

**CASE/0220/07/24**

## **COMPLAINANT v JAZZ PHARMACEUTICALS**

### **Allegations about a learning course**

#### **CASE SUMMARY**

This case was in relation to a five-minute screencast housed on a Professional Membership Body website; it was alleged that both the webpage on which the screencast was located and the screencast itself contained off-label promotion of Epidyolex. It was further alleged that no prescribing information or adverse event reporting statement was included.

The outcome under the 2021 Code was:

<b>Breach of Clause 5.1</b>	<b>Failing to maintain high standards</b>
<b>Breach of Clause 11.2</b>	<b>Promoting a medicine for an unlicensed indication</b>
<b>Breach of Clause 12.1</b>	<b>Failing to include up-to-date prescribing information</b>
<b>Breach of Clause 12.4</b>	<b>Failing to include prescribing information within the digital material or via a single, direct click link</b>
<b>Breach of Clause 12.6</b>	<b>Failing to include a clear, prominent statement as to where prescribing information can be found</b>
<b>Breach of Clause 12.9</b>	<b>Failing to include the prominent adverse event reporting statement</b>

<b>No Breach of Clause 2</b>	<b>Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry</b>
<b>No Breach of Clause 11.2</b>	<b>Requirement that a medicine must be promoted in accordance with the terms of its marketing authorisation and must not be inconsistent with the particulars listed in the summary of product characteristics</b>
<b>No Breach of Clause 12.1</b>	<b>Requirement to include up-to-date prescribing information</b>
<b>No Breach of Clause 12.4</b>	<b>Requirement to include prescribing information within the digital material or via a single, direct click link</b>
<b>No Breach of Clause 12.6</b>	<b>Requirement to include a prominent statement as to where the prescribing information can be found on promotional material on the internet</b>
<b>No Breach of Clause 12.9</b>	<b>Requirement that all promotional material must include the prominent adverse event statement</b>

**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 Jazz Pharmaceuticals (Jazz) 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:

“Jazz Pharmaceuticals manufactured Epidyolex which is a cannabidiol medication. Jazz Pharmaceuticals had provided funding to [a Professional Membership Body] for a course on Cannabinoid medicines. [URL provided] As can be seen on the link, the text provided by Jazz states Cannabinoid based medicines are available for use on the NHS for indications including spasticity in multiple sclerosis, and intractable epilepsy in children. However, this particular text and the subsequent course content is off-label promotion as it indicates Cannabinoid use in multiple sclerosis and intractable epilepsy in Children. Cannabinoid use is an indirect reference to Epidyolex which has specific indications in seizures associated with LGS [Lennox-Gastaut syndrome] or TSC [tuberous sclerosis complex] only. Epidyolex is not licensed for multiple sclerosis or intractable epilepsy as claimed on the [Professional Membership Body's] learning course. There was no prescribing information or adverse event reporting provided either. It is concerning that Jazz Pharma did not understand compliance requirements and it had to be considered by the PMCPA whether there was enough compliance understanding and resource within the company to fulfil compliance obligations. There were many breaches - clauses 11.2, 12.1, 12.4, 12.6, 12.9, 5.1, 2.”

When writing to Jazz, the PMCPA asked it to consider the requirements of Clauses 11.2, 12.1, 12.4, 12.6, 12.9, 5.1 and 2 of the 2021 Code.

### JAZZ'S RESPONSE

The response from Jazz is reproduced below:

“We received a complaint letter dated 3 July 2024. The letter notifies us that a healthcare professional has made allegations about the text on a webpage [URL provided] available on the [Professional Membership Body] website. The allegations are summarised as follows:

- The tile text wording (on the webpage) is off-label promotion, as this is an indirect reference to Epidyolex.
- The subsequent screencast is off-label promotion.
- There was no prescribing information and adverse event reporting.

The complainant provided, as evidence for the allegation, a screenshot of a webpage on the [Professional Membership Body] eLearning website, which included an image, text and login access to the screencast called 'Cannabis: understanding the terminology' that was intended for its members. The PMCPA provided a screenshot of the landing page for the link cited in the complainant's email. We subsequently informed the [Professional Membership Body] about the complaint and they responded by removing this content from their website. Jazz was requested to respond to this matter with consideration to the requirements of clauses 11.2, 12.1, 12.4, 12.6, 12.9, 5.1 and 2 of the ABPI Code version 2021 (the "Code"), as cited by the complainant.

An investigation has been conducted into the matters alleged by the complainant. In response to these allegations, we provide the following information and explanations.

