CASE/0226/07/24

COMPLAINANT v JAZZ

Allegations about a podcast

CASE SUMMARY

This case was in relation to a sponsored podcast titled, "Guidelines for prescribing cannabinoid-based medicines" which was available on demand or as a download within the educational section of a Professional Membership Body website for general practitioners (GPs).

The outcome under the 2021 Code was:

Breach of Clause 5.1 (x3)	**Failing to maintain high standards**
Breach of Clause 5.5	**Failing to be sufficiently clear as to the company's role and involvement**
Breach of Clause 6.1 (x2)	**Making a misleading claim**
Breach of Clause 11.2 (x2)	**Promoting a medicine in a manner that was not in accordance with the terms of its marketing authorisation**
Breach of Clause 12.1 (x2)	**Failing to include prescribing information**
Breach of Clause 12.6 (x2)	**Failing to include a clear, prominent statement as to where prescribing information could be found**
Breach of Clause 12.9	**Failing to include an adverse event reporting statement**

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 (x2)	**Requirement to 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 12.3	**Requirement to include the non-proprietary name in promotional material**

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 was received from a contactable complainant who described themselves as a health professional. The complainant later became non-contactable.

COMPLAINT

The complaint wording is reproduced below:

> "Jazz pharmaceuticals had funded a podcast titled guidelines for prescribing cannabinoid-based medicines. The podcast had a number of compliance issues. [link provided] At 5 minutes 49 seconds, it is said in the podcast that there is a cannabinoid medicine for dravet syndrome. This was an indirect reference to Epidyolex which is a Jazz medicine. However, Epidyolex has a specific indication as an adjunctive therapy for patients aged 2 years and above. The speaker stating that the medicine is for Dravet syndrome without discussing the specific indication is off-label misleading promotion. This is in breach of clauses 6.1, 11.2, 5.1 and 2. At 6 minutes 57 seconds, the speaker states that Sativex can be used in moderate to severe multiple sclerosis. The generic name of Sativex is not said by the speaker at first mention. This is a breach of clause 12.3. Sativex has a very specific indication - indicated as treatment for symptom improvement in adult patients with moderate to severe spasticity due to multiple sclerosis (MS) who have not responded adequately to other anti-spasticity medication and who demonstrate clinically significant improvement in spasticity related symptoms during an initial trial of therapy. The speaker only states moderate to severe multiple sclerosis which is off-label misleading promotion. This is in breach of clauses 6.1, 11.2, 5.1 and 2. At 16 minutes 9 seconds, the speaker states that Epidyolex and Sativex can be initiated by GPs. However, the SPCs for both products state that the products can only be initiated by specialists who have an expertise in the conditions for these products. The recommendation that products can be started by GPs is misleading and a real risk to patient safety considering the SPC guidance. Breach of clauses 6.1, 5.1 & 2. The podcast did not discuss side effects related to Sativex and Epidyolex, as a result the podcast was not fair and balanced. Breaches of clauses 5.1 and 2. The podcast did not state the Jazz had provided the funding for this podcast from the outset. Breach of clauses 5.5, 5.1 and 2. No prescribing information for either Sativex or Epidyolex or adverse event reporting was provided. Breach of clauses 12.1, 12.6, 12.9, 5.1 and 2 Jazz had not followed the compliance framework in funding such an uncompliant podcast which risked patient safety. Self-regulation principles had been neglected and compliance culture had to be questioned."

When writing to Jazz, the PMCPA asked it to consider the requirements of Clauses 5.1, 5.5, 6.1, 11.2, 12.1, 12.3, 12.6, 12.9 and 2 of the 2021 Code as cited by the complainant.

JAZZ'S RESPONSE

The response from Jazz is reproduced below:

> "We write in response to a complaint letter dated 8 July 2024. The complaint was from a healthcare professional concerning allegations about an educational podcast on cannabinoid-based medicines provided by the [named professional membership body] as an e-learning, which Jazz pharmaceuticals (Jazz) had supported. The allegations raised by the complainant are summarised as follows:
>
> - Indirect reference to Epidyolex, in relation to Dravet Syndrome, without discussing the specific indication is off label misleading promotion.

