

CASE AUTH/3390/9/20

COMPLAINANT v JANSSEN

Alleged promotion to the public on LinkedIn

A complainant alleged that a member of Janssen's UK team had promoted a yet to be licensed medicine on LinkedIn, a platform open to the general public. The complainant noted that a named Janssen UK employee, in response to a post from a senior Johnson and Johnson executive, stated how proud he/she was that a Janssen Covid-19 vaccine candidate had commenced phase 3 trials. The senior Johnson and Johnson executive's post referred to moving forward 'with optimism, confidence, and an unwavering commitment to upholding the highest ethical and scientific standards' and included an image of two Janssen vials with the vaccine candidate number Ad26.COV2.S. Johnson & Johnson was Janssen's parent company headquartered in the US.

The detailed response from Janssen is given below.

The Panel acknowledged that in the context of the current pandemic there would understandably be enormous public interest in the work being done by pharmaceutical companies and others to investigate possible treatments and vaccines for Covid-19. However, companies must ensure that materials and activities within the scope of the Code were compliant with it.

The Panel considered that the UK employee's LinkedIn post on his/her personal account in response to the US post would, on the balance of probabilities, have proactively disseminated the information within both the original US post and his/her response post to his/her LinkedIn connections. The Panel noted that such information would include, *inter alia*, the link to the article [The Next Phase of Our COVID-19 Vaccine Development] which referred in the most part to the work Janssen was doing in relation to the Covid-19 pandemic including the development of its lead vaccine candidate and the complex considerations involved and an image of two vials of Ad26.COV2.S, Janssen's SARS-CoV-2 vaccine candidate.

The Panel noted Janssen's submission that followers on the UK employee's LinkedIn account included members of the public and health professionals.

The Panel noted therefore that a Janssen UK employee had proactively posted and disseminated material which referred to Janssen's specific lead vaccine candidate entering a Phase 3 trial on a social media platform which the company acknowledged would be visible to members of the public.

It was clear that the Janssen vaccine was not yet licensed and thus Janssen did not have a prescription only medicine available in September 2020 when the LinkedIn post in question was published. On this very narrow technical point the Panel ruled no breach of the Code.

The Panel considered that the UK employee's proactive dissemination of material via his/her LinkedIn post in response to a US senior executive's post which discussed the Phase 3 clinical development program based on the interim results of its ongoing studies and referred to the company's 'lead Covid-19 vaccine candidate' and included an image of two vials of Ad26.COV2.S, promoted a medicine prior to the grant of its marketing authorization. A breach of the Code was ruled. 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 medicine by Janssen on LinkedIn. The complainant provided a screen shot in which a named Janssen UK employee, in response to a post from a senior Johnson and Johnson executive, stated how proud he/she was that a Janssen Covid-19 vaccine candidate had commenced phase 3 trials. The senior Johnson and Johnson executive's post referred to moving forward 'with optimism, confidence, and an unwavering commitment to upholding the highest ethical and scientific standards' and included an image of 2 Janssen vials with the vaccine candidate number Ad26.COV2.S. Johnson & Johnson was Janssen's parent company headquartered in the US.

COMPLAINT

The complainant alleged that a member of Janssen's UK team had promoted a yet to be licensed medicine on LinkedIn, a platform open to the general public.

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

RESPONSE

Janssen explained that the screenshot provided by the complainant was of a LinkedIn post on a Janssen UK named employee's personal LinkedIn account. The post was dated 1 week before the complaint was received, 30 September 2020. The post was in response to another post by a senior employee of Johnson and Johnson based in the US, also dated 1 week prior to the date of the complaint. That post was made from the US senior executive's personal LinkedIn account, and contained a link to an article titled 'The Next Phase of Our COVID-19 Vaccine Development'.

The intention of both posts was to inform their LinkedIn communities on the progress of the vaccine development in light of the global emergency faced with the Covid-19 pandemic.

Janssen stated that it took responsible use of social media seriously and had provided regular training on the personal individual use of social media. The named UK employee had completed training on responsible use of social media (details were provided).

Janssen noted that its policy on the personal individual use of social media stated:

'Any social media activity and engagement undertaken by Janssen employees via their own personal social media channels and accounts e.g. LinkedIn, Facebook, Twitter, Instagram or You Tube, is considered to be taking place in a public forum and is therefore subject to the ABPI/IPHA Code requirements – in the same way as the company's official company-owned activity/ accounts.'

