

COMPLAINANT v ROCHE**Allegations about Declaration of Involvement on Patient Organisation materials****CASE SUMMARY**

This case was in relation to an alleged lack of declaration of Roche involvement from the outset, on several materials associated with a patient education self-management programme. The programme was provided by a named patient organisation, and Roche had previously provided financial support for the programme.

The outcome under the 2021 Code was:

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 23.2	Requirement that company involvement should be made clear for donations and grants to the extent possible
No Breach of Clause 25.3	Requirement that companies must ensure that all sponsorship is clearly acknowledged from the outset

**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, contactable complainant who described themselves as a health professional.

COMPLAINT

The complaint wording is reproduced below with some typographical errors corrected:

“[Named patient organisation] who are a UK charity have recieved [received] financial support from Roche for the [named patient education self-management programme]. The programme had a number of materials associated with it. However, the declaration of Roche involvement was not provided from the outset on all of these materials to those who were undertaking/exposed to this programme (e.g. patients, public). Declaration of funding from Roche was also totally missing on certain materials related to the programme. Examples of the missing prominent declaration are as follows: [four URLs provided]. The charity website, a separate page made note of the fact that Roche had provided 15k funding. [URL provided] As the declaration of involvement has to be fully

clear from the outset on all materials related to the [named patient education self-management programme] Roche had funded, there were breaches of the following ABPI code clauses: - 23.2, 25.3, 5.1 and 2”

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

ROCHE’S RESPONSE

The response from Roche is reproduced below:

“Further to your recent correspondence regarding the above case, Roche would like to express extreme disappointment at receiving a complaint of this nature. Roche prides itself on integrity being a core value and ensuring we maintain high standards through compliance with the ABPI Code in all activities is fundamental to ensuring we stay true to this important principle.

Below is our response to the allegations made by the complainant in the context of clause 23.2, 25.3, 5.1 and 2 of the ABPI Code. Please note that as part of this response, we refer to an ongoing case with the PMPCA currently for consideration (Case AUTH/3893/4/24) and actions detailed below make reference to those as described in our response to that case.

In March 2023, Roche provided financial support (£15,000) to [named patient organisation] under a certified grant agreement, of which £5,000, contributed to supporting implementation of the [named patient education self-management programme] campaign. The complaint in this instance relates to declaration(s) of Roche’s involvement on the materials associated with the campaign that feature on the [named patient organisation] website with alleged breaches of clauses 23.2, 25.3, 5.1 and 2.

In the corporate funding section of the [named patient organisation] website, a list is provided of companies’ year on year that have provided support and how this has been attributed to various [named patient organisation] initiatives. The 2023 funding section was updated by the patient organisation in February 2024 (denoted by the asterisk below and associated footnote at the bottom of the funding section with last update date) and contains the following statement regarding Roche’s provision of support.

[Screenshot:

“Funding received in 2023*

- Roche £15,000
 - Contributed towards our helpline, Information Provisions and [named patient education self-management programme] campaign”]

The complainant makes specific reference to the lack of Roche’s declaration of involvement on the materials currently associated with the [named patient education self-management programme] campaign that feature on the [named patient organisation] website.

The [named patient education self-management programme] campaign is accessed via the [named patient organisation] website via the support tab on the homepage menu. This section of the website provides information regarding the campaign and access to the materials cited by the complainant.

[Screenshot of part of the homepage of named patient education self-management programme]

Whilst the materials cited by the complainant do not feature any declaration of pharmaceutical company, support the first page for the [named patient education self-management programme] campaign does have the following statement below further down the page (accessed 15th May 2024).

[Screenshot of declaration:

“Grateful thanks

[Named patient education self-management programme] has been supported by an education grant by [named pharmaceutical company] (part of [named pharmaceutical company]) who have had no input into the agenda or content [Pharmaceutical company logo]”

Roche response to allegations

At the time of receipt of the above case, and as a result of ongoing Case AUTH/3893/4/24, on the 1st May 2024 Roche instigated a review of all materials and activities that were outputs of the provision of support by Roche via a grant, sponsorship (including congress), donation, collaborative working or Investigator Initiated Study, to ensure that, where applicable, there were appropriate declaration(s) of Roche’s involvement. Any declarations of involvement on these materials that Roche did not consider were as clear as they should be led to immediate follow up action to remind the recipient organisation of the requirements of Clauses regarding company declarations being clear and unambiguous from the outset.

As part of this audit, the provision of support and materials associated with the [named patient education self-management programme] campaign had already been identified as requiring follow up with the patient organisation. As such, Roche had emailed the relevant contact at [named patient organisation]. Below is an extract from the communication exchange relating specifically to Roche’s declaration of support on the [named patient education self-management programme] campaign:

Just to clarify in terms of the [named patient education self-management programme] page – the reference to Roche was removed as the period of support has expired. [Named pharmaceutical company] funding is still current, which is why it remains on there.

We believe Roche’s support is indicated where it should be in all other areas, [information relating to a different grant]. [Named individual] will also go through and double check all other areas, just to ensure we’re satisfied that references appear everywhere they should do.

