CASE/0424/01/25 ***NO BREACH OF THE CODE***

COMPLAINANT v NEURAXPHARM

Allegations regarding a press release

CASE SUMMARY

This complaint was in relation to an article published on a global pharma news and resources website. The article was based on a press release for ublituximab issued by Neuraxpharm.

The complainant alleged that the press release was misleading as it claimed the *"most important adverse event reactions are infusion related reactions and infections",* in patients treated with ublituximab, and omitted the inclusion of neutropenia, which had been proven to be a serious and important side effect of ublituximab in studies.

The outcome under the 2024 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 5.1	**Requirement to maintain high standards at all times**
No Breach of Clause 6.1	**Requirement that information, claims and comparisons must not be misleading**

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 about Neuraxpharm from an anonymous, contactable complainant, who described themselves as a health professional. The complainant later became non-contactable.

COMPLAINT

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

> "A press release claims that ublituximab's most important adverse event reactions are infusion related reactions and infections [link provided]. The studies for ublituximab have proven that neutropenia is a serious side effect of ublituximab. There was [a] decrease in neutrophils compared to teriflunomide in studies. Neutropenia is also listed within the ublituximab SmPC as a common blood disorder side effect. Neutropenia can be fatal. The press release is misleading as neutropenia is a[n] important side effect. The press

releases breaches clause 6.1 and 5.1. As neutropenia is a patient safety risk press release breaches Clause 2."

When writing to Neuraxpharm the PMCPA asked it to consider the requirements of Clauses 6.1, 5.1 and 2 of the 2024 Code.

NEURAXPHARM'S RESPONSE

The response from Neuraxpharm is reproduced below:

"Further to your letter of 8 January 2025, please find below the response from Neuraxpharm relating to each alleged Clause breach (5.1, 6.1 and 2) of the 2024 ABPI Code of Practice.

The complainant alleges that a press release is misleading as a potential undesirable effect for ublituximab, neutropenia, has been omitted. The evidence provided by the complainant is an article published on a third-party website (5 Dec 2024) which is based on a Neuraxpharm press release which was examined by a medical signatory on 5 Dec 2024.

Neuraxpharm refute all allegations.

Press releases and liability for articles

Medical journalists are sent press releases that inform them of news and newsworthy topics that are relevant to their readers. Therefore, press releases are designed to share awareness of the most important developments and latest news - such as NICE approval. They are NOT intended to be used as complete prescribing information nor are they disseminated to individual health professionals for this purpose. Media outlets and journalists are free to write whatever they deem appropriate based on press releases without a pharmaceutical company being liable for their final article.

Factual and balanced non-promotional information

The article in question is based on the enclosed press release and whilst neutropenia has not been specifically called out as a common adverse event in the press release (the subject of which relates solely to NICE approval and not safety issues/data), the press release is based on the SPC.

It is unreasonable to consider press releases should be required to be as comprehensive as the product SPC, promotional material or prescribing information. Detailed information on ALL aspects of the medicine and appropriate prescribing can be found in the link to the SPC which was provided in the press release. As is customary with all press releases, further information including the SPC link is found at the end.

Neutropenia as an adverse event

The press release quotes directly from the SPC, as follows: " *The most important and frequently reported adverse reactions are IRRs (45.3%) and infections (55.8%)."* Please note that the complainant has misquoted this as "*the most important…".* Thereby, omitting the mention of the word "frequently", which is an integral part of the SPC.

In terms of substantiation of this information, the complainant has incorrectly stated that there was a higher frequency of neutropenia in the ublituximab group (*"there was a decrease in neutrophils compared to teriflunomide").* However, the SPC states clearly that "In active-controlled RMS trials, a **decrease** in neutrophils counts < LLN was observed in 15% of ublituximab patients compared with 22% of patients treated with teriflunomide" (emphasis added).

Information did not mislead the target audience

It is reasonable for a press release intended for the media about a subject like NICE approval to be non-promotional and balanced in terms of providing top-line efficacy and safety information and a link to further detailed information if required. It cannot be compared to providing detailed information to busy HCPs who need to make fully informed prescribing decisions for individual patients.

For a press release about NICE approval to be alleged or ruled as misleading for omitting an adverse event, would suggest that Neuraxpharm had directly or indirectly stated or implied in the press release that the medicine had NO other adverse events or that neutropenia is NOT an associated adverse event - neither of which occurred.

Neuraxpharm therefore refute all allegations that relate to Clauses 6.1 and therefore 5.1 and 2.

We hope that this information is clear and do let us know if you need anything further."

