NO BREACH OF THE CODE

CASE AUTH/3478/2/21

COMPLAINANT v BOEHRINGER INGELHEIM

Alleged promotion of unlicensed medicines on LinkedIn

An anonymous complainant, who described him/herself as a health professional, alleged that the use of LinkedIn by senior managers and other employees of Boehringer Ingelheim Limited was unethical as it promoted unlicensed medicines to, among others, health professionals, non-health professionals and members of the public. The complainant provided a link to a LinkedIn post which stated, '[Named person] likes this news story which mentions Boehringer Ingelheim "New SARS-CoV-2 neutralizing antibody enters clinical phase"'. There appeared to be a link to an article on a named website.

The complainant stated that the shared article named the new antibody as BI 767551 which was being examined and developed as a SARS-CoV-2 neutralising antibody administered through inhalation. The initial promotion (post), which detailed the company, the medicine and the proposed indication had been shared and 'liked' a number of times, further generating multiple views of the same post to all the recipient's connections, who each could then generate even more 'views' of the same article, with little or no control of the number of, or of whom the recipients might be. The complainant alleged that this activity promoted unlicensed medicines, failed to meet high standards and brought the industry into disrepute.

The detailed response from Boehringer Ingelheim is given below.

The Panel noted that the original article had, without the knowledge or consent of Boehringer Ingelheim, been 'liked' by two of its employees. The Panel considered that the UK employees' engagement with the post, on the balance of probabilities, had proactively disseminated the material to their connections and had thus brought the LinkedIn post and associated article within the scope of the UK Code.

The Panel noted that the article, published in December 2020, was from the German Centre for Infection Research and reported the initiation of two Phase 1/2a clinical trials of a SARS-CoV-2 neutralising antibody which were being conducted in collaboration with Boehringer Ingelheim. The Panel noted that a German university was the legal sponsor of the two trials, not Boehringer Ingelheim, and that the trials would not be conducted in the UK.

The Panel considered that it was clear that the compound in question was in the early stages of development and that if the planned studies showed that it was well tolerated, further studies would be conducted. The compound was investigational so was not a

prescription only medicine. The Panel thus did not consider that a prescription only medicine had been advertised to the public; no breaches of the Code were ruled.

The Panel considered that a compound, still only referred to by a number (BI 767551), which was just entering first-in-human (phase 1/2a) clinical trials, with no published clinical outcomes and available only in a clinical trial setting was a long way off being available as a medicine; it was clear that further work was needed. The Panel noted the early stage of development of the molecule and in that regard did not consider that a medicine had been promoted prior to the grant of a marketing authorisation. No breach of the Code was ruled.

The Panel noted that the Boehringer Ingelheim social media standard operating procedure clearly stated that employees must 'Never discuss topics related to prescription pharmaceutical brands, Boehringer Ingelheim product-related information (in market or development), or any information related to competitor products, on personal Social Media accounts'. An associated e-learning programme had to be completed annually by UK employees. Whilst the Panel considered that it was unfortunate that two employees had acted in breach of company policy and training, it noted its rulings of no breaches of the Code and consequently ruled no further breaches of the Code including Clause 2.

An anonymous complainant, who described him/herself as a health professional, alleged that the use of LinkedIn by senior managers and other employees of Boehringer Ingelheim Limited was unethical as it promoted unlicensed medicines to, among others, health professionals, non-health professionals and members of the public. The complainant provided a link to a LinkedIn post which stated, '[Named person] likes this news story which mentions Boehringer Ingelheim "New SARS-CoV-2 neutralizing antibody enters clinical phase"'. There appeared to be a link to an article which originated from a separate website, medicalxpress.com.

COMPLAINT

The complainant stated that the article posted some two months ago, that was shared, named the new antibody as BI 767551 which was being examined and developed as a SARS-CoV-2 neutralising antibody administered through single inhalation. The initial promotion (post), which detailed the company, the medicine and the proposed indication had been shared and 'liked' a number of times, further generating multiple views of the same post to all the recipient's connections, who each could then generate even more 'views' of the same article, with little or no control of the number of, or of whom the recipients might be. The complainant alleged that this activity promoted unlicensed medicines; the molecule detailed was not licensed and should not be promoted in this way. High standards need to be maintained at all times and this type of activity undermined the industry, whilst bringing it into disrepute.

When writing to Boehringer Ingelheim, the Authority asked it to consider the requirements of Clauses 3.1, 9.1, 26.1, 26.2 and 2 of the Code.

