

CASE AUTH/3422/11/20

COMPLAINANT v PFIZER

Alleged promotion of unlicensed Covid vaccine on LinkedIn

A complainant who described him/herself as a concerned UK health professional complained about the promotion of an unlicensed Covid-19 vaccine on LinkedIn by Pfizer Limited.

The complainant provided a link to, and a screenshot of, a named UK Pfizer employee's personal LinkedIn profile. The employee had 'liked' a LinkedIn post from Pfizer which mentioned the company's product prior to it receiving a marketing authorisation. The complainant alleged that this was promoting to the general public, the material had not been certified and the medicine referred to had yet to be licensed.

The detailed response from Pfizer is given below.

The Panel noted Pfizer's submission that the original LinkedIn post was posted by the Pfizer US organisation via the Global Pfizer LinkedIn account. However, three days later the post was 'liked' by a Pfizer UK colleague via his/her personal LinkedIn account and in that regard the Panel considered that the UK employee's engagement with the post, on the balance of probabilities, would have proactively disseminated the material to his/her LinkedIn connections which would predominantly be within the UK, and therefore brought the LinkedIn post within the scope of the UK Code. The Panel noted Pfizer's submission that the employee had made an error and acted contrary to company guidelines by interacting with the post.

The Panel noted Pfizer's submission that, following emergency use authorisation, the purchase of its Covid-19 vaccine was managed centrally by the UK Government and not by individual health professionals and so in that regard the company considered that it was difficult to see how liking the LinkedIn article could impact the prescription, recommendation, administration, purchase, sale or supply of the medicine. The Panel noted, however, that the Code applied to the promotion of medicines to members of the UK health professions and other relevant decision makers and in that regard provided no exemptions related to how a medicine was made available or accessed.

The Panel did not know how many connections the named employee had on LinkedIn and if they were all health professionals; the company made no submission in that regard. However, as it was a personal LinkedIn account, the Panel considered that on the balance of probabilities it was likely that the Pfizer UK employee's connections would include UK members of the public as well as UK health professionals.

The Panel noted Pfizer's submission that on 2 December 2020 the vaccine was granted temporary emergency use authorisation to supply in the UK by the Medicines and Healthcare products Regulatory Agency (MHRA) under Regulation 174 of the Human

Medicines Regulation. The Panel noted that the original LinkedIn post which had been 'liked' by the Pfizer UK employee in November 2020, and thus on the balance of probabilities proactively disseminated to his/her connections on LinkedIn, announced that the Pfizer/BioNTech vaccine candidate, based on an interim analysis, had shown efficacy against Covid-19. It was noted that efficacy along with safety and consistent manufacturing were required before the company could file for Emergency Use Authorisation and that this was the first critical step towards a 'safe and effective vaccine'. In the Panel's view it was clear that the Pfizer vaccine was not yet licensed and thus Pfizer did not have a prescription only medicine available in November 2020 when the LinkedIn post in question was 'liked' by the UK employee. 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 that the Pfizer UK employee's 'like' of the LinkedIn post, which discussed the positive efficacy results of Pfizer's unlicensed Covid-19 vaccine, and, on the balance of probabilities its subsequent proactive dissemination to all of his/her connections, constituted promotion of the vaccine prior to the grant of its marketing authorisation. A breach of the Code was ruled.

The Panel considered that by liking the Pfizer US post and thus placing it on his/her personal LinkedIn account and, on the balances of probabilities, disseminating it to his/her connections which would likely include health professionals, the Pfizer UK employee had created his/her own promotional material which had not been certified and a breach of the Code was ruled.

The Panel understood that employees might feel inclined to endorse articles related to their senior colleagues on LinkedIn or their company's corporate social media posts 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. This was particularly important if UK employees were likely to follow the social media accounts of colleagues in countries that had codes, laws and regulations that differed to the UK. In that regard the Panel noted that Pfizer had issued UK Social Media Guidelines which instructed employees not to interact ('like', share or comment) with content posted by Pfizer outside of the UK because such content might not meet requirements of the UK Code. That instruction was illustrated with a Pfizer Inc LinkedIn example. The Panel thus considered that the instructions to staff were clear and unambiguous. The employee in question had completed training on the guidelines in October 2019.

The Panel noted its comments and rulings above and considered that it was thus unfortunate that Pfizer had been badly let down by one of its UK employees not following company guidelines upon which he/she had been trained; an action that resulted in the creation of uncertified promotional material for an unlicensed medicine being proactively disseminated on LinkedIn. In that regard high standards had not been maintained. A breach of the Code was ruled.

A complainant who described him/herself as a concerned UK health professional complained about the promotion of an unlicensed Covid-19 vaccine on LinkedIn by Pfizer Limited.

COMPLAINT

The complainant provided a link to, and a screenshot of, a named UK Pfizer employee's personal LinkedIn profile. The employee had 'liked' a LinkedIn post from Pfizer which mentioned the company's product prior to it receiving a marketing authorisation.

