CASE AUTH/3854/11/23

COMPLAINANT v GSK

Off-label promotion on LinkedIn

CASE SUMMARY

This complaint was in relation to a UK-based employee within GSK's Global team who had clicked the 'celebrate' button on a LinkedIn post created by an American medical institute.

The LinkedIn post and linked press release announced "promising results" from a GSK-sponsored niraparib trial involving patients with newly diagnosed glioblastoma with unmethylated MGMT (06-methylguanine-DNA-methyltransferase).

The complainant alleged that the UK-based employee's actions amounted to promotion of a prescription only medicine to the public and promotion of a medicine which was unlicensed.

The outcome under the 2021 Code was:

Breach of Clause 5.1	**Failing to maintain high standards**
Breach of Clause 11.2	**Promoting a medicine for an unlicensed indication**
Breach of Clause 26.1	**Advertising a prescription only medicine to the public**

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 3.1	**Requirement that a medicine must not be promoted prior to the grant of its marketing authorisation**

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 an anonymous, non-contactable complainant who described themselves as a health professional.

COMPLAINT

The complaint wording is reproduced below:

> "A senior GSK employee, who appears to work for UK medical affairs, has liked a post about GSK drug data on LinkedIn. The data in question is off label. This is unacceptable unlicensed/off-label promotion to the public which fails to maintain high standards and undoubtedly brings discredit upon the industry. See link [URL provided] and images attached."

When writing to GSK, the PMCPA asked it to consider the requirements of Clauses 2, 3.1, 5.1, 11.2 and 26.1 of the 2021 Code.

GSK'S RESPONSE

The response from GSK is reproduced below:

> "GSK were extremely disappointed to receive a letter from the PMCPA dated the 21st of November 2023, informing us of an anonymous complaint by a person describing themselves as a Healthcare Professional (HCP). In it the complainant has alleged irregularities in relation to the liking of a LinkedIn post by a UK-based GSK employee. The PMCPA has asked us to consider clauses 3.1, 11.2, 26.1, 5.1 and 2 of the ABPI code of practice (the code).
>
> GSK takes its responsibility of abiding to the letter and spirit of the code very seriously and following the complaint have investigated the circumstances surrounding it. GSK acknowledges breaches of clauses 3.1, 11.2 and 26.1 but not clauses 5.1 and 2. Our response is laid out in more detail below.
>
> **Background**
>
> The [named Centre at an American medical institute] is a well-known independent organisation which carries out early phase clinical trials. GSK has provided support to the Centre to carry out a phase 0/2 trial of Niraparib in patients with newly diagnosed glioblastoma with methylated MGMT (06-methylguanine-DNA-methyltransferase). Niraparib is not licensed in the UK for glioblastoma but is licensed for use in a specific population of patients with ovarian, fallopian tube or peritoneal cancer. The centre independently released a press release in the USA to announce positive results from the study they were conducting, raising hopes for further exploration of Niraparib for this difficult to treat cancer. The centre also posted about it on LinkedIn with the post linking to the press release in question. Neither material was therefore approved by GSK.
>
> A UK-based employee within the GSK Global team (i.e., not an employee of the UK affiliate) 'celebrated' the post on LinkedIn, which GSK acknowledges brings it within the scope of the code. No other UK-based GSK employees reacted to the post. Upon receiving the letter of complaint from the PMCPA, the GSK employee immediately removed their 'celebrate' interaction with the post.
>
> The employee in question has been trained on the relevant GSK social media guidance and their certificate of completion is [copy provided]. Their LinkedIn network consists of

236 contacts of which 9 are HCPs, 45 GSK employees and approximately 70 colleagues from other pharmaceutical companies.

GSK response to clauses 3.1, 11.2 and 26.1

GSK acknowledges that by celebrating the post, the GSK employee brought it within the scope of the code. GSK also acknowledges that for this reason, clauses 3.1 and 11.2 of the code have been breached.

GSK further acknowledges that although niraparib is not licensed for use for glioblastoma, it is licensed for use in a sub-population of patients with ovarian, fallopian tube and peritoneal cancer and this therefore technically breaches clause 26.1 as well.

