CASE AUTH/3430/11/20

COMPLAINANT v ASTRAZENECA

Promotion of unlicensed Covid-19 vaccine on LinkedIn

A complainant who described him/herself as a concerned UK health professional, complained about the pre-licence promotion of a Covid-19 vaccine by AstraZeneca UK Limited on LinkedIn.

The complainant provided a screenshot of, and a link to, a named AstraZeneca employee's LinkedIn profile which stated:

'While this is just a start, I am thankful for all those who have worked tirelessly on this vaccine program. It offers new hope to nations around the world.'

Below this was a number of hashtags including #happythanksgiving, #vaccines, #astrazeneca, #covidinnovation, #immunization and #proudemployee followed by an image of a virus and link to a press release entitled 'AZD1222 vaccine met primary efficacy endpoint in preventing COVID-19'.

The complainant noted that AstraZeneca was a UK-based company and that the post had been 'liked' by staff in the UK and appeared on his/her LinkedIn feed. The complainant alleged that it appeared that extremely senior staff had little interest in the rules they chose to follow.

The complainant alleged that the post promoted a medicine prior to having any sort of licence being granted and it promoted to the public.

The complainant noted that this was not the first time that AstraZeneca had undertaken this activity and so alleged a breach of its undertaking related to Cases AUTH/3011/1/18 and AUTH/3248/9/19.

The detailed response from AstraZeneca is given below.

The Panel noted AstraZeneca's submission that the LinkedIn post was outside the jurisdiction of the UK. In the Panel's view, the post at issue came within the scope of the ABPI Code because it had been placed by a senior employee of a company located in the UK (AstraZeneca Global), albeit that the employee in question was based in the US.

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.

Regardless of the US-based global employee's actions, the Panel further noted AstraZeneca's submission that nine UK-based AstraZeneca employees had engaged with ('liked') the LinkedIn post in question. In that regard, the Panel considered that the nine UK employees' act of liking the post, which, on the balance of probabilities, would have been proactively disseminated to their connections within the UK, brought it within the scope of the UK Code. The Panel further noted that the associated press release referred to clinical trials of AZD1222 in the UK which, in the Panel's view, also brought the press release within the scope of the UK Code in its own right.

The Panel noted that the press release linked to from the post was dated November 2020 and was housed in the media section of the global corporate AstraZeneca website.

The Panel considered that there was a difference between making a press release available within the media section of a company's website or only to the press, to be published or not, and linking to it on a social media platform with the expectation that a wider audience would read it.

The Panel considered that the LinkedIn post had drawn attention to medical research regarding the prevention of Covid-19 at a time when there would be much public interest in the work being done by pharmaceutical companies and others to investigate possible treatments and vaccines for the disease. Companies must ensure that any materials and activities related to the current public health emergency and which fell within the scope of the Code, were compliant with it; there were no exemptions in that regard.

The Panel noted that the first paragraph of the press release stated 'Positive high-level results from an interim analysis of clinical trials of AZD1222 in the UK and Brazil showed the vaccine was highly effective in preventing COVID-19, the primary endpoint, and no hospitalisations or severe cases of the disease were reported in participants receiving the vaccine'. It further stated 'AstraZeneca will now immediately prepare regulatory submission of the data to authorities around the world that have a framework in place for conditional or early approval. The Company will seek an Emergency Use Listing from the World Health Organization for an accelerated pathway to vaccine availability in low-income countries'.

The press release contained a quote from an investigator of the Oxford Vaccine Trial:

'These findings show that we have an effective vaccine that will save many lives. Excitingly, we've found that one of our dosing regimens may be around 90% effective and if this dosing regime is used, more people could be vaccinated with planned vaccine supply.'

The press release also contained the prominent quotation from a senior AstraZeneca executive:

'Today marks an important milestone in our fight against the pandemic. This vaccine's efficacy and safety confirm that it will be highly effective against COVID-19 and will have an immediate impact on this public health emergency. Furthermore, the vaccine's simple supply chain and our no-profit pledge and commitment to broad, equitable and timely access means it will be affordable and globally available, supplying hundreds of millions of doses on approval.'

