the pandemic. Patients were instructed to stay away from hospital if they had symptoms of COVID – usually a persistent cough – and this is one of the main symptoms of lung cancer, which can only be diagnosed with a proper investigation. It is well known that early diagnosis of lung cancer increases likelihood of curative intent treatment and improved outcomes.

We strongly refute the suggestion that by supporting the increase in diagnosis of lung cancer rate during the pandemic that we didn’t protect the NHS or patient safety and therefore deny all alleged breach of Code clauses including clauses 9.1 and 2.

Allegation 5

Medical team were pressured into signing off materials for a MEG called Auxilium CRT which was targeted at underperforming centres

Our investigations have not revealed any evidence to this allegation and the complainant has not provided any evidence of this nature to suggest that the medical teams were pressured into signing off materials for a MEG called Auxilium CRT MEGs and targeted at underperforming centres.

We strongly refute the suggestion that the medical team were pressured into signing off materials for Auxilium CRTMEGs targeted at underperforming centres and therefore deny alleged breach of clauses 9.1, 12.1, 19.1 and 19.2.

Allegation 6

Slide 3, title ideal solutions that both Auxilium CRT (MEGs), and Homecare, where the Imfinzi would be provided to patients at home, which was a Patient Support Programme, underperforming centres were targeted

The slide presentation submitted by the complainant titled *"Imfinzi ideas to boost performance"* make reference to Auxilium CRT MEGs and homecare on slide 5 titled *"how do we increase cCRT rates and Imfinzi usage during a time of uncertainty due to COVID 19?:Long term"* refers to the Get It Right First Time (GIRFT) NHS initiative to improve patient pathways across many disease areas. The GIRFT team were auditing lung cancer patient services across many centres. The report had identified gaps in care, and one of the ideas was to engage with centres and work together on how AZ could be of support. AstraZeneca had the Auxilium CRT MEGs offering if there was a specific request from the centre, but this was never linked to Imfinzi.

There was a separate Imfinzi (homecare) patient support program that was only available for patients already initiated on Imfinzi – this was no way linked to Auxilium CRT MEGs. Please see Imfinzi homecare HCP info leaflet [copy provided] and associated briefing document [copy provided].

We strongly refute the suggestion that the Auxilium CRT MEGs and the patient support programme (PSPs) for Imfinzi was targeted at underperforming centres; PSPs are provided as an additional support to patients already prescribed Imfinzi. We, therefore, deny alleged breach of clauses 12.1, 19.1 and 19.2.

Allegation 7

Blatant and open nature of the non-compliant behaviour was done after a clear instruction by [senior leader]

Our investigation has not revealed any evidence to this allegation and the complainant has not provided any evidence of this nature to suggest that the [senior leader] instructed, directed, or encouraged "blatant and open nature of non-compliant behaviour" by staff members.

We strongly refute the suggestion that the [senior leader] instructed staff members to carry out non-compliant activities, which is not in line with AstraZeneca SOPs and standards. We, therefore, deny all alleged breach of clauses including clauses 9.1 and 2.

Allegation 8

I reported my concerns internally to AZ, no action has been taken since and senior leaders who display non-compliant behaviours are fully supported in the AZ UK organisation

In the spirit of the AstraZeneca Speak Up culture, any objections raised by employees are taken seriously. Concerns can be raised using different channels. There is an additional mechanism for any employee to report a concern anonymously via our externally managed AZ Ethics if required [copy provided].

Our investigations have not revealed evidence of any compliance concerns or issues being raised or reported about the conduct or non-compliant behaviour of senior leaders via our compliance reporting routes.

We strongly refute the suggestion that the complainant reported concerns internally about senior leaders' non-compliant behaviour and that no action was taken. We therefore deny alleged breach of Code clauses including clauses 9.1 and 2.

Summary of AstraZeneca's Position

In summary, AstraZeneca takes its obligations under the ABPI Code of Practice very seriously and have internal SOPs and processes in place to ensure that we uphold high ethical standards and abide by the spirit of the ABPI Code. As we have set out above, we strongly deny all the alleged breach of the clauses of the Code. AstraZeneca has a robust process in place for approving activities in a compliant manner: we take patient safety very seriously and strive to always maintain high standards. We, therefore, deny bringing the pharmaceutical industry into disrepute and refute a breach of clauses 2 and 9.1.

