

COMPLAINANT/CHIEF EXECUTIVE v ROCHE**Allegations about declaration of company sponsorship and breach of undertaking****CASE SUMMARY**

This case was in relation to an alleged lack of declaration of Roche sponsorship from the outset on the website of a healthcare partnership which the complainant further alleged was a breach of undertaking.

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 3.3	Requirement to comply with an undertaking
No Breach of Clause 5.1	Requirement to maintain high standards at all times
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 from an anonymous, contactable complainant about Roche. The complaint concerned an alleged breach of undertaking. As the PMCPA was responsible for ensuring compliance with undertakings, the complaint was also taken up in the name of the Director (now known as the Chief Executive).

COMPLAINT

The complaint wording is reproduced below [typographical errors corrected]:

“There is no prominent declaration of Roche sponsorship from the outset on a website that Roche had partnered with other organisations [named healthcare and patient organisations] to produce. The website is [URL provided] Date of Preparation: December 2023 Material Number: M-GB-00013651 The declaration of the sponsorship on this webpage is only provided right at the end of the webpage as opposed to in prominence at the start of the webpage. It is very concerning that despite Roche being found in breach around declarations, they had ignored previous undertakings provided in case AUTH/3676/7/22. In case AUTH/3676/7/22, a breach of clause 25.3 was ruled as the Roche declaration was not provided in prominence from the outset. This same breach was again present on [URL provided] considering no written declaration of Roche

involvement was provided at the beginning of the webpage. Undertakings were very significant to self-regulation so Roche should have ensured both the code and undertakings are followed every time, especially considering Roche have had a number of compliance breaches over the last few years. There are breaches of code clauses 25.3, 3.3, 5.1 and 2 on the [healthcare partnership] webpage. Request to be anonymous for obvious reasons.”

When writing to Roche, the PMCPA asked it to consider the requirements of Clauses 3.3, 25.3, 5.1 and 2 of the Code.

ROCHE’S RESPONSE

The response from Roche is reproduced below [typographical errors corrected]:

“Following your communication regarding the above case, including the alleged breach of undertaking, Roche would like to provide immediate reassurance that it takes this matter with the utmost seriousness. Roche prides itself on operating with high standards and its commitment to ensuring adherence to the Code of Practice in all activities, and was therefore incredibly disappointed to receive a complaint on this matter.

The allegations relate to Roche’s declaration of involvement on the website for [healthcare partnership] campaign and an associated breach of undertaking relating to Case AUTH/3676/7/22.

Below is a summary of the steps taken in relation to complying with the undertaking given in Case AUTH/3676/7/22 followed by our response to the complaint regarding declaration of involvements on [healthcare partnership] website in the context of compliance with Clauses 3.3, 25.3, 5.1 and 2 of the 2021 Code as cited by the complainant.

Compliance with undertakings in relation to Case AUTH/3676/7/22

Roche recognises the significance of undertakings, the importance of ensuring compliance with these, and the impact of this element of self-regulation on the reputation of the industry as a whole.

Based on the outcome of the appeal board in Case AUTH/3676/7/22, a number of activities were prioritised to ensure immediate corrective action. In addition, a programme has since been introduced to ensure that these learnings are embedded in the organisation with a view to ensuring compliance with the undertaking, specifically that we would, forthwith, take all possible steps to avoid similar breaches of the Code in the future.

Prior to signing the undertaking, all grant and donation agreement templates were reviewed. Whilst the relevant requirements regarding declarations of involvement being clear from the outset was already included in the terms and conditions of these templates, for the avoidance of doubt this requirement has been made more prominent and is now also clear in the body of the agreement.

In addition, a review was conducted of the central grants and donation tracker to check that there was no provision of support that may have resulted in outputs similar to that in Case AUTH/3676/7/22. Roche also engaged with the named patient organisation to inform them of the outcome of the case and the associated undertaking. After signing the undertaking related to Case AUTH/3676/7/22, Roche has continued with a series of measures designed to embed the learnings from the case and ensure compliance with the associated undertaking.

The Grants SOP has been updated to include a clear process step that in addition to following up with the grant requester to capture evidence that the grant has been administered as per the agreement, we also need to check that an appropriate Roche declaration of involvement is present on associated activities and materials.

As part of ongoing governance and oversight, the Roche compliance team will continue to implement the audit and monitoring plan which includes checks (where applicable) of appropriate declarations of involvement on Roche supported activities.

