CASE AUTH/3597/1/22

COMPLAINANT v ASTRAZENECA

Alleged promotion of AstraZeneca's Covid vaccine and Evusheld and a breach of undertaking by AstraZeneca

CASE SUMMARY

This case was in relation to two posts on LinkedIn and a BBC Radio 4 interview about AstraZeneca and an alleged breach of undertaking .

The Panel ruled a breach of the following Clause(s) of the 2021 Code on the basis that:

- **The first LinkedIn post in question by [illegible] UK employee which included a link to an inews article promoted AstraZeneca's Covid-19 vaccine prior to the grant of its marketing authorisation (Matter 1)**
- **A UK-based global employee's like of the second LinkedIn post disseminated positive information about Evusheld to the employee's connections and promoted the medicine prior to the grant of its marketing authorisation (Matter 2)The Panel considered, noting the content of the video transcript provided by AstraZeneca in relation to the BBC interview, that the interview given by the very senior AstraZeneca employee had promoted AstraZeneca's Covid-19 vaccine prior to the grant of its marketing authorisation (Matter 3) The Panel noted its three rulings of a breach of high standards in relation to the promotion of an unlicensed medicine in the three separate matters above, two of which resulted from the actions of very senior employees and it appeared that in relation to the first LinkedIn post both a very senior employee and AstraZeneca had failed to recognise the promotional nature of the LinkedIn post resulting in the placement of an uncertified promotional post on the senior employee's personal LinkedIn account.**

Breach of Clause 5.1 (Successfully appealed in Matters 1 and 3. Unsuccessfully appealed in Matter 2)	**Failing to maintain high standards**
Breach of Clause 2 (Successfully appealed)	**Bringing discredit upon, and reducing confidence in, the pharmaceutical industry**

The Panel ruled no breach of the following Clause(s) of the 2021 Code on the basis that:

- **the matters before it in this case were sufficiently different to Case AUTH/3412/10/20 such that there had been no breach of the undertaking given in that case,**
- **the complainant had not established that the BBC interview had been used in many other publications which showed lax processes or that statements made during the interview were not capable of substantiation,**
- **Clause 8.3 was not relevant as in the Panel's view the two LinkedIn posts and interview were promotional, and**
- **Clauses 26.1 and 26.2 only applied to prescription only medicines and neither AstraZeneca's Covid vaccine was not classified as such at the time the first**

LinkedIn post was made or the interview took place and an edited video of it was hosted on the BBC website and nor was Evusheld at the time the second LinkedIn post was liked by the UK-based employee.

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 3.3	**Requirement to comply with an undertaking**
No Breach of Clause 5.1	**Requirement to maintain high standards**
No Breach of Clause 6.2	**Requirement that information must be capable of substantiation**
No Breach of Clause 8.3	**Requirement to certify non-promotional material**
No Breach of Clause 26.1	**Requirement not to advertise prescription only medicines to the public**
No Breach of Clause 26.2	**Requirement that information about prescription only medicines which is made available to the public must be factual, balanced, must not raise unfounded hopes of successful treatment or encourage the pubic to ask their health professional to prescribe a specific prescription only medicine**

APPEAL

The Panel's ruling of a breach of Clause 5.1 in relation to Matters 1 and 3 was overturned and upheld in relation to Matter 2 at appeal. The Panel's overall ruling of a breach of Clause 2 in relation to Matters 1-3 was overturned at appeal.

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

FULL CASE REPORT

A contactable complainant who described themselves as a concerned UK health professional complained about two posts on LinkedIn and a BBC Radio 4 interview about AstraZeneca.

COMPLAINT

The complainant provided screenshots of two LinkedIn posts stating that they had come up on LinkedIn and referred to a very senior AstraZeneca UK employee choosing to post regarding the AstraZeneca vaccine, blatantly promoting to the general public and alleged that material to be used with the public should be certified to ensure that this sort of thing did not happen.

The first screenshot provided was of a post made by the very senior AstraZeneca UK employee on what appeared to be their personal LinkedIn account which read:

> 'Today is the one-year anniversary of the first Oxford/AZ vaccine administered in the UK:-). Since then 2.5 billion doses have been administered in more than 70 countries around the world. I'm quietly humbled and hugely proud of the tireless work of so many colleagues,

partners, healthcare workers, volunteers and members of the public who have stepped forward to support this incredible effort'.

The post included what appeared to be a link to an article on inews.co.uk which included a photograph of the UK prime minister and was titled '[Prime minister] praises "brilliant" scientists behind AstraZeneca jab one year on from approval'.

The second screenshot provided was of a LinkedIn post which stated 'AstraZeneca was mentioned in the news' followed by a photograph of what appeared to be an outdoor sign with the AstraZeneca corporate logo and a link to an article on reuters.com with the title 'AstraZeneca antibody cocktail works against Omicron in study'. The complainant stated that the post had been liked by members of AstraZeneca global and provided a screenshot of those who had done so.

Finally, the complainant provided a screenshot of what appeared to be a video of an interview with [another very senior AstraZeneca employee] on the BBC news website.

The complainant alleged that this very senior employee had undertaken an interview on BBC Radio 4 where they not only promoted their company's product, but made claims that could not be substantiated that the use of their company's vaccine was the reason for the improved response compared to Europe. The complainant alleged that this piece had been used in many other publications which raised a question about what processes were so lax for this to occur. The screenshot of the video included an image of the very senior employee followed by the heading 'COVID-19 AstraZeneca [very senior employee] on long-term protection from jab'. This was followed by text which stated, 'The [very senior employee] of pharmaceutical giant AstraZeneca says its coronavirus vaccine-developed with Oxford University-may have played a key role in reducing Covid-related hospitalisations in the UK. [The very senior employee] said [the] company's vaccine promoted a greater T-cell (part of the immune system which defends the body against specific infections) response in older people than some others. [The very senior employee] was speaking to the Today programme ahead of the formal opening of AstraZeneca's new science lab in Cambridge.'

The complainant stated that in Case AUTH/3412/10/20 it was apparently a single individual that let the company down but alleged that there was strong evidence that rules were being systemically ignored and all the above were examples that the company had broken its undertaking on several occasions.

When writing to AstraZeneca, the Authority asked it to consider the requirements of Clauses 2, 3.3, 5.1, 6.2, 8.3, 26.1 and 26.2 of the Code.

RESPONSE

AstraZeneca was disappointed that it had received yet another anonymous complaint about AstraZeneca's work related to the COVID-19 pandemic. If the complainant was from a competitor pharmaceutical company, the individual had by-passed the inter-company complaints route, and if they were an AstraZeneca employee, then they had by-passed AstraZeneca's whistle-blowing policy. In both instances AstraZeneca believed this could have been resolved without resorting to a formal process that was both prolonged and resource-consuming for both AstraZeneca and the PMCPA.

1 LinkedIn post by the very senior AstraZeneca UK employee

AstraZeneca submitted that the complainant was incorrect as the Code did not prohibit a pharmaceutical company from posting legitimate, accurate and balanced information about the company`s products, as long as it did not contravene the provisions of the Code. Were this to be the case, then no company would be able to mention any medicine (even indirectly) on any platform or forum without being accused of promoting the medicine in question.

AstraZeneca submitted that the LinkedIn post shared by the very senior AstraZeneca UK employee was a corporate statement made on behalf of AstraZeneca on the one-year anniversary of the first vaccine being administered in the UK, noting the number of doses and countries supplied worldwide. This was in response to a congratulatory 'Thank you' message from the UK Prime Minister, who recognised the hard work put in by all those involved. The post was factual, accurate, balanced and although it referred to the Oxford/AZ vaccine, it did not promote a medicine. The post was examined but not certified, because it did not meet the provisions of Clause 8.3 that required certification.

Secondly, the Code defined 'Promotion' (Clause 1.17) as any activity undertaken by a pharmaceutical company or with its authority which promoted the administration, consumption, prescription, purchase, recommendation, sale, supply or use of its medicines. AstraZeneca submitted that the post did not do any of these. Besides, as noted by the UK Prime Minister, the AstraZeneca vaccine was provided on a not-for-profit basis, so there was neither an intention nor any motivation to promote.

Thirdly, the AstraZeneca vaccine had a temporary authorisation to supply and did not yet have a full marketing authorisation in the UK, so it could not be designated as a Prescription Only Medicine at this time.

In essence, AstraZeneca believed this LinkedIn post did not constitute promotion of a prescription only medicine to the public and did not encourage members of the public to request a specific medicine. AstraZeneca therefore rejected a breach of Clauses 8.3, 26.1 and 26.2.

Linked article to the LinkedIn post entitled '[Prime minister] praises brilliant scientists behind AstraZeneca jab one year on from approval'

AstraZeneca submitted that the third party politics article by inews contained quotes from the UK Prime Minister and UK Health Minister as part of the UK government's campaign on vaccinating the UK population against COVID-19 infection. It included a discussion of the UK Government`s investment, funding, development and manufacturing of the vaccine. The Prime Minister and Health Secretary also thanked everyone involved in its development, including the scientists that worked on it and AstraZeneca for providing it to the Government on a not-for-profit basis.

AstraZeneca contended that linking to this article, which it believed was part of a strategic campaign to encourage vaccination by the UK Government, was not in breach of the Code, as vaccines were treated as unique exceptions, within the context of providing non-promotional information about medicines to the general public. This was in line with the provisions of Clause 11.3, as well as Clauses 3.2, 26.1 and 26.2.

