CASE AUTH/3880/2/24 ***NO BREACH OF THE CODE***

COMPLAINANT v GSK

Alleged promotion on LinkedIn

CASE SUMMARY

This case was in relation to a GSK employee commenting on a LinkedIn post about the acquisition of Aiolos Bio by GSK, which mentioned a product that Aiolos Bio had in in development and its possible indication. The complainant alleged that the post constituted pre-licence promotion to the public and health professionals and questioned whether the post and associated press release had been approved for sharing with the public.

There was an appeal by GSK of one of the Panel's rulings.

The outcome under the 2021 Code was:

No Breach of Clause 3.1	**Requirement that a medicine must not be promoted prior to the grant of its marketing authorisation**
No Breach of Clause 5.1 [Panel's breach ruling overturned at appeal]	**Requirement to maintain high standards at all times**
No Breach of Clause 8.1	**Requirement to certify promotional material**
No Breach of Clause 8.3	**Requirement to certify non-promotional material**
No Breach of Clause 26.1	**Requirement not to advertise prescription only medicines to the public**

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 about GSK UK Limited was received from a contactable complainant who described themselves as a concerned health professional.

COMPLAINT

The complaint wording is reproduced below:

> "Senior staff at GSK based in the UK (as is GSK itself) have commented on their latest acquisition along with the product they are going to be developing along with one indication on LinkedIn, which has an audience which includes the general public along with HCPs.

Note this also includes a 'call to action' to look at the press release from the included link.

[Screenshot showing a LinkedIn post ("Today we announce that GSK has completed its acquisition of Aiolos Bio. We are excited that GSK will deploy its resources and deep respiratory expertise to accelerate the development of AIO-001 in asthma and potentially other indications. See press release for more details:") with a link to a press release on GSK's website ("GSK completes acquisition of Aiolos Bio | GSK"), and a comment from a GSK employee ("Great to have you onboard <name redacted>!")]

Neither the press release nor this post appears to have been signed off for the purpose of sharing with the general public.

Please investigate."

When writing to GSK, the PMCPA asked it to consider the requirements of Clauses 3.1, 5.1, 8.1, 8.3 and 26.1 of the 2021 Code.

GSK's RESPONSE

The response from GSK is reproduced below:

"GSK was disappointed to receive a letter from the PMCPA dated the 19th of February 2024 in which you informed us of a complaint from a concerned health professional regarding alleged promotion on LinkedIn. The complainant has sent a screenshot of the post in their complaint, but no attachments were enclosed. The PMCPA has asked us to consider clauses 3.1, 5.1, 8.1, ,8.3 and 26.1 of the 2021 ABPI code of practice (the code).

As mentioned above, the complaint relates to a LinkedIn post about the acquisition of Aiolos Bio by GSK which also had a link to a press release about the same, and the subsequent liking of the post by another GSK employee. The post was by a new employee of GSK who had just transitioned across from Aiolos as part of the acquisition.

GSK takes its responsibility of abiding by the letter and the spirit of the code and all other relevant UK rules and regulations very seriously and we have reviewed the circumstances related to the post. GSK denies breaches of all the clauses which we were asked to consider. The rationale for this is set out in detail below.

Background

GSK completed the deal to acquire the biotechnology company Aiolos Bio, on the 15th of February 2024. Up to that point, the two companies operated entirely as separate entities. As part of this acquisition, employees of Aiolos Bio became the responsibility of GSK even though Aiolos continues to function with a level of independence after the deal was closed. Employees of Aiolos Bio could only be assigned GSK SOPs in their training plans on the day the acquisition was completed i.e. the 15th of February 2024 and not before, for legal reasons. The employees have

been assigned a set period of time to complete all mandatory training to reflect the volume of SOPs and a reasonable expectation of the time it would take to complete. Therefore, they were not fully trained on all the relevant GSK policies immediately after the acquisition was completed.

