CASE AUTH/3337/4/20 ***NO BREACH OF THE CODE***

ANONYMOUS v BIO PRODUCTS LABORATORY

Alleged promotion of an unlicensed medicine to the public

An anonymous non-contactable complainant who described him/herself as a member of the public/media, complained about an article in The Telegraph headlined 'UK research on Covid-19 treatment using survivors' blood "going at snail's pace"' shared in a LinkedIn post from Bio Products Laboratory.

The complainant alleged that the LinkedIn post which shared The Telegraph article promoted an unlicensed medicine and its off-label use to the general public.

The detailed response from Bio-Products Laboratory is given below.

The Panel noted that the article in question referred to the work Bio Products Laboratory was doing in relation to the pandemic and its specialism. The Telegraph article referred to antibody research and the need for more work, including clinical trials as well as the global alliance of plasma suppliers to pool knowledge and manufacturing capabilities.

The Panel noted Bio Products Laboratory's submission that the journalist had approached the company and no transcript of the interview was available. The Panel did not know exactly what had been said by the employee during his interview with The Telegraph. The company had not commented on the accuracy or otherwise of the article. The Panel noted that the LinkedIn post on Bio Products Laboratory's corporate account stated 'BPL'S [named employee] comments on "hyperimmune" shots and the aim for BPL to be manufacturing them by the end of July 2020' before providing a link to The Telegraph article. On the evidence provided, it appeared to the Panel that Bio Products Laboratory had set the potential availability of 'hyperimmunes' within the context of an aim to be manufacturing them once standards had been agreed. Further it was clear that more research was needed.

The Panel noted that whilst no specific product was mentioned within The Telegraph article, the company's potential antibody therapy 'hyperimmune shots' was referred to. It was clear that no such product was available yet and thus Bio Products Laboratory did not have a prescription only medicine available at the time. There was no prescription only medicine at the time of publication of the article in The Telegraph or when the LinkedIn post sharing it was published. On this very narrow technical point, the Panel ruled no breaches of the Code.

The Panel noted the company's submission with regard to the July 2020 date reflecting Bio Products Laboratory's aspiration and that it aligned with the anticipated start of the NIH-funded clinical trial in which the Alliance's hyperimmune would be tested against other hyperimmune products. The Panel noted its comments above regarding not knowing exactly what had been said by the employee during his interview with The

Telegraph and the lack of a transcript of the interview. The company had referred to ongoing work being required and standards being agreed before a hyperimmune would be available; it was clear that further work was required. On the evidence available, the Panel did not consider that Bio Products Laboratory had promoted an unlicensed medicine to the public as alleged and therefore ruled no breach of the Code.

An anonymous non-contactable complainant who described him/herself as a member of the public/media, complained about an article in The Telegraph headlined 'UK research on Covid-19 treatment using survivors' blood "going at snail's pace"' shared in a LinkedIn post from Bio Products Laboratory. The complainant provided links to the material at issue.

COMPLAINT

The complainant alleged that the LinkedIn post from Bio Products Laboratory which shared The Telegraph article promoted an unlicensed medicine and its off-label use to the general public.

When writing to Bio Products Laboratory, the Authority asked it to consider the requirements of Clauses 9.1, 26.1 and 26.2.

RESPONSE

Bio Products Laboratory noted at the outset that in May 2020 it deleted the post on LinkedIn that linked to The Telegraph article. Although the company did not consider that the LinkedIn post was in breach of the Code, it had been removed to avoid any potential for confusion. The copy of the post provided was the best copy Bio Products Laboratory had because it deleted the offending post in May 2020 and did not review the post under its standard operating procedures (SOP) regarding social media copy approval. The post was not reviewed under either of such SOPs because the company did not view the post as promotional material or falling into the category of non-promotional materials that required prior review and approval.

Article in The Telegraph

Bio Products Laboratory noted that a special correspondent from The Telegraph emailed the company on 20 April 2020 seeking expert input on a piece related to convalescent plasma treatment. This inquiry was not solicited by Bio Products Laboratory. The Telegraph request read:

> 'Given the global interest in convalescent plasma treatment, I am writing an article for the Telegraph about the issue, notably the hyperimmune collaboration which you are a part of. I am hoping to speak to an executive to hear more about this initiative. Do let me know who might be available. I won't take long and I am keen to ensure I get a good level of expert input before proceeding with the piece.'