AstraZeneca strongly refuted the allegation of blatant promotion of the AstraZeneca vaccine to the public through both the LinkedIn post and the linked inews article. Given AstraZeneca's

position that the company had not promoted a medicine, and that it refuted breaches of Clauses [3.2], 26.1, 26.2, AstraZeneca firmly attested that it had not breached high standards nor brought the industry into disrepute because of this LinkedIn post, and thus rejected breaches of Clauses 5.1 and 2.

2 Reuters article entitled AstraZeneca antibody cocktail works against Omicron in study

AstraZeneca stated that this article appeared to have been posted as 'a story that mentioned AstraZeneca' by LinkedIn. The article was not posted by AstraZeneca or by an AstraZeneca employee. The complainants 'screenshot' depicted three AstraZeneca global employees 'liking' the article. One employee was based in Cambridge, and two employees were based in Canada.

AstraZeneca stated that the employees were contacted in early January 2022 and asked to 'unlike' the post, and this was completed by the three individuals on the same day. The Global Standard for employee use of personal social media channels for AstraZeneca and work-related content version 3.0 instructed AstraZeneca employees not to like, share, or comment on any product-related content from third party sources (copy provided). The latest version of this Standard was first provided as a read and sign to all UK-based employees in Q2 2020. Since then, regular internal communications on an internal communication platform reminded employees about the key principles of personal social media use for AstraZeneca or work-related content. AstraZeneca sent the latest communication about personal use of social media in mid January 2022. Importantly, as part of the AstraZeneca Code of Ethics awareness training, a mandatory online e-learning course was delivered to all AstraZeneca employees on an annual basis. This training course was updated in 2021 to include a new section on personal use of social media for work-related content. The training was launched in mid October 2021, it was made available in 11 languages and it had a 30-day completion window.

AstraZeneca reiterated that if AstraZeneca employees' social media posts came to the attention of AstraZeneca, because an employee had not acted in accordance with its Global Standard, the appropriate action was immediately taken, as had been done in this case.

AstraZeneca stated that it did not believe that one, or even a small number of UK employees, liking a third party article of their own accord brought discredit upon, or reduced confidence in, the pharmaceutical industry (Clause 2).

AstraZeneca submitted that it had made it clear to the Panel in the signed undertaking related to two cases, Cases AUTH/3412/10/20 and AUTH/3430/11/20, that the company would take all precautionary steps to prevent a future issue, which AstraZeneca had diligently followed. AstraZeneca also clearly pointed out that AstraZeneca UK (or any other pharmaceutical company) could not guarantee that rare events of this nature would never occur in the future, regardless of the extensive measures put in place to prevent them. AstraZeneca therefore refuted any allegation of a breach of undertaking (Clause 3.3). AstraZeneca did not believe that it had breached high standards (Clause 5.1) since the company trained and communicated regularly on AstraZeneca's social media policy. It was important to consider both the letter and the spirit of the Code when considering the merits of this case, one UK-based AstraZeneca employee, who accidentally 'liked' a post and promptly 'unliked' it when alerted, should not constitute a breach of Clauses 26.1 and 26.2. Furthermore, as stated above, AstraZeneca did not accept breaches of Clauses 2, 3.3 and 5.1 on this matter.

Finally, with respect to this material, AstraZeneca re-iterated its position that the jurisdiction of the ABPI Code did not cover Global AstraZeneca employees who were based outside the UK. In this case, the two Canadian-based employees who liked the Reuters article, and who worked under Canadian contracts, were not subject to the requirements of the Code. Thus, this complaint distilled to one UK-based employee who liked the third party article. AstraZeneca would like to use this opportunity to stress the importance of employees having personal freedom to use their personal social media channels for work related content within the boundaries of company guidance and external regulations, but also balancing this with the fact that companies should not be severely reprimanded when one individual out of tens of thousands of employees who used social media, and who collectively made hundreds of thousands/millions of engagements (likes, emoticons), made what AstraZeneca considered genuine mistakes (human error) in terms of liking third-party posts.

3 The very senior AstraZeneca employee interview by BBC for the Today Programme

AstraZeneca stated that the very senior AstraZeneca employee was interviewed during the official unveiling of the AstraZeneca Discovery Centre (DISC) in Cambridge on 23 November 2021. During the course of the day, the very senior AstraZeneca employee was interviewed by invited media. A BBC journalist interviewed the very senior AstraZeneca employee for the Today Programme, and an edited video clip of that interview was subsequently hosted on the BBC website.

The transcript of this edited video was provided and included two questions which were asked by the journalist, but were not included in the video clip. Importantly, these two questions the very senior AstraZeneca employee was responding to provided the context to the information they discussed. The first question related to the mRNA technology and the second one related to the rate of hospitalisation in Europe compared to UK.

All questions were unsolicited, and they were answered accurately and succinctly, in a balanced way, acknowledging where data was missing, and all responses were capable of substantiation. There was no use of the brand name, and there were no claims about efficacy or safety of the vaccine, and no unfair comparisons were made to other COVID-19 vaccines. With respect to the complainant's allegation of promotion of the vaccine, AstraZeneca strongly disagreed – all responses provided were not promotional, and furthermore, with the vaccine being provided on a not-for-profit basis, it served AstraZeneca no gain (financial or otherwise) to promote the AstraZeneca COVID-19 vaccine during the course of the interview.

In line with independent media reporting, AstraZeneca had no editorial control of the final video that was hosted on the BBC website. All editorial rights remained with the BBC. AstraZeneca strongly refuted the allegations made by the complainant about this independent interview conducted by the BBC, and the company did not believe the content of this video was, in any way, in breach of Clauses 2, 3.3, 5.1, 6.2, [8.3], 26.1 and 26.2.

Summary

AstraZeneca refuted all allegations made by the complainant. AstraZeneca reiterated its position regarding the clear need for the PMCPA to revisit its procedure on how complaints of this nature were handled. This was even more important where it related to allegations based on misrepresentation or misinterpretation of the UK Code.

The current practice regrettably left companies exposed to unfair and vexatious allegations that aimed to disrupt AstraZeneca's work, with the full knowledge that the merit of the complaint itself would not be assessed at the outset by PMCPA – instead the burden was passed on directly to the companies to deal with, no matter how inaccurate the allegation.

The impact of this, which AstraZeneca knew was not the aim of the Code, was that very scarce resources were taken away from companies who wished to focus on developing interventions that addressed critical unmet needs for patients. This was not sustainable in the long run and needed to be addressed by the PMCPA urgently.

Due to the ever-evolving nature and complexity of social media platforms coupled with the volume of information that everyone with any social media accounts was exposed to, it would be extremely difficult to ensure that every employee got it right every single time, and therefore AstraZeneca did not believe it was necessary to go through such a heavy-handed process when a mistake was made, which was corrected promptly.

AstraZeneca stated that there needed to be a better mechanism to prompt companies to resolve the issue internally where minor mistakes had been made versus the PMCPA penalising companies even when the mistake had been corrected promptly and the company clearly demonstrated rigorous efforts to train employees appropriately and maintain high standards.

AstraZeneca stated that it took all allegations of non-compliance seriously and always strove to learn from any mistakes made, and implement the knowledge learnt into future practices.

In response to a request for further information from the Panel, AstraZeneca provided copies of the iNews article and Reuters article which it had downloaded from the third-party websites. AstraZeneca submitted that it did not have original copies of the articles because it had no involvement in the initiation, content creation, editing or publishing of the articles.

AstraZeneca submitted that the article from iNews was editorial and was written independently by the newspaper. The very senior AstraZeneca UK employee was not interviewed by the journalist, nor did they engage with the journalist in any way. AstraZeneca supplied a quote from the very senior AstraZeneca UK employee to the Government to support a press release issued by the Government on the one-year anniversary of the UK approval of the Oxford/AstraZeneca COVID-19 vaccine at the end of December 2021. AstraZeneca also provided the same quote to support a press release that AstraZeneca issued about its two employees who were honoured in The Queen's Honour's list. The news desk at iNews were a recipient of this information. However, nothing was sent to the specific journalist who wrote the iNews article and there were no follow-up questions, calls, or email exchanges.

With respect to questions about the Reuters article, AstraZeneca submitted that of the three AstraZeneca employees identified from the screenshot who liked the post, one employee was based in Cambridge at the time of the complaint, and the other two employees were based in Canada. The two Canadian employees had contracts with AstraZeneca Canada, which was also the case at the time of the complaint. The Reuters article was about Evusheld. Evusheld was an antibody combination of tixagevimab (150 mg in 1.5 and cilgavimab (150 mg in 1.5 mL) and was first approved in the UK on 17 March 2022 for pre-exposure prophylaxis of COVID-19 in adults who are not currently infected with SARS-CoV-2 and who have not had a known recent exposure to an individual infected with SARS-CoV-2 and: Who are unlikely to mount an adequate immune response to COVID-19 vaccination or for whom COVID-19 vaccination is not recommended.

PANEL RULING

The Panel noted that LinkedIn was different to some other social media platforms in that it was a business and employment-orientated network and was primarily, although not exclusively, associated with an individual's professional heritage and current employment and interests; its application was not limited to the pharmaceutical industry or to health care. In the Panel's view, it was of course not unacceptable for company employees to use personal LinkedIn accounts; the Code would not automatically apply to all activity on a personal account. The Panel noted that compliance challenges arose when the personal use of social media by pharmaceutical company employees overlapped with their professional responsibilities or the interests of the company.