Jazz provided funding to [Professional Membership Body] to support their online-learning programme. The [Professional Membership Body] website states that eLearning materials on its site are developed by the [Professional Membership Body] and are intended for GPs, primary healthcare professionals, GP Specialty Trainees and GP Educators. The content is written to reflect UK clinical practice [URL provided]. The agreement between Jazz and the [Professional Membership Body] describes the educational purpose of the project and the funding provided by Jazz. The agreement required that the [Professional Membership Body] include a prominent disclosure statement to acknowledge Jazz's involvement in the project. The agreement clearly stated that the screencast was intended to educate on the basics of cannabinoids and was strictly not to promote any products.

The complainant writes, "Cannabinoid based medicines are available for use on the NHS for indications including spasticity in multiple sclerosis and intractable epilepsy in children. However, this particular text... is off-label promotion as it indicates Cannabinoid use in multiple sclerosis and intractable epilepsy in children. Cannabinoid use is an indirect reference to Epidyolex". We believe the text description on the landing page is a crucial introduction that allows the reader to determine if the educational content will meet their learning need. As described previously, the intent of this project was to provide non-promotional education and the full description of the tile text read 'Cannabinoid based medicines are available for use on the NHS for indications including spasticity in multiple sclerosis and intractable epilepsy in children. This short screencast gives an introduction to the history of cannabinoid products in medicine, some of the terminology surrounding these medications, their use in the NHS and the products which our patients may be buying over the counter'. The full tile text description sets out the relevance of this overview topic for the primary care audience and is not pointing towards any specific medicine. There is no mention of Epidyolex or any medicine in the tile text description. Therefore, we believe that the synopsis on the landing page is a relevant description for the audience.

Cannabinoid is a term that is used to describe a group of substances found in the cannabis plant. More than 100 cannabinoids have been identified with many potential medical uses [URL provided]. As stated on the [Professional Membership Body] webpage, there are a number of therapeutic products, including products that patients can buy 'over the counter', that can be described as 'cannabinoids'. It is also important to note, that 'the cannabinoids' that are available have different indications, as described by the wording on the [Professional Membership Body] tile text. Cannabinoid, therefore, is not a term that applies exclusively to Epidyolex. Therefore, Jazz refutes the allegation "Cannabinoid use is an indirect reference to Epidyolex" and "this particular text... is off-label promotion". We reiterate that the tile text was only to allow the reader to determine if the learning would meet their educational needs and did not relate, either directly or indirectly, to any specific product.

The complainant goes on to allege that the "subsequent screencast content was off label promotion". However, the complainant has not provided any clear evidence nor specific allegations to identify which elements within the screencast they were referring to. Jazz is therefore unable to respond to the allegations of breaches of clauses 5.1, 11.2, 12.1, 12.4, 12.6, 12.9 and 2 and would respectfully submit that breaches of these clauses are not applicable.

There was no reference to any product or brand name in the tile text on the [Professional Membership Body] webpage. Since no medicine was mentioned, Jazz asserts that there is no requirement to include prescribing information and adverse event reporting. Furthermore, the page content was educational and not promotional so there was no requirement to include such information. Therefore, we believe that clauses 11.2, 12.1, 12.4, 12.6 and 12.9 do not apply and as such there cannot be breaches of these clauses.

The complainant made comments around resource issue and compliance understanding; at Jazz we believe we have a good compliance understanding. However, during our investigation of this complaint, we identified a deficiency that occurred during a period of organisational change. We have been unable to identify if an adequate examination of this material took place in accordance with the statement on the tile text on the [Professional Membership Body] webpage. We failed to recognise our responsibilities to document the review of the material in question. We accept that Jazz did not meet the high standards that the pharmaceutical industry expects of us, therefore we acknowledge a breach of clause 5.1.

The complainant further alleged a breach of clause 2. Clause 2 states that activities or materials must never be such as to bring discredit upon or reduce confidence in the pharmaceutical industry. The funding that we provided to [the Professional Membership Body] is a legitimate activity and has been conducted in line with the principles and rules of the ABPI Code. In particular, patient safety has not been compromised by this activity. Furthermore, the complainant has not provided any evidence that discredit has been brought upon or that there has been reduced confidence in the Pharmaceutical Industry. Therefore, Jazz refutes the allegation of a breach of clause 2.

I close this letter by reiterating my regret that during the company reorganisation, Jazz fell short of the standards required in the examination of this material. We have taken the learnings from this case, and we have implemented organisational and system changes which will safeguard against this error happening again. We remain strongly committed to the rules and principles of the Code and look forward to hearing from you in due course."

## FURTHER INFORMATION

Further information from Jazz was provided as follows:

"Thank you for your email regarding the above complaint. The final audiovisual file was built online and only existed within the [Professional Membership Body] eLearning platform, accessible by [Professional Membership Body] members only. We have been informed by the [Professional Membership Body] that the screencast has been removed from the platform, and because of the way the platform was built, the screencast no longer exists. This means we cannot produce a final transcript of the voice over which accompanied the screencast."