The Panel noted that the LinkedIn post included the title of the press release and considered that the title and content of the press release clearly referred to the clinical success of AZD1222 against Covid-19.

The Panel noted that AZD1222, was not classified as a prescription only medicine when the post and press release were posted by the global AstraZeneca employee and 'liked' by the nine UK-based employees. Clause 26.1 only applied to prescription only medicines. On that very narrow technical point, the Panel ruled no breach of the Code.

However, the Panel considered, noting their content, that the post and associated press release, which appeared on the global AstraZeneca employee's LinkedIn profile and, on the balance of probabilities, its proactive dissemination to the nine AstraZeneca UK employees' connections as a result of them liking it, constituted promotion of an unlicensed medicine and a breach of the Code was ruled.

The Panel considered that high standards had not been maintained in that regard and a breach of Clause 9.1 was ruled.

The Panel understood that employees might feel inclined to endorse articles related to their senior colleagues on Linkedln but noted that depending on the content such activity might or might not fall within the scope of the Code; companies would be well advised to cover the possibility of that activity in their social media policies.

The Panel noted AstraZeneca's submission that the senior US-based global executive had made the LinkedIn post using his/her own personal account at his/her own discretion and the post was in line with the US social media guidance, as written in the US Policy Handbook. The Panel noted, however, that the US policy handbook stated 'employees are not permitted to post original content that is product related (AZ products, product class or competitors) with the exception of members of the North America Leadership Team with the guidance and approval of Corporate Affairs'. It further stated that employees could only 'like' and share 'product-related social media messages from official US Corporate AstraZeneca channels and product-related social media messages from personal social media channels of members of the North America Leadership Team such as a product-related LinkedIn post from the North American Executive Vice President'.

The Panel further noted that the AstraZeneca Global Standard employee use of personal social media document, which was applicable to all global employees, stated in bold under Key Principles: '...you must not post self-created product-related or disease education/awareness content on your personal channels, or engage with (liking, sharing, commenting on) this type of content from 3rd-party sources'. In that regard, it appeared to the Panel that both the senior global executive and the nine UK-based employees had breached the company's global standard document. It further stated that engaging with product-related content from official AstraZeneca social media channels was only allowed in very few countries and readers should always familiarize themselves with country specific rules. The Panel noted that AstraZeneca did not provide any UK-specific social media guidance and made no submission in that regard.

The Panel noted that the supplementary information to Clause 2 included promotion prior to the grant of a marketing authorisation as an example of an activity that was likely to be in breach of that clause. The Panel noted its comments and ruling above. The Panel noted that a senior AstraZeneca global executive had proactively posted product-related material on to a personal social media account which contravened the company's global standard document and which the company acknowledged would be visible to the public. Furthermore, nine UK-based employees had engaged with the post resulting in its likely subsequent proactive dissemination to all of their LinkedIn connections which would, on the balance of probabilities, be a predominately UK audience. Although AstraZeneca had not commented on the seniority of the nine UK-based employees, the Panel was concerned that 'liking' the original LinkedIn post was clearly not an isolated occurrence. The Panel considered that in promoting the unlicensed vaccine, including to members of the UK public, AstraZeneca had brought discredit upon, and reduced confidence in, the pharmaceutical industry and a breach of Clause 2 was ruled.

With regard to the alleged breach of undertaking in relation to Cases AUTH/3011/1/18 and AUTH/3248/9/19, the Panel noted that Case AUTH/3011/1/18 did not involve the distribution of the press release via social media. The complaint now at hand, Case AUTH/3430/11/20, was in relation to dissemination of information on LinkedIn. The Panel considered that Case AUTH/3430/11/20 where, in its view, an unlicensed medicine had been promoted was also different to Case AUTH/3248/9/19 which involved promotion of a licensed medicine for an unlicensed indication.

