CASE AUTH/3524/6/21 ***NO BREACH OF THE CODE***

HEALTH PROFESSIONAL v GLAXOSMITHKLINE

Alleged use of LinkedIn to promote a medicine

A complainant, who described him/herself as a concerned UK health professional, complained about a LinkedIn post published on the GlaxoSmithKline global LinkedIn account.

The complainant provided a screenshot of the LinkedIn post and stated that it was not some 'minor employee' making a mistake but the company itself and a senior employee no less. The complainant alleged that GlaxoSmithKline was using a platform that was intended for the general public to promote a product before it was licenced. The complainant alleged that GlaxoSmithKline had previously used LinkedIn to promote to the general public (Case AUTH/3130/12/1[8]) and requested that this was taken into account whilst investigating the matter.

As the complaint concerned, *inter alia*, an alleged breach of undertaking, that aspect of the case proceeded in the name of the Director as the PMCPA was responsible for enforcement of undertakings.

The detailed response from GlaxoSmithKline is given below.

The Panel noted GlaxoSmithKline's submission that the post in question was published on the global headquarters corporate account, which had over 2.8 million followers at the time of posting, including over 227,000 from the UK. The Panel noted that the global headquarters was UK-based and GlaxoSmithKline recognised that all global posts from its corporate account were within the scope of the Code. In the Panel's view, activity conducted on social media that could potentially alert the account's followers to a post might be considered proactive dissemination of posted material and any material associated with a LinkedIn post, for example, a link within a post, would be regarded as being an integral part of that post.

In the Panel's view, in principle, it was not necessarily unacceptable for a company to refer, in very general terms, to its pipeline or work it was doing in response to the current pandemic. However, language, context, location, layout, intended audience and overall impression were important factors. The Panel queried whether a social media platform, such as LinkedIn, was the appropriate forum to share such information. The Panel noted that understandably there would be much interest in the work being done by pharmaceutical companies and others to investigate possible vaccines and treatments for Covid-19. However, companies must ensure that materials and activities complied with the Code.

The Panel noted that the post in question stated 'Great progress in our #COVID19 vaccine collaboration with Medicago announced today with positive interim results from a Phase 2 study for the adjuvanted #COVID19 #vaccine candidate, which combines their

innovative plant-based vaccine technology with our pandemic adjuvant. These results are part of the ongoing Phase 2/3 study. Learn more about our response to the pandemic: [link]'. Below the LinkedIn post was a photograph, including a quotation from a senior executive, which stated, 'We are delighted to see that the results suggest a very strong immune response. We now look forward to the outcome of the ongoing Phase 3 trial of this refrigerator-stable vaccine candidate as the next step forward in our contribution to the global response to the pandemic'.

The Panel noted GlaxoSmithKline's submission that the post referred to formed part of the wider global corporate communications strategy to enhance the global corporate image and reputation of the company with the 'informed' public (defined as 25 years or older, with at least a first degree, connected on social media, with interests such as current affairs, healthcare, charitable giving, science education and innovation).

The Panel noted GlaxoSmithKline's submission that the aim of the LinkedIn post was to deliver news about an ongoing collaboration with another company which formed part of the GlaxoSmithKline pandemic response; the post related to an investigational asset which was moving to Phase 3 after positive interim results from Phase 2. The Panel further noted GlaxoSmithKline's submission that the Phase 3 study had only just been initiated, and the results were unknown with no data having been filed anywhere in the world for authorisation. GlaxoSmithKline later reiterated that the results were part of the 'ongoing' (not completed) Phase 2/3 (pre-regulatory submission) study and linked to a page on the corporate website that discussed the overarching GlaxoSmithKline response to the pandemic, not to a page discussing this particular study, nor any results in detail.

The Panel noted GlaxoSmithKline's submission that the link within the post navigated to the GlaxoSmithKline Covid-19 response page titled 'Our response to CoViD-19', which was hosted on the GlaxoSmithKline corporate website within its media section's resource centre and discussed how GlaxoSmithKline was responding to the pandemic. On the landing page after the introductory paragraphs, a section beneath the tab 'Developing COVID-19 vaccines' described what adjuvants were and why they could be particularly useful in a pandemic to explain why GlaxoSmithKline was providing its adjuvant to a number of other companies which were developing vaccines. It stated that an adjuvant is added to some vaccines to enhance the immune response, thereby creating a stronger and longer lasting immunity against infections than the vaccine alone. Within this tab, it further described GlaxoSmithKline's Covid-19 vaccine collaborations with other companies; one example of a collaboration stated 'We are also collaborating with Canadian biopharmaceutical company, Medicago, to develop a COVID-19 vaccine by combining their plant-derived vaccine candidate with our adjuvant technology. The vaccine candidate entered phase 2/3 clinical trials in mid-November 2020 and, if successful, we aim to make the vaccine available, in the first half of 2021'. In this regard, the Panel noted that the LinkedIn post in question appeared to have been made in May 2021. The webpage also described how Medicago's plant-based approach used living plants to produce non-infectious versions of the viruses allowing them to be recognised by the immune system and eliciting a protective immune response. The page included two additional tabs, titled, 'Vaccine pricing and access' and 'Developing COVID-19 treatments'. The Panel did not have the content accessible from these tabs before it.

The webpage also included a link to a pdf entitled 'Our COVID-19 solutions key facts' which had an overview of the GlaxoSmithKline response to COVID- 19. The version

which, according to GlaxoSmithKline, was live at the time of the complaint stated, 'Our collaboration with Medicago is now in late-stage trials'. This document also described what an adjuvant was stating 'An adjuvant can be added to a vaccine to boost the body's immune response, which means less vaccine is needed for the same result. This is particularly important in a pandemic as more vaccine doses can be available to protect people around the world'.

The Code prohibited the promotion of prescription only medicines to the public. The Panel noted that the vaccine candidate referred to in the LinkedIn post was not yet classified as a prescription only medicine at the time of the LinkedIn post. On that very narrow technical point, the Panel ruled no breach of the Code.

The Panel noted the quote from a senior GlaxoSmithKline executive, within the LinkedIn post at issue and the information accessible from a link within the post, particularly the references to the benefit of using adjuvants, Medicago's plant-based approach and the fact that GlaxoSmithKline's collaboration with Medicago was in late-stage trials and, if successful, it aimed to make the vaccine available in the first half of 2021.

The Panel, noting the content of the LinkedIn post which discussed the positive efficacy results of GlaxoSmithKline's unlicensed vaccine and included a promotional claim from a senior executive that the results suggested a 'very strong immune response' and the vaccine candidate was 'refrigerator-stable', considered that the LinkedIn post promoted an unlicensed medicine to the public. Its promotional nature was compounded by the information within the linked webpage. The Panel ruled a breach of the Code which was appealed by GlaxoSmithKline.