- The generic name of Sativex is not said by the speaker at the first mention.
- The speaker only states moderate to severe multiple sclerosis which is off-label misleading promotion.
- The speaker states that Epidyolex and Sativex can be initiated by GPs. The recommendation that products can be started by GPs is misleading and a risk to patient safety.
- The podcast did not discuss side-effects of Sativex and Epidyolex, as a result it was not fair and balanced.
- The podcast did not state that Jazz had provided funding from the outset.
- No prescribing information or adverse event reporting was provided.
- Jazz had not followed the compliance framework in funding the podcast, which risks patient safety.

The complainant provided, as evidence, a link to an eLearning page on the [professional membership body]'s website, the link directed to an image, descriptive text and an audio recording (podcast) titled 'cannabinoid-based medicines'. The PMCPA provided a download of the podcast and a screenshot of the landing page for the link cited in the complainant's email. Jazz subsequently informed the [professional membership body] about this complaint and they responded by removing the content from their website. Jazz was requested to respond to this matter with consideration to the requirements of clauses 5.1, 5.5, 6.1, 11.2, 12.1, 12.3, 12.6, 12.9 and 2 of the ABPI Code, version 2021 (the 'Code'), as cited by the complainant.

Jazz provided funding to [professional membership body] to support their online-learning programme. The agreement with 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 [agreement provided]. The agreement clearly stated that the podcast was intended to educate on the NICE Guidelines (updated in March 2021) for cannabinoid-based medicines (NICE NG144). This guideline is described by NICE as covering 'prescribing of cannabis-based medicinal products for people with intractable nausea and vomiting, chronic pain, spasticity and severe treatment-resistant epilepsy'.

From the outset, Jazz agreed to support the podcast on the basis that it would deliver non-promotional educational content. Jazz had no input into the content of the podcast which was entirely created by the [professional membership body]. As part of our investigation of this complaint, we identified a deficiency that occurred during a period of organisational change. We are unable to confirm whether an adequate review of this podcast was completed. Had the podcast been adequately reviewed, Jazz should have identified that it contained promotional content. We realise that the material should have been recognised as containing some promotional elements and this deviated from our original intent. Based on this, we accept that the material should include products' indication, prescribing information, adverse event reporting. Therefore, Jazz acknowledges breaches of clauses 5.1, 12.1, 12.6 and 12.9.

Jazz refutes the allegation of breaches of clauses 5.5, 6.1, 11.2, 12.3 and 2. In response to these allegations, we provide the following information and explanations.

The complainant alleges ‘the podcast did not state that Jazz has provided funding from the outset’. The podcast was only accessible via the [professional membership body] webpage. The screenshot of the webpage provided as evidence by the PMCPA clearly states that funding for the podcast was received from Jazz and this was also reiterated verbally at the end of the podcast. As such, we refute breaches of clauses 5.1, 5.5 and 2 for this allegation.

The complainant alleges ‘the generic name of Sativex is not said by the speaker at the first mention’. We note that clause 12.3 requires that the non-proprietary name of the medicine be included in printed promotional materials and electronic advertisements. We believe that clause 12.3 relates only to promotional materials in instances where the visual inclusion of the brand name is applicable. In this podcast the brand name did not appear visually. Jazz, therefore Jazz refutes the allegation of a breach of clause 12.3.