The Panel thus considered that the matters at hand in the current case were different to Case AUTH/3011/1/18 and Case AUTH/3248/9/19 such that there was no breach of the undertaking given in either of those cases. The Panel therefore ruled no breach of Clause 29 and consequently no breach of Clause 2 in relation to each.

A complainant who described him/herself as a concerned UK health professional, complained about the pre-licence promotion of a Covid-19 vaccine by AstraZeneca UK Limited on LinkedIn.

The complainant provided a screenshot of, and a link to, a named AstraZeneca employee's LinkedIn profile which stated:

'While this is just a start, I am thankful for all those who have worked tirelessly on this vaccine program. It offers new hope to nations around the world.'

Below this was a number of hashtags including #happythanksgiving, #vaccines, #astrazeneca, #covidinnovation, #immunization and #proudemployee followed by an image of a virus and link to a press release entitled 'AZD1222 vaccine met primary efficacy endpoint in preventing COVID-19'.

COMPLAINT

The complainant noted that AstraZeneca was a UK-based company and that the post had been 'liked' by staff in the UK and appeared on his/her LinkedIn feed. The complainant alleged that it appeared that extremely senior staff had little interest in the rules they chose to follow.

The complainant alleged that the post promoted a medicine prior to having any sort of licence being granted and it promoted to the public.

The complainant noted that this was not the first time that AstraZeneca had undertaken this activity and so it was also in breach of its undertaking. The complainant stated that the alleged breach of undertaking related to Cases AUTH/3011/1/18 and AUTH/3248/9/19.

When writing to AstraZeneca, the Authority asked it to consider the requirements of Clauses 2, 3.1, 9.1, 26.1 and 29 of the Code.

RESPONSE

AstraZeneca submitted that the LinkedIn post was outside the jurisdiction of the UK Code since the employee was a US-based global AstraZeneca employee and had not targeted a UK audience, neither UK health professionals nor the UK general public. The AstraZeneca employee responsible for the post was the chief commercial digital officer. He/she had made the LinkedIn post using his/her own personal account at his/her own discretion as an appreciation of everyone who worked on the project. AstraZeneca submitted that the LinkedIn post was in line with the US social media guidance, as written in the US Policy Handbook (copy provided).

AstraZeneca submitted that the UK-based AstraZeneca employees who had 'liked' the post were demonstrating their support for the 'thanks' provided by the US-based senior leader and were not promoting a prescription medicine to the general public.

With respect to the alleged breaches of undertaking related to Cases AUTH/3011/1/18 and AUTH/3248/9/19, AstraZeneca stated that those cases were not applicable to the current complaint because the LinkedIn post was outside the jurisdiction of the UK Code, there was no promotion of a medicine prior to marketing authorisation and no promotion of a prescription only medicine to UK health professionals or the public and so the allegation was without merit.

AstraZeneca submitted that the LinkedIn post was an appropriate personal communication which recognized the commitment of individuals devoted to working on the vaccine and was not intended to promote a prescription medicine to the general public. AstraZeneca noted that it was well recognised that different coronavirus vaccines and technologies were being developed by several pharmaceutical companies, biotech and academic institutes that offered hope for addressing the Covid-19 pandemic across the globe, and individuals had worked tirelessly to bring those new vaccines to the independent regulatory assessors for potential emergency use/conditional use authorisation. Unsurprisingly, that was a highly topical, newsworthy issue with unprecedented public interest.

The LinkedIn post included a link to a press release entitled 'AZD1222 vaccine met primary efficacy endpoint in preventing COVID-19' (copy provided) which was housed in the media section of the global corporate AstraZeneca website, www.astrazeneca.com.

AstraZeneca noted that LinkedIn was a global social media tool with an estimated 722+ million members in more than 200 countries and territories worldwide. It was a professional tool to enable professional networking, and it was accepted that the majority of users would not qualify as health professionals but professionals working in many different fields.