The Panel noted that material could be disseminated or highlighted by an individual on LinkedIn in a number of ways, by posting, sharing, commenting or liking. The Panel understood that if an individual 'liked' a post it increased the likelihood that the post would appear in their 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. In addition, an individual's activity and associated content might appear in the individual's list of activities on their LinkedIn profile page which was visible to their connections; an individual's profile page was also potentially visible to others outside their network depending on the individual's security settings. Company employees should assume that such activity would therefore, potentially, be visible to both those who were health professionals or other relevant decision makers and those who were members of the public. In that regard, it was imperative that they acted with extreme caution when using all social media platforms, including LinkedIn, to discuss or highlight issues which impinged on their professional role or the commercial/research interests of their company. Whether the Code applied would be determined on a case-by-case basis, taking into account all of the circumstances including, among other things, content and distribution of the material. If an employee's personal use of social media was found to be in scope of the Code, the company would be held responsible.

The Panel considered that companies should assume that the Code would apply to all work-related, personal LinkedIn posts/activity by their employees unless, for very clear reasons, it could be shown otherwise. Any material associated with a social media post, for example, a link within a post, would be regarded as being part of that post. Companies must have comprehensive and up to date social medial policies that provide clear and unequivocal guidance on what was, and what was not, acceptable and it was extremely important that employees were trained upon them and followed them.

The Panel acknowledged that, in the context of the Covid-19 pandemic, there would be much interest in the work being done by pharmaceutical companies. The Panel recognised that the use of social media raised particular compliance challenges for companies and that employees might feel inclined to endorse social media posts related to their company or posted by senior colleagues and depending on the content such activity might or might not fall within the scope of the Code. Nonetheless, companies must ensure that materials and activities within the scope of the Code were compliant with it.

1 LinkedIn post by the very senior AstraZeneca UK employee

The Panel noted AstraZeneca's submission that the LinkedIn post shared by the very senior AstraZeneca UK employee was a corporate statement made on behalf of AstraZeneca which did not constitute promotion and that AstraZeneca believed the linked article was part of a strategic campaign **to encourage vaccination** by the UK Government (emphasis added by the Panel). The Panel noted that the LinkedIn post in question appeared to be content created by the very senior AstraZeneca UK employee AstraZeneca's UK president which included a link to the inews article rather than 'sharing' another account's content.

The Panel further noted AstraZeneca's submission that, as noted by the UK Prime Minister, AstraZeneca's vaccine was provided on a not-for-profit basis so there was neither an intention nor any motivation to promote. The Panel, however, noted the broad definition of promotion as stated in Clause 1.17; it meant any activity undertaken by a pharmaceutical company or with its authority which promoted the administration, consumption, prescription, purchase, recommendation, sale, supply or use of its medicines. The Panel noted that the Code applied to the promotion of medicines and in that regard provided no exemptions related to how a medicine was made available or accessed.

The Panel considered that the statement by the very senior AstraZeneca UK employee 'Today is the one-year anniversary of the first Oxford/AZ vaccine administered in the UK:-). Since then 2.5 billion doses have been administered in more than 70 countries around the world' was providing reassurance to the reader that the vaccine had been widely used. In addition, the Panel noted that the article titled, '[Prime Minister] praises "brilliant" scientists behind AstraZeneca jab one year on from approval' published on 29 December 2021, a link to which was included in the LinkedIn post and therefore formed part of the LinkedIn post created by the very senior AstraZeneca UK employee, stated 'He credited the Covid-19 vaccine for saving "millions of lives" as he marked the anniversary of the jab's creation' above a photograph of the Prime Minister.

The Panel noted that the article quoted the very senior AstraZeneca UK employee and stated, *inter alia*:

> '[very senior AstraZeneca UK employee], said he was "quietly humbled and hugely proud of the work we have done".
>
> This has only been possible thanks to the tireless efforts and is to the huge credit of so many colleagues, partners, healthcare workers, volunteers and members of the public who have stepped forward to support this unprecedented national effort," he said.
>
> "There remain huge challenges ahead, much vital work is still to be done, but in 2021 we achieved remarkable things and this should give us confidence and renewed hope for 2022."'

The article further stated:

> 'Following a successful Phase 3 trial – which saw thousands of members of the public volunteering to take part[y] – the vaccine was approved for use in the UK on 30 December 2020. It was the first country to do so and initial vaccinations outside of a clinical trial took place on 4 January 2021. Since then, it has been approved by several medicine agencies worldwide, including the European Medicines Agency (EMA) and the World Health Organisation (WHO). There was initial scepticism from some countries about the efficacy of the vaccine, and suggestions of a link between the jab and blood clots caused several to

> suspend use of the jab. Following a review, the WHO has said the benefits of the vaccine outweighs its potential risks, further recommending that vaccinations continue.'

The article went on to state:

> '[Prime Minister] said: "Our fight against Covid in the UK and around the world would not have been possible without the Oxford-AstraZeneca vaccine."
>
> "Developed by brilliant scientists at Oxford and delivered on a not-for-profit basis thanks to AstraZeneca, this vaccine has provided 50m doses to the British public and over 2.5bn to more than 170 other countries."
>
> "We can all be incredibly proud of – and grateful for – a jab that has saved many millions of lives."
>
> The Health Secretary said the "UK-made and government-funded vaccine" had been "absolutely pivotal in helping to save millions of lives around the world".
>
> "I'm incredibly proud of the role the UK has played in developing, researching and manufacturing ground-breaking vaccines and treatments during the pandemic," [the Health Secretary] said.'

The article ended with:

> 'Vaccines are the best way to protect people from Covid-19 and I'm urging everybody to play their part in this national mission – roll up your sleeves and get your jabs.'

Noting the definition of promotion and the content of the LinkedIn post including the article, the Panel considered that the LinkedIn post promoted AstraZeneca's Covid-19 vaccine.

The Panel disagreed with AstraZeneca's submission that linking to the article, which it believed was part of a strategic campaign to encourage vaccination by the UK Government, was not in breach of the Code, as vaccines were treated as unique exceptions, within the context of providing non-promotional information about medicines to the general public in line with the provisions of Clauses 11.3, as well as Clauses 3.2, 26.1 and 26.2. The Panel noted that Clause 11.3 of the 2021 Code stated that a medicine with a temporary supply authorisation must not be promoted unless it is part of a campaign that has been approved by health ministers. The supplementary information to Clauses 3.1 and 3.2, stated, *inter alia*, that in response to certain types of public health emergency, under UK law, the licensing authority may temporarily authorise the sale or supply of a medicine without a marketing authorisation. This might apply to medicines without UK marketing authorisations or indications without UK marketing authorisations. The campaign must be approved by the health ministers and all other relevant requirements of the Code will apply. In relation to advertising to health professionals and other relevant decision makers, further information is given in Clause 11.3 and its supplementary information. In relation to advertising to the public, further information is given in Clause 26.1 and its supplementary information. Companies should contact the Medicines and Healthcare products Regulatory Agency (MHRA) for information regarding approval of materials and activities.

The Panel noted its comments above that in its view the LinkedIn post, which included the article, was promotional.

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

The Panel noted AstraZeneca's submission that at the time the LinkedIn post was made, the AstraZeneca vaccine had a temporary authorisation to supply and did not yet have a full marketing authorisation in the UK. The Panel noted that Clauses 26.1 and 26.2 only applied to prescription only medicines; the AstraZeneca vaccine had not been classified as such at the time the LinkedIn post was made and so, on that very narrow technical point, the Panel did not consider that a prescription only medicine had been advertised to the public and **no breach of Clauses 26.1 and 26.2** were ruled.

The Panel, however, considered that the LinkedIn post made by the very senior AstraZeneca UK employee, which included the inews article, constituted the promotion of a medicine with a temporary supply authorisation. There was no evidence before it that the LinkedIn post had been approved as part of a campaign approved by the health ministers and therefore, it constituted the promotion of AstraZeneca's covid vaccine prior to the grant of its marketing authorisation. A **breach of Clause 5.1** was ruled in this regard.

The Panel noted the complainant's allegation that materials to be used with the public should be certified to ensure that promotion to the public did not happen. The Panel noted AstraZeneca's submission that the post was examined but not certified. The Panel noted that based on the complainant's allegation, AstraZeneca had been asked to consider the requirements of Clause 8.3 which required that certain non-promotional materials must be certified in advance in a manner similar to that provided by Clause 8.1 which covered the certification of promotional material. In this regard, the Panel noted its view that the LinkedIn post was promotional and thus Clause 8.3 was not relevant and therefore **no breach of Clause 8.3** was ruled.

2 Reuters article entitled AstraZeneca antibody cocktail works against Omicron in study

The Panel noted AstraZeneca's submission that this article appeared to have been posted as 'a story that mentioned AstraZeneca' by LinkedIn and that the article was not posted by AstraZeneca or by an AstraZeneca employee.

The Panel noted that the LinkedIn post was, however, 'liked' by three AstraZeneca global employees (AstraZeneca global was located in the UK). The Panel noted that it was an established principle under the Code that UK-based global or other such companies were subject to the Code. If such entities were not members of the ABPI, or on the list of non-member companies that otherwise complied with the Code, the UK company had to take responsibility for their acts and omissions under the Code. The Panel noted AstraZeneca's submission that two of the employees were Canadian-based Global employees and had contracts with AstraZeneca Canada. In the Panel's view, the actions of employees of a company located in the UK (AstraZeneca Global), albeit if the employees in question were based outside of the UK, would fall within the scope of the ABPI Code unless it could clearly be demonstrated otherwise. It was unclear whether the two employees, which AstraZeneca first described as Canadian-based Global employees and then subsequently described as 'Canadian employees', were employees

of UK-based AstraZeneca Global or of the affiliate company, AstraZeneca Canada. The Panel did not have a copy of the contracts before it. Regardless of the actions of the employees based in Canada, the Panel noted that, in addition, the post was 'liked' by a UK-based AstraZeneca Global employee, whose actions brought the LinkedIn post within the scope of the UK Code and, in that regard, the UK-based employee's engagement with the post, on the balance of probabilities, would have proactively disseminated the material to his/her LinkedIn connections, not all of which would likely meet the Code's definition of a health professional or other relevant decision maker and therefore the information had likely been made available to members of the UK public.