As previously described, the podcast was intended to be an educational overview of cannabinoid-based medicine from the perspective of the NICE NG144 guidelines, giving GPs a broader understanding of the range of medicines that may be initiated by specialists. Whilst GPs do not specialise in this area or initiate prescription, the [professional membership body] had recognised that GPs needed to understand the legislation and guidelines, to allow them to better support their patients’ needs given patients may ask for cannabinoid-based treatments. The complainant alleges that ‘Sativex has a very specific indication – indicated as treatment for symptom improvement in adult patients with moderate to severe spasticity due to Multiple Sclerosis (MS) who have not responded adequately to other anti-spasticity medication and who demonstrate clinically significant improvement in spasticity related to symptoms during an initial trial of therapy. The speaker only states moderate to severe multiple sclerosis which is off-label misleading promotion’. In the context of the podcast narrative, the speaker is clearly speaking about the NICE guideline recommendations specifically related to both the breadth of cannabis-based medicines and the quality of the evidence available, as described in the NICE NG144 guideline and not referring to any specific medicine. We believe that the podcast contained a proportionate level of ‘overview’ information suitable for the GP audience. Jazz therefore refutes the allegations of breaches of clauses 5.1, 6.1, 11.2 and 2.

The complainant alleges that ‘the speaker states that Epidyolex and Sativex can be initiated by GPs. However, the SPCs for both products state that the products can only be initiated by specialists who have an expertise in the conditions for these products. The recommendation that products can be started by GPs is misleading and a risk to patient safety’. It is factually incorrect to say that the speaker states that Epidyolex and Sativex can be started by GPs, as these words are not used in the podcast. The speaker mentions four times that prescription of cannabinoid medicines should be initiated by a specialist and that GPs should refer patients to a specialist if they request cannabinoid-based medicines. We would assert that the speaker does not invite GPs to commence prescription of cannabinoid medicines, but instead refers to what GPs can do based on NICE guidelines i.e. GPs can refer their patients to specialists, for further management of these complex conditions. The primary purpose of recommending specialist referral, in accordance with NICE guidelines, is for patient safety. Therefore, Jazz refutes breaches of clauses 5.1, 6.1 and 2, as alleged.

The complainant alleged that the podcast did not discuss side-effects of Sativex and Epidyolex, as a result the podcast is not fair and balanced. The podcast provided participants access to evidence-based learning. The [professional membership body] set out to increase awareness for GPs for cannabis-based products available within the context of NICE guideline NG144, and this was not a call to action for prescription. As discussed previously, the recommendation of the podcast is that GPs refer patients to a specialist. However, as the indication of Sativex was mentioned, we accept that the speaker should have referred to the product's safety profile, for balance. Therefore, we accept that the high standards that the pharmaceutical industry expects of Jazz were not met and we acknowledge a breach of clause 5.1. We do not believe that this omission constitutes a clause 2 because the podcast accurately reflects the contents of the NICE guidelines on cannabis-based products. Further, the podcast encourages GPs to refer patients to a specialist who can diagnose and treat the patient with the most appropriate course of action. We assert that at no point does this compromise patient safety. Therefore, we refute a breach of clause 2, as alleged.

In summary, the original purpose and intent of the podcast was to discuss the NICE guidelines and not to specifically promote or discuss Jazz' medicines. There was not a call to action for the prescription of any medicines. We believe the intent of this activity was legitimate, to educate GPs with the knowledge needed to navigate circumstances where patients might ask them for cannabinoid-based products. The overall impression that would be left with a listener was of a balanced educational summary of the NICE NG144 guidelines. Thus, we do not believe that by supporting this podcast Jazz has brought discredit on the industry. Therefore, Jazz refutes the allegation of a breach of clause 2.

Since the complaint. we have reviewed the circumstances which led to the lack of adequate review of the podcast and put measures in place to ensure that this does not happen again. I close this letter by reiterating my regret that Jazz fell short of the expected standards. We remain strongly committed to the rules and principles of the Code and look forward to hearing from you in due course."

PANEL RULING

This complaint related to a 19-minute podcast titled, "Guidelines for prescribing cannabinoid-based medicines" which was available on demand or as a download within the educational section of the Professional Membership Body website.