On the same day as the acquisition was completed, a UK-based former employee (employee 1) of Aiolos uploaded the post in question on LinkedIn. In it, they made reference to the acquisition of Aiolos Bio by GSK, mentioning that GSK would deploy its resources and deep respiratory expertise in accelerating the development of the molecule A10-001 in asthma and potentially other indications. They also referred to a press release about the acquisition and linked it to the post. The press release was hosted on the GSK global corporate website and had been reviewed by the GSK [global senior employee] (who is not a signatory) and medicines pipeline before it was published.

Employee 1 now works in the GSK global team and has the title of [senior employee]. They have 2308 contacts on LinkedIn in total, of which 12 are GSK staff. There are no HCPs in their network. They made the post in a personal capacity, and it was not planned or sanctioned by either company. The post was immediately taken down by the employee once GSK became aware of the complaint.

Following the post, another UK-based GSK employee (employee 2) working within the global team posted a comment to welcome employee 1 which said: ‘great to have you onboard’. Employee 2 has the title [senior employee] and had completed the GSK social media guidance training. Their LinkedIn network consists of 792 contacts of which 36 are GSK employees and 1 HCP (employee 2’s brother). Employee 2 also took down their post upon GSK becoming aware of the complaint. Both employees have roles which do not involve interactions with HCPs.

As already mentioned, the original post and press release referenced molecule A10-001 which is an investigational molecule about to begin a phase 2 trial. It is therefore a molecule which is very early in its lifecycle to the extent that it has not been assigned a medicinal product name as yet. As such, it is likely to be a long time (potentially years), if at all, before the A10-001 enters registration trials, let alone be submitted for an application for marketing authorisation in any indication which it may or may not receive. It does not therefore have a summary of product characteristics (SmPC) for us to be able to attach to our response.

Clause 3.1

GSK acknowledges the mention of the molecule A10-001 in the LinkedIn post and the press release linked to the post. However, GSK strongly contends that the post and press release are not promoting a medicine. As mentioned above, A10-001 is an experimental molecule, about to enter a phase 2 trial, and as such, years away from any potential application for marketing authorisation which is not guaranteed in any case. The molecule is not otherwise available for any HCPs to prescribe even if they wanted to.

Furthermore, GSK contends that the post in question is very clearly about the acquisition of Aiolos by GSK, and the mention of A10-001 is only in the context of GSK

having the capacity to develop the molecule further. We strongly believe that the content of the post and press release is clear enough for there to be no confusion in UK HCPs' minds that the molecule is still in development only and therefore not available for prescription under any circumstances.

The press release to which the post linked, which was hosted on the GSK global corporate website, has a clear prominent statement at the top of it highlighting that it is meant for Trade and Investor media only. GSK contends that even if an HCP were to click on the link and see the press release, it would be obvious that it was not aimed at them.

GSK therefore strongly contends that neither the post, nor the press release can be labelled as promotional materials and therefore that no promotion has occurred. In addition, there is only 1 identified HCP in the combined LinkedIn networks of the two employees, and this HCP happens to be [a close relative] of employee 2. We therefore also contend that no HCPs have been exposed to the post or associated press release and therefore cannot have been promoted to.

For these reasons, GSK contends that clause 3.1 of the code does not apply to this case and therefore deny a breach of the clause.

Clause 8.1 and 8.3

As described in detail above, GSK contends that the post and the associated press release cannot be seen to be promotional materials. GSK also contends that clause 8.1 of the code refers specifically to the certification requirements for promotional materials. Given that GSK does not believe that the post and associated press release are promotional in nature, we deny a breach of clause 8.1 for both.

GSK acknowledges the wording of clause 8.3 of the code which identifies certain materials which need to be certified for use, including those of a non-promotional nature. While this may be the case, GSK contends that both the LinkedIn post and press release in question do not fall under the list of materials specifically mentioned in clause 8.3 of the code. Furthermore, the supplementary information for clause 8.3 in the code specifically identifies press releases as one of the potential materials requiring examination by an AQP or signatory. As already mentioned above, the press release in question was indeed reviewed by the GSK [global senior employee] before it was published.