GSK response to clauses 5.1 and 2

GSK contends that the celebrating of the post by its UK-based employee was an isolated incident due to an error in judgement despite robust policies and systems in place regarding social media activities. We also contend that this isolated error in judgement is not significant enough to imply that high standards were not maintained. It is GSK's contention that the LinkedIn post, as well as original press release, are explicit in announcing the positive results for niraparib in a phase 0/2 study of a sub-set of glioblastoma patients, and that this may therefore guide the further exploration of the potential of the medicine in its clinical development. We contend that neither the post nor the press release would leave the potential reader (either HCP or member of public) with the wrongful impression that niraparib is available for use in glioblastoma. It follows therefore that GSK does not believe that we have failed to maintain high standards given the specific nature of medicines and the audience to which information is directed, with particular reference to the type, style and method of communication as defined in the wording of clause 5.1 of the code. We therefore deny breaching clause 5.1.

GSK also contends that there is no risk to the safety of patients in this situation. Niraparib is licensed for use in ovarian cancer but not for glioblastoma and GSK further contends that there is no chance that it could be prescribed to patients with glioblastoma by an HCP on the basis of the post or press release in question. Furthermore, GSK has provided evidence of the policy we have in place for social media use, to evidence the fact that we have robust processes in place. It is GSK's contention that this incident is therefore due to an isolated error in judgement rather than a systemic issue. For these reasons, GSK denies a breach of clause 2.

Summary

In summary, GSK acknowledges that a UK-based Global employee made an error in judgement by celebrating a post on Linked which was linked to a press release from an independent clinical research organisation in the USA which unwittingly brought it within the scope of the code. GSK concedes that clauses 3.1, 11.2 and 26.1 of the code may have been breached as a result. We deny breaching clauses 5.1 and 2 however, for the reasons set out above."

PANEL RULING

This complaint related to a UK-based employee within GSK's Global team clicking the 'celebrate' button on a LinkedIn post created by an American medical institute.

The Panel considered that the original LinkedIn post (made by a third party and independently of GSK), was not in scope of the Code. However, as acknowledged by GSK, by 'celebrating' the post, the UK-based GSK employee had brought this complaint within the scope of the Code.

The LinkedIn post announced "promising results from a collaborative Phase 0/2 trial of niraparib, supported by GSK, in patients with newly diagnosed #glioblastoma with unmethylated MGMT" (06-methylguanine-DNA-methyltransferase). It included a quote from a press release (to which there was also a link), which stated:

> "This clinical trial identifies niraparib as highly brain penetrant and raises the possibility that PARP inhibition in combination with radiotherapy may be effective for the two-thirds of newly diagnosed glioblastoma patients who are MGMT-unmethylated and insensitive to the standard of care (temozolomide)".

GSK submitted that niraparib was not licensed in the UK for glioblastoma, but that it was licensed for use in a specific population of patients with ovarian, fallopian tube or peritoneal cancer.

Noting the positive language about niraparib within the LinkedIn post and the linked press release, the Panel concluded that by 'celebrating' the post, the UK-based employee had proactively disseminated it to their connections, including members of the public. The Panel concluded that this constituted promotion of niraparib, a prescription only medicine, to the public and ruled a **breach of Clause 26.1**, as acknowledged by GSK.

Clause 3.1 of the Code stated that a medicine must not be promoted prior to the grant of the marketing authorisation which permits its sale or supply. Niraparib already had a marketing authorisation, albeit for a different indication than referred to in the LinkedIn post and press release and, on this technical point, the Panel ruled **no breach of Clause 3.1**.

The parties did not provide the Panel with a copy of the summary of product characteristics. However, the Panel noted from the eMC website that niraparib was not licensed in the UK for glioblastoma at any point during November 2023. Although the complainant's screenshot of the GSK employee 'celebrating' the LinkedIn post was undated, the Panel concluded that it must have happened between the date of the press release (17 November 2023) and the date of the complaint (21 November 2023). In this regard, the Panel considered niraparib had been promoted outside the terms of its marketing authorisation. The Panel ruled a **breach of Clause 11.2**, as acknowledged by GSK.

The Panel took account of the fact that this appeared to be an isolated incident by only one GSK employee, who had been trained on GSK's social media guidance use but had erred by departing from that guidance. The Panel noted that GSK's social media guidance 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". However, the Panel considered that promotion of a prescription only medicine to members of the public, and for an

unlicensed indication, was a serious matter and therefore high standards had not been maintained. The Panel ruled a **breach of Clause 5.1**.

Clause 2 was a sign of particular censure and reserved for such use. The Panel took account of the fact that the interaction was by a single employee and that GSK had training and guidance in place around the use of social media. The Panel did not consider that the circumstances of this case brought discredit upon, or reduced confidence in, the pharmaceutical industry and therefore ruled **no breach of Clause 2**.

Complaint received **18 November 2023**

Case completed **22 January 2025**