

CASE AUTH/3852/10/2023

VOLUNTARY ADMISSION BY ABBVIE

Uncertified promotional material

CASE SUMMARY

This case was in relation to a voluntary admission made by AbbVie regarding an uncertified registration webpage for health professionals.

The outcome under the 2021 Code was:

Breach of Clause 5.1	Failing to maintain high standards
Breach of Clause 8.1	Failing to certify promotional material

**This summary is not intended to be read in isolation.
For full details, please see the full case report below.**

FULL CASE REPORT

A voluntary admission was received from AbbVie about uncertified promotional material.

As Paragraph 5.6 of the Constitution and Procedure required the Director to treat a voluntary admission as a complaint the matter was taken up with AbbVie.

COMPLAINT

Whilst responding to Case AUTH/3834/10/23, AbbVie noted that the material at issue in that case had not been correctly certified. AbbVie therefore made a voluntary admission, as outlined below.

The voluntary admission wording is reproduced below:

“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.

Background:

The complainant [in Case AUTH/3834/10/23] has referred to an AbbVie registration webpage [provided]. AbbVie hosted this registration webpage for UK healthcare professionals (HCPs) with the primary purpose of allowing HCPs to register their contact details in order to access on-demand content included in the AbbVie promotional medical educational series ‘Clear Horizons’.

'Clear Horizons' is a series that aims to provide educational product related, and therefore promotional information relating to AbbVie medicines within the dermatology therapy area. This registration webpage was accessible via a direct link on the AbbVie promotional website addressed to UK HCPs, specifically via the 'Expert Perspectives' page [provided] on [weblink provided].

Voluntary Admission

Whilst responding to this case [Case AUTH/3834/10/23], AbbVie noted that the material in question had not been correctly certified. AbbVie engaged a third-party agency to develop the registration webpage for HCPs. The agency uploaded the registration webpage [provided] to the internal approval platform, and this material was certified by AbbVie. The third-party agency directly accessed this internal approval platform to obtain the certified copy which should have been used for the hosted registration webpage.

The third-party agency then inadvertently uploaded an incorrect version of the registration webpage with the same job code as the final certified material. The difference between the 2 pages was that the certified version had a checkbox list of 3 of the episodes of 'Clear Horizons' that HCPs could register for and the unapproved version had only the episode 3 listed. Therefore, the registration webpage flagged by the complainant, was not the correctly certified version and a certificate is unavailable.

AbbVie has reviewed the certification process related to this page and has identified this to be an isolated incident. To prevent any further incidents, AbbVie has conducted further training with the relevant teams including our partner agencies to mitigate any future issues. AbbVie would therefore like to make a voluntary admission of breach of clause 8.1: Failure to certify material in its final form.

Summary

In addition, AbbVie are making a voluntary admission of a breach of clause 8.1.

AbbVie takes its responsibility for compliance with the ABPI Code very seriously as we continuously endeavour to maintain high standards in all our activities."

ABBVIE'S RESPONSE

The response from AbbVie is reproduced below:

"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.

Background:

'Clear Horizons' is a series that aims to provide educational product related, and therefore promotional information relating to AbbVie medicines within the dermatology therapy area.

The registration webpage was intended for access by UK HCPs only, who could reach this registration webpage through a link hosted on the 'Expert Perspectives' page within the AbbVie promotional website [weblink provided]. This promotional website contained the necessary and obligatory attestation ramp to ensure only UK HCPs would access the promotional content.

Voluntary Admission: Breach of Clause 8.1

Whilst responding to Case 3834-10-7-23, AbbVie noted that the 'Clear Horizons' registration website had not been correctly certified. AbbVie engaged a third-party agency to develop the registration webpage for HCPs. The agency uploaded the registration webpage to the internal approval platform, and this material was certified by AbbVie. The third-party agency directly accessed this internal approval platform to obtain the certified copy which should have been used for the hosted registration webpage.

The third-party agency then inadvertently uploaded an incorrect version of the registration webpage with the same job code as the final certified material. The difference between the 2 pages was that the certified version had a checkbox list of 3 of the episodes of 'Clear Horizons' that HCPs could register for, and the unapproved version had only the episode 3 listed. Therefore, the registration webpage flagged by the complainant was not the correctly certified version and a certificate is unavailable.

