

COMPLAINANT v GSK

Allegations about declarations of involvement

CASE SUMMARY

This case was in relation to four articles published on a patient organisation website; the articles formed part of the work by the patient organisation which had been funded by way of a grant by GSK. The complainant alleged that the funding was not acknowledged from the outset of the articles and was only referred to at the end. Further that the declaration was unclear as the reader would not know if the funding had been by way of grant or sponsorship. The complainant also alleged that the material had not been certified which it should have been as disease awareness material, if the funding was provided by way of sponsorship.

The outcome under the 2021 Code was:

Breach of Clause 25.3	Failing to ensure sponsorship is clearly acknowledged from the outset.
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 5.1	Requirement to maintain high standards at all times
No Breach of Clause 8.3	Requirement to certify non-promotional material

**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 from an anonymous, non-contactable complainant about GSK.

COMPLAINT

The complaint wording is reproduced below:

“GSK had provided financial funding to [patient organisation], to produce 4 articles. However, this funding from GSK was not acknowledged from the outset of the articles and was only referred to at the end of the articles. Furthermore, the disclaimer at the end of the article read as follows: This patient information resource has been made possible with a financial contribution from GSK. The declaration was unclear as one could not

understand whether the funding from GSK was via a sponsorship or a grant. If GSK had not provided the funding via a grant, the content should have been certified as it was disease awareness material which members of the public would view. The 4 articles are available at: [URL provided] High standards and transparency had not been adhered to in view of the issues with the articles. There were breaches of code clauses 25.3, 5.1, 2 and 8.3. 8.3 is a potential breach if the funding was done as a sponsorship and no certification had taken place.”

When writing to GSK, the PMCPA asked it to consider the requirements of Clauses 8.3, 25.3, 5.1 and 2 of the Code.

GSK’S RESPONSE

The response from GSK is reproduced below:

“Thank you for your letter dated 9th May 2024 wherein you inform GSK that a complainant has raised concerns regarding GSK’s involvement in four articles on the [patient organisation] website. GSK is committed to following both the letter and the spirit of the ABPI Code of Practice and all other relevant regulations and takes this complaint very seriously. When responding, you have asked that GSK consider the requirements of Clauses 25.3, 8.3, 5.1 and 2 of the 2021 Code.

Background Information

GSK received an unsolicited request from [patient organisation], a patient organisation, to support its work to develop targeted patient-centred [medical condition] content across a variety of channels, via e-mail on 3rd November 2022[sic]. GSK approved the grant request for funding of £25,000 at its grants and donations committee meeting on 20th April 2022, subsequently certifying the agreement on 5th May 2022.

At the time of the unsolicited request, GSK did have an interest in this therapy area, with a potential medicine in development for the treatment of [medical condition] associated with [disease]. However an MHRA license was not sought for this investigational medicinal product and therefore it was not launched in the UK and is not available for prescription in the UK.

GSK provide grants and donations in response to unsolicited requests as part of our commitment to being a responsible business; to make a positive social impact; and to respond to challenges and opportunities in the healthcare or research system and our broader society. We recognise a responsibility to support activities in our medical community, whether related to medical education where there is patient need and common scientific interest, professional societies’ initiatives, or assisting healthcare organisations and projects that promote other healthcare goals. In all our interactions we aim to be transparent about our work, operate with integrity, and always put the interests of patients first.

[Patient organisation] is a leading [therapy area] charity offering advice, support and financial grants and assistance to thousands of [therapy area] patients and their families every year. The website is hosted and managed [patient organisation]. [Patient organisation] gives support to help improve the quality of life for everyone affected by

[disease]. Amongst its many offerings they provide patient information having a huge range of free information on many aspects of [disease], including diagnosis, treatment, and practical information about life with [disease].

Response to complaint

GSK's position is that it has complied with the requirements of the Code and denies breaches of Clauses 25.3, 8.3, 5.1 and 2, with the reasoning as detailed below.

Clause 25.3

Clause 25.3 refers to sponsorship, however this arrangement was a grant where GSK provided funds freely for the purpose of supporting [patient organisation] as described, with no consequent obligation to provide goods or services to the benefit of GSK in return. GSK therefore refute a breach of Clause 25.3 as stated by the complainant.