GSK would also like to highlight that employee 1 had only just transitioned from Aiolos Bio to GSK a few hours previously, and that it is unrealistic and unfeasible for new employees to have been adequately trained on GSK policies and processes in such a brief period of time despite best intentions. We therefore contend that there is strong mitigation for their actions due to a lack of knowledge of GSK policies. GSK therefore denies a breach of clause 8.3 for the LinkedIn post.

With respect to the press release, GSK contends that press releases do not need certification according to the code. Also as previously mentioned, GSK contends that the press release is intended for media and trade investors only. It is hosted on a page of the GSK corporate website where all global press releases are uploaded under the

tab ‘media.’ There is a clear and prominent statement at the top of the press release before the heading stating: ‘For media and investors only.’ GSK therefore denies a breach of clause 8.3 for the press release.

Clause 26.1

Clause 26.1 states that prescription only medicines must not be advertised to the public. Given the fact that the molecule referred to in the LinkedIn post and press release in question is still at an investigational stage, GSK contends that it is not a prescription only medicine and therefore clause 26.1 does not apply. Based on this technical point, GSK denies a breach of clause 26.1

Clause 5.1

As described in detail above, the LinkedIn post was made by an individual who had just transitioned from Aiolos Bio to GSK as a result of the acquisition of the former by the latter. Former employees of Aiolos Bio transitioning to GSK were therefore not trained on any of the GSK policies or processes as yet and their actions simply reflected an enthusiastic reaction to the acquisition. The comment to the post by employee 2, an existing UK-based GSK global team employee, welcoming employee 1, was an individual error in judgement despite the employee having been trained on the GSK social media guidance. In either case, as explained in detail above, GSK contends that none of the other clauses we were asked to consider have been breached.

The supplementary section of clause 5.1 of the code talks about the special nature of medicines and the audience to which information is directed, and goes on to specifically mention that certain types, styles, and methods of communication are unacceptable. GSK contends that this is not the case for either of the materials in question or the associated actions of either of the GSK employees.

GSK therefore denies a breach of clause 5.1.

Summary

In summary, GSK would like to reiterate that we take our responsibility of respecting and abiding within the ABPI code of practice extremely seriously. We are disappointed to have received this complaint and as set out above, believe this to have been because of a combination of an enthusiastic reaction by two of our employees to the acquisition of Aiolos Bio by GSK, and a lack of training on GSK policies by employee 1, rather than any accidental or deliberate attempt to promote any medicines. GSK therefore denies breaches of all the clauses of the code we were asked to consider (3.1, 5.1, 8.1, 8.3. and 26.1) for the reasons explained above.”

Further response from GSK

Further information was provided by GSK in response to a request from the case preparation manager for evidence of examination/review of the press release. The response from GSK is reproduced below:

> "GSK received your request for additional information related to the above case on the 22nd March 2024. In it, you specifically requested evidence of examination/review of the press release in question. Please find attached email evidence of the press release having been examined.
>
> GSK would also like to correct something we had stated in our original letter of response. In it, we had stated that the reviewer of the press release had been the GSK [global senior employee], and that they were not a signatory. This was inaccurate, as the employee in question was actually responsible for putting the press release together as well as putting it through examination, and not for examining it. GSK apologises for this error. The press release was in fact examined by the [global medical senior employee] who is a named signatory and a medical doctor by background."

PANEL RULING

This case was in relation to a LinkedIn post by a senior UK-based global employee of GSK about the company's acquisition of Aiolos Bio. The post mentioned a product that Aiolos Bio had in development and its possible indication. The post was subsequently commented on by another senior UK-based global employee. The complainant alleged that this post constituted pre-licence promotion to the general public and health professionals and questioned whether the post and associated press release had been approved for sharing with the general public.