The Panel considered that high standards had not been maintained in this regard and a breach of the Code was ruled which was appealed by GlaxoSmithKline.

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 that the LinkedIn post was made on the GlaxoSmithKline corporate account and considered that in promoting the unlicensed vaccine, to the public as alleged and failing to recognise that its content was promotional, meant that GlaxoSmithKline had brought discredit upon, and reduced confidence in, the pharmaceutical industry and a breach of Clause 2 was ruled which was appealed by GlaxoSmithKline.

With regard to the alleged breach of undertaking, the Panel noted that Case AUTH/3130/12/18 concerned the sharing of an independently authored article by a worker contracted by global headquarters which was based in the UK on his/her personal account in clear breach of the company's global social media policy; it was never posted or shared on a GlaxoSmithKline corporate social media account, or with its authority. The post in Case AUTH/3130/12/18 concerned a licensed prescription only medicine and referred to its use in an unlicensed indication and was found in breach of the Code.

The current case (Case AUTH/3524/6/21) was in relation to a post on the GlaxoSmithKline corporate social media account about an unlicensed medicine.

In the Panel's view, the current case, Case AUTH/3524/6/21, was sufficiently different to the previous case such that there had been no breach of the undertaking given in Case AUTH/3130/12/18 as alleged. The Panel therefore ruled no breaches of the Code including Clause 2.

The Appeal Board considered that in its appeal GlaxoSmithKline had provided further important detail regarding its arrangements with Medicago Inc which had not been provided to the Panel. GlaxoSmithKline had submitted that during the Covid-19 Pandemic it had entered into a collaboration with Medicago Inc. to provide clinical trial level volumes of its pandemic adjuvant and developmental support to Medicago in relation to Covifenz. GlaxoSmithKline had no commercialisation rights for Covifenz and GlaxoSmithKline was not the marketing authorisation holder. Covifenz was a COVID 'Virus Like Particle' vaccine currently only authorised for use in Canada for which Medicago was the marketing authorisation holder. There was no direct commercial supply by GlaxoSmithKline of its pandemic adjuvant to Medicago Inc. GlaxoSmithKline had agreements to supply this adjuvant to the Canadian and US governments. In response to a question from the Appeal Board, GlaxoSmithKline's representatives at the appeal stated that to produce its vaccine, Medicago Inc. would need to procure the adjuvant directly from the Canadian government.

The Appeal Board noted that the 2019 Code stated that 'The term "promotion" means any activity undertaken by a pharmaceutical company or with its authority which promotes the administration, consumption, prescription, purchase, recommendation, sale, supply or use of its medicines'.

The Appeal Board noted that GlaxoSmithKline had only agreed to provide Medicago Inc. with its adjuvant in the clinical trial stage and that it had no ongoing commercial arrangement with Medicago Inc in relation to Covifenz.

The Appeal Board, noting its comments above and taking all of the circumstances into consideration, did not consider that the Covid-19 vaccine referred to within the LinkedIn post was a GlaxoSmithKline medicine and therefore GlaxoSmithKline could not be seen to be promoting *its* medicine pre-licence as referred to in the Code. The Appeal Board therefore ruled no breach of the Code. The appeal on this point was successful.

The Appeal Board consequently ruled no breaches of the Code including Clause 2. The appeal on this point was successful.

A complainant, who described him/herself as a concerned UK health professional, complained about a LinkedIn post published on the GlaxoSmithKline global LinkedIn account. The LinkedIn post at issue stated:

> 'Great progress in our #COVID19 vaccine collaboration with Medicago announced today with positive interim results from a Phase 2 study for the adjuvanted #COVID19 #vaccine candidate, which combines their innovative plant-based vaccine technology with our pandemic adjuvant.
>
> These results are part of the ongoing Phase 2/3 study.
>
> Learn more about our response to the pandemic: [link].'

The post included a photograph of, and a quote from, a senior employee alongside the quotation 'We are delighted to see that the results suggest a very strong immune response. We now look forward to the outcome of the ongoing Phase 3 trial of this refrigerator-stable vaccine candidate as the next step forward in our contribution to the global response to the pandemic'.

COMPLAINT

The complainant provided a screenshot of a post that he/she had seen on LinkedIn and stated that it was not some 'minor employee' making a mistake but the company itself and a senior employee no less. The complainant alleged that GlaxoSmithKline was using a platform that was intended for the general public to promote a product before it was licenced. The complainant alleged that GlaxoSmithKline had previously used LinkedIn to promote to the general public in a previous case (Case AUTH/3130/12/1[8]) and requested that this was taken into account whilst investigating the matter.

As the complaint concerned, *inter alia*, an alleged breach of undertaking that aspect of the case proceeded in the name of the Director as the PMCPA was responsible for enforcement of undertakings.

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

RESPONSE

Introduction

GlaxoSmithKline submitted that the complainant had provided a screenshot of a LinkedIn post and alleged '*This isn't some minor employee making a mistake but the company itself – with [a senior executive] no less! Using a platform that is intended for the general public to promote a product before it is licensed'*. The complainant had not described in what way he/she believed the LinkedIn post was *'promoting a product before it is licensed'*, nor provided any evidence to support his/her assertion. It was not the job of the Authority or respondent to provide the evidence for the complainant. The complainant had also asserted that '*GSK have previously used LinkedIn to promote to the general public, in the case AUTH3130/12/1[sic]'* and requested the Authority '*take this into account whilst investigating'*.

GlaxoSmithKline submitted that as stated in the introduction to the PMCPA Constitution and Procedure, the Authority was not an investigatory body as such. 'It is essentially an adversarial process in which the evidence taken into account comes from the complainant and respondent company'. And went on, 'A complainant has the burden of proving their complaint on the balance of probabilities'. Despite this, the Authority had requested that copies of the material linked to were provided, yet there had been no complaint in this regard as the complainant made no mention of any concerns about the linked material. A previous case considered by the Authority limited their considerations to the social media posts themselves when no mention of concerns with the linked materials had been made (Case AUTH/2612/6/13), and GlaxoSmithKline believed the same principle should apply here. The complaint appeared to be that the post itself promoted a product before it was licensed, not that the post plus associated

linked content did, as the complainant did not refer to the linked content. Therefore, GlaxoSmithKline did not believe the linked material should be taken into consideration.

Background to the post

GlaxoSmithKline submitted that the post in question had come from the global headquarters corporate account of a multinational Research and Development (R&D) company based in the UK, not an individual's personal LinkedIn account. This account had the responsibility and remit to provide information to a broad audience on GlaxoSmithKline and its activities.