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

Whilst we fully respect that the complainant's wishes to remain anonymous and can categorically confirm that we have respected that right in our investigations of and response to these complaints, we find it concerning that a complainant can make a number of false and misleading representations concerning AstraZeneca's conduct with little to no supporting evidence. In our opinion, this creates a risk that the complainant was not acting in good faith. In light of this risk, we would like to continue to work with the PMCPA to better understand how the PMCPA can verify complaints in terms of their authenticity and intent.

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

PANEL RULING

The Panel noted the evidence provided by the complainant in support of the allegations related to 2020 and in particular to a meeting that took place in October 2020. The MEGS in question was ongoing at the time. While the complainant had cited a mixture of clauses from the 2019 and 2021 Codes the Panel decided that it was appropriate to consider the allegations under the 2019 Code which applied at the relevant time.

The Panel carefully considered this complaint and split it into two broad allegations:

Firstly, an allegation whereby AstraZeneca used a Medical and Educational Goods and Services called 'Auxilium CRT' to promote an underperforming product, Imfinzi, which the complainant alleged amounted to a breach of Clauses 19.1 and 19.2 and amounted to disguised promotion of a medicine, in breach of Clause 12.1. It was alleged this amounted to a failure to maintain high standards in breach of Clause 9.1 and brought discredit upon, and reduced confidence in, the industry, a breach of Clause 2.

Secondly, inextricably linked to the above, was an allegation concerning the poor culture demonstrated by AstraZeneca by its actions in the first allegation, namely:

- AstraZeneca acted against the advice and concerns of its compliance and medical teams not to use the MEGS in that way, and put pressure on its medical team to sign off materials for the MEGS;
- AstraZeneca knew its actions would be in breach of the Code but insisted on pressing on, therefore blatantly failing to comply with it ;
- AstraZeneca inappropriately wanted to keep patients in hospital to receive Imfinzi, and thus failed to care about protecting the NHS or patient safety;
- AstraZeneca specifically targeted underperforming centres;
- AstraZeneca failed to take action when the complainant reported their concerns internally.

The complainant alleged this amounted to a failure to maintain high standards, a breach of Clause 9.1 and brought discredit upon, and reduced confidence in, the industry, a breach of Clause 2.

The Panel noted the complainant had the burden of proving their complaint on the balance of probabilities. All complaints were judged on the evidence provided by the parties.

Allegation 1:

The Panel considered the email correspondence and PowerPoint slides provided by the complainant in support of the allegation. The email correspondence comprised an invitation to a meeting with the subject line 'Solution to improve CRT and Systemic Treatment rates during COVID-19' and a post-meeting email.

The invitation indicated the purpose of the meeting was to identify solutions to address leakages in rates of CRT and systemic treatment and to come up with 1-2 prioritised initiatives to boost Imfinzi in the context of the pandemic.

The subject title of post-meeting correspondence in October 2020 was 'UK Ideas - Solution to improve CRT and Systemic Treatment rates during COVID-19'. The Panel noted this email contained a single reference to the MEGS in question; it referred to consolidating the ideas into 3 short, medium and long term initiatives for the UK 'in addition to maximising implementation and up take *[sic]* of great initiatives like AUXILIUM CRT…'. In the Panel's view, the email implied that the Auxilium CRT was supplementary to the substantive short, medium, and long term initiatives identified in the meeting at issue.

The PowerPoint slides were headed 'How do we increase cCRT rates and Imfinzi usage during a time of uncertainty due to COVID-19?' Astra Zeneca submitted that the slides were created as the key output from the idea-generating meeting. The first slide summarised the current

situation and considerations and was followed by slides outlining the output of the meeting in terms of short, medium and long-term initiatives.

