

COMPLAINANT v CSL SEQIRUS

Allegation of promotion of an unlicensed medicine and a breach of undertaking

CASE SUMMARY

This case was in relation to a LinkedIn post from the CSL corporate account, headquartered in Australia, which had been liked by two of CSL Seqirus's UK-based employees. It was alleged that the post promoted an unlicensed medicine to the public and made unfounded claims about reducing disease burden. The complainant also alleged that this amounted to a breach of undertaking and queried whether the company had an updated social media standard operating procedure.

The outcome under the 2024 Code was:

Breach of Clause 3.1	Promoting a medicine prior to the grant of its marketing authorisation
Breach of Clause 5.1	Failing to maintain high standards
No Breach of Clause 2	Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry
No Breach of Clause 3.3	Requirement to comply with an undertaking
No Breach of Clause 5.1	Requirement to maintain high standards at all times

**This summary is not intended to be read in isolation.
For full details, please see the full case report below.**

FULL CASE REPORT

A complaint was received about CSL Seqirus from a contactable complainant who described themselves as a member of the public.

COMPLAINT

The complaint wording is reproduced below with some typographical errors corrected:

“CSL Seqirus senior leaders liked and engaged in a LinkedIn post which had a novel mode of action (self-amplifying mRNA), indication (Covid 19 vaccine) and a company name. 2 UK based directors [named] engaged with this post. This is a product with recent CHMP recommendation in Europe. This would be promotion of a yet unlicensed medicine to the public and making unfounded claims about reducing disease burden. This also is a breach of a recent undertaking where they were the first company to admit

liability. I wonder if they have an updated social media SOP that is required and trained out to UK staff.”

FURTHER INFORMATION PROVIDED BY THE COMPLAINANT

Further information was provided by the complainant in response to a request for additional information from the case preparation manager. The response from the complainant is reproduced below:

“There are 3 links to share: one is the chmp recommendation on 12 dec for the sa-mRNA Kostaive: [link provided]

Then, there is the CSL pipeline page to show that it is at registration stage: [link provided]

And finally, there is evidence of intention to launch in the UK through their contract with the MHRA to agree a pediatric investigation plan: [link provided]

There is only one sa-mRNA especially for vaccines that is licensed around the world, and this is a novel mode of action. Liking a social media post that talks about improving public health without substantive evidence is very poor, and it can only have the effect of trying to generate public excitement before launch.”

When writing to CSL Seqirus, the PMCPA asked it to consider the requirements of Clauses 2, 3.1, 3.3 and 5.1 of the 2024 Code.

CSL SEQIRUS’S RESPONSE

The response from CSL Seqirus is reproduced below:

“Thank you for your letter dated 28th January 2025, in which you raised an allegation from an anonymous contactable complainant. As per your letter, we have reviewed the requirements of Clauses 2,3.1,3.3 and 5.1 of the 2024 Code in relation to this allegation.

CSL Seqirus UK were aware of the referenced social media post and our E&C (Ethics and Compliance) Officer and Medical Director immediately contacted the 2 UK based employees who had engaged with the post to request they removed their “likes”. The 2 UK based employees were contacted before Midday on Tuesday 14th January 2025 and the likes were removed prior to the Complainant’s submission at 4:29pm.

The post in question was made by our US-based [named senior leader] and was aimed at highlighting the partnership within Japan, in which the vaccine is licensed. The post focuses on “how we can work together to help reduce the burden of COVID-19 and improve public health in Japan” which contradicts the Complainants allegation that the post is intended to “generate public excitement before launch”. The post was not intended or targeted at a UK audience; therefore, it was not certified, and we have not provided any US/Japanese certificates as out of scope of ABPI. Additionally given that the product is not available in the UK the mention of a ‘Covid vaccine’ is unlikely to result in a Healthcare Professional prescribing this medicine or a Member of the Public requesting this medicine. With this in mind, we do not accept a breach of Clause 3.1.

We acknowledge the complainant's reference to our Social Media Standard Operating Procedure (SOP) and training, as well as the allegation of a breach of undertakings. Our Global Social Media Policy applies globally across CSL and includes key guidance on engagement with social media content, including exercising caution when interacting with posts mentioning products and ultimately directing the reader to local regulations. To provide a more tailored guidance, we are also in the process of developing a CSL UK and Ireland-specific addendum, which will further refine local compliance directives for our UK and Ireland based employees across the enterprise.