The complainant made a number of allegations as follows:

- Reference to using a cannabinoid medicine for Dravet syndrome was an indirect reference to, and therefore off-label and misleading promotion of, Jazz's medicine Epidyolex, which is specifically indicated as an adjunctive therapy for patients aged 2 years and above;
- The speaker mentioned the Jazz product Sativex for use in moderate to severe multiple sclerosis (MS); it was alleged that the generic name was not stated by the speaker at the first mention of the product and reference only to moderate-severe MS was off-label and misleading promotion because the caveats in the full indication were not stated;

- It was alleged that the speaker stated that Epidyolex and Sativex could be initiated by GPs but their summary of product characteristics (SPCs) referred to both medicines only being initiated by specialists who had expertise in the conditions for these products;
- The podcast did not discuss the side effects for both medicines; it was therefore alleged that it was not fair and balanced;
- The podcast did not state that Jazz had provided funding for it at the outset;
- There was no prescribing information for Epidyolex or Sativex and no adverse event reporting statement included in the podcast; and
- It was alleged that Jazz had not followed the compliance framework in funding the podcast which risked patient safety and compliance culture had to be questioned.

The complainant alleged six breaches of Clause 2. As this was one podcast, the Panel considered this clause once, for the overall activity.

Below the title of the podcast on the Professional Membership Body's website, was a media player from which the podcast could be played, followed by an image of what appeared to be a medicine bottle alongside cannabis. The following text appeared below the image and in line of sight of the title and media player: *"Cannabinoid based medicines are prescribable on the NHS for certain indications, including spasticity in multiple sclerosis and use in children with intractable epilepsy. In this podcast, [named health professional] and [second named health professional] discuss how these medicines are commonly used and some of the practicalities of prescribing, including consultant initiation and then sometimes ongoing prescribing in primary care with the use of written shared care guidelines. They also touch on the use of cannabinoids on an over the counter basis. [second named health professional] is a neurologist with a particular interest in this area who sat on the NICE guideline committee and carries out research in this area.*

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

The Panel noted Jazz's submission that they had provided funding to the Professional Membership Body for non-promotional e-learning targeted at GPs, the intention of which was to provide an educational overview of cannabinoid-based medicines from the NICE NG144 guidelines; the NICE guideline discussed prescribing of cannabis-based medicinal products for patients experiencing intractable nausea and vomiting, chronic pain, spasticity and severe treatment-resistant epilepsy.

The Panel was provided with a copy of the sponsorship agreement and noted that the following funding statement was required to be included in all material produced, *"funding was received from Jazz Pharmaceuticals for the production of this [insert activity]. Jazz Pharma reviewed the content for scientific accuracy and full editorial control remains the sole responsibility of the [Professional Membership Body]".*

The Panel noted Jazz's response to the complaint and considered it was not clear if it had reviewed the content of the podcast for scientific accuracy as originally planned.

It was clear from the sponsorship agreement (and Jazz's submission) that Jazz had provided sponsorship to the Professional Membership Body, was aware the title for the podcast would be

"Guidelines for Cannabinoid-based Medicines", and that NICE guidelines (which include reference to licensed cannabidiol medication) would be discussed. The Panel considered therefore that Jazz would be aware that it was highly likely its products would be mentioned in the podcast.

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 than the arrangement could not be considered strictly arms-length.

The Panel took account of the written agreement between the parties and considered that Jazz would have had a clear idea of what would be covered in the podcast before agreeing to fund it. At the time the NICE guidelines were developed, Jazz had the only licensed cannabinoid-based medicines for use in spasticity (Sativex) and epilepsy (Epidyolex) and therefore the company would have known that the podcast would positively position its medicines when discussing those two conditions. Jazz's response did not dispute responsibility for the sponsored material under the Code and the written 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 podcast under the Code.

Alleged promotion of Epidyolex

The Panel considered the podcast at five minutes and forty-nine seconds where, the speaker said, "…*Dravet syndrome which has a licensed medication as a cannabis-based product*"; it was alleged that this statement was an indirect reference to Epidyolex.