Comprehensive communication and training is ongoing to ensure broad organisational understanding and awareness of the learnings from the case and the associated impact as summarised below:

Upon signing the undertaking the details of such were published on the internal Roche compliance website 'Compass', which includes an overview of Case AUTH/3676/7/22 as well as associated details of the undertaking. The following day (29th February 2024) the quarterly Roche ABPI Code Case update forum 'Grey Matters', was scheduled and a verbal update was provided to employees sign posting the new undertakings and reminding colleagues to regularly check to ensure learnings are applied from Cases and compliance with undertakings assured. The next Grey Matters quarterly Code case update scheduled for the 23rd May will provide the opportunity to have more detailed discussions regarding the case and our associated learnings.

On the 14th March 2024, the Roche Final Signatory forum took place, which provided an overview of Case AUTH/3676/7/22 followed by a workshop session on appropriate declarations of involvement and the role of the final signatory in ensuring that we comply with the relevant Clauses of the Code in this regard. The recording of this session was shared directly with all Final Signatories (including medical, non-medical and aspiring final) and on the 19th March 2024 this was also uploaded onto the Roche 'Compass' website for visibility to all employees.

Furthermore, the [senior compliance employee] attended a Medical Affairs Chapter meeting on the 18th March 2024 to provide a verbal overview of Case AUTH/3676/7/22 and associated learnings.

On the 20th March 2024 Issue 6 of the internal Roche Compliance newsletter was published to all UK colleagues which included a section specifically about the ruling in Case AUTH/3676/7/22 and the associated undertakings.

As Case AUTH/3676/7/22 related directly to a co-promote activity Roche's [senior compliance employee] attended the [named pharmaceutical company] final signatory forum on the 12th April 2024 to share the outputs from the case and associated

undertaking with colleagues involved in such activities. The relevant team members from [named pharmaceutical company] had initially been informed of the original case and appeal hearing throughout the process.

Furthermore, relevant training materials have been reviewed and updated to ensure ongoing awareness of the undertaking and again to provide an opportunity to share learnings from the case. For example, we have included additional detail regarding prominence of declarations of company involvement in our reviewer training materials. Our Initial ABPI Training Course (ITC) for new starters into the organisation already signposts to the internal 'Compass' website and makes particular reference to the importance of undertakings and where these can be found.

In addition, focus has been given on retraining colleagues who are actively involved in the management of grant and sponsorship requests. The Public Affairs team, who lead engagement with patient organisations, attended a learning session on the 18th April 2024 with a focus on the transparency of Roche declarations of involvement and the requirement that these are clear from the outset. This was followed up with an email summary.

Further mandatory workshops are scheduled for colleagues in Medical Affairs in June 2024.

Roche would like to reiterate the utmost seriousness in which it considers this alleged breach of undertaking and hopes the timely and robust actions taken demonstrates the commitment we have to honour the undertakings provided to the PMCPA in relation to Case AUTH/3676/7/22 in ensuring all possible steps are taken to avoid similar breaches in the future.

Declaration of company involvement on [healthcare partnership] website

[Healthcare partnership] was initially set up in July 2021 by the charities [named charity] as well as the [named patient organisation], and Roche Products Ltd. The aim of the initiative is to raise awareness of the importance of good eye health and campaign to improve the lives of people living with sight loss by enabling more patients to access eye care (including treatment and ongoing monitoring when needed) faster, by maximising capacity in eye health services across the NHS.

The [healthcare partnership] coalition is currently made up of the [named healthcare organisations, patient organisations and charities] and Roche Products Ltd. Roche provides sponsorship in the form of financial support to the medical communications company [named company] to act as secretariat to the group.

Roche's agreement with the organisations involved in the initiative included the stipulation that materials associated with the campaign would be approved by Roche to ensure compliance with the ABPI Code. A Roche Medical Final Signatory [qualification] certified [healthcare partnership] website in December 2023.

The complaint relates specifically to the prominence of the Roche declaration of involvement on [healthcare partnership] website with alleged breaches of Clause 25.3, 3.3, 5.1 and 2 of the ABPI Code. Given the nature of the complaint relates to an alleged

breach of undertaking, Roche immediately initiated the recall process for the material in question to ensure removal from circulation whilst the complaint was investigated.

[Healthcare partnership] website features the logos of all companies involved in the initiative in the top right hand corner and when users scroll further down the page the following statement is present along with larger logos and descriptions of each organisation in more detail.