GSK provided grant funding to [patient organisation] to develop patient materials. The funding was provided towards the cost of supporting the development of targeted, patient-centred [medical condition] content. Amongst the materials being developed was the content development and creation of [medical condition]-specific patient articles to raise greater awareness about what it is like to live with [disease] in the face of overwhelming financial and psychosocial challenges. No GSK products, marketed or in development, formed part of the grant request or content of final articles produced by [patient organisation].

GSK believe it is entirely acceptable for companies to respond to grant requests to support healthcare, scientific research or education (as per Clause 23.1 of the Code of Practice) as long as the grant does not, amongst other things, constitute an inducement to recommend and/or prescribe, purchase, supply, sell or administer specific medicines and does not bear the name of any medicine. GSK believe that in this regard, the grant complied with all aspects of Clauses 23.1 and 23.2.

The grant provided was an arm's length arrangement and GSK had no influence or involvement into the activity of [patient organisation]. GSK stipulated that [patient organisation] should ensure that the Grant provided is clearly acknowledged on all relevant materials and in a sufficiently prominent position to ensure that readers of materials are aware of it at the outset. To respect the arm's length nature of the grant arrangement, GSK do not review materials or have input into the materials generated from grants. This is to ensure that GSK have no influence or control over the final content/balance/scope of the material.

GSK contend that the grant is more specifically governed by Clause 23.2 of the Code, which refers to *"Donations and grants to healthcare organisations, patient organisations and other organisations"*. This Clause specifically requires that *"Company involvement should be made clear for all donations and grants to the extent possible."* (emphasis added). GSK believe that the disclosures of company involvement made on the [patient organisation] website associated with these articles meet the requirements of clause 23.2 by declaring company involvement to the extent possible, furthermore the text is clear on GSK's involvement and found within the body of the article text. The full acknowledgement in black text with white background reads:

“This patient information resource has been made possible with a financial contribution from GSK. GSK has had no editorial input into or control over the content which has been independently owned and created by [patient organisation].”

GSK had a written agreement in place, the written agreement was certified by a signatory registered with the MHRA. GSK had publicly declared this grant [URL provided], as required by the Code. GSK therefore refutes a breach of Clause 25.3 as stated by the complainant.

Clause 8.3

The complainant acknowledges that Clause 8.3 applies only if funding was provided as sponsorship as opposed to a grant. As this activity was a grant, GSK had no requirement to certify the content of the articles. The grant agreement was nevertheless certified by a medical signatory according to the requirements of the Code. GSK thus refute a breach of Clause 8.3.

Clauses 5.1 and 2

GSK fully assessed the nature of the grant request before agreeing to fund it. GSK have had no input or influence on the [patient organisation] website and this was an arm's length arrangement. GSK has a robust grants approval process including a grants and donation committee who assess the suitability of grants which includes only non-commercial staff amongst who are signatories and senior compliance staff. A certified agreement was in place with [patient organisation], which included, inter alia, the need for [patient organisation] to clearly declare GSK's funding in all relevant materials. GSK had publicly declared this grant. GSK believes that the requirements of the Code have been met and that high standards have been maintained, and thus refutes a breach of clause 5.1. Accordingly, GSK also refutes a breach of clause 2.

GSK acts with transparency and as this complaint has been raised with the PMCPA, GSK has subsequently approached [patient organisation] to remind them of the wording in this regard within the agreement to allow [patient organisation] to ensure the terms of the agreement continue to be met appropriately.

Summary

In summary, GSK takes its responsibilities of working within the letter and the spirit of the ABPI Code of Practice very seriously. GSK strongly denies breaches of Clauses 25.3, 8.3, 5.1 and 2 as this was funding of an unsolicited grant, that was formally approved by the GSK grants and donations committee with an arm's length arrangement. There was a certified agreement in place with [patient organisation] with clear terms and conditions regarding acknowledgement of GSK involvement. GSK has been fully compliant with both the letter and the spirit of the ABPI Code of Practice. GSK therefore refutes all the allegations made by the complainant. Please do not hesitate to ask if any further clarification or information is required.”

