CASE/0209/06/24

COMPLAINANT v JAZZ PHARMACEUTICALS UK

Allegations about a press release

CASE SUMMARY

This case was in relation to a press release issued by Jazz Pharmaceuticals titled "GW Pharmaceuticals receives approval for EPIDYOLEX® (cannabidiol) from the MHRA for the treatment of seizures associated with tuberous sclerosis complex". The complainant alleged that the press release was promotional for Epidyolex, because of "overuse" of the brand name, and therefore required prescribing information and the adverse events reporting statement. The complainant also alleged that the press release was "not fair and balanced" because it did not include discussion of "specific side effects (hepatocellular injury, seizures, pneumonia)" that occurred in the Phase 3 trial.

The outcome under the 2021 Code was:

Breach of Clause 6.1	**Providing material that was not sufficiently complete as to enable recipients to form their own opinion of the therapeutic value of the medicine**

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 12.1	**Requirement to include up-to-date prescribing information**
No Breach of Clause 12.6	**Requirement to include a prominent statement as to where the prescribing information can be found on promotional material on the internet**
No Breach of Clause 12.9	**Requirement that all promotional material must include the prominent adverse event reporting statement**

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 Jazz Pharmaceuticals UK was received 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:

> "A press release on MHRA approval of Epidyolex overused the brand name of the product which caused the press release to be promotional. Press releases should be non-promotional. Epidyolex/Epidiolex was mentioned 7 times in the press release in total. The press release was a promotional item due to overuse of brand name and requires the prescribing information and adverse event reporting to be provided. No specific side effects observed from the phase 3 trial were discussed in the press release despite the product having specific serious side effects shown during the trial. The press release is not fair and balanced without specific side effects (hepatocellular injury, seizures, pneumonia) that occurred during the trial being discussed. [URL provided] Clauses 6.1, 12.1, 12.6, 12.9, 5.1 and 2 had not been complied with."

When writing to Jazz, the PMCPA asked it to consider the requirements of Clauses 6.1, 12.1, 12.6, 12.9, 5.1 and 2 of the 2021 Code.

JAZZ'S RESPONSE

The response from Jazz is reproduced below:

> "Further to your letter of 18 June 2024 regarding a complaint made to the PMCPA about a historic press release issued by Jazz Pharmaceuticals (Jazz), please find herein our response.
>
> In short, Jazz rejects the allegations of breach of the ABPI Code of Practice in respect of this press release and we will set out our reasons for that in the following paragraphs.
>
> The press release referred to by the complainant was originally issued on 10th August 2021. Its purpose was to inform of the authorisation by the MHRA of a new indication for Epidyolex (cannabidiol) for the treatment of epileptic seizures in tuberous sclerosis complex.
>
> It is common practice for pharmaceutical companies to issue a press releases when a new medicine or a new indication for a medicine receives a marketing authorisation. The purpose of this press release was therefore simply to inform of the achievement of a regulatory milestone. The context in which the press release was issued and its content were entirely consistent with that non-promotional purpose.
>
> With respect to context, at the time of release, almost three years ago, it was disseminated to UK healthcare media and trade news outlets only. Since then the press release has been archived within an area of the Global Jazz corporate website. It can be found by website users who click 'News' in the top navigation bar of the corporate website, then 'Press Release Archive' from the drop down that appears. The user is then given access to the press release archive on the corporate site which lists press releases in reverse chronological order.

Given the passage of time since its release, the material at issue is currently on the twelfth page of archived press releases. Clicking on the relevant link on that page takes the user to the full press release at this url: [URL provided].

The complainant appears to be making two principle [*sic*] allegations as follows:

1. Due to the appearance of seven uses of the brand name, the press release is promotional. In alleging that the press release is promotional the complainant goes on to assert that it does not include prescribing information or an adverse event reporting statement and is therefore in breach of clauses 12.1, 12.6 and 12.9 of the Code.
2. The press release is not fair and balanced in respect of its omission of specific serious adverse events occurring in a trial referenced within the press release, in breach of clause 6.1 of the Code.

The complainant also alleges in respect of the above issues that Jazz has failed to maintain high standards in breach of clause 5.1 and has failed to uphold confidence in the pharmaceutical industry in breach of clause 2.

