

COMPLAINANT v ROCHE

Allegations about declaration of involvement

CASE SUMMARY

This case was in relation to a declaration of involvement statement on two pieces of material associated with a white paper looking at the management of a particular medical condition. The complainant alleged that the “*exact Roche involvement and funding statement was not provided accurately*” nor was it provided from the outset.

The outcome under the 2016 Code was:

Breach of Clause 9.10	Failing to be sufficiently clear as to the company’s role and involvement
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 9.1	Requirement to maintain high standards at all times
No Breach of Clause 9.10	Requirement to be sufficiently clear as to the company’s role and involvement
No Breach of Clause 19.1	Requirements regarding medical and educational good and services

**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 Roche Products Ltd, from an anonymous, non-contactable complainant, who described themselves as a member of the public/media.

COMPLAINT

The complaint wording is reproduced below:

“Roche had provided a grant to [named consultancy group] to conduct research on [medical condition] which was then included into a report on [medical condition]. However, exact Roche involvement and funding statement was not provided accurately nor was the Roche involvement provided from the outset for readers. Accuracy of exact company influence was a mandated code of practice regulation. 2 pieces of materials were in breach: [URLs provided] Breaches of clauses 23.2, 25.3, 5.1 & 2.”

The complainant had cited Clauses of the 23.2, 25.3, 5.1 and 2 of the 2021 Code. However, on receipt of the complaint, the PMCPA observed that the materials in question appeared to be dated November 2018. Therefore, when writing to Roche, the PMCPA asked it to consider the requirements of Clauses 9.10, 19.1, 9.1 and 2 of the 2016 Code.

ROCHE'S RESPONSE

The response from Roche is reproduced below:

“Roche Products Ltd are writing in response to the above case regarding allegations concerning declaration of involvement on a white paper titled ‘Changing paradigms in the management of [medical condition]’ which was published on the [named UK university] in November 2018.

Having integrity as a core value and taking pride in acting with high ethical standards, Roche considers it very disappointing to receive a historic case in this regard. Compliance with the ABPI Code is a fundamental operating commitment and one that Roche considers with the utmost seriousness.

In their initial complaint, the complainant has cited clauses 23.2, 25.3, 5.1 and 2 of the 2021 Code, however, as requested by the PMPCA, Roche have responded to the allegations from the following clauses in the 2016 Code; clauses 2, 9.1, 9.10 and 19.1.

In August 2016, F.Hoffman-La Roche received an unsolicited request for sponsorship from [named consultancy group] to support the development of a white paper looking to address current evidence regarding the management of [medical condition] and whether a change in approach was required. [Named consultancy group] is the business arm of the [named UK university] that commissions research and provides consultancy services by their academic specialists.

The request for sponsorship was received and reviewed by an International Health Policy Manager employed by F.Hoffman-La Roche in our Swiss offices and in November 2016 a sponsorship agreement was entered into. As part of this agreement, F.Hoffman-La Roche provided financial support to [named consultancy group] for the development of the white paper and as such would receive a copy of the report and reprints of publications.

Neither F.Hoffman-La Roche nor Roche Products Ltd (Roche) had influence or involvement in any element of development of the white paper.

The contract used was a F.Hoffman La-Roche global agreement that included the following requirements within the contract terms regarding transparency of Roche's involvement.

[Screenshot of ‘Transparency’ section of contract]

As the sponsorship recipient was a UK organisation, the contract also contained an appendix that included provisions for the ABPI Code that included the following clause.

[Screenshot of ‘Declarations of Involvement’ section of contract]

The white paper (dated November 2018) is available for download within the [named consultancy group] section of the [named UK university] website. The screenshot below (accessed 24th June 2024) identifies F.Hoffmann-La Roche as the client of the [named UK university] commissioned consulting services in this instance.

[Screenshot of webpage where white paper can be downloaded]

Once downloaded the white paper contains the following declaration:

[Screenshot of 'Acknowledgements' section of white paper]

This prominent statement appears in isolation on page three of the white paper, prior to any content, and refers to Roche's financial contribution towards the publication.