The post was intended for the 2500+ followers of the AstraZeneca employee. Those followers were from an internationally diverse peer group predominately with a background or interest in

digital innovation, health and science. AstraZeneca acknowledged that the followers could include members of the general public. The post was made in line with US social media guidance (as written in the US Policy Handbook) not targeted at a UK audience, including health professionals or general public.

As a US-based employee and senior leader, the person who posted on LinkedIn had authored and issued the post in a personal capacity, and not on behalf of the company. There was no requirement for certification of posts in the US. The employee in question had read and understood both the global standard and the US guidance on social media; both trainings were completed in 2020.

AstraZeneca submitted that as at 17 December 2020, nine UK-based AstraZeneca employees had engaged with ('liked') the LinkedIn post; they had done so in support of the senior leader's appreciation.

AstraZeneca denied a breach of Clause 26.1. The LinkedIn post was made by a US-based employee, in line with US social media guidance and was thus not within UK jurisdiction. Furthermore, the post did not promote a prescription medicine.

AstraZeneca denied a breach of Clause 3.1. The author of the post was resident in the US and the post was in line with the US social media guidance. A UK audience had not been targeted and was not the intended recipient of the post, thus it was not promotion of a medicine to a UK audience ahead of marketing authorisation.

AstraZeneca denied a breach of Clause 29 and noted that Case AUTH/3011/1/18 was about a press release issued by the global organization and was found in breach of Clauses 7.2, 7.3, 7.9, 7.10, 9.1 and 26.2. The LinkedIn post at issue did not provide information about an approved prescription only medicine, it did not raise unfounded hopes of successful treatment and nor was it misleading with respect to the safety of the product when the material was posted. The global press release linked from the LinkedIn post was accurate, balanced and was not misleading. The allegation of a breach of an undertaking was wrong and without basis.

AstraZeneca noted that Case AUTH/3248/9/19 was a voluntary admission of a UK-based global employee re-tweeting health professional tweets about an AstraZeneca medicine and new data, and AstraZeneca was found in breach of Clauses 3.2, 9.1, 14.3 and 26.1. In this case, Case AUTH/3430/11/20, the LinkedIn post had been authored and posted by a US-based AstraZeneca global employee which was outside the jurisdiction of the UK Code. The UK-based AstraZeneca employees had 'liked' the post in support of a senior leader's appreciation. The allegation of a breach of an undertaking was wrong and without basis.

AstraZeneca refuted the alleged breach of Clause 9.1 and contended that the organization had maintained high standards throughout.

AstraZeneca refuted the alleged breach of Clause 2; the company had maintained high standards throughout. The evidence submitted above demonstrated AstraZeneca's full commitment to upholding the reputation of the industry.

In summary, AstraZeneca refuted any suggestion that it had breached Clauses 2, 3.1, 9.1, 26.1 or 29 of the Code and believed this particular complaint was unfounded and might even be vexatious. AstraZeneca, therefore, re-affirmed its request that the ABPI/PMCPA consultation

team considered adding a step to the process where the PMCPA would assess the merit of complaints more formally, before passing them on to the company to provide a response.

PANEL RULING

The Panel noted AstraZeneca's submission that the LinkedIn post was outside the jurisdiction of the UK. In the Panel's view, the LinkedIn post at issue came within the scope of the ABPI Code because it had been placed by a senior employee of a company located in the UK (AstraZeneca Global) albeit that the employee in question was based in the US.

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.

Regardless of the US-based global employee's actions, the Panel further noted AstraZeneca's submission that nine UK-based AstraZeneca employees had engaged with ('liked') the LinkedIn post in question. In that regard, the Panel considered that the nine UK employees' act of liking the post, which, on the balance of probabilities, would have been proactively disseminated to their connections within the UK, brought it within the scope of the UK Code. The Panel further noted that the associated press release referred to clinical trials of AZD1222 in the UK which, in the Panel's view, also brought the press release within the scope of the UK Code in its own right.