Bio Products Laboratory stated that it made a named employee available to The Telegraph because he was a company representative to the steering committee for the CoVIg-19 plasma alliance, the alliance referenced by The Telegraph in its initial inquiry (the 'Alliance'). Bio Products Laboratory also provided the materials related to the Alliance (copies provided).

The Telegraph published the article titled, 'UK research on Covid-19 treatment using survivors' blood 'going at snail's pace' on 22 April 2020 (copy provided). The approximately 1300-word

article described the role of antibodies in fighting viruses and described the view of a Nobel prize winning scientist and an international society regarding the potential of convalescent plasma, the goals of ongoing trials involving direct transfusion of convalescent plasma, and the potential for hyperimmunes as another form of antibody therapy. This article included four paragraphs which attributed statements or quotations to the employee who was not consulted on the final text for the article.

Bio Products Laboratory stated that its LinkedIn page was not intended as a vehicle to communicate with health professionals or patients about the company's medicines. The LinkedIn page had approximately 3,700 followers who appeared to be primarily employees, potential employees and individuals interested in the plasma industry. The company's posts, reflecting this audience, highlighted individual contributions, employee events, new starters, job announcements, relevant disease awareness events and more recently, news stories relating to Covid-19. The central purpose of the LinkedIn page was to raise the company profile as an employer and key member of the plasma industry.

With regard to Clause 9.1, Bio Products Laboratory submitted that it had maintained high standards and there was no basis for finding a breach of Clause 9.1.

Bio Products Laboratory submitted that the Covid-19 pandemic presented an extraordinary challenge from a public health perspective which required the pharmaceutical industry to be innovative and nimble and for all potential medical solutions to be investigated. The Alliance represented a great example of collaboration that had the potential to accelerate the development and production of a hyperimmune product, and Bio Products Laboratory fully supported the goals of the Alliance.

Bio Products Laboratory stated that it was proud of the role it had played in addressing the threat of Covid-19. The company was operating 51 plasma collection centres in the US, and those centres began to collect convalescent plasma in the spring of 2020. The UK production facility produced essential medicines for use by those with immune and bleedings disorders and in critical care settings. The company was working with the UK government and the Alliance to accelerate the development of solutions that leveraged blood plasma.

The response of the employee to the author of The Telegraph article was factual, balanced and not intended to encourage discussion of hyperimmunes by patients with their doctors. The employee only responded to an unsolicited request for background for an article in a national newspaper. The employee described that Bio Products Laboratory could produce hyperimmune shots by July and that the 'aim for BPL to be manufacturing [hyperimmune shots] by the end of July 2020'. These comments were made in the course of providing background on the Alliance and knowing that the National Institutes of Health (NIH)-funded clinical trial including the Alliance's hyperimmune product was scheduled to begin in the summer of 2020. The employee made clear that hyperimmunes were not vaccines and that hyperimmunes would not be available during the 'first peak'. The employee described the Alliance's goal to produce a hyperimmune 'once standards are agreed'. Viewed together, these comments made clear that Bio Products Laboratory was describing its readiness to help, not promising the availability of a Bio Products Laboratory hyperimmune.

In addition, to the extent that The Telegraph article was viewed as relating to a future hyperimmune product produced by Bio Products Laboratory, the employee was clear that hyperimmunes were not vaccines and would not be ready to treat patients in the current first

peak of the disease. The July 2020 date reflected the company's aspiration and aligned with the anticipated start of the NIH-funded clinical trial in which the Alliance's hyperimmune would be tested against other hyperimmune products. In short, Bio Products Laboratory's LinkedIn post merely described the company's readiness to help at this time of extraordinary and urgent need.

