

CASE AUTH/3744/2/23

COMPLAINANT v BOEHRINGER INGELHEIM

Error with prescribing information link on a promotional website

CASE SUMMARY

This case was in relation to a technical error with the link to the Pradaxa and Praxbind prescribing information on a promotional website, 'Chronic Conditions'.

The Panel ruled a breach of the following Clauses of the 2021 Code because the promotional webpage in question did not include a functioning link to prescribing information from 7 February 2023 to 28 February 2023 and because of the Panel's concerns that the complainant had raised this issue with Boehringer Ingelheim directly via the medical information mailbox but the email had been treated as spam and deleted without being actioned:

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|------------------------------|---|
| Breach of Clause 5.1 | Failing to maintain high standards |
| Breach of Clause 12.1 | Failing to include up-to-date prescribing information |
| Breach of Clause 12.4 | Failing to include prescribing information in digital 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 complaint about Boehringer Ingelheim Limited, relating to missing prescribing information on a website, was received from an anonymous, contactable complainant.

COMPLAINT

The complainant stated they had sent an email to Boehringer Ingelheim on 13 February 2023 about their website, and 'after checking today (23 February 2023) they had not amended their website – there remained a missing Prescribing Information'. The complainant hoped Boehringer Ingelheim might address this if the matter was taken up by the Authority.

The complainant included a copy of their email to Boehringer Ingelheim which stated: 'On the website [webpage link], this link doesn't work: [prescribing information link] – the following appears'. The complainant included a screenshot of the error message they had received.

The complainant stated in their email to Boehringer Ingelheim: 'All the other links work so I do not think that this is a configuration issue on my side. If this is the link used for all the promotional items, then you might consider addressing it as a matter of some urgency'.

When writing to Boehringer Ingelheim, the Authority asked it to consider the requirements of Clauses 5.1, 12.1 and 12.4 of the 2021 Code.

RESPONSE

Boehringer Ingelheim stated that it took compliance with the Code very seriously. Boehringer Ingelheim UK stated it had steps in place to ensure robust procedures continued to underpin all of its activities and that it embraced a compliance culture that was fully embedded into the business with the support of senior leadership and the Ethics & Compliance department.

As per the requirements of the Code, Boehringer Ingelheim UK stated that it had a Standing Operating Procedure (SOP) in place for Materials Approval, which ensured that all materials were reviewed and certified for accuracy and compliance with Code requirements prior to being made available. Boehringer Ingelheim UK also ensured that all relevant staff completed SOP training, and that training emphasised the requirements for digital materials; in addition, other relevant training such as quarterly Code case review was expected for all staff involved in materials development and approval.

The nature of the complaint was a technical error with the link to the Pradaxa and Praxbind Prescribing Information for Great Britain on a third-party website. Boehringer Ingelheim outlined its response below:

- Boehringer Ingelheim UK acknowledged breaches of Clauses 12.1 and 12.4, as the single click link to prescribing information was not functional from 7 February 2023 until it corrected this by deactivating the webpage in question within 24 hours of receipt of the Authority's letter (effective 28 February 2023).
- An internal investigation revealed this was due to human error and not according to Boehringer Ingelheim's internal SOP.
- Due to the expediency with which Boehringer Ingelheim responded to correct this error and the fact that it had put in place processes to prevent further such errors occurring, Boehringer Ingelheim UK refuted a breach of Clause 5.1.

Boehringer Ingelheim stated that until receipt of the Authority's letter dated 24 February 2023, the brand team responsible for the website and material in question were unaware that the complainant had emailed the Boehringer Ingelheim UKIE Medical Information mailbox on Monday, 13 February 2023 informing Boehringer Ingelheim that they had identified a technical error with the link to the Pradaxa and Praxbind Prescribing Information for Great Britain from the Chronic Conditions website.

Boehringer Ingelheim immediately launched an internal investigation as to why the original complaint had not been acknowledged and forwarded it on to the relevant compliance and medical colleagues to investigate and address.

The investigation revealed that due to the nature of the email address, the subject line and the lack of any email signature indicating legitimacy, the email had been incorrectly flagged as a spam/phishing email and had been inadvertently deleted by the assistant monitoring the mailbox on 13 February 2023 without actioning the email or forwarding it on to the relevant colleagues to investigate and address.

Boehringer Ingelheim was concerned that such an email flagging an issue with its materials had been handled in this way and so had put in place additional training and checks on the Medical Information mailbox to ensure that a similar situation did not happen again. Boehringer Ingelheim stated it was committed to maintaining high standards in how it handled customer enquiries.