The post referred to formed part of the wider global corporate communications strategy to enhance the global corporate image and reputation of the company with the 'informed' public (defined as 25 years or older, with at least a first degree, connected on social media, with interests such as current affairs, healthcare, charitable giving, science education and innovation).

The need for such a campaign was based on the results of market research, conducted in 2014 and repeated most recently last year, which sought to determine how the public perceived GlaxoSmithKline as a company amongst its industry peers and how its image and reputation could be further enhanced. One of the key findings of this research was that the company should be more transparent in its research activities as well as with the various stakeholders with whom it engaged.

GlaxoSmithKline submitted that it was in a period that it had not seen before, with the current global pandemic, and an unprecedented focus on research institutions and pharmaceutical companies to demonstrate how they were working to develop new medicines to combat the current situation. For GlaxoSmithKline, historically a leader in vaccines, the initial results from a vaccine collaboration with Sanofi were not positive, and the global media coverage made sure everyone was aware of this disappointment. Thus, it had been even more important for GlaxoSmithKline global headquarters to provide informational updates on progress to reassure investors and the public that it was still committed to, and working hard in, this arena.

Unarguably, the CoViD 19 pandemic had called for exceptional responses by governments, healthcare, industry and individuals and similarly there was unparalleled public interest and desire for knowledge on progress in these areas. Even the UK Chief Scientific Officer, the ABPI, AstraZeneca and the Department of Health, had announced the arrival of the vaccine on social media, which GlaxoSmithKline believed was the right thing to do in this crisis.

Trustworthy communications had been shown to be particularly important in this era of fake news and misinformation. Providing factual information about ongoing trials, did not promote that potential treatment prior to licence, but simply informed the public that work was ongoing and that there was potentially further progress being made in the fight against the pandemic. Announcing positive interim results meant that the medicine could progress to the next stage of development, and not a confirmation of final success of a trial.

The LinkedIn post

The LinkedIn post referred to in this complaint related to a milestone in an area of need and was demonstrating how GlaxoSmithKline was very much committed to improving global health, were collaborative, and were making progress in helping to combat a global pandemic.

The opening sentence described the progress of the collaboration to highlight the companies were working well together (very rare pre-CoViD 19, and something GlaxoSmithKline had been particularly keen to cultivate and be seen to be leaders in) and they had achieved positive interim Phase 2 results for an asset that combined one component from Medicago and another component from GlaxoSmithKline. This was unusual in a collaboration, where the formulation comprised elements from both companies, but was a key part of the GlaxoSmithKline response to the pandemic where it had supplied its established adjuvant to multiple companies who were developing vaccines in an effort to help ensure adequate vaccine supplies globally. Adjuvants potentially allowed lower doses of vaccines to be given and thus for supplies to go further, an advantage particularly in pandemics.

Non-promotional nature of the LinkedIn post

GlaxoSmithKline refuted the allegation of promoting prior to authorisation. The aim of the post was to deliver news about an ongoing collaboration with another company which formed part of the GlaxoSmithKline pandemic response. It related to an investigational asset which was moving to Phase 3 after positive interim results from Phase 2. This was not 'pre-licence'. The Phase 3 study had only just initiated, the results were clearly unknown, the data had not been filed anywhere in the world for authorisation, and there were still numerous hurdles to overcome before a licence was attained (if at all). The fact it was Phase 2/3 was clearly communicated, and the vaccine referred to as a 'candidate' which was widely accepted terminology for an investigational asset.

Although there was no definition of what constituted 'pre-licence' it would seem unduly restrictive if any communication of positive results at any stage in the development of an asset were considered pre-licence promotion, especially when they related to research to help fight the pandemic which had unprecedented public interest.

Makes clear asset is in development

Whilst the LinkedIn post made mention of positive interim results, it also clearly stated that it was part of an ongoing trial program, and part of GlaxoSmithKline's ongoing response to the global pandemic, reinforcing the fact that this was not about promoting to the public or prior to licence, but was to advise that it was committed to playing its part in the current pandemic, and to enhance its corporate reputation as vaccine producer and global health advocate. The LinkedIn post used language that clearly communicated that this was part of an ongoing study; it talked of vaccine 'candidate' (ie not authorised), 'interim' results (ie not final) of a 'Phase 2' (early development) study, and later reiterated these results were part of the 'ongoing' (not completed) Phase 2/3 (pre-regulatory submission) study and linked to a page on the corporate website that discussed the overarching GlaxoSmithKline response to the pandemic, not to a page discussing this particular study, nor any results in detail.

The associated quotation from the senior executive referred to the fact GlaxoSmithKline 'look forward to the outcome of the ongoing Phase 3 trial' (making it clear the trial continued and no results were available yet). The senior executive also referred to this as the 'next step forward' in GlaxoSmithKline's contribution to the global pandemic, which, given its previous, very public

failed trial in this arena, again aimed to enhance the corporate and scientific reputation of GlaxoSmithKline which had been damaged.

The purpose of the LinkedIn post was to enhance GlaxoSmithKline's reputation in terms of still working hard to find a CoViD 19 vaccine with collaborators, persevering with scientific endeavour and demonstrating that it was fully committed to providing a contribution in the current global pandemic. The LinkedIn post was factual, made clear that the product was in development and although conveying pleasure in the positive results, was not promoting a medicine prior to licence. As such, GlaxoSmithKline did not believe it had promoted a medicine prior to marketing authorisation, and therefore it did not believe it had breached Clause 3.1.

Not a prescription only medicine

As had been ruled a number of times before (eg Cases AUTH/3051/6/18 and AUTH/3364/6/20), until an asset had marketing authorisation it was not a licensed medicine and therefore there could be no breach of Clause 26.1 which related to the prohibition of promotion of prescription only medicines to the public. As such, GlaxoSmithKline refuted the allegation.

It was notable that the CoViD 19 vaccines that were available were not prescribed individually by health professionals, but were bought on contract by central government as part of a vaccination program, and, as such, there would be no benefit to promoting individual vaccines to either health professionals or the public as they were unable to either request, nor prescribe a specific product.

Linked content

The LinkedIn post in question contained a link, however, the complainant made no mention of concerns about the link and did not provide any arguments or evidence to suggest he/she thought the link was inappropriate and, as such, GlaxoSmithKline did not believe the linked page should be considered as outlined above.