## PANEL RULING

This complaint related to a five-minute screencast titled "*Cannabis: understanding the terminology*" which Jazz Pharmaceuticals had provided funding for. The screencast was housed on a Professional Membership Body website in the Resources section.

The complainant made allegations that both the webpage on which the screencast was located and the screencast itself contained off-label promotion of Jazz's medicine Epidyolex (cannabidiol). The complainant further alleged that no prescribing information or adverse event reporting statement was included.

Jazz submitted that it provided funding to the Professional Membership Body to support their online-learning programme, which included the five-minute screencast in question, intended to provide non-promotional education to GPs, primary healthcare professionals, GP speciality trainees and GP educators on the basics of cannabinoids.

The Panel was provided with a copy of the sponsorship agreement and noted that the screencast title was included as: "*How to Change Your Practice*" with a 'Topic' description of "*understanding the terminology and a vocabulary tool for cannabinoid medicines*". The Panel noted that the title of the screencast differed on the webpage to that stated in the sponsorship agreement but the Panel considered both titles referred to the same screencast. The Panel noted that Jazz would have been aware of the title and topic for discussion in the screencast prior to funding. The agreement also set out the arrangement that Jazz would check the screencast for scientific accuracy, but that full editorial control would remain with the Professional Membership Body. The Panel noted Jazz's response to the complaint and considered it was not clear if an adequate review of the screencast for scientific accuracy had taken place, as originally planned.

It is possible for a company to sponsor material produced by an independent organisation which mentions its own products and not be liable under the Code for its contents, but only if, among other things, there has been a strictly arm's length arrangement between the parties. It is an established principle that if a company was aware prior to funding that the sponsored material would mainly discuss the company's medicine and/or positively position it above other treatments then the arrangement could not be considered strictly arms-length.

The Panel took account of the written agreement between the parties as a whole. The agreement set out four different areas that funding from Jazz would be spent on which included the screencast in question, a podcast about guidelines for cannabinoid-based medicines, the development of a cannabinoid medicine learning hub and a marketing package to promote the materials using a range of channels. At the time the written agreement was executed, Jazz had the only licensed cannabinoid-based medicine for use in epilepsy (Epidyolex) and therefore the Panel considered that Jazz would have known prior to funding that Epidyolex would likely be mentioned in the sponsored materials and positively positioned when discussing that therapeutic area. Jazz's response did not dispute responsibility for the sponsored material under the Code and the sponsorship agreement between the parties did not refer to an arms-length relationship. The Panel therefore determined that Jazz was responsible for the content of the material under the Code.

### **The webpage**

The screencast could be accessed through the Resources section of the Professional Membership Body website. The webpage included the title of the screencast above a thumbnail of a cannabis plant with a hyperlink to "*Login to access course*" underneath. The following information was provided next to the thumbnail of the screencast:

*"Cannabinoid based medicines are available for use on the NHS for indications including spasticity in multiple sclerosis, and intractable epilepsy in children. This short screencast gives an introduction to the history of cannabinoid products in medicine, some of the terminology surrounding these*

*medications, their use in the NHS and the products which our patients may be buying over the counter.*

*Funding was received from Jazz Pharmaceuticals for the production of this screencast. Jazz Pharmaceuticals reviewed the content for scientific accuracy and full editorial control remains the sole responsibility of the [Professional Membership Body].*

A Jazz logo appeared under the text.

The complainant alleged that the wording “*Cannabinoid based medicines are available for use on the NHS for indications including spasticity in multiple sclerosis, and intractable epilepsy in children*” was off label promotion of Jazz’s medicine Epidyolex which according to the complainant had specific indications in seizures associated with Lennox-Gastaut syndrome (LGS) or Tuberous Sclerosis Complex (TSC) only.

The Panel noted that the complainant’s allegations were limited to Epidyolex and therefore it limited its consideration to Epidyolex only.

The Panel first had to determine whether it considered the webpage promoted Epidyolex.

The Panel noted the indication for Epidyolex in the SPC was as follows:

*“Epidyolex is indicated for use as adjunctive therapy of seizures associated with Lennox-Gastaut syndrome (LGS) or Dravet syndrome (DS), in conjunction with clobazam, for patients 2 years of age and older.*

*Epidyolex is indicated for use as adjunctive therapy of seizures associated with tuberous sclerosis complex (TSC) for patients 2 years of age and older.”*

The Panel considered the broad definition of promotion as set out in Clause 1.17 and noted that it was possible for a medicine to be promoted without its name being mentioned. The Panel took account of Jazz’s submission that cannabinoid is a term used to describe a group of substances found in the cannabis plant and that more than 100 cannabinoids had been identified. The Panel did not accept the complainant’s assertion that ‘*cannabinoid use is an indirect reference to Epidyolex*’. The Panel took account of the enclosures in Jazz’s response which referred to three licensed cannabinoid-based medicines in the UK for various indications, an unlicensed cannabinoid ‘special’ medicinal product that was prescribed in the NHS, and cannabinoids that patients could purchase over the counter. While the Panel acknowledged that Epidyolex was the only licensed cannabinoid-based medicine used in epilepsy, the Panel considered that the description on the webpage was not limited to *licensed* cannabinoids. On this basis, the Panel considered that the brief text on the webpage did not promote Epidyolex and therefore the text was not off-label promotion of Epidyolex as alleged. The Panel ruled **no breach of Clause 11.2**.

