CASE/0219/06/24

COMPLAINANT v ORGANON

Allegations about declaration of involvement on a website

CASE SUMMARY

This case was in relation to funding provided by Organon to a healthcare organisation. The funding, provided as a grant, related to the production of a toolkit webpage. The complainant alleged that the declaration of funding only appeared at the end of the webpage.

The outcome under the 2021 Code was:

| Breach of Clause 23.2 and 25.3 | Failing to ensure that all sponsorship is clearly acknowledged from the outset (Panel made one ruling which applied to both Clauses) |
|--------------------------------|--|
| 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 |

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 Organon from an anonymous, contactable complainant who later became non-contactable.

COMPLAINT

The complaint wording is reproduced below:

"Organon had provided grant funding towards the [named healthcare organisation] web portal. The grant funding declaration was not provided from the beginning of the website but only given at the end of the website. [URL provided] 23.2 & 25.3 & 5.1 & 2 clauses had not been complied with."

When writing to Organon, the PMCPA asked it to consider the requirements of Clauses 23.2, 25.3, 5.1 and 2 of the 2021 Code.

ORGANON'S RESPONSE

The response from Organon is reproduced below:

"We are writing in response to the complaint received under Case AUTH/0219/06/24 regarding our grant funding towards the [named healthcare organisation]. We take all complaints very seriously and appreciate the opportunity to address these concerns thoroughly and transparently.

After a comprehensive internal review to fully understand the complaint, we aim to provide a clear and accurate response.

Commitment to Ethical Standards

At Organon, we are unwavering in our commitment to maintaining the highest standards of ethical conduct and regulatory compliance. We understand the importance of transparency and integrity, especially in our interactions with healthcare professionals and the public. We strive to ensure that all of our actions, including grant funding, are conducted transparently and in full compliance with relevant guidelines and codes of practice.

Background Regarding the Grant

The [named healthcare organisation] is a community interest company dedicated to supporting practitioners interested in women's health issues by providing education, resources, events, and news. In 2021, Organon provided grant funding to the [named healthcare organisation] to support the development and enhancement of Women's Health Hubs across the UK. The [named healthcare organisation] aimed to create a comprehensive toolkit to assist commissioners, providers, and decision-makers responsible for Women's Health services in their localities. The toolkit was to include resources such as a situational analysis data tool, a financial viability assessment tool, case studies, and more, designed to aid in the setup and delivery of core services.

Organon's funding was provided strictly at arm's length, meaning we had no influence over the activities or content produced by the [named healthcare organisation]. Consequently, we did not review or approve the content of the toolkit website page, which appears to be accessible via the [named healthcare organisation] main website homepage, redirecting users to a separate page. Organon has supported various [named healthcare organisations] initiatives in the past, including their educational endeavours.

Addressing the Complainant's Concerns

Clause 23.2

The grant funding provided to the [named healthcare organisation] was intended to support healthcare initiatives.

According to Clause 23.2 of the ABPI code:

"Company involvement should be made clear for donations and grants to the extent possible."

Given our arm's length support for a "toolkit," we agreed to include a declaration on all materials created as a result of the funding, ensuring our involvement was fully transparent. An initial wording for the declaration was discussed during our internal grants committee review process prior to the grant's approval. Upon approval of the grant, the final language for the declaration was agreed upon with the [named healthcare organisation] and they subsequently included this on the relevant toolkit webpage. The signed letter of agreement also explicitly mandated this wording, emphasising the importance of compliance with the ABPI code to the [named healthcare organisation].

Overall, however, we acknowledge that specific information regarding the prominence of such a declaration was not included in our written agreement for the grant. Therefore, we accept a breach of Clause 23.2 as the signed agreement did not specify that such declarations were to be "clearly acknowledged and apparent from the start," as mentioned in the supplementary information of Clause 23.2.

Clause 25.3

We understand the broad definition of sponsorship in terms of funding support and the importance of clear acknowledgment from the outset. The declaration was indeed included on the homepage of the Toolkit website towards the bottom of the page, with a bold statement below the declaration, "Statement on pharmaceutical industry funding," directing readers to this information. Clause 25.3 of the ABPI Code also states:

"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."

It is important to note that the [named healthcare organisation] main website, which provides a link to access to the toolkit webpage, also states the following information towards the bottom of the homepage:

"Should the [named healthcare organisation] receive grants from industry, these are received at arm's length, control remains with the [named healthcare organisation] at all times and organizations are not involved in the development of content. Where an activity is carried out by the [named healthcare organisation] connected to a received grant, a declaration will be made".

While the declaration of sponsorship on the actual webpage reflected our involvement and was accurate, we acknowledge it was not prominently presented from the "outset". Therefore, we accept a breach of Clause 25.3.

Clause 5.1

Organon consistently strives to maintain high standards by adhering to the ABPI Code's requirements. The grant funding provided to the [named healthcare organisation] was subjected to rigorous internal review and approval processes to ensure compliance with all relevant standards and guidelines. A statement regarding the importance of including

the declaration was indeed included within a written agreement and the declaration itself was present on the toolkit website. The disclaimer was accurate and reflected our involvement. There were also two occasions whereby a healthcare professional could access the relevant information regarding pharmaceutical industry involvement:

- General mention on the homepage of the [named healthcare organisation] website.
- Specific information relating to Organon's involvement on the toolkit webpage.