However, to reassure the Authority and provide a full response, the link within the LinkedIn post navigated to the GlaxoSmithKline CoViD 19 response page which was hosted on its corporate website. This landing page discussed GlaxoSmithKline's collaborations with other companies in a factual, scientific and informational tone. Its purpose was made explicitly clear in the opening paragraphs, providing context relating to the pandemic and how GlaxoSmithKline was responding. The landing page was intended as an overview of the efforts GlaxoSmithKline was making and was clearly labelled as 'Our response to CoViD 19' so the reader was clear what the purpose of the page was.

The landing page provided factual information on what GlaxoSmithKline was doing to help combat the global pandemic. On the landing page after the introductory paragraphs, it described what adjuvants were and why they could be particularly useful in a pandemic to explain why GlaxoSmithKline was providing its adjuvant to a number of other companies who were developing vaccines. The landing page then went on to describe GlaxoSmithKline's vaccine development collaborations with other companies and described the top line information about where these collaborations were in the development timeline, but without going into trial detail or results.

The landing page further described an agreement on how GlaxoSmithKline was utilising its vaccine manufacturing expertise and facilities to help support the manufacturing capabilities of CureVac, as well as clarifying its strategic collaboration.

Two other tabs could be clicked on to find out more about GlaxoSmithKline's work on developing potential CoViD 19 treatments under investigation or vaccines pricing and access.

Also on the landing page was a pdf that could be clicked on which had a complete overview and summary of the GlaxoSmithKline response to CoViD 19.

The versions of this landing page, and the pdf that were live at the time of the complaint, were provided.

The landing page was part of GlaxoSmithKline's corporate communication strategy to demonstrate and reassure visitors that it was contributing to the global pandemic and taking its social responsibilities seriously.

Maintaining high standards

In accordance with GlaxoSmithKline policies and to ensure high standards of Code compliance were maintained, the LinkedIn post was reviewed prior to publication by a registered physician who was an experienced Signatory. GlaxoSmithKline had robust procedures and processes in place to ensure compliance with the Code and associated regulations related to social media. All LinkedIn posts that related to diseases, medicines or assets were reviewed by a Signatory who also determined if they needed certification (by being education for the public). Very limited corporate communications personnel were authorised to post on social media using the corporate accounts and had had enhanced training on the Code by a well-established external trainer and both internal and external experienced Signatories.

In accordance with due process, this LinkedIn post was examined prior to publication by an experienced Signatory and therefore, GlaxoSmithKline did not believe it had breached Clause 9.1.

Fundamentally different from Case AUTH/3130/12/18

GlaxoSmithKline submitted that the complainant asked the Authority to take Case AUTH/3130/12/1 [*sic*] in to account whilst investigating. Case AUTH 3130/12/18 was fundamentally different to the present case as it involved the sharing of an independently authored article from a news agency by a contract worker based in the global headquarters who acted in clear breach of the company social media policy. The article concerned a licensed prescription only medicine and was shared with the caption 'Looks like another vaccines blockbuster!' and was found in breach of Clauses 26.1, 26.2 and 9.1. Unlike the present case, the article was never posted or shared on a GlaxoSmithKline corporate social media account, or with its authority, and as the current case did not involve a prescription only medicine, it could not be found in breach of Clauses 26.1 or 26.2. The Panel noted that the contractor had acted in breach of company policy and training and did not rule a breach of Clause 2.

GlaxoSmithKline took its obligation to comply with undertakings extremely seriously, and following Case AUTH/3130/12/18, GlaxoSmithKline took the following additional steps to ensure no further breach of a similar nature would occur in future:

- GlaxoSmithKline policies and guidance on personal use of social media were updated to be unquestionably clear and unambiguous as to how its employees could appropriately engage with content about GlaxoSmithKline on their personal social media channels.
- This was rolled out to all UK-based employees as mandatory training.
- The launch of this training was further accompanied with an internal Workplace campaign and specific site and function-led communications to raise awareness.

Furthermore, periodically and whenever there was a milestone attracting significant external coverage, staff were reminded of the social media guidelines to minimise the risk of non-compliant behaviour at particularly high-risk times.

GlaxoSmithKline submitted it had taken all possible action to ensure a similar breach would not occur in future as per its undertaking. The complainant had not provided any evidence to suggest otherwise and, as such, GlaxoSmithKline did not consider that it had breached its undertaking given in Case AUTH/3130/12/18 and denied breaching Clause 29.

Robust social media policies

As a UK headquartered company, GlaxoSmithKline recognised that all global posts from the corporate accounts were within the scope of the Code. This account was managed by the global communications team, with the remit of providing transparent, scientifically accurate, corporate and educational communications with the aim of improving transparency to GlaxoSmithKline's activities, in addition to enhancing not only its corporate reputation but the reputation of the pharmaceutical industry in general.

GlaxoSmithKline had robust procedures and processes in place to ensure compliance with the Code and associated regulations related to social media. The global communications team ensured that social media posts relating to diseases, medicines or assets were examined by a Signatory who also determined if they needed certification (by being education for the public). In addition, GlaxoSmithKline had social media plans reviewed by Legal when considered necessary (eg when related to quarterly results).

A very limited number of personnel were authorised to post on social media using the corporate accounts. These limited few received enhanced training on the Code by a well-established external trainer in February 2020, in addition to training from both internal and external experienced signatories.

Internal processes were complied with and this post was examined by a signatory prior to publication.

For completeness, GlaxoSmithKline provided its Social Media Guidance for employees list, but this particular case related to the use of the Global Headquarters LinkedIn account, not the actions of an employee on their personal account which was what this guidance applied to.

LinkedIn account statistics

The LinkedIn account referred to in the complaint, was the GlaxoSmithKline corporate headquarters account which had 2,834,399 followers at the time of the posting in question.

Currently, GlaxoSmithKline's LinkedIn account had 2,843,504 followers and the demographics were provided.

Enhancing the reputation of industry

GlaxoSmithKline submitted that it had been working tirelessly to respond to the pandemic in as many ways as it could to be most effective. Contrary to bringing the industry into disrepute, GlaxoSmithKline believed these activities had enhanced the reputation of the pharmaceutical industry, particularly amongst health professionals.

In addition, the current global pandemic had seen an improvement in the public perception and image of the pharmaceutical industry following the transparency seen around the efforts to develop vaccines and medications.

This was evident from a Harris Poll data published in March 2021 in the New York Times which had shown that the increase communication and transparency around the pharmaceutical industries CoViD 19 response had translated to the public viewing the pharmaceutical industry in a much more positive light than usual.

As the global headquarters of a multinational R&D company, GlaxoSmithKline recognised that sharing factual and trustworthy information about progress towards goals and routes out of the pandemic had been vital to ensure people were provided with reliable information. As could be seen in the Harris Polls, this not only built individual corporate reputation but also the wider industry as a whole. As such, GlaxoSmithKline refuted the allegation of bringing discredit to, and reduction of confidence in, the industry and denied breaching Clause 2.