RESPONSE

Boehringer Ingelheim stated that it took compliance with the Code very seriously; it had steps in place to ensure robust procedures underpinned all of its activities including two UK standard operating procedures (SOPs) related to social media use (Personal Use of Social Media and

Guidance for Social Media Communications) (copies provided) and it embraced a compliance culture that was fully embedded into the business with the support of the ethics and compliance department.

Boehringer Ingelheim stated that from a Google search the original article from the post could be found on the medicalxpress.com website which described itself as a provider of latest news and articles on medical research advances and health news.

The article (dated 18 December 2020) related to the announcement by a German hospital , a university , and the German Centre for Infection Research and Boehringer Ingelheim of the initiation of two Phase 1/2a clinical trials of a SARS-CoV-2 neutralising antibody. These trials were listed in the article, using their unique clinical trials.gov identifiers, as NCT04631705 and NCT04631666. The article stated:

> 'The new antibody BI 767551 was derived from blood samples of recovered COVID-19 patients at UKK, examined for SARS-CoV-2 neutralization at UMR and developed further in collaboration with Boehringer Ingelheim. The clinical study will be led by [named individuals at the hospital and Boehringer Ingelheim will supply the antibody.'

Boehringer Ingelheim submitted that the German university was the legal sponsor of the two trials not Boehringer Ingelheim. Furthermore, the trials were not being, nor were planned to be, run in the UK.

Boehringer Ingelheim stated that on receipt of the complaint, it immediately launched a formal investigation. One of the named employees, reassigned themselves the Personal Use of Social Media SOP and completed retraining. Further details were provided. The actions of both Boehringer Ingelheim employees were without knowledge or permission of Boehringer Ingelheim and their actions were prohibited under the Personal Use of Social Media SOP.

In addition to the above actions, the post was unliked/deleted and a company-wide communication was sent to all employees on 4 March 2021 (copy provided) which emphasised the requirement of compliance with the Personal Use of Social Media SOP with a link to associated training materials.

Boehringer Ingelheim noted that the post linked to an article that referred to an investigational molecule (BI 767551) which was just entering first-in-human (phase 1/2a) clinical trials. The molecule was only available in a clinical trial setting. Furthermore, the two clinical trials, the only two in which humans had received the medicine, were not being run in the UK, nor were they intended to be and neither were Boehringer Ingelheim trials; the legal sponsor for both was the German university.

Due to the investigational nature of the compound, it had no published clinical outcomes in humans and as such could not be considered a medicine. It was not available outside of the strict regulations of an approved clinical trial and associated trial sites and it was simply not possible to promote the compound as a medicine to health professionals. Additionally, there was no access to the compound for health professionals or patients in the UK.

Boehringer Ingelheim stated that it therefore did not consider that a substance in such early stages of research could be considered as pre-licence promotion of a medicine, reinforced by

the inaccessibility to the compound both by patients and health professionals in the UK, and so it denied a breach of Clause 3.1.

Boehringer Ingelheim stated that it had a robust Personal Use of Social Media SOP and associated e-learning programme, which was mandatory for completion by all employees in the UK and Ireland on an annual basis, or if the SOP was updated. The two named Boehringer Ingelheim employees had completed the annual training and had completed re-training of the SOP immediately following receipt of the complaint.

Boehringer Ingelheim's Personal Use of Social Media SOP and Guidance for Social Media Communications SOP provided clear unambiguous guidance on the use of social media and the personal use of social media to help ensure that such forums were not used by employees in a way that was potentially within the scope of the Code, particularly Clause 26. This included clear instruction on who was able to post or engage in social media activity on behalf of Boehringer Ingelheim, which was limited to authorised social media communicators and authorised third party agencies.

The Personal Use of Social Media SOP went further to state what was, and was not, permitted from employees when expressing their own opinions including that employees must 'Never discuss topics related to prescription pharmaceutical brands, Boehringer Ingelheim product-related information (in market or development), or any information related to competitor products, on personal Social Media accounts'. The SOP also provided direction on when employees could contribute to posts featuring in the Boehringer Ingelheim UK social media channels.

Boehringer Ingelheim stated that in this instance, the post by medicalxpress.com was not featured, shared on, or otherwise linked to any Boehringer Ingelheim UK channels and Boehringer Ingelheim could categorically state that it was not the source of the information used as a basis for the article/post.

