CASE AUTH/3672/6/22

COMPLAINANT v PFIZER

Incorrect colour of the black triangle and reference to the Medicines and Healthcare products Regulatory Agency (MHRA) within a press release

CASE SUMMARY

This case was in relation to a press release in the media section on the Pfizer UK website.

The Panel ruled a breach of the following Clause of the 2021 Code because in its view, the black triangle was a well-known and established symbol and its appropriate use was an important part of medicines regulation and irrespective of the fact that its presence in a non-promotional press release was not a Code requirement, the failure to publish it in the correct colour within the press release was, at the very least, inappropriate and might potentially cause confusion:

Breach of Clause 5.1	**Failing to maintain high standards**

The Panel ruled no breach of the following Clause of the 2021 Code because the complainant had not established that the press release in question was promotional and therefore Clause 15.2 did not apply:

No Breach of Clause 15.2	**Requirement that promotional material must not include any reference to the Commission on Human Medicines, the Medicines and Healthcare products Regulatory Agency (MHRA) or the licensing authority, unless this is specifically required by the licensing authority**

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

FULL CASE REPORT

A contactable complainant who described themself as a concerned UK health professional complained about a press release in the media section on the Pfizer UK website.

The press release dated 31 December was titled 'PFIZER'S NOVEL COVID-19 ORAL ANTIVIRAL TREATMENT AUTHORISED FOR SUPPLY AND USE BY THE MHRA' and included the header 'MEDIA / Pfizer's Novel COVID-19 Oral Antiviral Treatment Authorised For Supply And Use By The MHRA'. Below the title and the date were three bullet points, the first being Medicines and Healthcare products Regulatory Agency (MHRA) grants GB conditional marketing authorisation for the supply and use of PAXLOVID▼(PF-07321332 tablets and

ritonavir tablets) in adults who do not require supplemental oxygen and are at increased risk for progression to severe COVID-19.

COMPLAINT

The complainant provided a link to, and a partial screenshot of, the press release and alleged that the black triangle, which appeared after Paxlovid (nirmatrelvir, ritonavir) within the press release, was dark grey, not black as required and there were several mentions of the MHRA in relation to the product in the press release which appeared to be in breach of Clause 15.2.

When writing to Pfizer, the Authority asked it to consider the requirements of Clause 15.2 of the 2021 Code as cited by the complainant and Clause 5.1 in relation to the allegation about the black triangle.

RESPONSE

Pfizer stated that it took its commitment to working within the framework of the ABPI Code very seriously and had therefore thoroughly investigated the concerns raised by the complainant.

Background Information

Pfizer explained that the material that was the subject of the complaint was a copy of a press release issued by Pfizer that had been approved for publication on its corporate website, www.pfizer.co.uk.

The subject of the press release was the news of the MHRA's decision to grant conditional marketing authorisation (cMA) in Great Britain for Paxlovid, a Pfizer medicine for the treatment of COVID-19 in adults who did not require supplemental oxygen and who were at increased risk for progression to severe disease. Given the news in the UK at the time was heavily focused on rising COVID-19 cases, and associated pressures on the NHS, the company deemed the content to be newsworthy. The information was released to the UK media on 31 December 2021, the same day as confirmation was received about the cMA.

As well as sharing the press release with UK media via email, the press release was also uploaded to the media section of Pfizer's corporate website, www.pfizer.co.uk/media. The intended audience of this statement was UK media.

The press release was directed only to the media and was not promotional. Pfizer did not drive any health professionals or patients towards the press release on the website and, thus, the requirement for black triangle did not apply. It was included for transparency and completeness.

Regarding Clause 5.1

Pfizer stated that at the time of approval, the Pfizer signatory viewed the colour of the triangle as black. After publication to the website, it appeared that the standard text colour scheme was incorrectly auto-attributed to the black triangle symbol changing the intended black colour to a dark grey. Pfizer accepted that, in choosing to include the black triangle on this statement, it should have been presented as pure black. Pfizer accepted that high standards were not maintained with the webpage and accepted a breach of Clause 5.1.

Regarding Clause 15.2

Pfizer stated that with regard to the mentions of the MHRA in the press release, it strongly refuted a breach of Clause 15.2. Clause 15.2 prohibited reference to the licencing authority in promotional material. As the material was a press-release, non-promotional and not directed to health professionals in the UK, this clause did not apply.

Pfizer submitted a colour copy of the material at issue, a copy of the certificate approving the materials and a copy of the current Paxlovid summary of product characteristics (SPC) and confirmed the name and qualifications of the Pfizer signatory that approved the press release.

PANEL RULING

The Panel noted that the Code stated that when required by the licensing authority, all promotional material must clearly show the inverted black equilateral triangle to denote that additional monitoring was required in relation to adverse reactions and that the symbol should always be black.

The Panel noted Pfizer's submission that the press release was non-promotional and not directed to health professionals in the UK. The Panel noted that the inclusion of the inverted black triangle on press releases, which were non-promotional, was not a Code requirement.

The Panel noted Pfizer's submission that at the time of approval, the Pfizer signatory viewed the colour of the triangle as black. After publication to the website, it appeared that the standard text colour scheme was incorrectly auto-attributed to the black triangle symbol changing the intended black colour to a dark grey.

In the Panel's view, the black triangle was a well-known and established symbol. Its appropriate use was an important part of medicines regulation. Thus, in the Panel's view, irrespective of the fact that its presence was not a Code requirement, the failure to publish the triangle in the correct colour within the press release was, at the very least, inappropriate and might potentially cause confusion. A **breach of Clause 5.1** was ruled as acknowledged by Pfizer.

Clause 15.2 stated that 'Promotional material must not include any reference to the Commission on Human Medicines, the Medicines and Healthcare products Regulatory Agency (MHRA) or the licensing authority, unless this is specifically required by the licensing authority'. The Panel noted that the complainant had not established that the press release in question was promotional and thus Clause 15.2 did not apply and **no breach of Clause 15.2** was ruled.

Complaint received **29 June 2022**

Case completed **30 June 2023**