Summary

GlaxoSmithKline refuted the allegations and did not believe its corporate communications relating to the progress of one of its collaborations, which was striving to help end the global pandemic, had promoted a prescription medicine to the public (Clause 26.1), nor had it promoted a medicine without marketing authorisation (Clause 3.1).

GlaxoSmithKline had continued to comply with the undertaking given in Case AUTH/3130/12/18 and, as such, refuted the allegation of breaching Clause 29. GlaxoSmithKline took compliance with the Code seriously and had extensive training, policies and procedures in place to maintain high standards and, as such, did not believe it had breached Clause 9.1, and contrary to the allegations, it had not brought the industry into disrepute (Clause 2).

PANEL RULING

The Panel noted that LinkedIn was different to some other social media platforms in that it originated as a business and employment-orientated network; its application, however, was not limited to the pharmaceutical industry or to health care.

The Panel noted GlaxoSmithKline's submission that the post in question was published on the global headquarters corporate account, which had over 2.8 million followers at the time of posting, including over 227,000 from the UK. The Panel noted that the global headquarters was UK-based and GlaxoSmithKline recognised that all global posts from its corporate account were within the scope of the Code. In the Panel's view, activity conducted on social media that could

potentially alert the account's followers to a post might be considered proactive dissemination of posted material and any material associated with a LinkedIn post, for example, a link within a post, would be regarded as being an integral part of that post.

In the Panel's view, in principle, it was not necessarily unacceptable for a company to refer, in very general terms, to its pipeline or work it was doing in response to the current pandemic. However, language, context, location, layout, intended audience and overall impression were important factors. The Panel queried whether a social media platform, such as LinkedIn, was the appropriate forum to share such information. The Panel noted that understandably there would be much interest in the work being done by pharmaceutical companies and others to investigate possible vaccines and treatments for Covid-19. However, companies must ensure that materials and activities complied with the Code.

The Panel noted that the post in question stated 'Great progress in our #COVID19 vaccine collaboration with Medicago announced today with positive interim results from a Phase 2 study for the adjuvanted #COVID19 #vaccine candidate, which combines their innovative plant-based vaccine technology with our pandemic adjuvant. These results are part of the ongoing Phase 2/3 study. Learn more about our response to the pandemic: [link]'. Below the LinkedIn post was a photograph, including a quotation from a senior executive, which stated, 'We are delighted to see that the results suggest a very strong immune response. We now look forward to the outcome of the ongoing Phase 3 trial of this refrigerator-stable vaccine candidate as the next step forward in our contribution to the global response to the pandemic'.

The Panel noted GlaxoSmithKline's submission that the post referred to formed part of the wider global corporate communications strategy to enhance the global corporate image and reputation of the company with the 'informed' public (defined as 25 years or older, with at least a first degree, connected on social media, with interests such as current affairs, healthcare, charitable giving, science education and innovation).

The Panel noted GlaxoSmithKline's submission that the aim of the LinkedIn post was to deliver news about an ongoing collaboration with another company which formed part of the GlaxoSmithKline pandemic response; the post related to an investigational asset which was moving to Phase 3 after positive interim results from Phase 2. The Panel further noted GlaxoSmithKline's submission that the Phase 3 study had only just been initiated, and the results were unknown with no data having been filed anywhere in the world for authorisation. GlaxoSmithKline later reiterated that the results were part of the 'ongoing' (not completed) Phase 2/3 (pre-regulatory submission) study and linked to a page on the corporate website that discussed the overarching GlaxoSmithKline response to the pandemic, not to a page discussing this particular study, nor any results in detail.

The Panel noted GlaxoSmithKline's comments regarding the Authority's request for copies of the material linked to the post, as the complainant made no mention of any concerns about the linked material. The Panel considered the matter carefully and whilst noting that the complainant did not specifically refer to the link, he/she had referred to the LinkedIn post as an example of promoting to the public. The Panel, noting its comments above, considered that any associated link would be considered an integral part of the post itself. The Panel considered each complaint on the allegations made and the evidence provided by each party; it was also important to have the complete material in order to understand the context.

The Panel noted GlaxoSmithKline's submission that the link within the post navigated to the GlaxoSmithKline Covid-19 response page titled 'Our response to CoViD-19', which was hosted on the GlaxoSmithKline corporate website within its media section's resource centre and discussed how GlaxoSmithKline was responding to the pandemic. On the landing page after the introductory paragraphs, a section beneath the tab 'Developing COVID-19 vaccines' described what adjuvants were and why they could be particularly useful in a pandemic to explain why GlaxoSmithKline was providing its adjuvant to a number of other companies which were developing vaccines. It stated that an adjuvant is added to some vaccines to enhance the immune response, thereby creating a stronger and longer lasting immunity against infections than the vaccine alone. Within this tab, it further described GlaxoSmithKline's Covid-19 vaccine collaborations with other companies; one example of a collaboration stated 'We are also collaborating with Canadian biopharmaceutical company, Medicago, to develop a COVID-19 vaccine by combining their plant-derived vaccine candidate with our adjuvant technology. The vaccine candidate entered phase 2/3 clinical trials in mid-November 2020 and, if successful, we aim to make the vaccine available, in the first half of 2021'. In this regard, the Panel noted that the LinkedIn post in question appeared to have been made in May 2021. The webpage also described how Medicago's plant-based approach used living plants to produce non-infectious versions of the viruses allowing them to be recognised by the immune system and eliciting a protective immune response. The page included two additional tabs, titled, 'Vaccine pricing and access' and 'Developing COVID-19 treatments'. The Panel did not have the content accessible from these tabs before it.

The webpage also included a link to a pdf entitled 'Our COVID-19 solutions key facts' which had an overview of the GlaxoSmithKline response to COVID- 19. The version dated 21 March 2021 which, according to GlaxoSmithKline, was live at the time of the complaint stated, 'Our collaboration with Medicago is now in late-stage trials'. This document also described what an adjuvant was stating 'An adjuvant can be added to a vaccine to boost the body's immune response, which means less vaccine is needed for the same result. This is particularly important in a pandemic as more vaccine doses can be available to protect people around the world'.

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.

The Panel noted that the vaccine candidate referred to in the LinkedIn post was not yet classified as a prescription only medicine at the time of the LinkedIn post. 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.