The Panel noted the title of the article within the LinkedIn post which was published on 16 December 2021 was 'AstraZeneca antibody cocktail works against Omicron in study'. The Panel noted that the article stated, *inter alia*:

> 'Dec 16 (Reuters) - AstraZeneca (AZN.L) said on Thursday a lab-study of its COVID-19 antibody cocktail, Evusheld, found that the treatment retained neutralising activity against the Omicron coronavirus variant, showing promise for wider use of the therapy.'
>
> The study was conducted by independent investigators of the U.S. Food and Drug Administration, the company said: 'adding that more analyses of Evusheld against Omicron are being conducted by AstraZeneca and third-parties, with data expected "very soon"'.

In the Panel's view, the UK-based AstraZeneca Global employee's engagement with the post would have, on the balance of probabilities, proactively disseminate positive information about Evusheld to the employee's connections which would likely include members of the UK public and, in the Panel's view, promoted Evusheld.

The Panel noted AstraZeneca's submission that the employee had not acted in accordance with its Global Standard. The Panel noted that AstraZeneca had a global standard for employee use of personal social media channels for company and work-related content. The document reminded employees that there was special scrutiny from regulatory authorities when content related to its company's products or was about disease education/awareness. Employees were further reminded that as an organisation, AstraZeneca would be held accountable for Company-related content on its employees' personal social media channels. Employees were instructed not to post self-created product- related or disease education/awareness content on their personal channels, or engage with (liking, sharing, commenting on) this type of content from 3rd-party sources. It further stated 'To ensure we get this right, do not post self-created content about our products or about disease education/awareness to your personal channels. The same applies to sharing 3rd-party posts to your personal feeds that are product-related or about disease education/awareness. Further, just "liking" or commenting on such 3rd-party posts is considered a form of endorsement, so avoid reacting to posts if you are unsure if the post meets the requirements'. The Panel considered that this instruction was unambiguous. The Panel noted AstraZeneca's submission that the latest version of this Standard was first provided as a read and sign to all UK-based employees in 2020. Since then, regular internal communications reminded employees about the key principles of personal social media use for AstraZeneca or work-related content. According to AstraZeneca, it sent the latest communication about personal use of social media in January 2022 and as part of the AstraZeneca Code of Ethics awareness training, a mandatory online e-learning course was delivered to all AstraZeneca employees on an annual basis. This training course was updated in 2021 to include a new section on personal use of social media for work-related content. The training was launched in October 2021 and was

made available in 11 languages and it had a 30-day completion window. The Panel noted AstraZeneca's submission that the UK-based employee at issue had been asked to immediately withdraw the 'like' at issue which had been done.

The Panel noted AstraZeneca's submission that Evusheld was an antibody combination of tixagevimab (150 mg in 1.5 and cilgavimab (150 mg in 1.5 mL)) and was first approved in the UK on 17 March 2022 for pre-exposure prophylaxis of COVID-19 in certain adults.

The Panel noted that at the time of the engagement with the LinkedIn post by the UK-based employee, Evusheld did not have a marketing authorisation in the UK. The Panel noted that Clauses 26.1 and 26.2 only applied to prescription only medicines; the AstraZeneca medicine had not been classified as such at the time the LinkedIn post was 'liked' by the UK-based global employee and so, on that very narrow technical point, the Panel did not consider that a prescription only medicine had been advertised to the public and **no breach of Clauses 26.1 and 26.2** were ruled.

The Panel, however, considered that the UK-based global AstraZeneca employee's 'like' of the LinkedIn post and associated article, and on the balance of probabilities, its subsequent proactive dissemination to their connections, promoted the medicine prior to the grant of its marketing authorisation and **a breach of Clause 5.1** was ruled in this regard.

The Panel noted the complainant's allegation that materials to be used with the public should be certified to ensure that promotion to the public did not happen. The Panel noted that AstraZeneca had therefore been asked to consider the requirements of Clauses 8.3 which required that certain non-promotional materials must be certified in advance in a manner similar to that provided by Clause 8.1 which covered the certification of promotional material. In this regard, the Panel noted its view that the dissemination of information by the AstraZeneca employee was promotional and thus Clause 8.3 was not relevant and **no breach of Clause 8.3** was ruled in that regard.

3 Very senior AstraZeneca employee interview by BBC for the Today Programme

The Panel noted the complainant's concern that the very senior AstraZeneca employee had promoted the company's product and made unsubstantiated claims that use of AstraZeneca's vaccine was the reason for improved response compared to Europe.

The Panel noted AstraZeneca's submission that during the official unveiling of the AstraZeneca Discovery Centre (DISC) in Cambridge on 23 November 2021, the very senior AstraZeneca employee was interviewed by invited media which included an interview with a BBC journalist for the Today Programme; and an edited video clip of that interview was subsequently hosted on the BBC website. The Panel noted AstraZeneca's submission that it had no editorial control of the final video that was hosted on the BBC website; all editorial rights remained with the BBC.

The Panel noted that complaints about third party articles in the press etc were judged upon the acceptability of the information provided to that third party by the pharmaceutical company, such as any press release, unedited interview etc rather than the final published article.

The Panel did not have a copy of the edited or unedited video before it. AstraZeneca had provided a transcript of the video as it appeared on the BBC website and, in addition, included two questions which were asked by the journalist but not included in the published video as

AstraZeneca considered that those questions provided the context to the information the very senior AstraZeneca employee discussed. It was not clear to the Panel why AstraZeneca did not provide the full unedited transcript. According to the transcript provided, the first question asked by the journalist, but not included in the published BBC video, was:

> 'Taking a step back, is one of the lessons that we have learnt in the last year so that actually, the future is mRNA which is the technology that is Pfizer and Moderna and not this vaccine. That you've backed a vaccine that as you say has been enormously useful, still will be for some years to come, particularly the developing world but actually the future, particularly in West is not this technology.'

The Panel noted from the transcript that in response, the very senior AstraZeneca employee stated:

> 'Well, I would say mRNA is a great technology, but we also say that there are questions that are remaining. (This sentence was according to AstraZeneca not included in the edited video hosted on the BBC website). You know, you have two dimensions to this immune response and maybe more. But at least two we can identify, one is the antibody response and two is the so called T-cell response and the antibody response is what drives the immediate reaction or defence of the body. When you are attacked by the virus and the T-cell response takes a little longer to come in, maybe a couple of days or 3 days but it's actually more durable; it last longer and the body remembers that longer. So you see [anti and] everybody is focused on antibodies. But antibodies you see them decline over time. Right. Up to a point in time when the antibody level is quite low'.

Following a comment from the interviewer, 'Well you're seeing it now particularly in Germany and in other parts of Europe', the very senior AstraZeneca employee stated, *inter alia*:

> 'What remains and is very important is this T-cell response, and those T-cells are dormant and as soon as the virus attacks you they wake up and they come to rescue and defend you. And but it takes them a while so you may be infected, but then they come to the rescue and you don't get hospitalised, and it's really interesting when you look at the UK there was a big peak of infections, but not so many hospitalisations relative to Europe. In the UK this vaccine was used to vaccinate older people whereas in Europe initially people thought the vaccine [does work] in older people.'

In response to a further clarifying question from the interviewer:

> 'But hang on a second just to make clear what you're saying is we don't know this yet but you're saying that mistake by Europe could could be what has led now to this surge in cases, could be?.'

The very senior AstraZeneca employee stated:

> 'Well I am not saying there was any mistake done by anybody. I'm just saying that there's a lot of data that still need to be made available that we don't have.'

The Panel noted that the second question from the journalist, and not included in the published video, was:

> ‘But would you say that could be a link between what's happening now, the current situation with cases, hospitalisations in this country, relatively low but going hugely up in in Europe, that that could be linked to the fact that AstraZeneca wasn’t used in older people so that T-cell response isn’t there?’

In response, the very senior AstraZeneca employee stated:

> ‘What I am saying is that T-cells do matters and in particular as it relates to the durability of the response, especially in older people and this vaccine has been shown to stimulate T-cells to a higher degree in older people. And so, the older people are those that end up unfortunately hospitalised as you know. I mean, a 35 year old who is very healthy is very unlikely to be hospitalised especially if they have been vaccinated. So, you know we haven't seen many hospitalisations in the UK. A lot of infections, for sure. Everyone is talking about those, but what matters is are you severely ill or not, are you hospitalised or not and we haven't seen so many of these hospitalisations in the UK.’

which was included in the published BBC video.

The Panel considered that AstraZeneca’s submission that no brand names had been used in the interview was not relevant as it was a well-established principle that, depending on the context, a product could be promoted even without its name ever being mentioned. The Panel disagreed with AstraZeneca’s submission that there were no claims about efficacy of the vaccine; it was clear that within the interview, the AstraZeneca vaccine was being compared to the Pfizer and Moderna vaccines in terms of their mechanisms of action, the antibody response and the T-cell response and the benefits in relation to reduction in hospitalisations in this regard.

The Panel considered that the overall impression was that use of the Oxford/AstraZeneca vaccine in the elderly population in the UK had resulted in fewer hospitalisations compared to Europe and the message was promotional.