Bio Products Laboratory submitted that its LinkedIn post was similar to the tweet at issue in Case AUTH/3167/2/19, where the PMCPA found no breach on all counts. In both cases, no specific product was mentioned. This was not like cases where a company posted a link to a press release or described results from a study of a specific branded medicine. In this case, Bio Products Laboratory had described hyperimmunes generally, its capacity to produce a hyperimmune, and its participation in the Alliance. It had not referred to a Bio Products Laboratory product or sought to promote the hyperimmune product that the Alliance was developing.

With regard to Clause 26.1, Bio Products Laboratory submitted that it had not advertised a prescription-only medicine and as such it denied a breach of Clause 26.1.

The employee was interviewed in connection with an article that related to plasma-based medicines generally. The article in The Telegraph described the role of antibodies in fighting viruses, described the view of a Nobel prize winning scientist and an international society regarding the potential of convalescent plasma, the goals of ongoing trials involving direct transfusion of convalescent plasma and the potential for hyperimmunes as another form of antibody therapy.

Neither the article nor the LinkedIn post sought to encourage a conversation between a doctor and patient about a Bio Products Laboratory hyperimmune. The statements attributed to the employee and the LinkedIn post regarding The Telegraph article focussed on the production timeline for a potential hyperimmune.

Bio Products Laboratory submitted that as in Case AUTH/3167/2/19, there was no direct or indirect reference to a specific Bio Products Laboratory medicine in The Telegraph article or the post from the company regarding such article.

Bio Products Laboratory stated that likewise, no breach of Clause 26.2 has occurred because it has not raised unfounded hopes or presented information in a manner that was misleading with respect to the safety of a Bio Products Laboratory product.

When the article in The Telegraph was read in full, it was clear that a hyperimmune globulin product had the potential to be one option but that much work remained to be done before such a medicine could be available. Indeed, the author's point in The Telegraph article was that research was not going as quickly as it could. This was the context in which the aspiration for Bio Products Laboratory to be manufacturing by July 2020 was described. This did not promise availability. This did not promise hyperimmunes as a solution to the Covid-19 pandemic. It merely described Bio Products Laboratory 's readiness to help.

The interview with The Telegraph was not solicited by the company and was not intended to uncover specific information about any Bio Products Laboratory product. The company submitted that it had responded to an unsolicited request from a national newspaper that had sought background for a story about blood plasma-based therapies and the activities of the

Alliance, including the Alliance's planned initiation of a clinical trial to evaluate a hyperimmune starting in the summer of 2020. This was not a situation where a manufacturer had encouraged the public to ask their doctor about a medicine that was pending approval or had been recently approved. This was a situation where the PMCPA could and should look to Case AUTH/3167/2/19 as precedent for concluding that no breach had occurred.

In conclusion, Bio Products Laboratory stated that it had not intended to promote or otherwise provide information about any Bio Products Laboratory medicine when it responded to The Telegraph's requests for comments and posted a link to that article on LinkedIn. The company had merely provided background for an article that related to plasma-based therapies and highlighted the steps the company had taken to fight, and its readiness to help with the fight, against Covid-19. The company regretted that the complainant thought its LinkedIn post was inappropriate, and it had removed it to avoid any confusion. The company denied, however, that it had breached the Code.

PANEL RULING

The Panel noted that the article in question referred to the work Bio Products Laboratory was doing in relation to the pandemic and its specialism. The Telegraph article referred to antibody research and the need for more work, including clinical trials as well as the global alliance of plasma suppliers to pool knowledge and manufacturing capabilities. Understandably there would be much interest in the work being done by pharmaceutical companies and others to investigate possible treatments for Covid-19. However, companies must ensure that materials and activities complied with the Code.

The Panel noted the complainant's allegation that the LinkedIn post from Bio Products Laboratory which shared The Telegraph article promoted an unlicensed medicine and its off-label use to the general public.

The Panel noted that the case preparation manager raised Clauses 26.1 and 26.2. Clause 26.1 prohibited the promotion of prescription only medicines to the public. Clause 26.2 stated that information about prescription only medicines which was made available either directly or indirectly to the public must be factual, presented in a balanced way, must not raise unfounded hopes of successful treatment and must not encourage members of the public to ask their health professional to prescribe a specific prescription only medicine.