As part of the remedial actions directly arising from Case 0308/10/24, our E&C Officer conducted comprehensive social media training for the UK Commercial, Medical, and extended teams including Communications (based in our Maidenhead office) and our Liverpool-based Senior Leadership Team, in December 2024.

Additionally, we are in the process of launching a company-wide ABPI Code training program purchased via [named ABPI Code training provider] to extend the current training provided to CSL Seqirus UK based employees.

Furthermore, prior to receiving your letter, it had already been agreed that our E&C Officer would present at our CSL Seqirus Maidenhead site townhall on 26th February 2025. This session will provide additional education and reinforcement to CSL Seqirus UK based employees, including Global employees based in the UK, on social media compliance under the ABPI Code of Practice.

We believe we have demonstrated our commitment to our previous undertakings by the training already undertaken and our continuation of education for our employees via online modules and planned Townhall sessions, we therefore do not accept a breach of Clause 3.3.

We remain dedicated to maintaining the highest compliance standards within our organisation, thanks to awareness and diligence of our employees and the efforts of our E&C Officer and Medical Director we were aware of the post and were able to act quickly upon the 2 engagements from the UK office, given this immediate action we feel we have maintained high standards and therefore do not accept a breach of Clause 5.1.

We believe our dedication to our undertakings, monitoring and immediate actions do not bring discredit or distrust upon the industry and therefore do not accept a breach of Clause 2.

We trust that this response, along with the supporting enclosures, provides assurance of our proactive and diligent approach to this matter and ongoing compliance efforts."

PANEL RULING

This case was in relation to a LinkedIn post from the CSL corporate account, headquartered in Australia, which had been liked by two of CSL Seqirus's UK-based employees. It was alleged that the post promoted an unlicensed medicine to the public and made unfounded claims about reducing disease burden. The complainant also alleged that this amounted to a breach of undertaking and queried whether the company had an updated social media standard operating procedure.

The Panel accepted CSL Seqirus's submission that the post was authored by a senior US-based leader. As such, the Panel determined that the Code did not apply to the original post. CSL Seqirus acknowledged that the post had been 'liked' by two UK-based employees, as highlighted by the complainant. In the Panel's view, the UK-based employees' engagement with the post would have proactively disseminated it to their LinkedIn connections in the UK. The Panel determined that this brought the LinkedIn post within the scope of the ABPI Code. It was well established that if an employee's personal use of social media was found to be in scope of the Code, the company would be held responsible.

The post in question stated: *"Everything is better together. [named senior leader], #CSLSeqirus [job title], and [named senior employee], [job title] were part of a CSL delegation that recently met with [named pharmaceutical company], our COVID-19 vaccine distribution partner in Japan. #CSLSeqirus #Collaboration #PublicHealth #Innovation #Covid19 #Vaccines #DrivenByOurPromise".*

The post was accompanied by an image of a group of people adjacent to the following quote attributed to the senior leader at CSL Seqirus: *"It was wonderful to meet [named individual], [senior job title] of [named pharmaceutical company], and hear about the company's history in Japan. Together, we toured a new state-of-the-art sa-mRNA manufacturing facility, visited Japanese Lawmakers, and learned many things about how we can work together to help reduce the burden of COVID-19 and improve public health in Japan."*

CSL Seqirus confirmed that the vaccine referred to within the post was licensed in Japan but was not available in the UK.

Promotion of an unlicensed medicine

The complainant alleged that the post contained a novel mode of action (self-amplifying mRNA), an indication (Covid-19 vaccine) and a company name, and therefore amounted to the promotion of an unlicensed medicine to the public.

CSL Seqirus submitted that the intention of the post was to highlight the partnership within Japan and that given that the product was not available in the UK, a reference to 'Covid vaccine' would have been unlikely to result in a healthcare professional prescribing the medicine or a member of the public requesting the medicine. As such, it denied promoting an unlicensed medicine.

Clause 3.1 of the 2024 ABPI Code states: *"A medicine must not be promoted prior to the grant of the marketing authorisation which permits its sale or supply".*

Given that the Code made no stipulation that a medicine must be available to be prescribed or requested for this Clause to apply, the Panel considered the availability of the medicine in the UK at the time of the complaint as irrelevant.

In considering whether the post was promotional, the Panel made the following observations:

- The post was made by the company's corporate LinkedIn account.
- The post did not contain the name of the medicine.
- The post referred to the medicine's indication (Covid-19 vaccine) both in the main body of the post and as a hashtag.