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

The Panel noted that at the time the interview took place and an edited video of it was hosted on the BBC website on 23 November 2021, the AstraZeneca vaccine had a temporary authorisation to supply and did not yet have a full marketing authorisation in the UK. Clauses 26.1 and 26.2 only applied to prescription only medicines, therefore based on this technical point the Panel ruled **no breach of Clauses 26.1 and 26.2.**

The Panel, however, noting the content of the video transcript provided by AstraZeneca, considered that the interview given by the very senior AstraZeneca employee had promoted a medicine with a temporary supply authorisation. There was no evidence before it that the interview had been approved as part of a campaign approved by the health ministers and therefore, it constituted the promotion of AstraZeneca’s medicine prior to the grant of its marketing authorisation. **A breach of Clause 5.1** was ruled in this regard.

The Panel noted the complainant’s allegation that the very senior AstraZeneca employee made claims that the use of AstraZeneca’s vaccine was the reason for the improved response compared to Europe, which the complainant alleged could not be substantiated. The Panel

noted that very senior AstraZeneca employee had stated during the interview 'there's a lot of data that still need to be made available that we don't have' in response to a question whether Europe made a mistake by not using the AstraZeneca vaccine. However, the Panel considered that the complainant bore the burden of proof and they had not provided evidence to show that the very senior AstraZeneca employee's statements were not capable of substantiation as alleged and **no breach of Clause 6.2** was ruled.

The Panel noted the complainant's allegation that materials to be used with the public should be certified to ensure that promotion to the public did not happen. The Panel noted that AstraZeneca had therefore been asked to consider the requirements of Clause 8.3 which required that certain non-promotional materials must be certified in advance in a manner similar to that provided by Clause 8.1 which covered the certification of promotional material. In this regard, the Panel noted its view that the interview was promotional and thus Clause 8.3 was not relevant and **no breach of Clause 8.3** was ruled.

The Panel noted that the complainant had alleged that the interview had been used in many other publications which raised the question what processes were so lax for this to occur but had not provided information about other publications. The Panel considered that the complainant had not discharged their burden of proof in this regard and **no breach of Clause 5.1** was ruled.

Clause 2

The Panel noted that promotion prior to the grant of a marketing authorisation was an example of an activity likely to be in breach of Clause 2. The Panel noted its three rulings of a breach of Clause 5.1 above in relation to the promotion of an unlicensed medicine in three separate matters.

The Panel noted its comments above and considered that it was unfortunate that in relation to Matter 2, AstraZeneca had been let down by one of its UK-based employees not following company guidelines on which they had been trained; an action that resulted in a medicine being promoted prior to the grant of its marketing authorisation.

The Panel was concerned that Matters 1 and 3 involved very senior employees whose actions had resulted in the promotion of an AstraZeneca medicine prior to the grant of the marketing authorisation which permits its sale or supply.

Further, the Panel was concerned that in Matter 1, it appeared that both a very senior UK employee and AstraZeneca had failed to recognise the promotional nature of the LinkedIn post resulting in the placement of an uncertified promotional post on the senior employee's personal LinkedIn account which resulted in the promotion of a medicine prior to the grant of its marketing authorisation including to members of the public as alleged.

The Panel, noting its comments above, considered that AstraZeneca had brought discredit upon, and reduced confidence in, the pharmaceutical industry and a **breach of Clause 2** was ruled.

4 Alleged breach of undertaking

The Panel noted the complainant's allegation in relation to a breach of undertaking given in Case AUTH/3412/10/20.

The Panel noted that Case AUTH/3412/10/20 concerned a UK-based AstraZeneca employee 'liking' a LinkedIn post made by a Daiichi-Sankyo US marketing company employee which linked to a Press Release about a medicine used in breast cancer which was unlicensed in the UK at the time the post was engaged with by the AstraZeneca employee. AstraZeneca and Daiichi-Sankyo had a joint development and commercialisation agreement for the compound at the time of the complaint. In that case, (Case AUTH/3412/10/20) the Panel ruled that an unlicensed medicine had been promoted in breach of Clause 3.1 of the 2019 Code.

The Panel noted its rulings in relation to the current case (Case AUTH/3597/1/22) were in relation to promotion of unlicensed medicines related to COVID-19. The first matter was in relation to a LinkedIn post created by a senior UK AstraZeneca employee which included a link to an inews article, the second was in relation to a Reuters LinkedIn post which had been 'liked' by a UK-based global employee and the third was in relation to the very senior AstraZeneca employee's comments during a BBC interview, all three of which were found to be in breach for promoting an AstraZeneca medicine prior to the grant of its marketing authorisation. Despite its rulings, the Panel considered that the matters were sufficiently different to Case AUTH/3412/10/20 such that there had been no breach of the undertaking given in Case AUTH/3412/10/20. The Panel therefore ruled **no breach of Clause 3.3** and consequently **no breach of Clauses 5.1 and 2** in this regard.

APPEAL BY ASTRAZENECA

AstraZeneca submitted that it strongly disagreed with the Panel's rulings in this case. AstraZeneca provided its reasons for this appeal in relation to the Panel's rulings of breaches of Clauses 5.1 (x3) and Clause 2.

AstraZeneca's appeal was structured as follows:

A. AstraZeneca's reasons for appealing each of the breaches of the Code:

    1) LinkedIn post by AstraZeneca very senior AstraZeneca UK employee;
    2) Reuters article entitled 'AstraZeneca antibody cocktail works against Omicron in study' and
    3) A very senior AstraZeneca employee interview by BBC for the Today Programme.

B. Applicability of Clause 2 to the three matters listed above.

<u>Matter 1: LinkedIn post by a very senior AstraZeneca UK employee</u>

AstraZeneca submitted that this complaint related to a post on the personal LinkedIn account of a very senior AstraZeneca UK employee, on 4 January 2022 and included a link to an article on inews.co.uk titled '[Prime Minister] praises 'brilliant' scientists behind AstraZeneca jab one year on from approval' (the 'iNews article').

Background

AstraZeneca submitted that its Covid-19 vaccine (the 'Vaccine' or 'Vaxzevria') was granted an authorisation under Regulation 174 Human Medicines Regulations 2012 (the 'Regulation 174 Authorisation') by the UK Licencing Authority on 30 December 2020 in the context of the global

SARS-CoV-19 crisis and the first dose was administered to a UK recipient under the UK Government's vaccination programme on 4 January 2021. Regulation 174 provided that an unlicensed product maybe be sold or supplied where so authorised by the MHRA on a temporary basis in response to, *inter alia*, the spread of pathogenic agents which might cause harm to human beings. A medicinal product authorised under Regulation 174 had undergone rigorous assessment by MHRA and the benefits of use had been found to outweigh the risks. However, a Regulation 174 Authorisation was a temporary authorisation for emergency use and not a marketing authorisation.

AstraZeneca submitted that the Licensing Authority subsequently granted it a conditional marketing authorisation ('CMA') for the Vaccine on 24 June 2021. A CMA was a tool for approval of a medicine granted where the risk benefit ratio of the product was positive, but the MHRA required collection of additional evidence about the safety and efficacy of the product. It was valid for one year and must be renewed annually until a full marketing authorisation was granted. A CMA would only be renewed if the risk benefit balance remained positive. The CMA for Vaxzevria was renewed by the Licensing Authority on 24 June 2022.

AstraZeneca submitted that following grant of the conditional marketing authorisation on 24 June 2021, it continued to supply Vaxzevria in accordance with the Regulation 174 Authorisation, with the approval of the UK Government, up until May 2022. During this period, large quantities of the Vaccine were being produced each week and the pause in production required to transfer from the Regulation 174 labelling to the CMA labelling would have resulted in significant disruption to the supply chain.

AstraZeneca submitted that in the weeks leading up to 4 January 2022, it corresponded with the teams at Number 10 Downing Street ('No 10'), DHSC and the Department for Business, Energy and Industrial Strategy ('BEIS') in relation to the communications that would be published to mark the one year anniversary of the first authorisation of the Vaccine, and the one year anniversary of its first use under the Government's vaccination programme, clearly matters of substantial public interest. The statement by the very senior AstraZeneca UK employee, posted on their LinkedIn account, was also provided by AstraZeneca to No 10, DHSC and BEIS.

AstraZeneca submitted that the DHSC's press release regarding the one year anniversary of authorisation of the AstraZeneca vaccine, was issued on 30 December 2021. The focus of the DHSC press release, which included various comments by very senior government ministers and the very senior AstraZeneca UK employee was the extraordinary work by scientists and healthcare professionals and the investment by the UK Government (copy provided).

AstraZeneca submitted that on 31 December 2021, two AstraZeneca employees were recognised in the Queen's New Year's Honours for their outstanding achievements in UK life sciences and for supporting the UK and Global response to the Covid-19 pandemic (copy provided).

On 4 January 2022, the anniversary of the first administration of the AstraZeneca Covid-19 vaccine, the very senior AstraZeneca UK employee posted on their personal LinkedIn account a comment almost identical to that shared with and published by DHSC in its press release of 30 December 2021 and also linked to an iNews article, based on the same DHSC press release.

<u>The Post</u>

The post stated:

> 'Today is the one-year anniversary of the first Oxford/AZ vaccine administered in the UK;-). Since then 2.5 billion doses have been administered in more than 70 countries around the world. I'm quietly humbled and hugely proud of the tireless work of so many colleagues, partners, healthcare workers, volunteers and members of the public who have stepped forward to support this tremendous effort.'

The iNews article

AstraZeneca submitted that the post linked to an iNews article, published on 4 January 2022 (copy provided), which was substantively based on DHSC's press release of 30 December 2021.