ABPI Code Training to Third Party Agency

AbbVie has a specific SOP that outlines the training requirements of the ABPI Code of Practice for AbbVie UK and third-party agents. Details of this can be found in Procedure for ABPI Code Training, Section 2.2 [provided].

As outlined in the email from the third-party agency [provided], the agency had been appropriately trained on the ABPI code at the time. Initially, this was provided directly by AbbVie and in 2021 this transitioned to an independent ABPI expert consultant, [named consultant].

Corrective and Preventative Actions:

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

- Further training with the relevant teams including our partner agencies to mitigate any future issues. Please refer to [email exchange provided] for evidence of internal and external training.
- Detailed presentations of the facts in 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.

AbbVie has reviewed the certification process related to this page and has 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. We believe this incident does not signify a systemic problem within our organisation. More information on our material review and approval process can be found in AbbVie's SOP [provided].

Our contracts with third parties deal comprehensively with our policies and procedures. This includes the use and withdrawal of materials both during and after the contracted period. Our Master Services Agreement contains a section detailing the responsibilities of the third-party agent, including the requirement to complete AbbVie Training and adhere to AbbVie policies and procedures. This is outlined in – Master Services Agreement with Agency – Principal and Account Director responsibilities [provided].

We believe the company 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.

Considering all the above, we believe AbbVie has maintained high standards and clause 5.1 was not breached.

AbbVie takes its responsibility for compliance with the ABPI Code very seriously as we continuously endeavour to maintain high standards in all our activities.”

PANEL RULING

The Panel noted AbbVie had made a voluntary admission in relation to a 'Clear Horizons' webinar registration webpage on an educational and promotional website directed at health professionals.

Clause 8.1 of the 2021 Code stated, amongst other things, that promotional material must not be issued unless its final form, to which no subsequent amendments will be made, has been certified by one person on behalf of the company in the manner provided for by this clause, subject to the provisions of the supplementary information to this clause where relevant. This person must be a registered medical practitioner, or a pharmacist registered in the UK.

In relation to the webinar registration page, the Panel noted AbbVie's voluntary admission that the material published on the website differed in content to that which had been certified. The Panel noted that the most immediately apparent difference related to the addition of a new section in the left-hand column which included a checkbox list of three webcasts that health professionals could register for access to. The addition of this section moved the 'Overview' section from the left-hand to the right-hand column. The Panel noted other minor changes, such as the placement of a checkbox and minor wording changes (for example from "will focus on" to "focuses on"). Noting the differences between the webpage that was certified and the webpage that was published, the Panel ruled a **breach of Clause 8.1**, as acknowledged by AbbVie.

The Panel noted AbbVie's submission that a third-party agency had published the uncertified material in error without AbbVie's knowledge. The Panel also noted AbbVie's submission that it had taken preventative measures, such as conducting training to mitigate further similar issues and presenting detailed facts of the case to members of the senior leadership teams.

The Panel noted Clause 1.24 which states that companies are responsible for the acts and omissions of their third parties which come within the scope of the Code, even if they act contrary to the instructions which they have been given.

In the Panel's view, the certification process underpinned self-regulation. It was concerning that despite the third-party agency completing training it appeared that, in this instance, it had failed to adhere to AbbVie's standard operating procedure setting out the process for promotional and non-promotional material review and approval. The Panel noted that AbbVie's "Process of Promotional & Non Promotional Material Review and Approval" stated that "No material should be used prior to confirmation that the status is Approved for Distribution, with the exception of time critical press release material."

It was also concerning that the uncertified material only came to AbbVie's attention further to receipt of a complaint to the PMCPA (Case AUTH 3834/10/23) despite a statement in AbbVie's standard operating procedure that once a material had been "Approved for Distribution" an AbbVie employee or contractor was responsible for checking the live published website against the approved webpages.

The Panel noted from AbbVie's submission that following identification of this error, AbbVie had promptly required that relevant staff and the agency completed retraining. Nonetheless, in the Panel's view, AbbVie had been badly let down by its agency and high standards had not been maintained. The Panel, therefore, ruled a **breach of Clause 5.1**.

Complaint received **25 October 2023**

Case completed **6 September 2024**