The LinkedIn post at issue stated:

> "Today we announce that GSK has completed its acquisition of Aiolos Bio. We are excited that GSK will deploy its resources and deep respiratory expertise to accelerate the development of AIO-001 in asthma and potentially other indications. See press release for more details: [link to a press release about the acquisition on GSK's corporate website]"

The Panel noted that it was a well-established principle under the Code that any material associated with a social media post, for example a link to a press release within a post, would be regarded as being part of that post. As such, the Panel considered both the original LinkedIn post and the associated press release as subject to this complaint and ruled accordingly.

GSK submitted that the LinkedIn post was created by a former employee of Aiolos Bio who had become a UK-based global GSK employee on the day that the post was issued which corresponded to the day GSK's deal to acquire Aiolos Bio completed. GSK submitted that the linked press release was intended for trade and investor media only and had been examined by a named signatory.

Both the employee who created the post and the second employee that commented on the post were based in the UK, albeit in global roles, and as such, the Panel considered their actions fell within the scope of the Code.

The Panel noted that, while the second employee's comment made no reference to the product in development, in commenting on the post, the second employee had disseminated it to their own contacts.

In response to the complainant's allegation that the post promoted a pre-licence medicine, GSK submitted that AIO-001 was an experimental molecule about to enter a phase 2 trial and, as

such, years away from any potential application for a marketing authorisation. GSK submitted that the post and press release made it clear that this was a molecule in development and therefore not available for prescription under any circumstances. GSK further submitted that the press release had contained a clear prominent statement highlighting that it was meant for trade and investor media only. GSK contended that neither the post, nor the press release could be labelled as promotional materials, and therefore no promotion had occurred.

The Panel carefully considered the status of AIO-001 at the time of the LinkedIn post and noted that it appeared to be an investigational molecule, which had yet to be assigned a medicinal product name or enter phase 2 clinical studies. In the Panel's view, both the LinkedIn post and the press release clearly referred to the developmental nature of AIO-001. The LinkedIn post communicated GSK's ability to "accelerate the development of AIO-001" and the press release stated that AIO-001 was "ready to enter phase II clinical development".

The Panel noted the early stage of development of the molecule, that no application for a license had been submitted and was in fact likely to be some years away, and that the molecule was still referred to by a number. Accordingly, the Panel did not consider that the investigational molecule could be considered a medicine at the time of the LinkedIn post and in that regard did not consider that a medicine had been promoted prior to the grant of a marketing authorisation. **No breach of Clause 3.1** was ruled based on this technical point.

The Code prohibited the promotion of prescription only medicines to the public. Whilst the complainant appeared not to have made any specific allegation in respect of this, the Panel noted that the molecule, AIO-001, was not classified as a prescription only medicine when the LinkedIn post and associated press release were issued, and on this technical point ruled **no breach of Clause 26.1**.

In response to the complainant's allegation that neither the post nor press release appeared to have been signed off for the purpose of sharing with the general public, GSK submitted that neither material could be seen as promotional materials requiring certification under Clause 8.1. Additionally, they contended that neither material fell under the list of materials specifically mentioned in Clause 8.3 of the Code (non-promotional materials requiring certification). However, in line with the supplementary information for Clause 8.3 which identified press releases as one of the potential materials requiring examination by an AQP or signatory, GSK confirmed the press release was examined by a named signatory who believed it to be in accordance with the ABPI Code and non-promotional in nature.

Clause 8.1 stipulated that promotional material must not be issued unless its final form had been certified. Given its determination above that AIO-001 could not be considered a medicine at the time of publication of the LinkedIn post and linked press release, the Panel concluded that the materials in question were not covered by Clause 8.1. The Panel ruled **no breach of Clause 8.1**.