The Panel noted the quote from a senior GlaxoSmithKline executive, within the LinkedIn post at issue, which stated, 'We are delighted to see that the results suggest a very strong immune response. We now look forward to the outcome of the ongoing Phase 3 trial of this refrigerator-stable vaccine candidate as the next step forward in our contribution to the global response to the pandemic' and considered that it was a claim for the company's candidate Covid-19 vaccine. The Panel further noted the information accessible from a link within the post, particularly the references to the benefit of using adjuvants, Medicago's plant-based approach and the fact that GlaxoSmithKline's collaboration with Medicago was in late-stage trials and, if successful, it aimed to make the vaccine available in the first half of 2021.

The Panel, noting the content of the LinkedIn post which discussed the positive efficacy results of GlaxoSmithKline's unlicensed vaccine and included a promotional claim from a senior executive that the results suggested a 'very strong immune response' and the vaccine candidate was 'refrigerator-stable', considered that the LinkedIn post promoted an unlicensed medicine to the public. Its promotional nature was compounded by the information within the linked webpage. The Panel ruled a breach of Clause 3.1.

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

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 rulings above. The Panel noted that the LinkedIn post was made on the GlaxoSmithKline corporate account and considered that in promoting the unlicensed vaccine, to the public as alleged and failing to recognise that its content was promotional, meant that GlaxoSmithKline 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, the Panel noted that Case AUTH/3130/12/18 concerned the sharing of an independently authored article by a worker contracted by global headquarters which was based in the UK on his/her personal account in clear breach of the company's global social media policy; it was never posted or shared on a GlaxoSmithKline corporate social media account, or with its authority. The post in Case AUTH/3130/12/18 concerned a licensed prescription only medicine. It was headed 'Looks like another potential vaccines blockbuster' and referred to Bexsero as a 'men B shot' and its 'promise against gonorrhea' which was an unlicensed indication and was found in breach of Clauses 26.1, 26.2 and 9.1.

The current case (Case AUTH/3524/6/21) was in relation to a post on the GlaxoSmithKline corporate social media account about an unlicensed medicine.

In the Panel's view, the current case, Case AUTH/3524/6/21, was sufficiently different to the previous case such that there had been no breach of the undertaking given in Case AUTH/3130/12/18 as alleged. The Panel therefore ruled no breach of Clause 29. The Panel consequently ruled no breach of Clauses 9.1 and 2 in that regard.

Appeal by GlaxoSmithKline

GlaxoSmithKline appealed the breach of Clauses 3.1, 9.1 and 2 and outlined its grounds for appeal below.

Background

GlaxoSmithKline submitted that the original LinkedIn post in May 2021, now more than one year ago, concerned phase 2 interim results of a COVID-19 vaccine candidate still in development. During the pandemic GlaxoSmithKline entered a collaboration with Medicago Inc. via a clinical supply agreement to provide clinical trial level volumes of GlaxoSmithKline's Pandemic Adjuvant and developmental support to Medicago in the development of Covifenz. The post, which was the subject of complaint, was therefore intended to provide information about GlaxoSmithKline's efforts to support development of vaccines against COVID-19 for reputational reasons (as

discussed in its original response) and not to promote any GlaxoSmithKline product, as GlaxoSmithKline was not the marketing authorisation holder (MAH). GlaxoSmithKline was not the sponsor of the phase II/III trial referenced. Covifenz was a COVID 'Virus Like Particle' vaccine currently only authorised for use in Canada, of which Medicago was the MAH holder. The vaccine was made by pairing the plant based antigen produced by Medicago with GlaxoSmithKline's pandemic adjuvant. This adjuvant was not a medicinal product *per se* but was added to the vaccine to allow lower doses of antigen to be used, enabling more doses for the same amount of antigen and thus wider coverage.

GlaxoSmithKline submitted that it did not have a direct commercial supply agreement with Medicago and GlaxoSmithKline had no rights to commercialise the asset. GlaxoSmithKline only provided Medicago with sufficient supply of its pandemic adjuvant for the clinical trials and did not provide commercial levels of the adjuvant to Medicago to produce Covifenz. GlaxoSmithKline did separately provide this adjuvant to the governments of the United States and Canada. The Code was concerned with the promotion of a company's own products; 'The term "promotion" means any activity undertaken by a pharmaceutical company or with its authority which promotes the administration, consumption, prescription, purchase, recommendation, sale, supply or use of **its** medicines' (GlaxoSmithKline's emphasis). It was an established principle under the Code that companies did not promote other company's products, and as such it was difficult to see how GlaxoSmithKline could be found in breach of promoting Medicago's unauthorised vaccine prior to licence when GlaxoSmithKline had no rights to commercialise it. This information was not available to the Panel during their consideration of the case. However, even if this had been a GlaxoSmithKline asset in development, GlaxoSmithKline believed the post in question was not promoting prior to licence.

Appeal of Clause 3.1

GlaxoSmithKline considered that there were four aspects relevant to the appeal:

1 The information provided in the LinkedIn statement was not promoting prior to licence.
2 The associated web page was not promotional.
3 It was appropriate for a pharmaceutical company to make factual statements related to its pipeline and collaborations on the LinkedIn social media platform.
4 A global pharmaceutical company was permitted to make such announcements to a global public audience from its UK headquarters.

1 The information provided in this LinkedIn statement was not promoting prior to licence

GlaxoSmithKline submitted that the LinkedIn post was a factual update of a research collaboration. It was clear to any reader that the vaccine candidate was in early stage development and had only just had very interim phase 2 results. This was further supported by the fact that the vaccine candidate was still not licensed in the UK, more than one year later than the post in question.

The statement from the senior executive via the corporate account was 'We are delighted to see that the results suggest a very strong immune response. We now look forward to the outcome of the ongoing Phase 3 trial of this refrigerator-stable vaccine candidate as the next step forward in our contribution to the global response to the pandemic'. GlaxoSmithKline considered that this represented a factual description of the data and vaccine. At the time of the post there were

still many restrictions in place due to the pandemic and there was considerable public interest in receiving factual information about the industry's response to Covid-19. A statement on vaccine efficacy was not made. Use of the word 'suggest' showed a signal, and not the final confirmed efficacy results. The interim Phase 2 result indicated that the results were promising enough for the asset to continue with its development in a phase 3 trial.

To consider 'very strong immune response' in isolation from the whole statement 'the results suggest a very strong immune response' was misleading and changed the emphasis of this statement. GlaxoSmithKline considered, as a whole, that the statement was not, in itself, promotional but simply stated the results of the study. Further, GlaxoSmithKline considered that any reader of the statement would be clear that this was still a development candidate only and was not close to being approved.

GlaxoSmithKline submitted that it found this Panel ruling inconsistent with previous rulings. In Case AUTH/3442/12/20 two LinkedIn posts from the GlaxoSmithKline Corporate headquarters were found not in breach despite one using similar wording and the other linking to the same page as the post at issue today. In the case under consideration, the Panel determined that the statement of 'suggest a very strong immune response' was promotional, yet 'robust available data' was found not in breach in Case AUTH/3442/12/20.