[Screenshot of declaration statement which appears as white text on a grey-green background:

“[healthcare partnership] is a partnership of [named healthcare organisations, patient organisations and charities] and Roche Products Ltd. Roche had funded the activities of the partnership.

The partnership works collaboratively across the eye care sector to advocate for and champion improvements to patient care and outcomes, so that everyone can access the right care, where and when they need it”]

The website was generated, and certified by Roche, as part of [healthcare partnership] initiative in December 2023 prior to the ruling of Case AUTH/3676/7/22 and signing of the associated undertaking. [Healthcare partnership] material differs in a number of ways to the activity/material ruled in breach in that instance:

- Provision of the support was in the form of sponsorship and not under an arm's length grant agreement
- The website was part of a broader campaign with a variety of other materials signposting the website which included the appropriate declarations of involvement and it is unlikely (although not impossible) that a visitor would view the site without having been signposted from one of these materials
- Roche and other partners' logos were visible at the top of the website and further supported by the declaration further down the page.

Given the above Roche strongly refutes the alleged breach of Clause 3.3 in this instance and considers compliance with the undertaking provided in Case AUTH/3676/7/22 has been maintained.

Clause 25.3 of the Code states the following: *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.*

Roche acknowledges that a company logo in isolation is not sufficient in terms of making clear the extent of company involvement. In this instance however, with the Roche logo being present at the outset of the website and further supported by the declaration of company involvement lower down the page Roche would welcome a PMCPA panel ruling on this to provide clarity on the application of the Code in this regard. As such, Roche do not consider a breach of Clause 25.3.

Furthermore, Roche considers high standards were maintained at all times and strongly refutes any breach of Clause 5.1 or Clause 2 in this instance.

Further actions taken since alleged breach of undertaking

Whilst an exercise was conducted prior to signing the undertaking in Case AUTH/3676/7/22, this was to specifically identify situations where Roche had provided support to patient organisations for the development of websites. Given the seriousness of the allegations, Roche would like to share with the PMCPA further actions that have been taken since receipt of this complaint and associated alleged breach of undertaking.

On the 1st May 2024, an audit 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 was initiated to ensure that, where applicable, appropriate declaration(s) of Roche's involvement were in place.

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 25.3 and 5.5 of the ABPI Code.

Given the above, Roche would like to reiterate their statement that high standards were maintained at all times and as such, no breach of clauses 25.3, 3.3 and particularly 5.1 or 2 have occurred in this case as alleged.

Roche hopes the information summarised above provides the PMPCA with confidence to see that all appropriate steps were, and continue to be, taken to ensure compliance with the undertaking in Case AUTH/3676/7/22 and that Case AUTH/3893/4/24 is suitably independent in nature."

PANEL RULING

The complaint related to a lack of declaration of Roche sponsorship from the outset on the website of [named healthcare partnership]. The complainant alleged that Roche had partnered with other organisations to produce this website but that the declaration of sponsorship was only provided right at the end of the webpage.

The Panel considered the involvement of Roche in [named healthcare partnership]. Roche submitted that [named healthcare partnership] was an initiative originally set up by Roche in partnership with the charities [named charities], to raise awareness of the importance of good eye health and campaign to improve the lives of people living with sight loss by enabling more patients to access eye care faster, by maximising capacity in eye health services across the NHS. At the time of the complaint, the partnership was made up of a coalition [named healthcare organisations, patient organisations and charities] and Roche Products Ltd.

The Panel noted, as per Roche's submission, that Roche provided sponsorship in the form of financial support to a medical communications company to act as secretariat for the group and that any materials associated with the campaign would be approved by Roche to ensure compliance with the ABPI Code.

No screenshots of the material involved was provided by the complainant, and so the Panel referred to the screenshot taken by the Case Preparation Manager at the time the complaint was received, and a screenshot provided by Roche, which were identical.

The screenshot showed what appeared to be the homepage of [named healthcare partnership] website. The homepage began with a prominent [named healthcare partnership] banner in the top left corner of the webpage. A small version of the partnership's logo appeared in the top right corner of the webpage, with small logos of the six organisations which made up the partnership at the time, including Roche, underneath. Beneath this was a call-to-action statement, a link to contact your MP, a video regarding the partnership, and links to facts about sight loss and the partnership's policy priorities for eye care.