The LinkedIn post at issue read:

'UPDATE: We are proud to announce, along with BioNTech SE, that our mRNA-based #vaccine candidate has, based on an interim analysis, demonstrated initial evidence of efficacy against #COVID19 in participants without prior evidence of SARS-CoV-2 infection.

Efficacy in the majority of participants, safety data and consistent manufacturing are the three requirements that are needed before we are able to file for Emergency Use Authorization. This is a first but critical step as we continue our work to try to deliver a safe and effective vaccine:[link].'

The complainant alleged that this was promoting to the general public, the material had not been certified and the medicine referred to had yet to be licenced.

When writing to Pfizer, the Authority asked it to consider the requirements of Clauses 3.1, 9.1, 14.1 and 26.1 of the Code.

RESPONSE

Pfizer stated that the LinkedIn post at issue was posted by the Pfizer US organisation on 9 November 2020 via the Global Pfizer LinkedIn account which was 'liked' a few days later by a Pfizer UK colleague via his/her personal LinkedIn account.

Pfizer stated that on 9 November 2020, together with BioNTech, it announced that its vaccine candidate against Covid-19 had achieved success in the first interim efficacy analysis from the Phase 3 study. On 2 December 2020 the vaccine was granted temporary emergency use authorisation to supply in the UK by the Medicines and Healthcare products Regulatory Agency (MHRA) under Regulation 174 of the Human Medicines Regulation. That was not a marketing authorisation and consequently no summary of product characteristics (SPC) was currently available. Instead, information for prescribers was supplied via Regulation 174 Information for Health Professionals. All available batches of the vaccine were being supplied directly to the UK Government for distribution as part of the national vaccination campaign implemented according to the criteria set by the Joint Committee on Vaccination and Immunisation (JCVI). There was no private or other supply of the vaccine available in the UK to health professionals or members of the public.

Pfizer stated that it provided comprehensive guidance and training to colleagues on the personal use of social media in relation to the Pfizer business. Pfizer's UK policy on colleagues' use of social media was set out in 'Social Media Policy for Pfizer UK Colleagues and Contingent Workers 01-Dec-2019'. In summary the policy stated the following in relation to interacting with social media related to Pfizer business:

- If colleagues wished to interact with social media content related to Pfizer business, they must first disclose their association with Pfizer

- Colleagues may 'like', share or comment on any content published by a Pfizer UK owned social media account
- **Colleagues must not interact with any content posted by Pfizer organisations based outside the UK**
- Colleagues may 'like', share or comment on posts about Pfizer from third parties, as long as the content does not directly or indirectly reference (or link to) information on licensed or unlicensed medicines
- If writing a comment or post related to Pfizer business, colleagues must not reference or link to information on licensed or unlicensed medicines.

Pfizer stated that all UK colleagues received online training on this policy via Pfizer's global training system (copy provided). Training was only considered complete when the colleague had answered all knowledge check questions correctly. The employee whose LinkedIn post was in question, completed the training with a score of 100% in October 2019. A one-page summary of the policy was also available to colleagues to support day-to-day implementation. Regular reminders of the key policy points were included in any written and verbal briefings on topics that might appear in social media posts eg Pfizer issued a reminder to colleagues when the Regulation 174 temporary authorisation in the UK was announced on 2 December 2020.

Pfizer stated that since receiving this complaint, it had also developed a Covid-19/vaccines specific version of its one-page social media policy summary. The summary was made available to colleagues on 7 January 2021 with the aim of providing further support and clarity on implementation of Pfizer's social media policy in the current environment.

Interacting with the LinkedIn post that was the subject of this complaint was not consistent with Pfizer UK's policy on individual colleague's use of social media as the post originated from a Pfizer entity based outside the UK. The colleague made an error by interacting with this post.

Pfizer stated that when the Pfizer colleague 'liked' the global Pfizer LinkedIn post (November 2020), the Pfizer/BioNTech vaccine candidate had not been granted any form of authorisation in the UK and Pfizer therefore did not believe that the vaccine met the definition of a prescription only medicine. Further, Clause 1.2 of the Code defined promotion 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 medicine.' Given that following emergency use authorisation the vaccine could only be purchased by central Government for administration according to the strict criteria determined by the JCVI, it was difficult to see how liking the LinkedIn article could impact the consumption, purchase or use of the vaccine by a member of the public. Therefore, Pfizer did not believe that liking the article represented a breach of Clause 26.1. It was also difficult to see how liking the article could impact the prescription, recommendation, administration, purchase, sale or supply by health professionals as this was managed centrally by the UK Government and not by individual health professionals. Therefore, Pfizer did not consider that liking the LinkedIn article promoted the vaccine to health professionals prior to marketing authorisation or represented a breach of Clause 3.1.

Pfizer stated that as it did not consider that liking the post met the definition of promotion, or that the post constituted promotional material, it therefore followed that Clause 14.1 did not apply and the post did not require promotional certification.