PANEL RULING

The complaint related to four articles published on a patient organisation website. GSK had provided funding by way of a grant to the patient organisation to support work to develop targeted patient centred content in a particular therapeutic area; the four articles formed part of this work. The complainant alleged that the funding was not acknowledged from the outset of the articles and was only referred to at the end. Further that the declaration was unclear as the reader would not know if the funding had been by way of grant or sponsorship. The complainant also alleged that the material had not been certified which it should have been as disease awareness material, if the funding was provided by way of sponsorship.

The articles in question appeared on the patient organisation website under pages about managing [medical condition] and [disease]. The articles appeared in a question and answer style aimed at patients living with those conditions. All of the articles appeared in the same format and structure on the website. At the top of the page under drop down tabs appeared a large banner with a short summary of the article. Underneath on the left-hand side of the page was a rectangular text box which contained five links to different question and answer pages including the four articles identified by the complainant. Text appeared on the right-hand side of the page in a column of questions and answers. At the bottom of the text in italics and the same size font it stated,

“This patient information resource has been made possible with a financial contribution from GSK. GSK has had no editorial input into or control over the content which has been independently owned and created by [patient organisation].”

The Panel noted GSK’s submission that the provision of funding to the patient organisation was by way of an arm’s length arrangement and GSK had no influence or involvement in the activity, nor did they review the materials. The Panel were provided with a copy of the grant agreement which set out the purpose of the grant, with a further breakdown of how the funding would be spent. The Panel noted that GSK’s funding amounted to 0.85% of the patient organisation’s total income for that year, however it appeared this particular activity was fully funded by GSK. The arrangements reflected the nature of an arm’s length agreement.

The Panel observed that the grant agreement included a requirement for the patient organisation to “ensure that the Grant provided by GSK is clearly acknowledged on Recipient’s website, prior to live events and in printed or digital announcements and other materials distributed in connection with the Purpose in a meaningful way (as determined by Recipient) and in a sufficiently prominent position to ensure that readers of materials are aware of it at the outset”.

The Panel bore in mind the broad definition of sponsorship at Clause 1.22 and the definition of donations and grants at Clause 1.5 and considered that the terms were not mutually exclusive. Clause 25.3 stated that “Companies must ensure that all sponsorship is clearly acknowledged from the outset. The wording of the declaration of sponsorship must be unambiguous and accurately reflect the extent of the company’s involvement and influence over the material.” The Panel considered that Clause 25.3 applied to all forms of sponsorship arrangements in place and was not limited in its application, reflecting the broad definition of sponsorship in Clause 1.22. The Panel accepted that this was an arm’s length grant but that did not preclude it from falling within the broad definition of sponsorship to which Clause 25 applied. It’s intention, in line

with the spirit of the Code, was to ensure transparency in declaring a company's involvement. It also closely mirrored the requirements of Clause 23 which related specifically to grants.

The Panel considered the wording of the declaration at the bottom of each of the articles. The Panel considered the wording to be proportionate and unambiguous as to GSK's involvement.

The Panel next considered the location of the declaration on each of the four articles and noted that it did not appear within the first field of vision. A reader would need to scroll to the bottom of each page to see the declaration and the Panel deemed it possible that a reader could read some of the page or click through to other links without knowing it had been funded by GSK. The declaration was not acknowledged from the outset and did not meet the requirements of Clause 25.3 in this regard. On this narrow basis, the Panel ruled **a breach of Clause 25.3**. On the basis that this funding was provided by way of a grant, Clause 8.3 did not apply, as acknowledged by the complainant. The Panel ruled **no breach of Clause 8.3**.

The Panel considered that there was no evidence provided by the complainant to support an allegation that GSK had failed to maintain high standards. A certified written agreement for the grant was in place with a requirement to declare GSK's funding in a sufficiently prominent position to ensure that readers of materials are aware of it at the outset. On the basis of its findings above, the Panel did not consider that GSK had failed to maintain high standards and ruled **no breach of Clause 5.1**. It follows that the Panel ruled **no breach of Clause 2**.

Complaint received 04 May 2024

Case completed 30 June 2025