The Panel noted that The Telegraph article described transfusions of blood plasma from patients who had recovered at least 28 days before, purifying it and giving it back to patients currently fighting the disease, hoping the boost in antibodies would help them and referred to ongoing trials to establish the concentration, or tier of antibodies required to make the most difference. The article then referred to the next most sophisticated antibody therapy, 'hyperimmune' injections, which concentrated the antibodies from a transfusion into a small quantity that could be stored in a phial and administered in an injection rather than through an IV drip – saving time and effort in hospitals. The article explained that Britain had a single hyperimmune production facility, run by Bio Products Laboratory at Elstree, Hertfordshire.

The Panel noted that comments from Bio Product Laboratory employee reported in The Telegraph article included that:

> ‘such injections have two purposes. “One, if you’re a struggling patient, then immediately you get the injection, you have antibodies fighting the infection. What we’re hoping is that will reduce the number of people going into ICU. Two, you could regularly inject frontline health workers. So they’re always carrying antibodies in a prophylactic way.”
>
> He says the Elstree factory, which currently processes 400 litres of plasma a week, could produce such hyperimmune shots by the end of July. “I'd like to be bringing something out in three months,” … said. He emphasised that such hyperimmunes are “not vaccines, they are a stop gap” and would not be ready to treat patients in the current “first peak” of the disease.’

The Panel noted the company’s submission that the July 2020 date reflected Bio Products Laboratory’s aspiration and aligned with the anticipated start of the NIH-funded clinical trial in which the Alliance’s hyperimmune would be tested against other hyperimmune products.

The Panel noted that The Telegraph article did not mention that the July 2020 date reflected Bio Products Laboratory’s aspiration although the article included the following comments from the employee ‘I’d like to be bringing something out in three months’ and ‘But currently [BPL] is part of an unprecedented global alliance of six major plasma suppliers to pool knowledge and manufacturing capabilities to produce enough hyperimmunes once standards are agreed’.

The Panel noted that The Telegraph article referred to research on Covid-19 treatment using antibodies from survivors’ blood not going as quickly as it could.

The Panel noted Bio Products Laboratory’s submission that the journalist had approached the company and no transcript of the interview was available. The Panel did not know exactly what had been said by the employee during his interview with The Telegraph. The company had not commented on the accuracy or otherwise of the article. The Panel noted that the LinkedIn post on Bio Products Laboratory’s corporate account stated ‘BPL’S [named employee] comments on “hyperimmune” shots and the aim for BPL to be manufacturing them by the end of July 2020’ before providing a link to The Telegraph article. On the evidence provided, it appeared to the Panel that Bio Products Laboratory had set the potential availability of ‘hyperimmunes’ within the context of an aim to be manufacturing them once standards had been agreed. Further it was clear that more research was needed.

The Panel noted that whilst no specific product was mentioned within The Telegraph article, the company’s potential antibody therapy ‘hyperimmune shots’ was referred to. It was clear that no such product was available yet and thus Bio Products Laboratory did not have a prescription only medicine available at the time. There was no prescription only medicine at the time of publication of the article in The Telegraph or when the LinkedIn post sharing it was published. Clauses 26.1 and 26.2 only applied to prescription only medicines. On this very narrow technical point, the Panel ruled no breach of Clauses 26.1 and 26.2 of the Code.

The Panel noted the company’s submission with regard to the July 2020 date reflecting Bio Products Laboratory’s aspiration and that it aligned with the anticipated start of the NIH-funded clinical trial in which the Alliance’s hyperimmune would be tested against other hyperimmune products. The Panel noted its comments above regarding not knowing exactly what had been said by the employee during his interview with The Telegraph and the lack of a transcript of the interview. The company had referred to ongoing work being required and standards being agreed before a hyperimmune would be available; it was clear that further work was required.

On the evidence available, the Panel did not consider that Bio Products Laboratory had promoted an unlicensed medicine to the public as alleged and therefore ruled no breach of Clause 9.1.

Complaint received **23 April 2020**

Case completed **7 January 2021**