Boehringer Ingelheim submitted that both employees were extremely remorseful and recognised they had had momentary lapses of judgement. Whilst Boehringer Ingelheim considered that, on this occasion, they had failed to demonstrate the standards the company required of them in relation to compliance with SOPs, it did not consider that they had breached the Code as the post and its related article did not relate to a medicine, nor that which could been promoted.

Boehringer Ingelheim therefore did not consider that it had failed to achieve high standards in relation to the Code, nor brought discredit to or reduced confidence in, the pharmaceutical industry.

Boehringer Ingelheim reiterated that the compound referred to in the article was an investigational molecule, which had only just started first-in-human trials, Boehringer Ingelheim was not the legal sponsor of the trials and neither of the trials were run, or intend to be run, in the UK. Therefore, the molecule was not a medicine per se, and it could not be promoted as such to health professionals or the public.

Boehringer Ingelheim noted that Clauses 26.1 and 26.2 only applied to prescription only medicines (as demonstrated in Cases AUTH/3343/5/20 and AUTH/3287/12/19) and as such, Boehringer Ingelheim denied breaches of Clauses 26.1 and 26.2.

In summary, Boehringer Ingelheim submitted that whilst it felt let down by the two employees who 'liked' the post, as they had contravened the relevant SOP, it did not consider that it had breached the Code:

- the molecule referenced in the post was an investigational medicine, entering first-in-human trials, under the legal responsibility of the German university and not being run in the UK. The molecule could not be considered a medicine, and could not be promoted to health professionals or public

- Boehringer Ingelheim had a robust social media SOP that, had it been followed by the two employees, would have prevented any such commentary on this post in the first place, regardless of whether or not its contents fell within the scope of the Code

- Boehringer Ingelheim acted quickly to investigate the circumstances of its two employees' actions, who themselves had taken their own appropriate corrective ('unliking'/deleting the post) and preventative (relearning of the SOP) actions

- Boehringer Ingelheim had used this case as a means to remind all employees of the standards it required in relation to social media.

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. Employees should consider whether such platforms were appropriate for the distribution of the material in question. 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 that the original article from medicalxpress had, without the knowledge or consent of Boehringer Ingelheim, been 'liked' by two of its employees. The Panel considered that the UK employees' engagement with the post, on the balance of probabilities, had proactively disseminated the material to their connections and had thus brought the LinkedIn post and associated article within the scope of the UK Code.

The Panel noted that the article, published in December 2020, was from the German Centre for Infection Research and reported the initiation of two Phase 1/2a clinical trials of a SARS-CoV-2 neutralising antibody which were being conducted in collaboration with Boehringer Ingelheim. The Panel noted that a German university was the legal sponsor of the two trials, not Boehringer Ingelheim, and that the trials would not be conducted in the UK.

The Panel considered that it was clear from the article that the compound in question was in the early stages of development and that if the planned studies showed that it was well tolerated, further studies would be conducted. The Panel noted that Clauses 26.1 and 26.2 only applied to prescription only medicines; the compound referred to in the article linked to the LinkedIn post was an investigational compound and so was not a prescription only medicine. The Panel thus did not consider that a prescription only medicine had been advertised to the public or that information about such a medicine had been made available to the public; no breach of Clauses 26.1 and 26.2 was ruled.

The Panel noted that Clause 3.1 stated that a medicine must not be promoted prior to the grant of a marketing authorisation. In that regard, the Panel considered that a compound, still only referred to by a number (BI 767551), which was just entering first-in-human (phase 1/2a) clinical trials, with no published clinical outcomes and available only in a clinical trial setting was a long way off being available as a medicine; it was clear that further work was needed in relation to the potential SARS-CoV-2 neutralising antibody. The Panel noted the early stage of development of the molecule and in that regard did not consider that a medicine had been promoted prior to the grant of a marketing authorisation. No breach of Clause 3.1 was ruled.

The Panel noted that Boehringer Ingelheim had a social media SOP which clearly stated that employees must 'Never discuss topics related to prescription pharmaceutical brands, Boehringer Ingelheim product-related information (in market or development), or any information related to competitor products, on personal Social Media accounts'. The Panel further noted that an associated e-learning programme had to be completed annually by all employees in the UK and Ireland. Whilst the Panel considered that it was unfortunate that two employees had acted in breach of company policy and training, it noted its rulings of no breach of Clauses 26.1, 26.2 and 3.1 and consequently ruled no breach of Clauses 9.1 and 2.

Complaint received **22 February 2021**

Case completed **7 September 2021**