The iNews article included comments by very senior government ministers and the very senior AstraZeneca UK employee, taken from DHSC's press release and focussed, like the DHSC's press release and the post, on the extraordinary work by scientists and healthcare professionals and the investment by the UK Government. This was particularly reflected in the title of the iNews article '[Prime Minister] praises "brilliant" scientists behind AstraZeneca jab one year from approval'. The article also contained factual statements regarding the development of the Vaccine, but no product claims, save negative information regarding efficacy and safety concerns and the neutral conclusion by the WHO that the benefit risk remained positive. The article concluded with a statement from the Health Secretary:

> 'Vaccines are the best way to protect people from Covid-19 and I'm urging everybody to play their part in this national mission – roll up your sleeves and get your jabs.'

The Panel's findings

The Panel quoted the first two sentences from the post and various extracts from the iNews article and found that these were promotional.

The Panel stated that, in circumstances where the Vaccine was the subject of a Regulation 174 temporary authorisation to supply and not a full marketing authorisation, the LinkedIn post constituted the promotion of the Vaccine prior to the grant of its marketing authorisation and ruled a breach of Clause 5.1 of the Code.

Appeal

AstraZeneca appealed firstly on the basis that the content of the post, including the linked article was not promotional, and submitted:

- The finding of the Panel that the first two sentences of the post were 'providing reassurance to the reader that the vaccine had been widely used' was disputed. These sentences contained purely factual information, as background to the message of thanks in the remainder of the post in the context of an event of significant public interest. They did not fall within the definition of promotion at Clause 1.17 of the Code.
- While the Panel quoted various extracts from the iNews article, it had provided no explanation for its conclusion that these were promotional. In fact, they constituted factual information about the development of the Vaccine and Government's involvement in this endeavour.

- The final statement in the iNews article, quoted by the Panel and referenced above, related to vaccines generally and not to the Vaccine or any other specific Covid-19 vaccine.

In summary, AstraZeneca submitted that the intent of the very senior AstraZeneca UK employee's message was to join with Government in expressing thanks to scientists and healthcare workers for their remarkable efforts, in the context of the year anniversary and the New Year's Honours list, which was, as acknowledged by the Panel, a topic of particular media interest at the time.

AstraZeneca noted that the Appeal Board should be aware that AstraZeneca had no interest in promoting the vaccine to healthcare professionals or to the public. Supply of Vaxzevria was determined by contracts with Government agreed before 4 January 2022, which involved fixed quantities of product allocated by Government. Usage of the Vaccine would not be increased by any statement issued by AstraZeneca.

Secondly, AstraZeneca submitted that the regulatory status of the Vaccine at the time of the post was, as indicated above, complex. While, at that time, Vaxzevria continued to be supplied under the Regulation 174 Authorisation, the Vaccine had been granted a CMA by the UK Licensing Authority on 24 June 2021, following detailed assessment by MHRA. It was not therefore correct to conclude, as the Panel had done, that no marketing authorisation had been granted, even though the Vaccine in circulation in the UK at that time, was not supplied in accordance with that authorisation. In particular, the reasons for prohibiting promotion of a medicinal product prior to the grant of a marketing authorisation at Clause 3.1 of the Code, namely that such a product had not been assessed and authorised by the regulatory authority, did not apply to Vaxzevria on 4 January 2022.

In conclusion, AstraZeneca submitted that the content and objective of the post was not promotional and the post was not published prior to the grant of a marketing authorisation for Vaxzevria. The Panel's finding that the post failed to maintain high standards in breach of Clause 5.1 of the Code, was therefore based on an incorrect assessment of the facts and should be set aside.

Matter 2: Reuters article entitled AstraZeneca antibody cocktail works against Omicron in study

AstraZeneca noted that this complaint concerned a LinkedIn post, that was generated and posted by LinkedIn itself on 16 December 2021 as a story that mentioned AstraZeneca and was subsequently 'liked' by three AstraZeneca employees.

Background

AstraZeneca submitted that the LinkedIn post showed a photograph of what appeared to be an outdoor sign of the AstraZeneca corporate logo outside AstraZeneca's North America Headquarters and linked to an article on reuters.com with the title 'AstraZeneca antibody cocktail [Evusheld] works against Omicron in study'. The article described a laboratory study of Evusheld conducted by independent investigators from the US Food and Drug Administration, which had found that the product retained neutralising activity against the Omicron coronavirus variant, showing 'promise' for wider use of the therapy.

AstraZeneca submitted that the post was 'liked' by three AstraZeneca employees, only one of which was based in the UK. Following receipt of the complaint on 6 January 2022, the employees were contacted and the 'likes' were promptly removed on 7 January 2022.

The Panel's findings

The Panel noted that it had not been established if two of the employees, who were based in Canada, were employees of UK-based AstraZeneca Global and ruled solely on the 'like' by one UK-based employee. The Panel considered that the UK-based employee's 'like' of the LinkedIn post and associated article and, on the balance of probabilities, its subsequent proactive dissemination to his/her connections, promoted Evusheld prior to the grant of its marketing authorisation. On this basis, the Panel concluded that high standards had not been maintained, in breach of Clause 5.1.

Appeal

AstraZeneca confirmed that the two employees based in Canada were employed by AstraZeneca Canada. AstraZeneca accepted that its employees should not engage with posts of this nature. However, in the context of the clear company position and rigorous training provided to employees by the company, AstraZeneca did not agree that the single 'like' referenced by the complainant was indicative of high standards not being maintained.

In response to the complaint, AstraZeneca disclosed to the Panel a document, 'The Global Standard for employee use of personal social media channels', on which all employees were routinely trained and assessed. As the Panel had noted, the wording in the document as regards 'liking' of posts on LinkedIn was 'unambiguous'. Thus, AstraZeneca submitted, its employees were clearly being given the correct message about liking of posts on LinkedIn in compliance with the high standards set by AstraZeneca. AstraZeneca employees additionally were required to undergo comprehensive training about interacting on social media (copy provided). Finally, as soon as the 'like' was drawn to AstraZeneca's attention, the employees in question were immediately contacted and the 'like' was promptly removed.

AstraZeneca submitted that it, or any pharmaceutical company, could not guarantee that rare events of this nature would never occur regardless of the extensive measures put in place to prevent them. Indeed, the Panel had noted that it was 'unfortunate' that AstraZeneca had been 'let down by one of its UK-based employees not following company guidelines on which they had been trained'. The position was particularly challenging for UK head quartered companies, such as AstraZeneca, who had thousands of employees, many of whom did not focus on the UK market. In this context, AstraZeneca respectfully submitted that a single mistake, despite comprehensive company policies and training and prompt corrective action should not result in a finding that high standards had not been met, in breach of Clause 5.1.

Matter 3: A very senior AstraZeneca employee interview by BBC for the Today Programme

AstraZeneca submitted that this complaint concerned an interview given by a very senior AstraZeneca employee, to a BBC journalist during the official unveiling of the AstraZeneca Discovery Centre in Cambridge on 23 November 2021. An edited video clip of that interview was subsequently hosted on the BBC website.

The complainant alleged that a very senior AstraZeneca employee had promoted the AstraZeneca Covid-19 vaccine and made unsubstantiated claims that use of AstraZeneca's vaccine was the reason for improved response compared to Europe.

The Panel considered that the overall impression was that use of the Oxford/AstraZeneca vaccine in the elderly population in the UK had resulted in fewer hospitalisations compared to Europe and the message was promotional. The Panel, noting the content of the video transcript provided by AstraZeneca, considered that the interview had promoted a medicine with a temporary supply authorisation and ruled a breach of Clause 5.1. However, the Panel ruled that the complainant had not provided evidence to show that the very senior AstraZeneca employees, statements were not capable of substantiation and no breach of the Code was ruled in this regard.

AstraZeneca disagreed that a medicine without a marketing authorisation had been promoted and that high standards had not been maintained by the way in which the interview was handled by the very senior AstraZeneca employee.

Background

AstraZeneca noted that the Panel was obliged to make rulings based on what was stated, rather than the edited published product. Therefore, quotations by a very senior AstraZeneca employee, could only be considered in the context of the whole interview. In response to the complaint, AstraZeneca submitted only the parts that seemed to be relevant to the complaint, namely a transcript of the published parts of the interview plus two questions asked by the journalist that had been edited out. However, in its decision, the Panel questioned why a transcript of the full interview had not been provided and this was therefore disclosed (copy provided). AstraZeneca had no editorial control or right to review the edited portions of the interview that were published.

AstraZeneca recognised the care and consideration that must be put into responding to journalists' questions and senior AstraZeneca employees were regularly briefed on the latest regulatory and scientific developments regarding the vaccine and were provided with accurate and appropriate answers, for reactive use only, to questions they might be asked. The relevant regulatory and scientific briefing document at the time of the interview which was produced for internal use only and was clearly marked as for 'REACTIVE USE ONLY' was provided: AstraZeneca, AZD1222 (Covid-19 vaccine) Q&A: Updated in line with latest publications, EU approval of Vaxzevria brand name, and EU/US supply (the 'Briefing Document').

<u>The Interview</u>

AstraZeneca submitted that the interview was given on 23 November 2021 in the context of the opening of AstraZeneca Discovery Centre. A briefing pack provided to journalists attending the opening was provided. This focussed entirely on the research to be conducted at the Discovery Centre, without reference to any specific products, as reflected in the quoted statement by the very senior AstraZeneca employee:

> 'Our ambition today is to not only unveil a building, but to also drive the next wave of scientific innovation. Our new Discovery Centre in Cambridge raises the bar for sustainable R&D and global collaboration across our industry. It will allow us to break new

> boundaries in the understanding of disease biology, bring life- changing medicines to patients and power the next stage of our company's growth.'