The Panel noted the PowerPoint slides made two references to Auxilium CRT, one on the 'short term' slide where paragraph 2, Local Virtual meeting, within a section titled 'Idea/Tactic' 'MY4 Meeting' listed 'AUXILIUM CRT?' as one of three possible solutions, and one on the 'long term' slide where it stated 'AZ to be first partner to help centre with solutions like AUXILIUM, Homecare, etc' as one of six considerations for 'Pathway redesign in partnership with NHS'.

The Panel noted that AstraZeneca's response stated that the 'short term' slide featured ideas which focussed on sharing best practice through virtual means. AstraZeneca submitted the 'long-term' slide referred to how it could support the NHS Get It Right First Time (GIRFT) initiative to improve patient pathways, as lung cancer patient services were being audited at the time, and help address the gaps identified. According to AstraZeneca the meeting objective was to identify potential ways in which AstraZeneca could support the NHS to address declining lung cancer patient diagnosis rates in the UK. The slides were not intended as a briefing of any kind. It strongly refuted that the meeting in October was linked to the MEGS or that it had been agreed to use the MEGS to boost Imfinzi sales.

The Panel noted that under Clause 19 of the 2019 Code medical and educational goods and services which enhanced patient care or benefited the NHS and maintained patient care could be provided subject to the provisions of Clause 18.1. They must not be provided to individuals for their personal benefit. The supplementary information to Clause 19.1 gave further details. The Panel noted that Clause 19.2 stated that medical and educational goods and services were only allowed if they complied with Clause 19.1, and among other things did not constitute an inducement to prescribe.

The Panel noted AstraZeneca's description of the MEGS in question, Auxilium CRT, that it was a fully tailored and bespoke support and education programme to both patients and their treating clinicians in relation to the provision of Chemo-Radiation Therapy. The MEGS' purpose was to improve patients' opportunity to successfully complete curative intent treatment with CRT. It was provided to centres where patients had been diagnosed with Stage III NSCLC who have planned Chemo-Radiation Therapy or were already undergoing Chemo-Radiation Therapy treatment. In this regard, the Panel noted the CRT MEGS Concept Approval Form stated among other things in response to the question 'Who will the goods or services to be offered to?[sic]' that 'Under the circumstances where resources are limited requests for the service will be prioritised based on the greatest number of patients benefitting'.

The Panel noted that pharmaceutical companies investing in MEGS were very likely to have commercial interests in the area and one of the questions to be considered was whether the MEGS would likely lead to the use of a particular medicine bearing in mind the therapy area and available treatment options. In this regard the Panel noted AstraZeneca's submission that subsequent treatment could include pharmacological and non pharmacological options and these were the sole responsibility of the treating physician. According to the MEGS Concept Approval Form options on completion of Auxilium CRT included but were not limited to: surveillance, other systemic treatment, chemotherapy, clinical trials, best supportive/palliative care and /or no treatment.

The Panel noted that the reporting obligations of the service provider to AstraZeneca and the Key Performance Indicators as set out in the Statement of Works dated May 2020 were not related to the product, Imfinzi.

The Panel noted that contrary to the implication in the complaint the MEGS was approved in March 2020, some seven months before the meeting in October 2020. In addition, the Panel noted the documentary evidence provided by AstraZeneca. There was no mention of Imfinzi in the Concept Approval Form which set out the service, in addition the only reference to any medicine in the Auxilium MEGS literature was to Imfinzi, where it was made clear that the MEGS was a non-promotional offering linked to the provision of a service to medicine. The briefing documents were clear that the MEGS should not be discussed with customers alongside a conversation about Imfinzi, and stipulated it could only be discussed at the end of an interaction and should never be linked to brand. There was a separate Imfinzi support (homecare) program that was only available for patients already initiated on Imfinzi – there was no evidence to show this was linked to the MEGS in question and it was not the subject of the complaint.

The Panel considered the meeting itself and its purpose as an ideas generating meeting. The Panel considered that it was important to be careful about references to non promotional activities such as MEGS at such meetings bearing in mind the potential consequences of such references and the requirements of the Code. In its view, noting that it was an ideas generating meeting, there was no evidence that the meeting, slides or emails constituted briefing material or, in any way, affected the delivery of the service or that anyone present was influenced by any of the alleged comments in relation to Auxilium CRT.