GlaxoSmithKline submitted that the term 'refrigerator stable' was also not promotional, but a key element of interest to investors as the extreme storage requirements of other vaccines made its availability for developing countries highly unlikely. Refrigerator stability was not a feature unique to the vaccine candidate in question and was relevant to several other vaccines in development at the time. The data from the investigation of the asset, informed us that the asset was refrigerator stable, and this quote repeated this factual statement.

2 The associated web page was not promotional

GlaxoSmithKline submitted that the Panel considered that 'any material associated with a LinkedIn post, for example a link within a post, would be regarded as being an integral part of that post'. The Panel further noted 'the information accessible from a link within the post, particularly the references to the benefit of using adjuvants, Medicago's plant-based approach and the fact that GlaxoSmithKline's collaboration with Medicago was in late-stage trials and, if successful, it aimed to make the vaccine available in the first half of 2021'.

GlaxoSmithKline noted that this post linked to the corporate Covid-19 response page. The complainant did not refer to, nor make any complaint about, this page. The Panel noted that the post in question was posted in May 2021, and that the GlaxoSmithKline Covid-19 response page, that was live at the time, referred to a summary of corporate collaborations. With regard to this vaccine candidate, it stated that 'if successful, we aim to make the vaccine available in the first half of 2021'.

The Panel noted that the page stated 'Our collaboration with Medicago is now in late-stage trials', perhaps leading the Panel to consider the product close to licence, but as was stated in the post, the Phase 3 element (which could be considered 'late-stage' compared to Phase 1 or 2 trials) of the study program had only just begun. Once again, GlaxoSmithKline noted it had no rights to commercialise this vaccine candidate and it was still not licenced in the UK or the EU, over a year later.

GlaxoSmithKline submitted that the Panel also appeared concerned that the web page included a factual description of what an adjuvant did. Adjuvants were routinely used in many vaccines in the UK and were not exclusive to GlaxoSmithKline. Vaccine adjuvants were not medicines in their own right, but were added to vaccines to enhance the immune response generated. Aluminium was first used in human vaccines in 1932 and was the only adjuvant in use in licensed vaccines for approximately 70 years (Di Pasquale, *et al* 2015). The webpage did not describe any specific GlaxoSmithKline adjuvant and thus describing how adjuvants work was not promoting any specific medicine or pipeline asset directly or indirectly as they were a standard component in most vaccines.

As described above, GlaxoSmithKline submitted that the Panel ruling was inconsistent with previous rulings. In Case AUTH/3442/12/20 two LinkedIn posts from the GlaxoSmithKline Corporate headquarters were found not in breach despite one using similar wording and the other linking to the same page as the post at issue today. In the case under consideration, the Panel determined that the statement of 'very strong immune response' was promotional yet 'robust available data' was found not in breach in Case AUTH/3442/12/20. Similarly, the second post in Case AUTH/3442/12/20 linked to the Covid-19 response page just as the post at issue today did and yet it was not determined to be promotional, but in this case the Panel determined that it 'compounded' the promotional nature of the LinkedIn post.

3 It was appropriate for a pharmaceutical company to make factual statements related to its pipeline and collaborations on the LinkedIn social media platform

GlaxoSmithKline submitted that the Panel had noted that 'LinkedIn was different to some other social media platforms in that it originated as a business and employment-orientated network; its application, however, was not limited to the pharmaceutical industry or to health care'.

GlaxoSmithKline agreed with the Panel in that 'it was not necessarily unacceptable for a company to refer in very general terms to its pipeline or work it was doing in response to the current pandemic'. GlaxoSmithKline also agreed when 'the Panel noted that understandably there would be much interest in the work being done by pharmaceutical companies and others to investigate possible vaccines and treatments for Covid-19. However, companies must ensure that materials and activities complied with the Code'.

The 'Panel queried whether a social media platform such as LinkedIn was the appropriate forum to share such information'. GlaxoSmithKline did not agree with this statement. The post in question had come from the Global Headquarters corporate account of a multinational R&D company based in the UK, not an individual's personal LinkedIn account. This account had the responsibility and remit to provide information to a broad global audience on GlaxoSmithKline and its activities. LinkedIn was one of the key platforms where journalists, investors, potential investors and potential new hires look for information about pharmaceutical companies. A recent survey of 2,482 journalists revealed that nearly two thirds always, or usually check, the company's social media channels when covering a story, and 86% referred to them at least some of the time. It was thus vital that a multinational R&D organisation could post factual information about their pipeline progress, particularly in this era of disinformation.

GlaxoSmithKline submitted that the aim of the LinkedIn post was to deliver news about an ongoing collaboration with another company which formed part of GlaxoSmithKline's pandemic response, which GlaxoSmithKline considered to be of public interest and highly relevant to investors and potential investors. Trustworthy communications had been shown to be

particularly important in this era of fake news and misinformation. Providing factual information about ongoing trials did not promote that potential treatment prior to licence, but simply informed the public that work was ongoing and that there was potentially further progress being made in the fight against the pandemic. Announcing positive interim results meant that the medicine could progress to the next stage of development and not a confirmation of final success of a trial.

Followers of GlaxoSmithKline on LinkedIn had made the decision to follow the activities of the company.

4 A global pharmaceutical company was permitted to make such announcements a global public audience from its UK headquarters

GlaxoSmithKline recognised that with a UK headquarters, any activities emerging from that headquarters were subject to the Code of practice. However, global activities and information emerging from UK headquarters were destined for a global audience, only some of whom would be UK members of the public, patients and health professionals. A large part of the intended audience would be beyond the UK borders. GlaxoSmithKline endeavoured to provide sufficient factual information about the company and its activities to this broad audience.

GlaxoSmithKline submitted that it was important for global companies and their audiences that there was a uniform approach to how this information was regarded and that factual information was recognised as such. This case represented an important way of working for any pharmaceutical company with a global headquarters in the UK, in relation to placing corporate information on social media. GlaxoSmithKline considered this information in this case to be factual and globally relevant.

Investors and potential investors were used to seeing non-UK based pharmaceutical companies announce their milestones on social media and it created an uneven playing field if R&D that was headquartered in the UK could not also share this information. 45% of the investor audience on GlaxoSmithKline corporate social media channels was in the US, with another 41% from other non-UK countries (data from GlaxoSmithKline market research) and it was vital that the company was able to share basic milestone information to maintain public interest and belief in the company and encourage new investment.