Based on the ruling above, the Panel ruled **no breach of Clauses 12.1, 12.4, 12.6 and 12.9** in relation to the webpage.

### **The screencast**

The Panel then considered the allegations that the screencast was off label promotion for Epidyolex and that it should have included prescribing information and an adverse event reporting statement.

The Panel first had to determine whether it considered the screencast promoted Epidyolex.

Jazz submitted that the removal of the screencast from the Professional Membership Body website following receipt of the complaint meant it no longer existed and so, a final transcript of the voiceover was not available and could not be evaluated by the Panel. A slide presentation that was used during the screencast was however provided to the Panel. The Panel noted that the complainant had the burden of proving their complaint on the balance of probabilities and it was not for the Panel to make out their complaint. The Panel made its ruling based on the slides which were shown during the screencast.

The Panel considered the slides, specifically slide five which was titled “*Exocannabinoids in the NHS*”; below the title, the slide had four bullet points, which read:

- “*Cannabidiol*:
  - *Lennox-Gastaut Syndrome*.
  - *Dravet Syndrome*.
  - *Tuberous sclerosis complex*.
- *Nabiximols*:
  - *Spasticity in multiple sclerosis*.
- *Nabilone*:
  - *Nausea and vomiting caused by cytotoxic chemotherapy*.
- *Full-extract cannabis oil*:
  - *Not licensed*.
  - *Specialist use only*.”

The Panel noted that the complainant’s allegations were limited to Epidyolex and therefore it limited its consideration to Epidyolex only.

The Panel noted that at the time of the screencast, Epidyolex (active ingredient cannabidiol) was the only licensed cannabinoid-based medication for use in epilepsy with indications related to LGS, DS and TSC. The Panel considered that the reference to “cannabidiol” on the slide, with indications for LGS, DS and TSC was an indirect reference to Epidyolex. Noting its decision above that the sponsorship was not strictly arms-length and that Jazz was thus responsible for the content under the Code, the Panel considered that the screencast promoted Epidyolex.

The Panel noted that the screencast did not include the full indication for Epidyolex. The Panel considered the screencast implied that Epidyolex could be used as a monotherapy and/or in any age, which was inconsistent with the summary of product characteristics. The Panel considered on that basis that the screencast promoted Epidyolex in a manner that was not in accordance with the terms of its marketing authorisation. The Panel ruled a **breach of Clause 11.2**.

Clause 12.1 stated, among other things, that the prescribing information listed in Clause 12.2 must be provided in a clear and legible manner and must be positioned for ease of reference. Clause 12.4 required that the prescribing information in digital material be included in the digital material itself or provided by way of a clear and prominent direct single click link. Clause 12.6 required that

promotional material provided on the internet must include a clear prominent statement as to where the prescribing information can be found.

The Panel noted that the screencast did not include prescribing information either in the material itself or by way of a link. Nor did the material include a statement as to where prescribing information could be found. The Panel therefore ruled **breaches of Clauses 12.1, 12.4 and 12.6** in this regard.

Clause 12.9 stated that 'All promotional material must include the prominent statement "Adverse events should be reported. Reporting forms and information can be found at [website address which links directly to the MHRA Yellow Card site]. Adverse events should also be reported to [relevant pharmaceutical company]".' Given the Panel's determination that the material promoted Epidyolex, an adverse event reporting statement was required. In the absence of such, the Panel ruled a **breach of Clause 12.9** of the Code.

In their response, Jazz explained that a deficiency had been identified during a period of organisational change. The Panel noted its comments and rulings of breaches of the Code above and considered that, although this activity occurred at a time of organisational change for the company, it had failed to maintain high standards. A **breach of Clause 5.1** was ruled as acknowledged by Jazz.

The Panel considered that the rulings of breaches adequately covered this matter and an additional ruling of a breach of Clause 2 would be disproportionate in the particular circumstances of this case. A ruling of a breach of Clause 2 was used as a sign of particular censure and reserved for such use. The Panel therefore ruled **no breach of Clause 2**.

**Complaint received**      **3 July 2024**

**Case completed**      **21 November 2025**