The PMPCA has asked for consideration of clause 9.10 of the 2016 Code in this instance as the complainant has alleged that the exact Roche involvement and funding statement was not provided accurately nor was the Roche involvement provided from the outset for readers. Clause 9.10 of the 2016 Code states the following:

9.10 Material relating to medicines and their uses, whether promotional or not, and information relating to human health or diseases which is sponsored by a pharmaceutical company must clearly indicate that it has been sponsored by that company.

Roche notes that clause 9.10 of the 2016 Code makes reference to company involvement being clearly indicated on sponsored materials, which Roche considers obvious on the website and white paper. The 2016 Code does not have the same requirements as the 2021 Code that stipulates that the **role** of the company must be clearly indicated.

However, considering the additional guidance provided in the supplementary information of Clause 9.10 Roche acknowledges that this statement could be more expansive to give clarity to readers regarding the hands off nature of the financial support. As such, Roche accepts a breach of clause 9.10 of the 2016 Code in this regard.

The PMCPA has also asked Roche to consider clause 19.1 of the 2016 Code in this instance. As this relates to the requirements regarding Medical and Educational Goods and Services Roche does not consider this applicable in this instance and as such does not consider a breach of clause 19.1 of the 2016 Code in this case.

Roche has a strong focus on continuous improvement, and given the provision of financial support occurred in 2016, the systems and processes at Roche have evolved significantly since then. This is coupled with broader industry knowledge and clarity on expectations of Code applicability as we learn from case precedent. There is a robust process in place for affiliate approval of cross border sponsorships that is now enabled by a system that allows for end-to-end visibility and tracking of such requests. In addition, our global and local contract templates have been significantly updated to make clear the Code requirements and associated expectations of recipients in terms of prominence and appropriate wording as it relates to Roche's declaration of involvement.

Given the above, whilst acknowledging a breach of Clause 9.10 of the 2016 Code in this instance Roche feels strongly that high standards have been maintained and the reputation of the industry upheld. Roche would never seek to disguise or not be completely transparent about their declarations of support and have the appropriate systems and processes in place to enable this.

As such, Roche strongly refutes the alleged breaches of Clauses 9.1 and 2 of the 2016 Code in this instance.”

PANEL RULING

This case related to a declaration of involvement statement on two pieces of material associated with a white paper looking at the management of [medical condition]. The complainant alleged that the “*exact Roche involvement and funding statement was not provided accurately*” nor was it provided from the outset. F.Hoffman-La Roche (Roche Products Ltd) had providing funding to a consultancy group associated with a UK university to support the development of the white paper.

Roche submitted that they had received an unsolicited request for funding from the consultancy group in August 2016 to support the development of a white paper looking to address current evidence regarding the management of [medical condition] and whether a change in approach was required. This request was approved internally, and an agreement was entered into in November 2016. Roche submitted that neither F.Hoffman-La Roche nor Roche Products Ltd had influence or involvement in any element of the development of the white paper, but it was agreed they would receive a copy of the report and reprints of publications.

The complainant had cited Clauses 23.2, 25.3, 5.1 and 2 of the 2021 Code. However, on receipt of the complaint, the PMCPA observed that the materials in question appeared to be dated November 2018. Therefore, the PMCPA had asked Roche to consider the closely similar clauses from the 2016 Code which would have been applicable at the time: Clauses 2, 9.1, 9.10 and 19.1.

The Panel noted that Roche had referred to the arrangements as a sponsorship in their submission, whereas the declaration in the white paper referred to a grant. The Panel had not been provided with a copy of the agreement between Roche and the consultancy group and so could not deduce the precise nature of the relationship between the two parties.

The complainant had provided links to two materials cited in their complaint. The Panel considered each material individually.

Material 1

Material 1 appeared to the Panel to be the webpage from where the white paper could be downloaded and provided information on the white paper. The webpage was entitled ‘Changing paradigms in the management of [medical condition]’ which mirrored the title of the white paper and appeared to be accessed via the consultancy group webpage on the website of the UK university. The webpage included a visual of the front cover of the white paper, next to which was background information on [medical condition] and information on what the white paper covered. On the right-hand side of the webpage, underneath icons by which to share the

webpage, it stated “Client: F-Hoffman-La Roche” beneath which was the name of the authors of the white paper and then a clickable red box stating, “Download white paper”.