The BBC did not inform the very senior AstraZeneca employee, of the questions he would be asked, or topics that would be covered, prior to the interview. This commenced by discussing the Discovery Centre, as anticipated by AstraZeneca. The journalist then referred to the Vaccine and asked:

> 'taking a step back, is one of the lessons that we have learnt in the last year so that actually the future is mRNA which is the technology that is Pfizer and Moderna and not this vaccine.'

AstraZeneca submitted that the very senior AstraZeneca employee, provided a neutral response commencing with 'I would say mRNA is a great technology'. However, this was clearly an incomplete answer to the question from the journalist and he went on to clarify 'there are questions that are remaining' and referred to the difference between the antibody response and the T-cell response elicited by Covid-19 vaccines generally. The very senior AstraZeneca employee said it took time for the T-cell response to occur after a person was infected but that T-cells 'come to the rescue' so that hospitalisation was less likely. This explanation responded directly to the question from the journalist and reflected the current state of knowledge as reflected in the Briefing Document (copy provided). The very senior AstraZeneca employee concluded with two factual, and well-publicised, statements: (i) in the UK there was a peak of infections but not as many hospitalisations when compared to the EU; and (ii) in the UK it was Vaxzevria that was used to vaccinate older people whereas initially in Europe the Vaccine was thought not to work in older people.

The journalist then stated:

> 'you're saying that that mistake by Europe could could [sic] be what has led now to this surge in cases.'

The very senior AstraZeneca employee, promptly corrected the journalist:

> 'I am not saying there was a mistake done by anybody. I'm just saying that there's a lot of data that still need to be made available.'

This was a measured response to the question from the journalist that deliberately avoided a promotional statement in relation to Vaxzevria and stated that more data needed to be considered.

The journalist pressed the topic again and asked the very senior AstraZeneca employee if they would say the relatively low hospitalisations in the UK at the time of the interview, relative to the situation in Europe 'could be linked to the fact AstraZeneca wasn't used in older people so that T-cell Response isn't there?'.

Again, the very senior AstraZeneca employee answered the question based on available scientific knowledge:

> 'What I am saying is that T-cells do matter and [unclear] as it relates to the durability of the response, especially in older people and this vaccine has been shown to stimulate T-cells

> to a higher degree in older people. And so you know we haven't seen many hospitalisations in the UK.'

The very senior AstraZeneca employee therefore responded to the repeated questions from the Journalist using scientific evidence, consistent with the Briefing Paper.

The journalist continued to press the very senior AstraZeneca employee on this subject, stating: 'and that could be because the AstraZeneca vaccine wasn't used among older people' [referring to Europe]? their response however was balanced, fair and non-promotional:

> 'we don't know. There is no proof of anything. We don't know but we need more data to analyse this and get the answers.'

The Panel's findings

The Panel referred to the quoted extracts from the interview with the very senior AstraZeneca employee and concluded that these included claims of efficacy, compared the Vaccine with the Pfizer and Moderna vaccines in terms of their mechanisms of action, the antibody response and the T-cell response and the benefits in relation to reduction in hospitalisations in this regard and were therefore promotional. In addition, the Panel referred to the Vaccine's Regulation 174 Authorisation and suggested that the interview promoted a medicine prior to grant of a marketing authorisation. On this basis, the Panel ruled a breach of Clause 5.1 of the Code.

Appeal

AstraZeneca submitted that the statements by its very senior employee were not promotional. The interview was intended to be about the Discovery Centre, rather than vaccines, and AstraZeneca had no input into the questions posed by the journalist. All statements made by the very senior AstraZeneca employee in relation to the vaccine were factual and balanced and were provided in response to unsolicited questions; they therefore fell outside the definition of promotional statements in accordance with Clause 1.17 of the Code.

Furthermore, AstraZeneca submitted that while the Panel considered that the overall impression was that the vaccine's mechanism of action had been compared to that of Pfizer's and Moderna's vaccines, suggesting that use in the elderly population in the UK had resulted in fewer hospitalisations compared to Europe and the message was promotional, this was largely based on statements by the journalist. At no time did the very senior AstraZeneca employee make such an assertion and, in fact, he went to lengths to refute the journalist's statements to this effect: (i) 'I am not saying there was a mistake done by anybody'; (ii) 'there's a lot of data that still need to be made available'; (iii) 'we don't know'; (iv) 'There is no proof of anything' and (iv) 'We don't know but we need more data to analyse this and get the answers'.

Overall, AstraZeneca submitted that the very senior employee responded accurately and succinctly to unsolicited questions, in line with latest scientific developments and the Briefing Document. All questions were answered in a balanced manner, acknowledging where data were missing, and all responses were capable of substantiation. It was appropriate for an individual of the very senior AstraZeneca employee's seniority, to answer the unsolicited questions put to him on a topical and current issue in the context of the unique nature of the pandemic and the associated public interest. The very senior AstraZeneca employee responses were not promotional in tone or content and were in line with the high standard expected of the industry.

AstraZeneca submitted that in addition, while the Panel based its finding of breach of Clause 5.1 of the Code on its understanding that, at the time of the BBC interview on 23 November 2021, no marketing authorisation had been issued in relation to the Vaccine, this was not in fact the position. As indicated above, the Licensing Authority had granted a CMA for the Vaccine on 24 June 2021 although, at the relevant date of 23 November 2021, Vaxzevria continued to be supplied in the UK in accordance with the Regulation 174 Authorisation.

In conclusion, AstraZeneca submitted that the interview was not promotional and did not take place prior to the grant of a marketing authorisation for Vaxzevria. The Panel's finding that, for these reasons, the interview failed to maintain high standards in breach of Clause 5.1 of the Code, should be set aside.

Applicability of Clause 2

AstraZeneca noted that in ruling a breach of Clause 2 of the Code, the Panel referred to its three rulings of breaches of Clause 5.1 and that promotion prior to the grant of a marketing authorisation was an example of an activity likely to be in breach of Clause 2.

As a preliminary matter, AstraZeneca submitted that it was relevant that all three issues raised by the complainant were unrelated:

- While two matters involved use of social media, they related to different medicinal products and different activities ('posting' including a linked site, versus 'liking') and
- While two matters involved the Vaccine, they were not connected, one involving a post on LinkedIn and one a BBC interview.

AstraZeneca submitted that the fact that the complainant had picked up these three unrelated matters did not mean that they were, in any way, linked or cumulative. They could equally well have been the subject of three separate complaints. AstraZeneca therefore suggested that the fact they appeared on the same complaint should not be a factor when considering the application of Clause 2.

AstraZeneca submitted that in considering the content of the statements criticised by the complainant, it was relevant to take into account that, as recognized by the Panel, in the context of the Covid-19 pandemic 'there would be much interest in the work being done by pharmaceutical companies'. Similarly, the Appeal Board, in previous cases, had considered the 'level of public awareness was not irrelevant' – 1 and 'the unique circumstances of the Covid-19 pandemic' – 2 were important factors in deciding against a ruling of a breach of Clause 2. AstraZeneca contended that these principles also applied in the context of this complaint.

AstraZeneca submitted that furthermore, a principal reason for the Panel's finding of a breach of Clause 2 was based on its understanding that two of the relevant activities took place prior to the grant of a marketing authorisation for the Vaccine. In fact, as indicated above, while at material times, Vaxzevria was supplied in the UK in accordance with the Regulation 174 Authorisation (which is not a marketing authorisation), the Licensing Authority had granted a conditional marketing authorisation before either of the two activities which were the subject of the complaint in relation to the Vaccine took place.

Therefore, in AstraZeneca's submission, none of the activities referenced in the complaint might be viewed as 'such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry' or should result in the particular censure associated with a finding of a breach of Clause 2.

Matter 1

AstraZeneca submitted that, as demonstrated above, the majority of the material in issue was shared in advance with No 10, DHSC, and BEIS in the context of an event of public importance and for the purposes of thanking scientists and healthcare workers. AstraZeneca suggested that failure by it to contribute to such thanks would have been notable in the context of the recognition given by others and that such an omission would have been open to criticism. In contrast, it was entirely appropriate for a senior member of AstraZeneca publicly to thank staff, particularly in the context of the recognition of AstraZeneca employees in the Queen's New Year's Honours List, for their involvement in activities of significant public importance.

Matter 2

AstraZeneca submitted that the actions of one employee, in this context, should not result in a finding of a breach of Clause 2. AstraZeneca reiterated the comprehensive training that its employees underwent regarding interacting on social media (copy provided) and the fact that the employee was contacted and the 'like' was promptly removed on 7 January 2022. In this context, AstraZeneca queried whether the fact that one individual, out of tens of thousands of employees, made a genuine mistake, contrary to strict company policy, could reasonably be considered to bring discredit upon, or reduce confidence, in the pharmaceutical industry.

Matter 3

AstraZeneca submitted that the interview which was the subject of complaint involved a senior employee answering unsolicited questions, which they did in a factual, balanced manner by reference to the latest scientific position. The interview was not therefore promotional, and the impression referred to by the Panel was largely drawn from the questions asked by the journalist rather than the responses by the very senior AstraZeneca employee.

Conclusion

In summary, AstraZeneca submitted that the three findings of a breach of Clause 5.1 were not justified or that the conclusion of breach of Clause 2 as a result of these three unrelated complaints was in any way appropriate.

FINAL COMMENTS FROM THE COMPLAINANT

The complainant did not provide any comments.

APPEAL BOARD RULING

1 LinkedIn post by the very senior AstraZeneca UK employee

The Appeal Board reminded itself of the broad definition of promotion in Clause 1.17: any activity undertaken by a pharmaceutical company or with its authority which promoted the administration, consumption, prescription, purchase, recommendation, sale, supply or use of its medicines. The Appeal Board also noted that the Clause which it was considering, Clause 5.1, did not require a finding about whether or not an activity was promotional: the question was about whether high standards had been maintained.