Summary

GlaxoSmithKline submitted that it entered a collaboration with Medicago Inc. via a clinical supply agreement to provide clinical trial level volumes of GlaxoSmithKline's pandemic adjuvant and developmental support. GlaxoSmithKline had no commercialisation rights for the candidate vaccine and GlaxoSmithKline was not the MAH in the UK. The post was to enhance corporate reputation about a collaboration and could not be promotion prior to licence.

Even if the vaccine candidate was a GlaxoSmithKline product, or was considered to be, then on the basis of the points made in these four sections, GlaxoSmithKline submitted that the post was not promotional, the linked web page, that did not feature in the complaint, was factual and that it is appropriate and not a breach of the Code for global pharmaceutical companies to make non-promotional factual statements about its pipeline and collaborations on LinkedIn. Given this, GlaxoSmithKline considered that there had been no breach of Clause 3.1 of the Code and

that a medicine had not been promoted prior to the grant of the marketing authorisation which permitted its sale or supply.

As it would appear the breach of Clause 9.1 was simply consequential on a breach of Clause 3.1, GlaxoSmithKline appealed this ruling on two counts.

GlaxoSmithKline submitted that Clause 3.1 was not breached by the factual announcement on LinkedIn that a collaboration between two pharmaceutical companies was progressing in the right direction and the Phase 2 ('early stage') results were positive so that Phase 3 could commence.

GlaxoSmithKline submitted that it had systems and processes in place to ensure compliance with the Code. This post was drawn up by the Global Communications team who had had enhanced training on the Code and the post and linked pages were examined by an experienced Signatory. As such, GlaxoSmithKline did not consider that there had been a breach of Clause 9.1 of the Code and that high standards had been maintained.

GlaxoSmithKline did not consider that there had been breaches of Clauses 3.1 and 9.1 of the Code and considered that there had been no promotion of an unlicensed medicine or failure to maintain high standards.

The supplementary information to Clause 2 stated 'A breach of Clause 2 is a sign of particular censure and is reserved for such circumstances'. GlaxoSmithKline submitted that there was no evidence at all that this post had prejudiced patient safety in any way, nor was there evidence of a breach of promoting a prescription only medicine to the public, as ruled by the Panel. The sharing of basic, factual information about a pre-licence asset or collaboration was an essential part of a communications strategy that upheld the need for transparency about GlaxoSmithKline's research and respect for all stakeholders, enhanced the reputation of the company and interests potential and current investors. 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. GlaxoSmithKline noted that there had been several cases related to social media where a Clause 3.1 breach was ruled, but Clause 2 was not (Cases AUTH/3422/11/20, AUTH/3411/10/20, AUTH/3412/10/20, AUTH/3390/9/20, AUTH/3287/12/19 and AUTH/3483/3/21). It seemed unnecessarily harsh to consider the sharing of positive early stage results of a collaboration to warrant a ruling of Clause 2 in the present case (Case AUTH/3524/6/21) under consideration.

As a Global R&D company GlaxoSmithKline hoped that the Appeal Board recognised the legitimate need to share information in ways, and on platforms that the intended global audience now consumed it. GlaxoSmithKline submitted that this global corporate social media post and associated global corporate web page did not warrant such censure. GlaxoSmithKline did not consider that these actions brought discredit upon, or reduced confidence in, the pharmaceutical industry in the UK.

RESPONSE FROM THE COMPLAINANT

The complainant provided no response to the appeal.

APPEAL BOARD RULING

The Appeal Board noted that the post in question, which appeared to be made in May 2021, stated 'Great progress in our #COVID19 vaccine collaboration with Medicago announced today with positive interim results from a Phase 2 study for the adjuvanted #COVID19 #vaccine candidate, which combines their innovative plant-based vaccine technology with our pandemic adjuvant. These results are part of the ongoing Phase 2/3 study. Learn more about our response to the pandemic: [link]'. Below the LinkedIn post was a photograph including a quotation from a senior executive which stated, 'We are delighted to see that the results suggest a very strong immune response. We now look forward to the outcome of the ongoing Phase 3 trial of this refrigerator-stable vaccine candidate as the next step forward in our contribution to the global response to the pandemic'. GlaxoSmithKline submitted that the post formed part of the wider global corporate communications strategy. The Appeal Board further noted the content of the linked webpage as described by the Panel which stated 'We are also collaborating with Canadian biopharmaceutical company, Medicago, to develop a COVID-19 vaccine by combining their plant-derived vaccine candidate with our adjuvant technology. The vaccine candidate entered phase 2/3 clinical trials in mid-November 2020 and, if successful, we aim to make the vaccine available, in the first half of 2021'.

The Appeal Board considered that in its appeal GlaxoSmithKline had provided further important detail regarding its arrangements with Medicago Inc which had not been provided to the Panel. GlaxoSmithKline had submitted that during the Covid-19 Pandemic it had entered into a collaboration with Medicago Inc. to provide clinical trial level volumes of its pandemic adjuvant and developmental support to Medicago in relation to Covifenz. GlaxoSmithKline had no commercialisation rights for Covifenz and GlaxoSmithKline was not the marketing authorisation holder. Covifenz was a COVID 'Virus Like Particle' vaccine currently only authorised for use in Canada for which Medicago was the marketing authorisation holder. There was no direct commercial supply by GlaxoSmithKline of its pandemic adjuvant to Medicago Inc. GlaxoSmithKline had agreements to supply this adjuvant to the Canadian and US governments. In response to a question from the Appeal Board, GlaxoSmithKline's representatives at the appeal stated that to produce its vaccine, Medicago Inc. would need to procure the adjuvant directly from the Canadian government.

The Appeal Board noted that Clause 1.2 of the 2019 Code stated that 'The term "promotion" means any activity undertaken by a pharmaceutical company or with its authority which promotes the administration, consumption, prescription, purchase, recommendation, sale, supply or use of its medicines'.

The Appeal Board noted that GlaxoSmithKline had only agreed to provide Medicago Inc. with its adjuvant in the clinical trial stage and that it had no ongoing commercial arrangement with Medicago Inc in relation to Covifenz.

The Appeal Board, noting its comments above and taking all of the circumstances into consideration, did not consider that the Covid-19 vaccine referred to within the LinkedIn post was a GlaxoSmithKline medicine and therefore GlaxoSmithKline could not be seen to be promoting *its* medicine pre-licence as referred to in Clause 3.1. The Appeal Board therefore ruled no breach of Clause 3.1. The appeal on this point was successful.

The Appeal Board consequently ruled no breach of Clauses 9.1 and 2. The appeal on this point was successful.

Complaint received **22 June 2021**

Case completed **15 September 2022**