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 noted Jazz's submission that it was unable to confirm whether or not an adequate review of the material had been conducted; but if it had, Jazz would have identified that the podcast contained promotional content. Jazz was not specific on which parts of the podcast it considered to be promotional.

The Panel noted from page 21 of the NICE guideline that Epidyolex was the only cannabis-based medication licensed in the UK for Dravet syndrome and as such the speaker could only have been referring to Epidyolex. Although the name of the product was not referred to explicitly, the Panel considered that Epidyolex was identifiable and referred to alongside its use in Dravet syndrome, which the Panel considered was promotional. The Panel observed that the podcast did not include prescribing information or a clear prominent statement as to where it could be found. The Panel therefore ruled a **breach of Clauses 12.1 and 12.6** as acknowledged by Jazz.

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]"'. The Panel noted that no such statement was included in the podcast and a **breach of Clause 12.9** was ruled as acknowledged by Jazz.

The complainant also alleged that as Epidyolex is specifically indicated as an adjunctive therapy for patients aged 2 years and above, the speaker stating the medicine was for Dravet syndrome without discussing the specific indication, amounted to off-label promotion.

The Panel considered the indication for Epidyolex from the SPC:

> "*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 noted that Clause 6.1 required, among other things, that claims must not mislead either directly or by implication and material must be sufficiently complete to enable recipients to form their own opinion of the therapeutic value of the medicine. The Panel noted that the full indication for Epidyolex in Dravet syndrome was not stated anywhere within the material. The Panel noted the target GP audience and considered that the omission that Epidyolex was only for use as an adjunctive therapy in patients 2 years of age and older could misleadingly imply that it could be used as a monotherapy and/or in any age. The Panel ruled a **breach of Clause 6.1**.

Clause 11.2 required that the promotion of a medicine must be in accordance with the terms of its marketing authorisation and must not be inconsistent with the particulars listed in its summary of product characteristics. The Panel considered that the material for the reasons stated above 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**.

The Panel acknowledged Jazz's submission that it had identified a deficiency which occurred during a period of organisational change and that the company should have recognised that the podcast was promotional material. The Panel was concerned about the oversight of the podcast which resulted in misleading promotion of Epidyolex without the required obligatory information. The Panel considered that in this regard, high standards had not been maintained and therefore ruled a **breach of Clause 5.1**.

Alleged promotion of Sativex

The Panel considered the podcast at six minutes and fifty-seven seconds where the speaker said, *"…was in relation to using Sativex which is already a licensed medication for moderate to severe spasticity related to multiple sclerosis".*

Firstly, the Panel noted the broad definition of promotion at Clause 1.17 of the Code, which referred to any activity which promotes the administration, consumption, prescription, purchase, recommendation, sale, supply or use of its medicines. The podcast mentioned Sativex by brand name, along with its use in spasticity related to multiple sclerosis, therefore the Panel considered the podcast promoted Sativex. The podcast did not include prescribing information or a clear prominent statement as to where it could be found. The Panel therefore ruled a **breach of Clauses 12.1 and 12.6** as acknowledged by Jazz.

In relation to the allegation about a lack of adverse event reporting statement, the Panel considered that it's ruling of a breach of Clause 12.9 above adequately covered the matter for both medicines in this podcast and therefore it made no further ruling.

The complainant alleged that the generic name for Sativex was not stated by the speaker at first mention. The Panel noted that Clause 12.3 required that for electronic advertisements the non-proprietary name must appear immediately adjacent to the brand name at its first appearance in a size such that the information is easily **readable** (emphasis added). The Panel considered that Clause 12.3 did not apply to what was verbalised by the speaker in the audio and on this basis, the Panel ruled **no breach of Clause 12.3**.