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 healthcare. 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 his/her connections' LinkedIn feeds, appearing as '[name] likes this'. In the Panel's view, activity conducted on social media that could potentially alert one's connections to the activity might be considered proactive dissemination of material. In addition, an individual's activity and associated content might appear in the individual's list of activities on his/her LinkedIn profile page which was visible to his/her connections; an individual's profile page was also potentially visible to others outside his/her 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 noted that the LinkedIn post in question stated:

'While this is just a start, I am thankful for all those who have worked tirelessly on this vaccine program. It offers new hope to nations around the world.'

The Panel further noted that the LinkedIn post was followed by a number of hashtags including #covidinnovation and #proudemployee and included an image of a virus and the title of the press release 'AZD1222 vaccine met primary efficacy endpoint in preventing COVID-19' with a link to it. The press release dated November 2020 was housed in the media section of the global corporate AstraZeneca website, www.astrazeneca.com.

The Panel considered that there was a difference between making a press release available within the media section of a company's website or only to the press, to be published or not, and linking to it on a social media platform with the expectation that a wider audience would read it.

The Panel considered that the LinkedIn post had drawn attention to medical research regarding the prevention of Covid-19 at a time when there would be much public interest in the work being done by pharmaceutical companies and others to investigate possible treatments and vaccines for the disease. Companies must ensure that any materials and activities related to the current public health emergency and which fell within the scope of the Code, were compliant with it; there were no exemptions in that regard.

The Panel noted that the first paragraph of the press release stated 'Positive high-level results from an interim analysis of clinical trials of AZD1222 in the UK and Brazil showed the vaccine was highly effective in preventing COVID-19, the primary endpoint, and no hospitalisations or severe cases of the disease were reported in participants receiving the vaccine'. It further stated 'AstraZeneca will now immediately prepare regulatory submission of the data to authorities around the world that have a framework in place for conditional or early approval. The Company will seek an Emergency Use Listing from the World Health Organization for an accelerated pathway to vaccine availability in low-income countries'.

The press release contained a quote from an investigator of the Oxford Vaccine Trial:

'These findings show that we have an effective vaccine that will save many lives. Excitingly, we've found that one of our dosing regimens may be around 90% effective and if this dosing regime is used, more people could be vaccinated with planned vaccine supply.'

The press release also contained the prominent quotation from a senior AstraZeneca executive:

'Today marks an important milestone in our fight against the pandemic. This vaccine's efficacy and safety confirm that it will be highly effective against COVID-19 and will have an immediate impact on this public health emergency. Furthermore, the vaccine's simple

supply chain and our no-profit pledge and commitment to broad, equitable and timely access means it will be affordable and globally available, supplying hundreds of millions of doses on approval.'

The Panel noted that the LinkedIn post included the title of the press release and considered that the title and content of the press release clearly referred to the clinical success of AZD1222 against Covid-19.

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 AZD1222, was not classified as a prescription only medicine when the LinkedIn post and associated press release at issue was posted by the global AstraZeneca employee and 'liked' by the nine UK-based employees. Clause 26.1 only applied to prescription only medicines. On that very narrow technical point, the Panel ruled no breach of Clause 26.1 of the Code.

However, the Panel considered, noting their content, that the post and associated press release, which appeared on the global AstraZeneca employee's LinkedIn profile and, on the balance of probabilities, its proactive dissemination to the nine AstraZeneca UK employees' connections as a result of them liking it, constituted promotion of an unlicensed medicine and a breach of Clause 3.1 was ruled.

The Panel considered that high standards had not been maintained in that regard and a breach of Clause 9.1 was ruled.

The Panel understood that employees might feel inclined to endorse articles related to their senior colleagues on LinkedIn but noted that depending on the content such activity might or might not fall within the scope of the Code; companies would be well advised to cover the possibility of that activity in their social media policies.