The Panel noted Clause 8.3 and its supplementary information. The Panel did not consider the post or press release fell under the list of materials requiring certification as specified in Clause 8.3. In addition, the press release had, in fact, been examined by a named signatory in accordance with the supplementary information to Clause 8.3. The Panel ruled **no breach of Clause 8.3**.

The Panel noted that GSK's social media guidance provided clear guidance on how to interact on social media and included the wording "If the content mentions or refers to GSK prescription products, R&D assets or competitor products, you must not like, comment, share or post". The senior employee who had made the post had not been trained on this guidance as they had only become a GSK employee on the day the post was made. However, the second senior employee who had commented on the post had completed training on this guidance, albeit in 2021, and had erred by departing from this guidance. The Panel was concerned, given the intricacies of employees' interactions with social media and the potential consequences of not adhering to internal guidance, that the second employee had apparently not received training on the social media guidance more recently than 2021.

While the Panel concluded AIO-001 could not be classed as a medicine and therefore the post and press release could not be classed as promotional material for a medicine, the Panel was concerned to note that the press release at issue appeared to contain overtly promotional language. In the Panel's view, statements that "…AIO-001, a potentially best-in-class, long-acting anti-thymic stromal lymphopoietin (TSLP) monoclonal antibody ready to enter phase II clinical development for the treatment of adult patients with asthma" and "AIO-001 has the potential to be administered every six months due to its high potency and long half-life, which could redefine the standard of care" (emphasis added by the Panel) went beyond providing factual and balanced information and presented AIO-001 in a promotional way. The Panel disagreed with GSK's assertion that the press release was non-promotional in nature. Senior employees had proactively disseminated beyond the intended audience, via a post on LinkedIn, a press release containing positive and promotional statements regarding a molecule in early development, contrary to GSK's social media policy. The Panel concluded that GSK had, therefore failed to maintain high standards and ruled a **breach of Clause 5.1**.

APPEAL BY GSK

GSK's written basis for appealing is reproduced below:

> "GSK acknowledges the PMCPA's rulings of no breach of Clauses 3.1, 8.1, 8.3, and 26.1 of the 2021 ABPI Code of Practice (the Code) in relation to AUTH/3880/2/24. However, GSK disagrees with the ruling of a breach of Clause 5.1. GSK is committed to adhering to both the letter and the spirit of the Code and all other relevant UK rules and regulations. GSK believes that it has maintained high standards with respect to the activity in question.
>
> The complaint pertains to a LinkedIn post about GSK's acquisition of Aiolos Bio, (on 15 February 2024) which included a link to a press release about the acquisition. Both the LinkedIn post and the press release mentioned the investigational molecule AIO-001 and its potential use in adult patients with asthma.
>
> GSK conducted a thorough investigation on receipt of the complaint and remains confident that it has maintained high standards. In addition, the press release was examined by a medical signatory prior to its scheduled release on the 15th of February 2024. GSK is, therefore, appealing the ruling of a breach of Clause 5.1, and the rationale for this appeal is detailed below.
>
> **Rationale for Appeal**

GSK completed the acquisition of Aiolos Bio on15 February 2024. On the same day, a UK-based former employee of Aiolos created the post in question on LinkedIn. The press release, to which the post linked, was hosted on the GSK global corporate website page for media and investors. This page is prominently labelled, above the press releases 'For media and investors only', thus, the intent would be clear to anyone following the link. The purpose of the press release, which is the subject of the ruling of a breach of Clause 5.1, was to announce the acquisition of Aiolos and the inclusion of the Aiolos' investigational molecule aimed to highlight this key business milestone and scientific rationale to its media and investor audience.

As noted in your letter dated 11 March 2025, molecule AIO-001 was at an early development stage, not entered phase 2 clinical trial, with no application for a licence submitted and likely several years away from such an application. Therefore, AIO-001 could not be considered a medicine at the time of the press release and subsequent LinkedIn post.