Following receipt of the Authority's letter outside of business hours on Friday, 24 February 2023, on Monday, 27 February 2023 (the next working day) the brand team contacted the third party responsible for managing the Chronic Conditions website to request that the webpage in question be taken down with immediate effect whilst an investigation was made into the technical error. On 28 February 2023, the third party confirmed that the webpage was deactivated and this was double-checked by the brand team.

An internal investigation was immediately initiated into when the technical error with the link to the Pradaxa and Praxbind Prescribing Information for Great Britain occurred. The link was working as intended at the time of certification of the webpage (10 May 2022). In January 2023 an internal decision was made to no longer actively promote Pradaxa and to therefore retire related promotional materials. This included the Prescribing Information and the Chronic Conditions webpage which were retired by Boehringer Ingelheim UK on 7 February. Unfortunately, due to human error, the third party was not informed of the withdrawal which was the cause of the broken link from the Chronic Conditions webpage. Boehringer Ingelheim stated they had conducted an additional audit of third-party brand materials to ensure there were no other similar instances and Boehringer Ingelheim apologised for this human error.

Boehringer Ingelheim stated that the webpage in question was a promotional website hosted by a third party on their Chronic Conditions website. The purpose of the webpage was to allow healthcare professionals who had registered to attend the Boehringer Ingelheim UK-sponsored symposium as part of the 'Chronic Conditions Month 2022: The Big Debate' in May 2022 to access relevant resources including an on-demand video of the Boehringer Ingelheim UK-sponsored symposium.

Boehringer Ingelheim responded to the alleged breaches as follows:

Clause 12.1 Prescribing Information must be provided in all promotional material for a medicine

Clause 12.4 In digital material the prescribing information may be provided by way of a clear and prominent direct single click link

Clause 5.1 High standards must be maintained at all times.

Boehringer Ingelheim stated at the time the promotional website in question was certified (10 May 2022) and until 7 February 2023, the clear and prominent direct single click link to prescribing information functioned as intended.

Boehringer Ingelheim UK acknowledged that at the time the complainant viewed the website in question the single click link to prescribing information was not functional, as required by Clause 12.4 of the Code. Boehringer Ingelheim UK acknowledged that this was an oversight on its behalf which did not meet the requirements of Clause 12.1 and 12.4 of the Code. Boehringer Ingelheim immediately informed the third party who took down the webpage within 24 hours,

launched an internal investigation and conducted an additional audit of third-party brand materials to ensure there were no other similar instances, and had put additional processes in place to ensure that such links on third party websites were more regularly checked. While Boehringer Ingelheim acknowledged that from 7 February 2023 the single click link to prescribing information was not functional, Boehringer Ingelheim did not believe that it had failed to maintain high standards because of its rapid corrective and preventative actions taken and so refuted a breach of Clause 5.1.

PANEL RULING

The complaint was in relation to a technical error with the link to the Pradaxa and Praxbind prescribing information on a promotional website, 'Chronic Conditions'. The Panel noted the complainant had attempted to access the prescribing information but had failed to do so; the complainant had emailed Boehringer Ingelheim to address this issue as a matter of urgency on 13 February. Due to no action being taken, a complaint was submitted to the Authority ten days later.

The Panel noted Boehringer Ingelheim's submission that it had decided to no longer actively promote Pradaxa and therefore retired its promotional materials on 7 February; the website was managed by a third party who was not informed when the webpage in question and the prescribing information were both retired from use. As such, the webpage remained live but the link to prescribing information was no longer functional from 7 February 2023 to 28 February 2023.

Clause 12.1 required that, amongst other things, prescribing information must be provided in promotional material; Clause 12.4 stated in digital material, the prescribing information 'may be provided either:

- by inclusion in the digital material itself, or
- by way of a clear, and prominent, direct, single click link.'

The Panel noted the promotional webpage was live at the time of the complaint; due to the absence of a functioning link to the prescribing information, the Panel ruled **breaches of Clause 12.1 and Clause 12.4**, as acknowledged by Boehringer Ingelheim.

The Panel noted the complainant's submission that they had contacted Boehringer Ingelheim directly about this issue on 13 February 2023 but had received no response. The Panel noted Boehringer Ingelheim's submission that due to the nature of the complainant's email address, the subject line and the lack of any email signature indicating legitimacy, the email had been flagged as a spam/phishing email and had been inadvertently deleted by the assistant monitoring the mailbox. The Panel noted the contents and subject line of the email, 'Technical error with your PI link', and was concerned that such an email sent to the medical information mailbox had been treated as spam and deleted.

The Panel, noting its comments above and the lack of prescribing information on the promotional webpage, considered Boehringer Ingelheim had failed to maintain high standards and ruled **a breach of Clause 5.1**.

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Complaint received **23 February 2023**

Case completed **19 January 2024**