Response to the points raised in the complaint

1. The press release is promotional and requires additional obligatory information

The allegation that the press release is promotional is based solely on an observation that the brand name, Epidyolex/Epidiolex [sic], appears seven times within the entirety of the press release.

Whilst use of the brand name of a medicine may be one factor to consider when assessing whether a press release has been issued with promotional intent, use of a brand name does not, of itself, make a piece of written material promotional.

Notwithstanding this general point, Jazz limited the use of the brand name in the body copy of the press release to reduce the risk of misperception of the company's intent. Within the body of this press release the UK brand name (Epidyolex) has been used just once (in the title) and the non-proprietary name (cannabidiol) has been used thereafter. This is consistent with the non-promotional purpose of the information being provided.

The majority of uses of the brand name mentioned by the complainant are within the 'Additional information' section of the press release. Additional information is provided to journalists to give context to news information in the body of the press release to facilitate accurate reporting. Its provision is consistent with the supplementary information to clause 26.2 of the Code, with respect to information provided to the media, and it is common practice within the industry to provide it.

In the press release at issue, additional information about the licensed status of the branded medicine worldwide is provided to give context to the UK licensed status. The medicine is branded as Epidiolex in the US and Epidyolex in the EU and UK, and the additional information also makes this clear, reducing the risk of any confusion.

Overall we consider the use of the brand name within this press release proportionate and appropriate. Jazz rejects the notion that the press release is promotional in intent or execution and consequently denies any breach of the Code in respect of clause 12.1, 12.6 or 12.9. Indeed, adding prescribing information would have been wholly inappropriate.

2. The press release is not fair or balanced in respect of its omission of specific serious adverse events

The complainant alleges that some serious adverse events that occurred within a trial referenced in the press release should have been highlighted within the main body of the text. Whilst Jazz accepts that appropriate information about the safety profile of a medicine is important when the primary purpose of a communication is to relate the results of a clinical trial, that was not the primary purpose of this press release.

This short press release was intended only to communicate a regulatory milestone, supporting that with some brief information about why that may be important, with pertinent information regarding the reasons for regulatory approval i.e. there was efficacy in the target population with no new safety findings identified. It was not germane or necessary to enter into a detailed description of the study, which led to the extended licence, or its outcomes.

Given the purpose of the press release we consider the limited information provided in a single paragraph about the clinical efficacy and safety of cannabidiol is sufficient and proportionate to the aim. Jazz does not accept the information provided is misleading, unbalanced or unfair in any respect and rejects the suggestion there has been a breach of clause 6.1.

Summary

In accordance with the supplementary information to clause 8.3 of the Code, the press release in question was examined by a Jazz nominated ABPI signatory prior to issue to ensure it did not contravene the Code or relevant statutory requirements. Jazz maintains that the assessment of the signatory who reviewed the item at the time was correct.

The press release at issue was entirely appropriate for the purposes of communicating a regulatory milestone. Its purpose was non-promotional, as was its execution, and the information provided within it was relevant and sufficient.

The company therefore denies there has been a breach of clause 6.1, 12.1, 12.6 or 12.9 in respect of this press release. In consequence, Jazz also rejects any suggestion it has failed to maintain high standards, in breach of clause 5.1, or failed to uphold confidence in the industry, in breach of clause 2."

PANEL RULING

This complaint was about a press release issued by Jazz Pharmaceuticals titled "GW Pharmaceuticals receives approval for EPIDYOLEX® (cannabidiol) from the MHRA for the treatment of seizures associated with tuberous sclerosis complex". The Panel noted Jazz's

submission that the press release had been issued in June 2021, almost three years before receipt of this complaint, and that it was now archived within the 'Press Release Archive' section of the 'News' area of the corporate website.

The complainant alleged that the press release was promotional for Epidyolex and therefore required prescribing information and the adverse events reporting statement. The Panel noted that this allegation was specifically in reference to the "overuse" of the brand name, which they alleged appeared seven times within the press release. It was not for the Panel to infer other reasons to support the allegation on behalf of the complainant.

The Panel carefully considered the definition of promotion as set out in Clause 1.17 and was mindful that each complaint was judged on a case-by-case basis and on the evidence provided by the parties.

The Panel considered where within the press release the seven mentions of the brand name occurred. The brand name was mentioned once within the title of the press release, and six times within the "Additional information" at the end of the press release, in a section titled "About EPIDIOLEX®/EPIDYOLEX® (cannabidiol). This section provided information about the licensed status of the medicine and its indication. The brand name was not mentioned at all within the main body of the press release. The Panel considered that the use of the brand name in this context was not inappropriate.