GSK had no intention to, and believes it did not, promote the administration, consumption, prescription, purchase, recommendation, sale, supply, or use of a medicine. In the Panel's letter of 11 March, page 3 the Panel states:

"While the Panel concluded AIO-001 could not be classed as a medicine and therefore the post and release could not be promotional material for a medicine "

GSK agrees with the Panel and because AIO-001 cannot be classified as a medicine AIO-001 is out of the scope of the Code, and thus the LinkedIn Post and press release are out of scope the Code.

GSK disagrees that the language used in the press release, such as how AIO-001 "could refine the standard of care" or be "potentially best-in-class," is as the panel asserts "overtly promotional", as AIO-001 is a molecule and is not therefore a medicinal product and therefore is not available as a medicine to promote.

Further, the statements in the Press Release highlight the business and scientific opportunity for GSK. AIO-001 targets the novel TSLP pathway, crucial for 40% of severe asthma patients with low T2 inflammation where new treatment options are needed. Early studies in healthy volunteers and asthma patients have shown safety, tolerability, pharmacokinetics, and biological activity, which may make it possible to administer every six months due to its half-life extension technology potentially redefining the standard of care in this area.

This LinkedIn post links to a press release clearly directed at GSKs investors and financial media about a significant GSK acquisition. When making acquisition announcements, public companies must explain the rationale for the transaction to their investors- this press release sought to do just that as would be seen as a customary obligation of public companies to communicate with their investor community.

In summary, GSK believes that:

- Neither a GSK LinkedIn Post that references a press release nor the press release directed to shareholders and media relating to such an early asset is

within scope of the code.

- GSK disagrees the ruling for the press release "contained overtly promotional language" as the ruling does not take into account the molecule's early development status together with the fact no license application has been made to be considered a medicine- a process that is likely to take many years.

- The press release was a communication of an acquisition, based on a justified scientific and business rationale. As a listed company, GSK has a regulatory requirement to notify investors about acquisitions which is typically done through press releases on our media and investor site.

- GSK had no intention to and believes because AO-001 is not a medicine (as acknowledged by the panel) it has not promoted the administration, consumption, prescription, purchase, recommendation, sale, supply or use of a medicine."

RESPONSE FROM THE COMPLAINANT

There was no response from the complainant.

APPEAL BOARD RULING

The Appeal Board observed that GSK had now determined that the LinkedIn post at issue was created by a UK-based former employee of Aiolos Bio and not a GSK employee. The representatives from GSK at the appeal said that this individual never became a GSK employee. This was information that the Panel did not have.

The Appeal Board accepted GSK's submission that the senior GSK employee's comment on the post ("Great to have you onboard [name redacted]!") had been made contrary to their training. GSK had a policy and training in place that dictated that such a comment should not have been made. On discovery of the post and comment, as a result of the complaint, GSK had ensured they were taken down.

The Appeal Board accepted the Panel's conclusion that AIO-001 could not be classed as a medicine and therefore the post and linked press release could not be classed as promotional material for a medicine. The Appeal Board acknowledged, however, that the scope of the Code was not only restricted to activities involving medicines.

The Appeal Board considered that the press release used language that, although strong, was consistent with aspirational language typically seen in stock exchange announcements directed to an investor audience (the original intended audience of the press release).

The Appeal Board took account of the following factors:

- The original LinkedIn post was not made by a GSK employee
- The senior GSK employee's comment on the post brought the post and linked press release within scope of the Code
- While commenting on the post was against GSK's social media guidance, it was the action of a single employee who had received training

- The Appeal Board considered that the language in the linked press release was not necessarily inappropriate given the particular circumstances of this case

The Appeal Board considered that the actions of the senior GSK employee did not mean that GSK had failed to maintain high standards and the Appeal Board ruled no breach of Clause 5.1. The appeal on this point was successful.

Complaint received **19 February 2024**

Case completed **22 May 2025**