Clause 9.10 of the 2016 Code stated that material relating to medicines and their uses whether promotional or not, and information relating to human health or diseases which is sponsored by a pharmaceutical company must clearly indicate that it has been sponsored by that company. The supplementary information to Clause 9.10 further stated that the declaration of sponsorship must be sufficiently prominent to ensure that readers of sponsored material are aware of it at the outset and that the wording of the declaration must be unambiguous so that readers will immediately understand the extent of the company’s involvement and influence over the material.

The Panel noted that the webpage contained information about the incidence, cost and causative factors of [medical condition], which appeared to reflect paragraphs from the executive summary of the white paper. As such, the Panel considered it information relating to diseases which had been sponsored by a pharmaceutical company. The Panel considered that the webpage therefore required an unambiguous prominent declaration. The only mention to Roche on the webpage was a single reference describing them as the client. Although this mention appeared in the first visual on the webpage and was in similar font to the rest of the webpage, the Panel considered that this declaration was ambiguous. Whilst describing Roche as a client may indicate to a reader that there was likely to have been some financial relationship between the two parties, it did not allow a reader to immediately understand the extent of the company’s involvement and influence over the material. The Panel considered that this ambiguous declaration failed to satisfy the requirements of the Code and **a breach of Clause 9.10** of the 2016 Code was ruled, as acknowledged by Roche.

Material 2

Material 2 was a pdf of what appeared to the Panel to be the white paper that Roche had provided funding to develop. The white paper was a 35-page document titled ‘Changing paradigms in the management of [medical condition]’. The front page featured the logo of the UK university, the name of the authors and the date of publication (November 2018). The second page was mainly blank with details of the consultancy group including contact details in the bottom left corner. The third page of the report was titled ‘Acknowledgements’ and featured the following statement:

“The authors are grateful for the financial contribution received from F.Hoffman-La Roche Ltd through an unrestricted educational grant to support the research presented in this paper”.

Nothing else appeared on this page. The following pages featured a table of contents and an executive summary before the report started in full on page eight.

The Panel noted the requirements of Clause 9.10 of the 2016 Code as outlined above.

The Panel considered the ‘Acknowledgements’ section to be at the outset of the report before the reader reached any content or detail of the report itself. Whilst it might have been helpful to a reader to have been informed that Roche had no involvement or influence on the content of the report, the Panel considered that the declaration made it immediately clear to readers that Roche had funded the research. Roche had submitted that they had no influence or involvement in any element of development of the white paper. The complainant had provided no evidence

that Roche's involvement had extended beyond providing financial support. The Panel considered that the complainant had failed to establish why they believed the declaration to not be accurate or at the outset of the material, or that Roche had any influence or involvement in the white paper other than financial support. The Panel therefore ruled **no breach of Clause 9.10** of the 2016 Code.

Overall

Roche had been asked to respond to Clause 19.1 of the 2016 Code. They submitted that they did not consider this clause applicable in this instance. Clause 19.1 of the 2016 Code related to Medical and Educational Goods and Services and the circumstances under which they could be provided. The Panel did not consider that a specific allegation had been made regarding this and so ruled **no breach of Clause 19.1** of the 2016 Code.

Roche submitted that the sponsorship agreement with the consultancy group included certain requirements regarding transparency and declarations of involvement. A copy of the full agreement had not been provided to the Panel. The Panel was concerned that, from the snippets that Roche had submitted, the agreement did not clearly stipulate that a declaration of sponsorship must be unambiguous and sufficiently prominent to be clear at the outset. However, the Panel acknowledged that, from the evidence before it, the agreement did refer to acknowledging the support from Roche and that Roche's involvement was clear to readers in the white paper. Taking all the above into account, whilst the Panel had considered the declaration on the webpage to be insufficient, on balance it did not consider that Roche had failed to maintain high standards in this case. The Panel ruled **no breach of Clause 9.1** of the 2016 Code.

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** of the 2016 Code.

Complaint received 07 June 2024

Case completed 08 August 2025