The Panel noted that it did not have sight of all of the AUXILIUM materials used with the healthcare organisations, health professionals and patients.

The Panel noted the requirements of Clauses 19.1 and 19.2 of the 2019 Code as set out above. Having considered the allegations, the email correspondence and PowerPoint slides provided by the complainant and AstraZeneca's submission the Panel considered that the complainant had not demonstrated on the balance of probabilities, that Auxilium CRT was being used to promote Imfinzi or that it constituted an inducement to prescribe Imfinzi.

Consequently and noting its comments above the Panel considered that the complainant had not established that Auxilium CRT had failed to satisfy the requirements of Clause 19.1 and therefore ruled **no breach of Clause 19.1 of the 2019 Code**.

The Panel noted the requirements of Clause 19.2 as set out above. The Panel did not consider that the complainant had established that Auxilium CRT was offered as an inducement. Further Auxilium CRT did not appear to bear the name of any medicine. The Panel therefore ruled **no breach of Clause 19.2 of the 2019 Code**.

Considering whether the MEGS amounted to 'disguised promotion' of Imfinzi, thus a breach of Clause 12.1 (Disguised Promotion), the Panel was assisted by Clause 1.2 of the 2019 Code which defines promotion:

> 1.2 The term 'promotion' means any activity undertaken by a pharmaceutical company or with its authority which promotes the administration, consumption, prescription, purchase, recommendation, sale, supply or use of its medicines.

For the same reasons set out above, the Panel was not satisfied that the Auxilium CRT was used to promote Imfinzi and therefore the complainant had not established Auxilium CRT was a disguised promotional activity. The Panel, therefore ruled **no breach of Clause 12.1 of the 2019 Code**.

In the Panel's view the complainant had not demonstrated that AstraZeneca had failed to maintain high standards at all times, therefore it ruled **no breach of Clause 9.1 of the 2019 Code** for this allegation.

Taking the totality of the above rulings together and with the aforementioned reasons, the complainant had not established that AstraZeneca had brought discredit upon, or reduced confidence in, the industry, therefore the Panel ruled **no breach of Clause 2 of the 2019 Code** for this allegation.

Allegation 2:

The Panel noted the allegation was in essence that AstraZeneca demonstrated a poor culture and therefore had not maintained high standards at all times.

AstraZeneca strongly refuted the complainant's allegations that it:

A. had acted against the advice or concerns of its medical and compliance teams, and put pressure on its medical team to sign off materials for the MEGS
B. knew its conduct would be in breach of the Code but insisted on pressing on
C. inappropriately wanted to keep patients in hospital to receive Imfinzi, and thus failed to care about protecting the NHS or patient safety
D. specifically targeted underperforming centres, and
E. failed to take action when the complainant reported their concerns internally.

The Panel noted that the parties' accounts differed; it was difficult in such cases to know exactly what had transpired. A judgement had to be made on the available evidence. The complainant bore the burden of proof and had to establish their case on the balance of probabilities.

Whilst noting the important nature of the allegations the Panel further noted that it was unclear whether certain allegations (e.g. allegation E) as standalone items were matters covered by the Code. AstraZeneca had not commented on this point.

In relation to allegations B, C, and D the Panel considered that its rulings and comments above were relevant. The Panel noted that the complainant had not provided any evidence in relation to allegations A, B and D such as detail as to what advice was specifically given and what was said by the recipient of said advice or the detail of any concerns raised.

In the Panel's view the absence of evidence provided by the complainant, AstraZeneca's response and the Panel's comments and rulings above meant that the complainant had not established on the balance of probabilities that high standards had not been maintained. **No breach of Clause 9.1 of the 2019 Code** was ruled.

Consequently it was clear to Panel that AstraZeneca had not brought discredit upon, or reduced confidence in, the industry, and it ruled **no breach of Clause 2 of the 2019 Code**.

Complaint received	**22 July 2023**
Case completed	**1 July 2024**