CASE/0533/04/25 ***NO BREACH OF THE CODE***

COMPLAINANT v NEURAXPHARM

Allegations about a press release for Briumvi

CASE SUMMARY

This case was in relation to a press release for Briumvi (ublituximab) issued by Neuraxpharm. The complainant alleged that the press release was misleading as it implied that Briumvi is always given over a one-hour duration for all infusions and failed to provide information that the first infusion is administered over four hours.

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 that companies must maintain high standards at all times**
No Breach of Clause 6.1	**Requirement that information/ claims/ comparisons must not be misleading**
No Breach of Clause 6.2	**Requirement that information/ claims/ comparisons must be capable of substantiation**

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 UK Ltd, 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 for Briumvi is misleading. In the press release it is claimed that Briumvi can be administered in a one-hour infusion twice a year following the starting dose. This claim implies Briumvi is always given over a one-hour duration for all infusions. The claim fails to provide information that the first infusion is administered over four hours. This information is not provided later in the press release either. It is concerning that the press release has not provided full information for the healthcare audience on the total duration times of all infusions. The press release is not balanced

and misguides clinicans [clinicians]. The press release is – [URL provided] Breach of Clause 6.1, 6.2, 5.1 and 2."

When writing to Neuraxpharm, the PMCPA asked it to consider the requirements of Clauses 6.1, 6.2, 5.1 and 2 of the 2024 Code.

NEURAXPHARM'S RESPONSE

The response from Neuraxpharm is reproduced below:

"Further to your letter of 7 April 2025, please find below the response from Neuraxpharm relating to each alleged Clause breach (5.1, 6.1, 6.2 and 2) of the 2024 ABPI Code of Practice.

The complainant alleges that a press release misguides clinicians and is not balanced as it implies that Briumvi is always given over a one-hour duration for all infusions, failing to provide information that the first infusion is administered over four hours.

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.

The particulars of the posology and administration of Briumvi are detailed in the SPC, which the press release refers to. To provide the necessary context to this response, please see the table below (from the SPC) which describes how the dosing for Briumvi is scheduled:

[Screenshot of 'Dose and schedule' table from Briumvi SPC]

As described above, the starting dose of Briumvi is given as a 150mg intravenous (IV) infusion over four hours. Thereafter, the second dose is given 2 weeks later as a 450mg IV infusion over one hour. Subsequent doses are then administered every 24 weeks (from the starting dose), over one hour.

The relevant statement in the press release regarding dosing, reads as follows:

'*It is the first and only anti-CD20 monoclonal antibody approved in the United States (US) and European Union (EU) for adult patients with RRMS that can be administered in a one-hour infusion, twice a year**, following the starting dose**'.*

Therefore, the press release clearly states that the one-hour infusion is applicable '*following the starting dose*' and thus, the press release does not misguide the reader into thinking that Briumvi is always given over a one-hour duration for all infusions (as alleged by the complainant).

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

Information did not misguide 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, safety and posology 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 this press release to be considered misleading for omitting dosing information, the Panel would have to agree that Neuraxpharm stated or implied that Briumvi is only given as a one-hour infusion twice a year, **with no mention or explanation** that this only applies **after** the starting dose.

Neuraxpharm therefore refute all allegations that relate to Clauses 5.1, 6.1, 6.2 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 Briumvi (ublituximab) issued by Neuraxpharm. The complainant alleged that the press release was misleading as it implied that Briumvi is always given over a one-hour duration for all infusions and failed to provide information that the first infusion is administered over four hours.

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 noted that the second paragraph of the press release stated, among other things, *“It is the first and only anti-CD20 monoclonal antibody approved in the United States (US) and European Union (EU) for adult patients with RRMS that can be administered in a one-hour infusion, twice a year, following the starting dose.”* (emphasis added by the Panel). This statement was faithfully reproduced in the article, provided by the complainant in support of their complaint.

Neuraxpharm submitted that the press release clearly stated that the one-hour infusion was applicable “*following the starting dose*” and therefore the press release did not misguide the reader into thinking that Briumvi was always given over a one-hour duration for all infusion as alleged by the complainant. Neuraxpharm further submitted that it was unreasonable that press releases should be as comprehensive as the product Summary of Product Characteristics (SPC), promotional material or prescribing information.

The Briumvi SPC, Section 4.2, Posology and method of administration, included a table outlining the dose and schedule for Briumvi. This table listed the duration of first infusion as “*4 hours*”. The duration of the second infusion and subsequent infusions was listed as “*1 hour*”.

In the Panel’s view, whilst it may have been helpful for the press release to include the fact that the initial dose was administered over four hours, the statement at issue in the press release, *“…that [Briumvi] can be administered in a one-hour infusion, twice a year, following the starting dose”* accurately reflected the SPC for Briumvi, in that Briumvi can be administered in a one-hour infusion for all doses following the initial dose.

The Panel considered the impression created by the press release. In the Panel’s view, the press release did not create the impression that Briumvi was always given over a one-hour duration for all infusions. The Panel noted that the press release contained two links to the full SPC for Briumvi where a reader could access further information regarding posology and administration, 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 that the press release implied that Briumvi is always given over a one-hour duration for all infusions as alleged. The Panel, therefore, ruled **no breach of Clauses 6.1 and 6.2.**

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 **31 March 2025**

Case completed **1 December 2025**