Pfizer submitted that it had comprehensive policies and training in place covering colleagues' personal use of social media in relation to the Pfizer business and, in that regard, the company considered that it had maintained the high standards required by Clause 9.1. On this occasion a colleague had made an error of judgement in the application of company policy due to the exceptional circumstances for the vaccine candidate in the context of the global pandemic. Given the arrangement in the UK for the central supply and administration of the vaccine by the Government, Pfizer did not consider that liking the LinkedIn post promoted the administration, consumption, prescription, purchase, recommendation, sale, supply or use of the vaccine to either health professionals or members of the public.

Pfizer stated that it had issued an additional briefing on its social media policy as applied to vaccines to supplement the comprehensive existing policy, resources and training. Pfizer accepted that this case represented an error of judgement by one individual, but the company strongly believed that the UK organisation had demonstrated high standards throughout and therefore it denied a breach of Clause 9.1.

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 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 media 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 Pfizer's submission that the original LinkedIn post was posted by the Pfizer US organisation via the Global Pfizer LinkedIn account. However, three days later the post was 'liked' by a Pfizer UK colleague via his/her personal LinkedIn account and in that regard the Panel considered that the UK employee's engagement with the post, on the balance of probabilities, would have proactively disseminated the material to his/her LinkedIn connections which would predominantly be within the UK, and therefore brought the LinkedIn post within the scope of the UK Code. The Panel noted Pfizer's submission that the employee had made an error and acted contrary to company guidelines by interacting with the post.

The Panel noted Pfizer's submission that, following emergency use authorisation, the purchase of its Covid-19 vaccine was managed centrally by the UK Government and not by individual health professionals and so in that regard the company considered that it was difficult to see how liking the LinkedIn article could impact the prescription, recommendation, administration, purchase, sale or supply of the medicine. The Panel noted, however, that the Code applied to the promotion of medicines to members of the UK health professions and other relevant decision makers and in that regard provided no exemptions related to how a medicine was made available or accessed.

The Panel noted the broad definition of promotion as stated in Clause 1.2; it encompassed 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 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 did not know how many connections the named employee had on LinkedIn and if they were all health professionals; the company made no submission in that regard. However, as it was a personal LinkedIn account, the Panel considered that on the balance of probabilities it was likely that the Pfizer UK employee's connections would include UK members of the public as well as UK health professionals.

The Panel noted Pfizer's submission that on 2 December 2020 the vaccine was granted temporary emergency use authorisation to supply in the UK by the Medicines and Healthcare products Regulatory Agency (MHRA) under Regulation 174 of the Human Medicines Regulation. The Panel noted that the original LinkedIn post which had been 'liked' by the Pfizer UK employee in November 2020, and thus on the balance of probabilities proactively disseminated to his/her connections on LinkedIn, announced that the Pfizer/BioNTech vaccine candidate, based on an interim analysis, had shown efficacy against Covid-19. It was noted that efficacy along with safety and consistent manufacturing were required before the company could file for Emergency Use Authorisation and that this was the first critical step towards a 'safe and effective vaccine'. In the Panel's view it was clear that the Pfizer vaccine was not yet licensed and thus Pfizer did not have a prescription only medicine available in November 2020 when the LinkedIn post in question was 'liked' by the UK employee. 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 that the Pfizer UK employee's 'like' of the LinkedIn post, which discussed the positive efficacy results of Pfizer's unlicensed Covid-19 vaccine, and, on the

balance of probabilities its subsequent proactive dissemination to all of his/her connections, constituted promotion of the vaccine prior to the grant of its marketing authorisation. A breach of Clause 3.1 was ruled.

The Panel considered that by liking the Pfizer US post and thus placing it on his/her personal LinkedIn account and, on the balances of probabilities, disseminating it to his/her connections which would likely include health professionals, the Pfizer UK employee had created his/her own promotional material which had not been certified and a breach of Clause 14.1 was ruled.

The Panel understood that employees might feel inclined to endorse articles related to their senior colleagues on LinkedIn or their company's corporate social media posts 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. This was particularly important if UK employees were likely to follow the social media accounts of colleagues in countries that had codes, laws and regulations that differed to the UK. In that regard the Panel noted that Pfizer had issued UK Social Media Guidelines which instructed employees not to interact ('like', share or comment) with content posted by Pfizer outside of the UK because such content might not meet requirements of the UK Code. That instruction was illustrated with a Pfizer Inc LinkedIn example. The Panel thus considered that the instructions to staff were clear and unambiguous. The employee in question had completed training on the guidelines in October 2019.

The Panel noted its comments and rulings above and considered that it was thus unfortunate that Pfizer had been badly let down by one of its UK employees not following company guidelines upon which he/she had been trained; an action that resulted in the creation of uncertified promotional material for an unlicensed medicine being proactively disseminated on LinkedIn. In that regard high standards had not been maintained. A breach of Clause 9.1 was ruled.

Complaint received **12 November 2020**

Case completed **4 June 2021**