The complainant also alleged, in relation to the same section of the podcast that, *"Sativex has a very specific indication…The speaker only states moderate to severe multiple sclerosis which is off-label misleading promotion".*

The Panel considered the audio referred to by the complainant at six minutes and fifty-seven seconds which stated:

> *"…with regards to spasticity, it was felt that the only significant evidence to make a recommendation for use was in relation to using Sativex which is already a licensed medication for moderate to severe spasticity related to multiple sclerosis."*

The Panel noted the context of the statement and that the speaker was discussing the evidence base and quality of evidence for making NICE recommendations regarding treatment for spasticity related to multiple sclerosis.

The Panel noted Jazz's submission that, *"we believe the podcast contained a proportionate level of 'overview' information suitable for the GP audience".*

The Panel considered the indication for Sativex from the SPC:

> *"Sativex is indicated as treatment for symptom improvement in **adult** patients with moderate to severe spasticity due to multiple sclerosis (MS) **who have not responded adequately to other anti-spasticity medication** and who demonstrate clinically significant improvement in spasticity related symptoms during an initial trial of therapy" (emphasis added by the Panel).*

The Panel considered whether the omission of the full indication by the speaker was misleading. The speaker's statement suggested that Sativex was licensed for all patients with moderate to severe spasticity due to multiple sclerosis which was incorrect. The Panel noted that the full indication for Sativex was not stated anywhere within the material. The Panel considered that the podcast created a misleading impression in this regard, and the Panel ruled a **breach of Clause 6.1**.

As set out above, Clause 11.2 required that the promotion of a medicine must be in accordance with the terms of its marketing authorisation and must not be inconsistent with the particulars listed in its summary of product characteristics. The Panel considered that the lack of clarification of the licensed indication in the podcast meant that Sativex was promoted in a manner that was not in accordance with the terms of its marketing authorisation. The Panel ruled a **breach of Clause 11.2**.

In line with the Panel's rulings above, it was concerned about the oversight of the podcast which resulted in misleading promotion of Sativex without the required obligatory information. The Panel considered that in this regard, high standards had not been maintained and therefore ruled a **breach of Clause 5.1**.

Initiating cannabinoid-based products

The complainant alleged that in the podcast, the speaker stated that Epidyolex and Sativex could be initiated by GPs, and that this was misleading and a risk to patient safety as the SPC for both Epidyolex and Sativex stated that they should be initiated by a specialist. The Panel considered the podcast at sixteen minutes and nine seconds, where the speaker was asked of any scenarios in which a GP might initiate a cannabinoid-based product and answered:

> *"…as I've mentioned any of the licensed products a GP could initiate, I think in the guidelines we recommend that it is by a specialist, but these are guidelines. I think in* ***palliative care*** *and perhaps in other areas, that a GP may have a role to prescribe something because for the individual patient, if it was thought in their best interests and you want to access something close to home without sending them to a specialist centre, I think this will become an area where GPs would possibly prescribe in. I don't think that is established at this time,* ***but I think in the future*** *as we have more research and more knowledge about these agents, I think we will start identifying the key areas they can be useful in because I think they will have a use but we just haven't got all the evidence at the moment to support increasing access to them* (emphasis added by the Panel)*."*

The Panel noted that the SPC for Epidyolex stated:

> "*should be initiated and supervised by physicians with experience in the treatment of epilepsy*."

Whilst the SPC for Sativex stated:

> "*Treatment must be initiated and supervised by a physician with specialist expertise in treating this patient population*."