Just over halfway down the continuously scrolling webpage in small white text on a grey background was the following statement: '[Named healthcare partnership] is a partnership of [named healthcare organisations, patient organisations and charities] and Roche Products Ltd. Roche had funded the activities of the partnership'. This was followed in a separate paragraph by, 'The partnership works collaboratively across the eye care sector to advocate for and champion improvements to patient care and outcomes, so that everyone can access the right care, where and when they need it'. Immediately beneath were six large logos of the organisations that made up the partnership at the time, each within a separate yellow box, and each accompanied by a couple of sentences explaining who they were. The footer of the continuously scrolling webpage stated: 'Roche Products Ltd has funded the activities of [named healthcare partnership]'. This was followed by the address for Roche Products Ltd. The Panel estimated that in total, the homepage covered roughly two pages although on a mobile device it might be more. The Panel did not know what device the complainant had used to access the webpage.

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".

Noting [named healthcare partnership] was a collaboration of organisations, and bearing in mind the established principle of transparency, the Panel considered that it was important that viewers of the website, which likely included patients, be aware of any company involvement and the nature of the support at the outset.

The Panel considered the immediate and overall impression to a reader. The logos of the six organisations which appeared in the top right corner of the webpage were small and the Panel considered that this alone was insufficient to indicate sponsorship and to accurately reflect the nature of the support. Also within the first field of vision on the homepage, was a thumbnail of a video which appeared to be about the partnership. The thumbnail displayed the following: '[Named healthcare partnership] is a partnership of [named patient organisations and charities]...' and '...[named healthcare organisations] and Roche' alongside images of campaign materials in situ on the London Underground.

The Panel considered that the overall length of the homepage was rather short, with only four distinct links present which would redirect a reader to an additional page, and a full declaration regarding Roche's involvement was included if an individual scrolled down twice. The Panel considered that the presence of the Roche logo and the statement about the organisations involved in the partnership, in the first field of vision, meant it would have been clear to the

reader that Roche had been involved in the activity. The reader would then have seen the full declaration of Roche's involvement which included a prominent Roche logo which was the same size as the other organisations involved in the partnership and the wording:

'[Named healthcare partnership] is a partnership of [named healthcare organisations, patient organisations and charities] and Roche Products Ltd. Roche had funded the activities of the partnership. The partnership works collaboratively across the eye care sector to advocate for and champion improvements to patient care and outcomes, so that everyone can access the right care, where and when they need it.'

The Panel acknowledged the importance of transparency that readers are immediately able to understand the extent of the company's involvement and influence and that in this website, the positioning of Roche's declaration of funding statement alone was not prominent enough to achieve this. However, given that Roche's involvement was referenced twice in the first field of vision on the homepage through the logo in the top right and the statement on the video thumbnail, the relatively short length of the homepage, the limited content to take a reader away from the homepage, the repeated references to Roche in at least nine places on the webpage, two of which were declarations of funding, overall the Panel considered it very unlikely that a reader could use the website and not be aware of Roche's involvement.

Having carefully considered all the evidence before it, the Panel determined, on balance, that Roche's involvement was sufficiently clear at the outset of the website and the Panel ruled **no breach of Clause 25.3**.

In alleging a breach of undertaking, the complainant had cited Case AUTH/3676/7/22, which was in relation to the provision of a grant by Roche to support the development of a patient organisation website, where it was alleged that the declaration of support by Roche was not clear from the outset of the website. The Panel, in that case, ruled a breach of the Code because the length of the continuously scrolling homepage was such that the statement of involvement by Roche would not appear until the reader had scrolled down to the bottom of the webpage. The Panel had noted that some readers might not scroll to the bottom of the page and might thereby be left with the impression that there was no industry involvement. This breach of the Code had been upheld by the Appeal Board.

The Panel considered that the current case was similar to Case AUTH/3676/7/22 in that it was regarding the declaration of Roche's support on a third-party website. However, in light of the Panel's reasoning and ruling of no breach of Clause 25.3 above, the Panel did not consider that Roche had breached the undertaking given in Case AUTH/3676/7/22 and ruled **no breach of Clause 3.3**.

Given its ruling of no breaches of Clauses 3.3 and 25.3 above, the Panel considered that there was no evidence that Roche had failed to maintain high standards. The Panel ruled **no breach of Clause 5.1**.

The Panel noted that the supplementary information to Clause 2 included inadequate action leading to a breach of undertaking as an example of an activity likely to be in breach of Clause 2. Having taken into consideration the facts of this case and rulings of no breach of Clauses 3.3, 25.3, and 5.1 above, the Panel ruled **no breach of Clause 2**.

Complaint received 29 April 2024

Case completed 11 June 2025