'This means we all need to take particular care when liking, posting, sharing or commenting on content that relates to our industry, our Company, our products or our therapy areas. This can result in the original post appearing on your personal news feed or home page, which could in turn be deemed as you sharing the information (and indeed promoting this) to members of the public.'

'This applies to posts that have been posted or shared by our parent company Johnson & Johnson and/or other Janssen affiliates since the rules in the UK and Ireland differ greatly from those in the US and indeed, in other countries around the world.'

Janssen submitted that based on interviews with the named UK employee, it had been ascertained that the employee's intention of posting the post and article from the senior US executive was not to promote to the public. The UK employee intended to share the breakthrough in vaccine development with his/her LinkedIn community as a response to high interest in this global emergency.

Janssen submitted that the post did not mention any product names, nor make any claims of the efficacy and safety profile of the vaccine candidate. It also did not raise any unfounded hopes of successful treatment. It simply informed of the vaccine candidate's progress to phase 3 trials.

Janssen submitted that one other UK employee had 'liked' the post in question (screen shot provided). Similarly, that employee had also completed the standard operating procedure (SOP) training on Personal Individual Use of Social Media in August 2020 and received the company-wide emails on posting on social media on 27 April 2020 and on Covid-19 vaccine on 14 August 2020.

Janssen stated that the post from the senior US executive also focused on the vaccine clinical trial development and did not mention any product names, make any claims on efficacy and safety profile, nor did it raise unfounded hopes of successful treatment. The intention was to inform on the development phase of the vaccine. The subject of the post was ENSEMBLE, a large-scale, multi-country phase 3 study of the vaccine candidate. As this was a subject of great global public, regulatory and governmental interest and scrutiny, Johnson and Johnson US headquarters was committed to ensure transparency and the full unredacted study protocol was openly available online (web link provided).

Janssen submitted that the full LinkedIn account of the named UK employee was not open to the general public. To review the profile a connection request had to be submitted to the employee for approval and acceptance. A Google search would result in a top line summary of the employee's name, job title, location and current company. The profile was open to the public in LinkedIn and everyone on LinkedIn might view the employee's posts on 30 September 2020.

The company provided details of the number of followers on the UK employee's LinkedIn account and a breakdown which showed that whilst the vast majority were pharmaceutical company employees they included some health professionals, and some who were classed as members of the public from personal connections.

Janssen stated that the Johnson and Johnson's vaccine candidate Ad26.COV2.S entered phase 3 trials to investigate the single dose regimen for the prevention of SARS-CoV-2-mediated COVID-19 in adults in September 2020.

The phase 3 trial ENSEMBLE included trial sites in Argentina, Brazil, Chile, Colombia, Mexico, Peru, South Africa and the United States. The UK was not a trial site for ENSEMBLE.

On 14 August, Johnson & Johnson announced the collaboration in principle with the UK on an additional phase 3 study to investigate a two-dose regimen of the vaccine candidate. Planning for this study was underway and was subject to regulatory approval.

Janssen submitted that if and when the company's vaccine candidate was approved for emergency use, it would be for the UK Government and health authorities in the UK - not Janssen - to determine how the vaccine programme would be rolled out to members of the public.

No regulatory filing for marketing authorisation for this vaccine candidate had been made anywhere in the world.

Janssen stated that the named UK employee had taken down the original post from his/her LinkedIn account.

Janssen welcomed the Panel's opinion on the potential breach of Clauses 3.1 and 26.1. Janssen reiterated that the UK employee's intention was simply to inform during this unprecedented time on the progress towards finding a Covid-19 vaccine, and not to promote. Janssen also did not consider that it had failed to maintain high standards as it had ensured training was provided for, and completed by, company employees on the responsible personal individual use of social media and therefore, it did not consider that there had been a breach of Clause 9.1.

PANEL RULING

The Panel noted that complex 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. LinkedIn was a global business and employment-oriented network and was primarily, although not exclusively, associated with an individual's professional heritage and current employment interests. In the Panel's view, it was not unacceptable for pharmaceutical company employees to use personal LinkedIn accounts although they needed to be mindful of the compliance issues that might arise. The Panel considered that companies should assume that the Code would apply to all corporate LinkedIn posts and all work-related, personal LinkedIn posts by their employees unless, for very clear reasons, it could be shown otherwise. Whether the Code applied would be determined on a case-by-case basis, taking into account all of the circumstances including, *inter alia*, content and who had posted the material.