The Panel noted AstraZeneca's submission that the senior US-based global executive had made the LinkedIn post using his/her own personal account at his/her own discretion and the post was in line with the US social media guidance, as written in the US Policy Handbook. The Panel noted, however, that the US policy handbook stated 'employees are **not** permitted to post original content that is **product related** (AZ products, product class or competitors) with the exception of members of the North America Leadership Team with the guidance and approval of Corporate Affairs'. It further stated that employees could only 'like' and share 'product-related social media messages from official US Corporate AstraZeneca channels and product-related social media messages from personal social media channels of members of the North America Leadership Team such as a product-related LinkedIn post from the North American Executive Vice President'.

The Panel further noted that the AstraZeneca Global Standard employee use of personal social media document, which was applicable to all global employees, stated in bold under Key Principles: '...you must not post self-created product-related or disease education/awareness content on your personal channels, or engage with (liking, sharing, commenting on) this type of content from 3rd-party sources'. In that regard, it appeared to the Panel that both the senior global executive and the nine UK-based employees had breached the company's global

standard document. It further stated that engaging with product-related content from official AstraZeneca social media channels was only allowed in very few countries and readers should always familiarize themselves with country specific rules. The Panel noted that AstraZeneca did not provide any UK specific social media guidance and made no submission in that regard.

The Panel noted that the supplementary information to Clause 2 included promotion prior to the grant of a marketing authorisation as an example of an activity that was likely to be in breach of that clause. The Panel noted its comments and ruling above. The Panel noted that a senior AstraZeneca global executive had proactively posted product-related material on to a personal social media account which contravened the company's global standard document and which the company acknowledged would be visible to the public. Furthermore, nine UK-based employees had engaged with the post resulting in its likely subsequent proactive dissemination to all of their LinkedIn connections which would, on the balance of probabilities, be a predominately UK audience. Although AstraZeneca had not commented on the seniority of the nine UK-based employees, the Panel was concerned that 'liking' the original LinkedIn post was clearly not an isolated occurrence. The Panel considered that in promoting the unlicensed vaccine, including to members of the UK public, AstraZeneca had brought discredit upon, and reduced confidence in, the pharmaceutical industry and a breach of Clause 2 was ruled.

The Panel noted the complainant's allegation of a breach of undertaking in relation to Cases AUTH/3011/1/18 and AUTH/3248/9/19.

The Panel noted that in Case AUTH/3011/1/18 a complaint was submitted about various statements contained within an AstraZeneca PLC press release. Case AUTH/3011/1/18 did not involve the distribution of the press release via social media. The complaint now at hand, Case AUTH/3430/11/20, was in relation to dissemination of information on LinkedIn. The Panel thus considered that the matters at hand in the current case were different to Case AUTH/3011/1/18 such that there was no breach of the undertaking given in that case. The Panel therefore ruled no breach of Clause 29 and consequently no breach of Clause 2 in that regard.

The Panel noted that in Case AUTH/3248/9/19 the Panel considered that the re-tweet by a UK-based global AstraZeneca employee of nine tweets originally posted by health professionals about the DAPA-HF clinical trial results promoted dapagliflozin (Forxiga) for an unlicensed indication and advertised a prescription only medicine to the public and breaches of Clauses 3.2 and 26.1 were ruled as acknowledged by AstraZeneca.

The Panel noted its comments and rulings above in relation to the current case (Case AUTH/3430/11/20) where, in its view, an unlicensed medicine had been promoted and considered that it was thus different to Case AUTH/3248/9/19 which involved promotion of a licensed medicine for an unlicensed indication. The Panel therefore did not consider that AstraZeneca had breached the undertaking given in Case AUTH/3248/9/19 and no breach of Clause 29 was ruled. The Panel consequently ruled no breach of Clause 2 in that regard.

Complaint received 24 November 2020

Case completed 14 December 2021