The Appeal Board noted some features of the statement by the very senior AstraZeneca UK employee: 'Today is the one-year anniversary of the first Oxford/AZ vaccine administered in the UK:-). Since then 2.5 billion doses have been administered in more than 70 countries around the world'. The Appeal Board considered that the post, which was made at a time when there was reluctance to take up the Oxford/AZ vaccine due to safety concerns, was providing reassurance to the reader that this vaccine had been widely used.

In addition, the Appeal Board noted the iNews article titled, '[Prime Minister] praises "brilliant" scientists behind AstraZeneca jab one year on from approval' published on 29 December 2021, a link to which was included in the LinkedIn post and therefore formed part of the LinkedIn post created by the very senior AstraZeneca UK employee. Appeal Board members also noted the particular circumstances of the Government campaign to encourage vaccination. The Appeal Board did not make a discrete ruling about promotion as the issue, in relation to Clause 5.1, was whether the company had failed to maintain high standards.

The Panel had based its finding of a breach of Clause 5.1 of the Code on its understanding that the LinkedIn post on 4 January 2022 constituted the promotion of AstraZeneca's Covid-19 vaccine prior to the grant of its marketing authorisation. The Appeal Board, however, considered that at the time of the LinkedIn post on 4 January 2022, although the only AstraZeneca vaccine being supplied in the UK was technically unlicensed, it accepted that the UK Licensing Authority had granted a CMA for Vaxzevria (AstraZeneca's Covid-19 vaccine) on 24 June 2021, and that, in any event, the vaccine had been authorized for distribution under regulation 174. The Appeal Board noted AstraZeneca's submission that a CMA was a tool for approval of a medicine granted where the risk benefit ratio of the product was positive but the MHRA required collection of additional evidence about the safety and efficacy of the product.

The Appeal Board focused on the question of whether the LinkedIn post was a failure to maintain high standards. The Appeal Board bore in mind the unique circumstances of the Covid-19 pandemic, that Vaxzevria had been granted a CMA on 24 June 2021, that it was being distributed under a regulated process, and that there was a Government campaign to encourage vaccine take up. The Appeal Board considered that, in the particular circumstances of this case, AstraZeneca had not failed to maintain high standards and it therefore ruled **no breach of Clause 5.1**. **The appeal on this point was successful**.

2 Reuters article entitled AstraZeneca antibody cocktail works against Omicron in study

The Appeal Board noted that the LinkedIn post was 'liked' by a UK-based AstraZeneca Global employee, whose actions brought the LinkedIn post within the scope of the UK Code and, in that regard, the UK-based employee's engagement with the post would have, on the balance of probabilities, proactively disseminated positive information about Evusheld to the employee's connections which would likely include members of the UK public and, in the Appeal Board's view, promoted Evusheld which was at the time unlicensed.

The Appeal Board noted AstraZeneca's submission that the employee had not acted in accordance with its global standard for employee use of personal social media channels for company and work-related content. The day after the complaint was received, the employee was contacted and the 'like' was removed.

The Appeal Board considered that the UK-based global AstraZeneca employee's 'like' of the LinkedIn post and associated article, and its subsequent proactive dissemination to their connections, promoted Evusheld prior to the grant of its marketing authorisation. Although only one employee had been involved, the company remained responsible for that employee's actions, and had failed to maintain high standards. The Appeal Board **upheld the Panel's ruling of a breach of Clause 5.1 and the appeal on this point was unsuccessful**.

3 The very senior AstraZeneca employee interview by BBC for the Today Programme

The Appeal Board noted AstraZeneca's submission that during the official unveiling of the AstraZeneca Discovery Centre (DISC) in Cambridge on 23 November 2021, a very senior AstraZeneca employee was interviewed by invited media which included an interview with a BBC journalist for the Today Programme; and an edited video clip of that interview was subsequently hosted on the BBC website. AstraZeneca's submitted that it had no editorial control of the final video that was hosted on the BBC website; all editorial rights remained with the BBC.

The Appeal Board noted that complaints about third party articles in the press etc were judged upon the acceptability of the information provided to that third party by the pharmaceutical company, such as any press release, unedited interview, etc rather than the final published article.

At appeal, AstraZeneca provided the full unedited transcript of the interview which had not been before the Panel.

The Appeal Board accepted that the purpose of the interview was to highlight the unveiling of the AstraZeneca Discovery Centre in Cambridge on 23 November 2021. The briefing pack provided to journalists attending the opening focused entirely on the Discovery Centre and the research to be conducted there and did not relate to Covid-19. The Appeal Board noted AstraZeneca's submission that it was appropriate for the very senior AstraZeneca employee to answer questions put to them by journalists on a topical issue in the particular context of the pandemic given the associated public interest.

The Appeal Board considered the full transcript of the interview. One of the journalist's questions was:

> 'Taking a step back, is one of the lessons that we have learnt in the last year so that actually, the future is mRNA which is the technology that is Pfizer and Moderna and not this vaccine. That you've backed a vaccine that as you say has been enormously useful, still will be for some years to come, particularly the developing world but actually the future, particularly in West is not this technology.'

The very senior AstraZeneca employees response:

> ‘Well, I would say mRNA technology is a great technology but we also say that there are questions that are remaining. You know, you have two dimensions to this immune response and maybe more. But at least two we can identify, one is the antibody response and two is the so called T-cell response and the antibody response is what drives the immediate reaction or defense of the body. When you are attached [sic] by the virus and the T-cell response takes a little longer to come in, but it's actually more durable; it last longer and the body remembers that longer. So you see on T [sic] and everybody is focused on antibodies But antibodies you see them decline over time.’

According to the full transcript, the journalist later stated:

> ‘But [but] just to make clear what you’re saying is we don’t know this yet but you’re saying that that mistake by Europe could could [sic] be what has led now to this surge in cases could be.’

According to the full transcript, the very senior AstraZeneca employee responded:

> ‘Well I am not saying there was any mistake done by anybody. I’m just saying that there’s a lot of data that still need to be made available that we don’t have.’

The journalist pressed the topic again and asked the very senior AstraZeneca employee if they would say the relatively low hospitalisations in the UK at the time of the interview, relative to the situation in Europe ‘could be linked to the fact AstraZeneca [vaccine] wasn’t used in older people so that T-cell response isn’t there?’.

According to the full transcript, the very senior AstraZeneca employee responded:

> ‘What I am saying is that T-cells do matter and [imperative?] as it relates to the durability of the response, especially in older people and this vaccine has been shown to stimulate T-cells to a higher degree in older people. And so you know we haven’t seen many hospitalisations in the UK. A lot of infections for sure. I’m not talking about those but what matters is are you severely ill or not, are you hospitalised or not and we haven’t seen so many of these hospitalisations in the UK.’

The journalist continued to press the very senior AstraZeneca employee on this subject, stating:

> ‘And that could be because the AstraZeneca vaccine wasn’t used among older people’ [referring to Europe]?

The very senior AstraZeneca employee responded:

> ‘I mean we don’t know. There is no proof of anything. We don’t know but we need more data to analyse this and get the answer.’

The Appeal Board noted that it appeared from the full transcript that the journalist had persisted in a line of questioning about the differences in the modes of action between the Pfizer and Moderna and AstraZeneca vaccine and what this meant in terms of the clinical implications in the UK and across Europe when different vaccines were used in different populations, despite the very senior AstraZeneca employee clarifying that there was ‘no proof of anything’ and more data was needed in this regard to get answers. The Appeal Board considered that, despite the reason

for the interview, the setting and the briefing, the journalist had chosen to ask questions about the Covid-19 vaccine. The Appeal Board noted AstraZeneca's submission that senior AstraZeneca employees were regularly briefed on the latest regulatory and scientific developments regarding the vaccine and were provided with accurate and appropriate answers, for reactive use only, to questions they might be asked.

The Panel had based its finding of a breach of Clause 5.1 of the Code on its understanding that, the interview given on 23 November 2021 by the very senior AstraZeneca employee constituted the promotion of AstraZeneca's Covid-19 vaccine prior to the grant of its marketing authorisation. The Appeal Board noted that the Clause which it was considering, Clause 5.1, did not require a finding about whether or not an activity was promotional: the question was about whether high standards had been maintained. The Appeal Board did not make a discrete ruling about promotion, as the issue, in relation to Clause 5.1, was whether the company had failed to maintain high standards.

The Appeal Board took into account the unique circumstances of the Covid-19 pandemic, the licensing status of the vaccine at the relevant time, and the very senior AstraZeneca employee's care in answering the questions, and did not consider that, in the particular circumstances of this case, the responses constituted a failure to maintain high standards, and therefore **no breach of Clause 5.1 was ruled**. T**he appeal on this point was successful**.

Clause 2

The Appeal Board considered that it was unfortunate that, in relation to Matter 2, AstraZeneca had been let down by one of its UK-based employees not following comprehensive company guidelines on which they had been trained; an action that resulted in a medicine being promoted prior to the grant of its marketing authorisation. However, the 'like' was rapidly removed on receipt of the complaint. The Appeal Board did not agree with the submission that breaches could not be considered cumulatively when considering Clause 2, but, in any event, the Appeal Board had only found one breach. The failure, in relation to Matter 2, did not bring the industry into disrepute, and so did not warrant a ruling of a breach of Clause 2 which was a sign of particular censure and was reserved for such use. **No breach was ruled**. The appeal on this point was successful.

Complaint received **4 January 2022**

Case completed **8 August 2023**