While it was possible, given the broad definition of promotion, for material to be promotional when only the name of the medicine was present, in the particular circumstances of this case, the Panel did not consider that the complainant had established that the presence of the brand name once in the title of the press release and six times in an 'additional information' section constituted promotion of Epidyolex. It therefore followed that there was no requirement for the press release to include prescribing information or the adverse events reporting statement and the Panel ruled **no breaches of Clauses 12.1, 12.6 and 12.9**.

Clause 6.1 of the Code required, among other things, that information, claims and comparisons must be accurate, balanced, fair, objective and unambiguous. The complainant alleged that the press release was "not fair and balanced" because it did not include discussion of "specific side effects (hepatocellular injury, seizures, pneumonia)" that occurred in the Phase 3 trial. The complainant did not provide further explanation as to why they considered that this information was required within the press release at issue. The Panel did not have a copy of the phase 3 trial results before it.

The Panel noted that Section 4.8 of the Epidyolex summary of product characteristics listed pneumonia and seizure as two of a number of common adverse reactions and included discussion of hepatocellular injury, which was also included in the 'Special warnings and precautions for use' section (4.4).

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 and intended audience of the press release.

Jazz submitted that the short press release was intended only to communicate a regulatory milestone, including "pertinent information regarding the reasons for regulatory approval i.e. there was efficacy in the target population with no new safety findings identified." The Panel

accepted Jazz's submission that, at the time of release, the press release had been disseminated to UK healthcare media and trade news outlets only.

The Panel noted that one of the six paragraphs within the main body of the press release referred to the Phase 3 trial:

> *"This approval, made through the European Commission Decision Reliance Procedure (ECDRP), is based on data from a positive Phase 3 safety and efficacy study evaluating 25 mg/kg/day of GW's cannabidiol. The study met its primary endpoint, which was the reduction in seizure frequency compared to baseline of cannabidiol vs placebo, with seizure reduction of 49% in patients taking cannabidiol 25 mg/kg/day compared with 27% for placebo (p=0.0009). All key secondary endpoints were supportive of the effects on the primary endpoint. The safety profile observed was consistent with findings from previous studies, with no new safety risks identified. GW's development programme represents the only well-controlled clinical evaluation of a cannabinoid medication for patients with refractory epilepsy."*

The Panel accepted Jazz's submission that the primary purpose of the press release was not to communicate the results of a clinical trial but to announce the regulatory milestone of a new indication. The Panel noted, however, that the press release contained a paragraph about the Phase 3 study, including efficacy data.

While the medicine was initially granted marketing authorisation in September 2019, two years before the date of the press release at issue, the Panel considered that the intended audience would not necessarily be familiar with the side effects associated with the medicine.

The Panel was concerned about the lack of detail for the safety claim in the press release to an audience that was, in effect, members of the public. The Panel took into account the likelihood of the therapeutic area and class of medicine attracting particular interest. There was no further information in the press release about side effects, and no reference to the published Phase 3 study results or to the summary of product characteristics. The supplementary information to Clause 26.2 stated that it was good practice to reference the summary of product characteristics with a press release or press pack relating to a medicine.

The Panel considered that the safety profile information from the Phase 3 study had not been presented in a balanced way because the press release did not include sufficient information about adverse reactions or a reference to the summary of product characteristics. On balance, the Panel ruled a **breach of Clause 6.1**.

While the complainant alleged a breach of Clause 5.1, the Panel noted that there were no specific allegations on this point. The Panel considered that the ruling above adequately covered this matter. The Panel took into account that the primary purpose of the press release was not to communicate the results of a clinical trial, that the intended audience of the press release was limited to UK healthcare media and trade news outlets, and that the press release was archived at the time of the complaint. The Panel considered that the statement "the safety profile observed was consistent with findings from previous studies, with no new safety risks identified" was not the same as stating that there were no safety risks. The Panel therefore ruled **no breach of Clause 5.1**.

The Panel did not consider that the particular circumstances of this case warranted a breach of Clause 2, which was reserved to indicate a particular censure. The Panel ruled **no breach of Clause 2**.

Complaint received **13 June 2024**

Case completed **8 August 2025**