For these reasons, we, therefore, deny a breach of Clause 5.1.

Clause 2

We have made every effort to provide the relevant declaration transparently, clearly stating our involvement. Organon is committed to transparency in all our activities, aiming to be open with the public and healthcare professionals about our involvement and influence. The declaration provided on the toolkit webpage aligns with this commitment, ensuring that our role is acknowledged without breaching ethical standards. Although there were missing elements to ensure that the statement was presented from the outset, we do not believe that we have brought discredit upon or reduced confidence in the industry. Therefore, we deny a breach of Clause 2.

Corrective Action

To ensure ongoing compliance with the ABPI code, we have implemented the following corrective actions with regards to this specific complaint and for other future sponsorship initiatives:

- Contacted the [named healthcare organisation] to request that the declaration be moved to the beginning of the page, prominently at the outset. This has now been actioned.
- We ensure that in future agreements the requirement for "acknowledgment at the outset" is included.

Conclusion

In conclusion, having thoroughly investigated the complaint and based on historical PMCPA case precedence, we accept breaches of Clauses 23.2 and 25.3 due to the declaration not being present from the outset on the toolkit website, along with the lack of specific instructions in our written agreement to ensure that the [named healthcare organisation] would acknowledge this declaration from the outset on any materials produced as a result of the funding. However, since the statement was indeed present and correct on the toolkit website and due to the nature of the arm's length agreement, we deny breaches of Clauses 5.1 and 2. We have acted in good faith, maintaining transparency and high ethical standards in our support of the [named healthcare organisation]. This was an arm's length arrangement with an independent organisation."

PANEL RULING

This case related to funding provided by Organon to a healthcare organisation. The funding, provided as a grant, related to the production of a toolkit webpage. The complainant alleged that the declaration of funding only appeared at the end of the webpage.

Organon submitted that they had provided grant funding to the healthcare organisation in 2021 to support the development and enhancement of Women's Health Hubs. The healthcare organisation aimed to create a comprehensive toolkit to assist commissioners, providers and decision-makers responsible for women's health services in their localities. Organon submitted that it had provided funding at arm's length and had no influence over the activities or content produced by the healthcare organisation, nor had it reviewed or approved the content of the toolkit webpage.

Screenshots of the webpage in question had not been provided by the complainant and so the Panel based its ruling on those provided by Organon. This included a screenshot of the webpage for the toolkit as well as the healthcare organisation home page which the reader could navigate to the toolkit from.

The webpage began with the healthcare organisation logo and a statement that "This site is intended for healthcare professionals, commissioners and associated professionals". This was followed by information on the different steps in the toolkit, featured resources and FAQs. At the bottom of the webpage under the heading 'The Women's Health Hub Toolkit' was the following declaration: "This resource has been developed with the support of a Grant from [named pharmaceutical companies], Organon Pharma (UK) Limited and [named pharmaceutical company]. [Named pharmaceutical companies], Organon Pharma (UK) Limited and [named pharmaceutical company] had no editorial control or scientific input". The declaration appeared alongside information about the healthcare organisation, quick links to toolkit content and contact information for the healthcare organisation. The font was a similar size to the rest of the webpage. At the very bottom of the webpage, underneath the declaration, was a statement in bold that said, "Statement on Pharmaceutical Industry funding".

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 a grant but that did not preclude it from falling within the broad definition of sponsorship to which Clause 25 applied. The intention of Clause 25, in line with the spirit of the Code, was to ensure transparency in declarations of company involvement. It also closely mirrored the requirements of Clause 23 which related specifically to grants.

The Panel considered the location of the declaration and whether it was at the outset as required by Clause 25.3. Given the significant amount of content on the webpage, which included links to additional pages, and the location of the declaration at the very bottom of the webpage, the Panel considered it highly possible that a reader would view this page without being aware that it was funded by Organon and other pharmaceutical companies.

The Panel considered that a declaration of involvement at the very bottom of the webpage was inadequate and failed to satisfy the requirements of Clause 25.3 that the sponsorship should be

clearly acknowledged from the outset. A **breach of Clause 25.3** was ruled, as acknowledged by Organon.

The Panel also noted the relevant requirements of Clause 23.2 that "company involvement should be made clear for donations and grants to the extent possible". In addition, the supplementary information to this clause set out that written agreements for donations and grants should include "a statement that all parties are fully aware that the donation or grant must be clearly acknowledged and apparent from the start". Taking into account its ruling above in relation to Clause 25.3, the Panel considered that the declaration of involvement also did not meet the requirements of Clause 23.2. The Panel ruled a **breach of Clause 23.2**, as acknowledged by Organon. However, the Panel noted the similarities in the requirements for the declaration under Clauses 25.3 and 23.2 and treated the allegation on this point as one matter for the purposes of its ruling.

As part of its response to this complaint, Organon provided a copy of the written grant agreement. Although the complainant had not made a specific allegation on this point, the Panel was concerned that the agreement did not set out requirements for the location of the declaration of involvement, in accordance with the Code. However, the Panel acknowledged that the agreement did refer to a requirement for a declaration and the Panel had sight of corrective action taken by Organon on being notified of the complaint. On balance, the Panel did not consider that Organon had failed to maintain high standards. The Panel ruled **no 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 26 June 2024

Case completed 01 July 2025