- The post included positive language with regards to a “*state-of-the-art sa-mRNA manufacturing facility*”. CSL Seqirus’s Covid-19 vaccine contains a self-amplifying mRNA (sa-mRNA) molecule.

Even though the post did not include the name of the medicine, the definition of promotion in Clause 1.17 of the Code is broad and it is an established principle under the Code that a medicine can be promoted without its name being mentioned.

The Panel understood that the intent of the post had been to highlight the partnership between CSL Seqirus and its Japanese distributors. However, in the Panel’s view, by referring to the vaccine (through its mention of ‘Covid-19 vaccine’ and its mode of action (sa-mRNA)) in the context of a post which referred to helping to reduce the burden of Covid-19, meant that the medicine had been promoted on social media to a UK audience. At the time of the post, the vaccine in question was not licensed in the UK and so a medicine had been promoted prior to the grant of its marketing authorisation and the Panel therefore ruled a **breach of Clause 3.1**.

Claims about reducing disease burden

The complainant alleged that the post made an unfounded claim about reducing disease burden.

The Panel noted that Clause 6.1 had not been raised by the case preparation manager and so considered this allegation under Clause 5.1.

The Panel observed that the reference to reducing disease burden appeared in the quote attributed to the senior CSL Seqirus leader: “....*and learned many things about how we can work together to help reduce the burden of Covid-19 and improve public health in Japan*”.

In the Panel’s view, the complainant had not established that the claim (which related to reducing the burden of Covid-19 in Japan) was unfounded. CSL Seqirus’ Covid-19 vaccine was licensed in Japan. The Panel concluded that the complainant had failed to discharge their burden of proof in relation to this aspect of their complaint and the Panel therefore ruled **no breach of Clause 5.1**.

Breach of undertaking

Regarding the alleged breach of undertaking, the Panel noted that Case/0308/10/24 concerned the sharing of a post by a UK employee of CSL Seqirus. The post in Case/0308/10/24 related to a licensed prescription only medicine and was found in breach of Clause 26.1 of the Code for promoting this medicine to the public.

Although the current case (Case/0437/01/25) involved the dissemination of a post by UK employees, it related to a post about an unlicensed medicine in the UK and amounted to a breach of Clause 3.1.

In the Panel’s view, the two cases related to different medicines and different clauses of the Code and were therefore sufficiently different such that there had been no breach of the undertaking given in Case/0308/10/24 as alleged. The Panel therefore ruled **no breach of Clause 3.3**.

Clause 5.1 and Clause 2

The Panel considered that the promotion of an unlicensed medicine is a serious matter. In deciding whether there was evidence in this case that CSL Seqirus had failed to maintain high standards, the Panel took account of CSL Seqirus's submission that they had immediately contacted the two UK employees who had engaged with the post and requested they removed their 'likes' *prior* to the current complaint being submitted.

The Panel also considered that, following Case/0308/10/24, CSL Seqirus conducted social media training for the UK Commercial, Medical and extended teams in December 2024. However, it was unclear to the Panel whether the two employees who had engaged with the post in this case had received that training.

The Panel was concerned to note that CSL Seqirus, at the time of complaint, had no UK-specific social media guidance for employees. The Panel observed that the CSL Global Social Media Policy stated in a section titled 'SOCIAL MEDIA FOR PERSONAL USE':

"Exercise caution when sharing, discussing, or liking anything containing information about CSL products. Local regulations may prohibit this type of activity. Product communications are highly regulated and if employees or affiliates post, share, re-tweet, or like information about CSL products, then CSL and the individual can both be held legally responsible".

The Panel was concerned that, given that this policy was a global one, it lacked specificity in relation to the UK, and also did not appear to have been updated since 2018.

The Panel noted that the complainant had also queried whether CSL Seqirus had an *"updated social media SOP [standard operating procedure] that is required and trained out to UK staff"*.

In the Panel's view it was not sufficient to only instruct employees to *"exercise caution"* when engaging with posts about CSL products. This was especially concerning given CSL Seqirus had previously received a breach for a UK employee's action on social media. By failing to provide clear and prescriptive guidance to UK employees regarding the acceptable use of social media, the Panel considered that CSL Seqirus had failed to maintain high standards and ruled a **breach of Clause 5.1**.

The Panel noted that Clause 2 was a sign of particular censure and reserved for such use. The Panel considered that the matters raised by the complainant were adequately covered by its rulings above and did not consider that a breach of Clause 2 was warranted. The Panel therefore ruled **no breach of Clause 2**.

Complaint received **14 January 2025**

Case completed **06 October 2025**