PANEL RULING

This case was in relation to a press release for ublituximab issued by Neuraxpharm. The complainant alleged that the press release was misleading as it claimed the *"most important adverse event reactions are infusion related reactions and infections",* when neutropenia had been proven to be a serious and important side effect of ublituximab in studies.

The link provided by the complainant was to an article available on a global pharma news and resources website. The Panel noted that when complaints were received about information that an independent journalist had published in the press, its rulings were made upon the material released by the company that might have prompted the article, and not the article itself. The tone, language and content of any relevant press release(s) provided by the company, and any interactions the company had with the journalist, would be important considerations in this regard. For this reason, the Panel made its rulings based on the original press release, as submitted by Neuraxpharm.

The press release, published on 5 December 2024, was titled "NICE Recommends ublituximab (BRIUMVI®▼) as an Option for Treating Relapsing-Remitting Multiple Sclerosis (RRMS)" and

was directed to press in London, UK, Barcelona, Spain and Düsseldorf, Germany. The press release described the positive NICE recommendation for ublituximab (150 mg concentrate for solution for infusion) in the treatment of relapsing-remitting multiple sclerosis (RRMS) and included further information on the properties of the medicine, succinct statements regarding the efficacy results seen in clinical studies and adverse reactions reported, quotes from two senior employees of Neuraxpharm and a statement regarding a commercial agreement. Following the main content of the press release were sections headed: "About ublituximab", "About Multiple Sclerosis" and "About the Neuraxpharm Group".

The Panel considered that whether information on side effects needed to be highlighted within a press release depended on a consideration of all of the circumstances, including the nature of the side effects and the content of the press release.

The Panel noted that the third paragraph of the press release stated, among other things, *"Results of clinical studies show that ublituximab significantly suppressed relapses and sub-clinical disease activity measured by MRI compared with oral teriflunomide 14 mg. The most important and frequently reported adverse reactions are infusion related reactions and infections"*. This statement was faithfully reproduced in the article provided by the complainant in support of their complaint.

Neuraxpharm submitted that the complainant had misquoted the statement at issue in their complaint and had omitted mention of the term "frequently". Neuraxpharm further submitted that the press release quoted directly from the Summary of Product Characteristics (SPC) for Briumvi and it was unreasonable that press releases should be as comprehensive as the product SPC, promotional material or prescribing information.

The Briumvi SPC, Section 4.8, Undesirable effects, Summary of the safety profile, stated, *"The most important and frequently reported adverse reactions are IRRs [infusion-related reactions] (45.3%) and infections (55.8%)".* Upper respiratory tract infections, respiratory tract infections and infusion-related reactions were listed as very common adverse reactions, whereas herpes virus infections, lower respiratory tract infections, neutropenia and pain in extremity were listed as common side effects. In a subsection titled 'Neutrophil counts', the SPC stated: *"In active-controlled RMS trials, a decrease in neutrophils counts <LNN was observed in 15% of ublituximab patients compared with 22% of patients treated with teriflunomide"*. The Panel noted that Section 4.4, Special warnings and precautions for use, included special warnings in relation to infusion-related reactions and infection; there were no special warnings or precautions for use in relation to neutrophil count.

In the Panel's view, the statement at issue in the press release, "*The most important and frequently reported adverse reactions are infusion-related reactions and infections*" accurately reflected the SPC for Briumvi, that the most important *and* frequently reported adverse reactions were IRRs and infections.

The Panel considered the impression created by the press release. In the Panel's view, the press release did not create the impression that IRRs and infections were the only important or frequently reported adverse reactions following treatment with ublituximab. The Panel noted that the press release contained two links to the full SPC for Briumvi where a reader could access further information regarding adverse reactions, one within the "About ublituximab" section and the other within the reference list. However, only the link in the reference list appeared in the published article.

The Panel took into account the intent of the press release which was to highlight the positive NICE recommendation of ublituximab and that it was not intended to be a comprehensive prescribing guide. Within this context, and based on its comments above, the Panel considered that the complainant had not established why the omission of neutropenia as a side effect of Briumvi was misleading. The Panel, therefore, ruled **no breach of clause 6.1**.

Given its rulings of no breaches of the Code above, and without any further allegations or evidence, the Panel considered that the complainant had not established that Neuraxpharm had failed to maintain high standards or brought discredit upon, or reduced confidence in, the pharmaceutical industry. The Panel ruled **no breach of Clauses 5.1 and 2**.

Complaint received **7 January 2025**

Case completed **20 November 2025**