

CASE AUTH/3891/4/24

COMPLAINANT v ABBVIE

Alleged failure to recertify materials

CASE SUMMARY

This case was in relation to a landing page within the AbbVie Pro website which had not been recertified at an interval of no more than two years as required by the Code.

The outcome under the 2021 Code was:

Breach of Clause 8.5	Using material for more than two years without re-certification
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 from an anonymous, non-contactable complainant who described themselves as a member of the public/media about AbbVie.

COMPLAINT

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

“Complaint: Failure to recertify materials at intervals of no more than two years. The oncology section of the AbbVie site ‘abbviepro.com’ for healthcare professionals displays a certification date of May 2020. The certification code shown is [provided]. Date of preparation: May 2020.”

When writing to AbbVie, the PMCPA asked it to consider the requirements of Clauses 5.1 and 8.5 of the 2021 Code.

ABBVIE’S RESPONSE

The response from AbbVie is reproduced below with some typographical errors corrected:

“Thank you for your letter of April 2024 regarding a complaint received by the PMCPA related to concerns about the recertification of a webpage on AbbVie Pro website.

We take our responsibility for compliance with all applicable laws and regulations including the ABPI Code of Practice (“Code”) very seriously and we continuously endeavor to maintain these high standards in all our activities.

Complaint

An anonymous non-contactable member of the public/media has expressed concern about the recertification of the Oncology Focus webpage available on AbbVie Pro website.

Context

‘AbbVie Pro’ is an AbbVie website that aims to provide educational information to healthcare professionals relating to AbbVie medicines. Members of the public/media do not have access to the Therapeutic Focus Areas of the AbbVie Pro Website unless attested to be an HCP.

The webpage subject of this complaint, “Oncology Focus Area page” [job code provided] is a landing page that includes a link to AbbVie Haematology product information, a link to report adverse events, and a link to contact AbbVie. There is no information about AbbVie medicines or any other information that could be deemed promotional on this landing page.

Response

Whilst responding to this case, AbbVie noted that the “Oncology Focus Area page” [job code provided] expired on 11 May 2023 and was not recertified after this date. AbbVie accepts a breach of clause 8.5 for failure to recertify this material. AbbVie has reviewed the certification process and conducted a full review of the AbbVie Pro Website and can confirm that all promotional information has been certified in the last 2 years. Following this review, we identified this to be an isolated incident caused by human error. AbbVie have strong policies and procedures that govern the review and approval of both promotional and non-promotional materials. All AbbVie Commercial and Medical teams receive annual training on material review and the approval process. Our [named] material approval system, is designed to send automatic emails reminders to users about upcoming expiration dates and the status of materials. In addition, the AbbVie commercial and medical teams run quarterly trackers to support the management and re-certification of materials. We believe this incident does not signify a systemic problem within our organisation.

Corrective and Preventative Actions:

On receipt of this complaint, the Oncology Focus landing page was immediately recertified.

To prevent any further incidents, AbbVie has conducted the following activities:

- We reviewed internally all promotional materials on the AbbVie Pro website to ensure they are appropriately certified in line with Code requirements.

- We re-trained our Commercial and Medical teams to ensure similar oversights do not occur again in the future.
- We prepared and delivered a detailed presentation of the case at the Affiliate Compliance Insights Forum, an AbbVie forum comprising of key members of the leadership teams, that meets on a quarterly basis to discuss key developments in Code compliance and ensure the high standards of the Code are understood and followed consistently across all our business lines.

Clause 5.1 High Standards must be maintained at all times.

We believe AbbVie implemented the appropriate corrective and preventative actions to effectively address this incident in a timely manner and ensure similar incidents do not occur again in the future. The failure to recertify the Oncology landing page (non-promotional webpage) is an isolated incident caused by human error. We confirm that all promotional information on AbbVie Pro has been certified in the last 2 years and we have a robust process in place (as described above) that ensures content hosted on the AbbVie Pro website is regularly reviewed and re-certified in a timely manner, in line with the Code requirements. We believe AbbVie has maintained high standards and clause 5.1 was not breached.

Summary

AbbVie takes its responsibility for compliance with the ABPI Code very seriously as we continuously endeavour to maintain high standards in all our activities. We are confident that our policies and processes are robust, and this was an isolated occurrence caused by human error. We have taken immediate comprehensive action to prevent similar issues from re-occurring in the future.

We also believe this case is a good example of matter that could be resolved in an efficient and resource-sparing way once the new abridged case management process is introduced in the PMCPA Constitution & Procedure, and we encourage the PMCPA to prioritise the enactment of the proposed reforms.

We remain available to answer any further questions you may have.”

PANEL RULING

The complaint related to a landing page (“Oncology Focus Area page” [job code]) within the AbbVie Pro website.

The Panel noted that the landing page included a statement near the top that this website was intended for UK Healthcare Professionals only. The landing page comprised a bold heading of ‘Oncology Focus Areas’ with a link to ‘Haematology’ immediately underneath. The top-right of the webpage included a link to report an adverse event and another link to “other therapy areas”. The bottom of the webpage included a grey banner which included, among other things, a link to another therapy area of Immunology and a link to report an adverse event. The grey banner, which appeared to represent the footer of the landing page, had a different job code to the landing page at issue. There was no promotional information on the landing page.

The Panel noted that Clause 8.5 required, among other things, that material which is still in use must be recertified at intervals of no more than two years to ensure that it continued to conform with the relevant regulations relating to advertising and the Code. The Panel considered that a robust certification procedure underpinned self-regulation.

The Panel noted AbbVie's submission that the "Oncology Focus Area page" expired on 11 May 2023 and was not recertified after this date. The Panel ruled **a breach of Clause 8.5** as acknowledged by AbbVie.

The Panel took account of AbbVie's submission that the webpage at issue was immediately recertified following receipt of this complaint, that AbbVie reviewed the certification process, and conducted a full review of the AbbVie Pro Website, confirming that all promotional information had been certified in the last 2 years. Further, AbbVie asserted that following its investigation it identified this to be an isolated incident caused by human error and did not signify a systemic compliance issue. The Panel also considered that AbbVie took corrective and preventative actions to re-train its Commercial and Medical teams and delivered a detailed presentation of the case at its Affiliate Compliance Insights Forum. The Panel considered that in the particular circumstances of this case, including that the allegation was limited to the landing page at issue, the matter was adequately covered by its ruling of a breach of the Code above, and ruled **no breach of Clause 5.1**.

Complaint received 24 April 2024

Case completed 10 March 2025