The Panel considered the wording of the complaint, that "the speaker states that Epidyolex and Sativex can be initiated by GPs" and considered that this was not accurate and the context in terms of the question the speaker was asked was important. The Panel considered that the speaker was referring to licensed products generally which included products other than Jazz's Epidyolex and Sativex (there was a third, non-Jazz, licensed cannabinoid medicine used in the treatment of nausea and vomiting caused by chemotherapeutic agents). In addition, the speaker stated that NICE guidelines recommended that these products be initiated by a specialist and used wording such as "may have a role" and "possibly prescribe in" making reference to GPs in the future. Indeed, the speaker who asked the question then states "*Yes it might be interesting to listen to this in 5 or 10 years time and see how much more we are doing*". The Panel took account of Jazz's submission that the speaker mentioned four times in the 19 minute podcast that prescription of cannabinoid medicines should be initiated by a specialist and that GPs should refer patients to a specialist if they request cannabinoid-based medicines. The webpage that hosted the podcast also referred to consultant initiation. While the Panel acknowledged that the response by the health professional at 16 minutes 9 seconds was not fully clear, it

considered, in the context of the full podcast at issue, that the material was not misleading overall on this point and therefore ruled **no breach of Clause 6.1**.

Given the reasons provided for the ruling of Clause 6.1, the Panel concluded that **no breach of Clause 5.1** was warranted.

Side effects

The Panel considered the allegation that the podcast did not discuss the side effects of Sativex and Epidyolex and was therefore not fair and balanced. As detailed by Jazz in their response, the podcast was acknowledged to be promotional. The podcast indirectly referred to Epidyolex in the context of Dravet syndrome, and Sativex was also mentioned directly by brand name in the context of spasticity related to multiple sclerosis. It was an established principle that material must be sufficiently complete to enable recipients to form their own opinion of the therapeutic value of the medicine. The Panel considered that the material promoted Epidyolex and Sativex without sufficient information about either medicine's side effects and a **breach of Clause 5.1** was ruled as acknowledged by Jazz.

Declaration of involvement

The Panel considered the allegation that the podcast did not state that Jazz had provided funding from the outset; in doing so, the Panel took into account the requirements of Clause 5.5 and the Supplementary Information which stated that the declaration of sponsorship must be sufficiently prominent so that the audience is aware from the outset.

The Panel noted that the webpage for the Professional Membership Body website where the podcast was located, included the following statement, "*funding was received from Jazz Pharmaceuticals for the production of this podcast. Jazz Pharmaceuticals reviewed the content for scientific accuracy and full editorial control remains the sole responsibility of the [Professional Membership Body]*" .

To the right-hand side of the image there was an option to "Download audio". The Panel considered from the screenshot provided that it appeared the podcast could be downloaded and therefore needed to standalone.

The Panel noted that Jazz's involvement was mentioned at the end of the 19 minute podcast as follows, "*funding was received from Jazz Pharmaceuticals for the production of this podcast. Jazz Pharmaceuticals reviewed the content for scientific accuracy and full editorial control remains the sole responsibility of the [Professional Membership Body]*" .

The Panel took account of Jazz's submission that a declaration was included on the Professional Membership Body's website, however, noting that the audio could be downloaded, the Panel considered that the audio should be capable of standing alone. The Panel considered that a declaration at the end of a 19-minute podcast did not meet the Code requirement of from "the outset" and therefore ruled a **breach of Clause 5.5**.

The Panel noted that whilst Jazz's declaration of involvement did not meet the requirements of Clause 5.5, it was included at some point in the audio and there was a requirement in the agreement for such a declaration to be included. The Panel therefore ruled **no breach of Clause 5.1**.

Overall

Clause 2 was a sign of particular censure and reserved for such use. While the Panel was concerned Jazz had not recognised at the time of funding that the podcast constituted promotional material, there was no evidence that Jazz influenced what the health professionals said on the podcast published by the Professional Membership Body. The Panel accepted Jazz's submission that the podcast was intended to be a brief overview of the NICE NG144 guidelines so that GPs could have a better understanding of the cannabinoid medicines that may be initiated by specialists. The Panel considered that the complainant had not established that the podcast prejudiced patient safety as alleged nor had they provided any evidence to support their comment about the culture within Jazz. The Panel determined that the multiple breach rulings above adequately covered the matters raised in this case and it ruled **no breach of Clause 2**.

Complaint received **7 July 2024**

Case completed **29 October 2025**