The Panel acknowledged that in the context of the current pandemic there would understandably be enormous public interest in the work being done by pharmaceutical companies and others to investigate possible treatments and vaccines for Covid-19. However, companies must ensure that materials and activities within the scope of the Code were compliant with it. The Panel recognised that employees might feel inclined to endorse social media posts related to their company or posted by more senior colleagues and depending on the content such activity might or might not fall within the scope of the Code; therefore, companies needed to issue unambiguous guidance and regular training on personal use of social media. 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.

The Panel noted Janssen's submission that the UK employee's LinkedIn post at issue on his/her personal account was in response to a post by a senior executive of Johnson and Johnson based in the US, which was included as part of the UK employees post, and stated:

'Today, Johnson & Johnson announced the launch of a large-scale, multi-country Phase 3 trial of a single dose of our Covid-19 vaccine candidate. We're moving forward with optimism, confidence, and an unwavering commitment to upholding the highest ethical and scientific standards' [accompanied by an image of 2 Janssen vials with the vaccine candidate number Ad26.COV2.S].

The Panel noted that the US senior executive's post also contained a link to an article titled 'The Next Phase of Our COVID-19 Vaccine Development' which referred in the most part to the work Janssen was doing in relation to the Covid-19 pandemic including the development of its lead vaccine candidate and the complex considerations involved. The Panel noted that this article stated:

'Today, we're pleased to announce that based on interim results from our ongoing studies, the Janssen Pharmaceutical Companies of Johnson & Johnson are launching ENSEMBLE, a large-scale, multi-country Phase 3 trial of a single dose of our vaccine candidate. This is big news for our company and I'm incredibly proud of the way our vaccine development teams and supply chain experts across the world have collaborated and produced such a breakthrough in a very challenging environment'.

The Panel noted the article included a link to the ENSEMBLE study protocol and ended with:

'These considerations create complexity, but they are all necessary to get the best results. It's why our company is able to mark milestones like the one we're sharing today- and move forward with both optimism and confidence'.

The Panel noted that the UK employees LinkedIn post in response stated:

'Incredibly proud that the Janssen vaccine has commenced phase 3 trials, only 6 months after it was identified as a potential candidate. Whatever the outcomes are the work that has gone into this is truly amazing. Huge thanks to my colleagues around the world who have worked tirelessly to make this happen #janssen #vaccinedevelopment #j&j'

The Panel considered that the UK employee's post in response to the US post would, on the balance of probabilities, have proactively disseminated the information within both the original US post and his/her response post to his/her LinkedIn connections. The Panel noted that such information would include, *inter alia*, the link to the article referred to above [The Next Phase of Our COVID-19 Vaccine Development] and an image of two vials of Ad26.COV2.S, Janssen's SARS-CoV-2 vaccine candidate.

The Panel noted Janssen's submission regarding the followers on the UK employee's LinkedIn account which included members of the public and health professionals.

The Panel noted therefore that a Janssen UK employee had proactively posted and disseminated material which referred to Janssen's specific lead vaccine candidate entering a Phase 3 trial on to a social media platform which the company acknowledged would be visible to members of the public.

The Panel noted 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.

It was clear that the Janssen vaccine was not yet licensed and thus Janssen did not have a prescription only medicine available in September 2020 when the LinkedIn post in question was published. Clause 26.1 only applied to prescription only medicines. On this very narrow technical point the Panel ruled no breach of Clause 26.1 of the Code.

The Panel noted the requirements of Clause 3.1 and considered that the UK employee's proactive dissemination of material via his/her LinkedIn post in response to a US senior executive's post which discussed the Phase 3 clinical development program based on the interim results of its ongoing studies and referred to the company's 'lead Covid-19 vaccine candidate' and included an image of two vials of Ad26.COV2.S, promoted a medicine prior to the grant of its marketing authorization. A breach of Clause 3.1 was ruled. High standards had not been maintained; a breach of Clause 9.1 was ruled.

Complaint received **30 September 2020**

Case completed **1 March 2021**