Given the fact that the provision of funding for the [named patient education self-management programme] campaign and associated materials was for the duration of

2023, and that the ongoing implementation of the programme through 2024 is now being supported by funding from another pharmaceutical company, Roche do not consider clauses 23.2 and 25.3 to apply in this instance. For transparency and completeness the [named patient organisation] corporate partner section of the website contains historic levels of support provided by companies and as such Roche is listed in the funding section of the [named patient organisation] website in 2023 for its historic support of the [named patient education self-management programme] campaign.

In light of the above Roche also strongly refutes the alleged breach of 5.1 and associated alleged breach of Clause 2.

Roche hopes that the above provides sufficient information and context for the PMCPA in this matter but please do let me know if anything further is required."

PANEL RULING

The complaint related to a lack of declaration of Roche involvement from the outset on a number of materials associated with the [named patient education self-management programme], a programme from [named patient organisation] for which Roche had allegedly provided financial support. The complainant specifically referred to, and provided links to, four webpages which allegedly had missing prominent declarations of involvement.

The Panel considered the involvement of Roche in the [named patient education self-management programme]. Roche submitted that in March 2023 they provided £15,000 to support [named patient organisation] under a certified grant agreement, of which £5000 contributed to supporting the [named patient education self-management programme] campaign. This grant agreement was not provided to the Panel and therefore the Panel was unclear whether the grant contributed to overall running costs or towards the development of specific materials/activities. The Panel noted Roche's submission that this 2023 funding was reflected in the corporate funding section of the [named patient organisation] website, which had been updated in February 2024. This corporate funding section was the fifth webpage the complainant referred to in their complaint.

Following communication with named patient organisation], Roche submitted that the provision of funding for the implementation of the [named patient education self-management programme] campaign and associated materials was for the duration of 2023 and that the ongoing implementation of the programme through 2024 was funded by another pharmaceutical company. As a result, Roche did not consider Clauses 23.2 and 25.3 to apply to the materials cited by the complainant. The Panel were provided with a copy of the email correspondence between Roche and [named patient organisation] attesting to Roche's period of support for the [named patient education self-management programme] having expired. The Panel had not been provided with any evidence to establish that Roche's support for the implementation of the [named patient education self-management programme] extended beyond 2023.

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 whether a declaration of sponsorship was required on materials if the period of sponsorship had ended would depend on whether the materials in question had been created during the period of, and as a result of, the sponsorship and whether there had been

any subsequent changes to the material. As with any complaint, the complainant had the burden of proving their complaint on the balance of probabilities; the complainant would need to establish that a company had originally funded the materials in question, to which no substantive changes had been made, and that the materials remained available after the end of the sponsorship.

The complainant had cited four webpages in relation to the [named patient education self-management programme] in their complaint. The Panel considered each webpage individually and whether a declaration of sponsorship from Roche was required.

Webpage 1 was entitled '[named patient education self-management programme] workshops' and from the navigation bar which appeared on the left-hand side of the webpage, was part of the [named patient education self-management programme] available on the [named patient organisation] website. The webpage appeared to advertise workshops intending to take place from May through to November 2024. There was no mention or declaration of any pharmaceutical company on this webpage.

Webpage 2 was a pdf of what appeared to be a template programme for a meeting titled '[named patient education self-management programme]: living with and beyond [condition]'. The programme itself contained no date, apart from a copyright date of December 2023. The Panel noticed the URL address contained a date of February 2024, which suggested this was the date the webpage was published. There was no mention or declaration of any pharmaceutical company on this webpage.

Webpage 3 appeared to be the homepage for the [named patient education self-management programme] hosted on the [named patient organisation] website. Towards the bottom of the page appeared a declaration of support from another pharmaceutical company. From the email correspondence between Roche and [named patient organisation] provided to the Panel, it appeared that this page had included reference to Roche at some point, but that this reference had been removed once Roche's support of the programme had ended. The other pharmaceutical company's declaration remained as their sponsorship was still ongoing.

Webpage 4 was titled 'About [named patient education self-management programme] for CNSs' and from the navigation bar which appeared on the left-hand side of the webpage, was part of the [named patient education self-management programme] available on the [named patient organisation] website. The webpage appeared to focus on the impact of the [named patient education self-management programme] on attendees and feedback from nurses. There was no mention or declaration of any pharmaceutical company on this webpage.

The Panel noted that given the complaint was received several months after the expiry of the grant agreement, the linked webpages post-dated Roche's involvement. Whilst the Panel accepted that in certain circumstances a declaration of involvement ought to appear on materials after the expiry of a grant or sponsorship agreement, the complainant had not provided any evidence or reasons to demonstrate why such a declaration ought to appear on the webpages at issue.

On the basis of the above, the Panel did not consider that the complainant had established that the omission of a declaration of involvement by Roche on the cited webpages amounted to a breach of Clause 25.3. The Panel therefore ruled **no breach of Clause 25.3**.

The Panel noted Clause 23.2 had been cited by the complainant but that they appeared not to have made any specific allegation in respect to this. The Panel, therefore, ruled **no breach of Clause 23.2.**

Given its rulings of no breaches of 25.3 or 23.2 above, the Panel considered there was no evidence that Roche had failed to maintain high standards or brought discredit upon the pharmaceutical industry. The Panel ruled **no breach of Clauses 5.1 and 2.**

Complaint received 7 May 2024

Case completed 25 April 2025