CASE AUTH/3856/11/23 ***NO BREACH OF THE CODE***

COMPLAINANT v IDORSIA

Alleged off-license promotion

CASE SUMMARY

This case was in relation to two advertisements by Idorsia that appeared on a UK news website for general practitioners. Both advertisements were related to Quviviq (daridorexant); a medicine used to treat insomnia. The allegation was that the advertisements' use of the term "chronic insomnia" was inconsistent with the licensed indication for Quviviq.

The outcome under the 2021 Code was:

No Breach of Clause 5.1	**Requirement to maintain high standards at all times**
No Breach of Clause 6.1 (x2)	**Requirement that information/ claims/ comparisons must not be misleading**
No Breach of Clause 11.2 (x2)	**Requirement that a medicine must not be promoted outside the terms of its marketing authorisation**

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 Idorsia was received from an anonymous, contactable complainant.

COMPLAINT

The complaint wording is reproduced below:

> "The following adverts are / were on the [URL provided] website:
>
> [Text of Advertisement 1:
>
> 'Promotional Material from Idorsia Pharmaceuticals UK Ltd
> Click here for Prescribing information and Adverse Event reporting
> Overactive signalling as a cause
> of Chronic Insomnia
> by [named health professional]
> (Professor of Psychiatry & Neurology)
> 2-MIN SUMMARY

WATCH now
For UK healthcare professionals only
September 2023 UK-DA-00181'

Text of Advertisement 2:

'Promotional Material from Idorsia Pharmaceuticals UK Ltd
For UK healthcare professionals only. September 2023 UK-DA-00183
Click here for Prescribing information and Adverse Event reporting
Summary from two Phase 3 studies on
efficacy and safety of daridorexant
in patients with chronic insomnia
Download now Plain language summary']

As can be seen by the PI attached, the indication of this product is much more narrowly defined than merely 'Chronic insomnia'. As such, this product is being sold off licence."

When writing to Idorsia, the PMCPA asked it to consider the requirements of Clauses 5.1, 6.1 and 11.2 of the 2021 Code.

IDORSIA RESPONSE

The response from Idorsia is reproduced below:

"The anonymous complainant enclosed an Idorsia electronic banner advert, and states:

'*As can be seen by the PI attached, the indication of this product is much more narrowly defined than merely "Chronic insomnia". As such, this product is being sold off licence*.'

Idorsia strongly refutes the allegation that daridorexant (QUVIVIQ) is being promoted '*off licence*'. Idorsia asserts that the promotion of daridorexant is in accordance with the terms of its marketing authorisation and is not inconsistent with the particulars listed in its Summary of Product Characteristics.

The SmPC licensed indication states: 'QUVIVIQ is indicated for the treatment of adult patients with insomnia characterised by symptoms present for at least 3 months and considerable impact on daytime functioning.'

We draw your attention within the approved licensed indication specifically to the insomnia symptom duration (at least 3 months), and the considerable effect on daytime functioning. Both of these are fundamental to the definition of chronic insomnia, as described below.

1. Code 7A00 within the **World Health Organisation International Classification of Diseases 11th Revision (WHO ICD-11)**, the global standard for diagnostic health information.
   'Chronic insomnia is a frequent and persistent difficulty initiating or maintaining sleep that occurs despite adequate opportunity and circumstances for sleep and that

results in general sleep dissatisfaction and some form of daytime impairment. Daytime symptoms typically include fatigue, depressed mood or irritability, general malaise, and cognitive impairment. The sleep disturbance and associated daytime symptoms occur at least several times per week for at least 3 months....'

2. The relevant **NICE Insomnia Clinical Knowledge Summary (CKS)** defines that: 'Insomnia is difficulty in getting to sleep, difficulty maintaining sleep, early wakening, or non-restorative sleep, which occurs despite adequate opportunity for sleep and results in impaired daytime functioning.
   - Daytime symptoms typically include poor concentration, mood, disturbance, and fatigue.
   - Sleep disturbances in the absence of daytime impairment is not considered to be insomnia disorder.'

   Insomnia is further sub-classified by symptoms into either short-term insomnia or chronic insomnia. A key differentiator is whether the symptom duration is less than or more than 3 months, i.e.:
   - Short-term insomnia: Insomnia symptoms occurring for less than three months duration (typically a few days or weeks).
     Chronic insomnia: Insomnia symptoms occurring on at least three nights per week for three months or more."

3. Daridorexant's positive **NICE technology appraisal guidance [TA922]** states: 'Daridorexant is recommended for treating insomnia in adults with symptoms, lasting for three nights or more per week for at least three months, and whose daytime functioning is considerably affected, only if....'.

   These accurate and unambiguous explanations substantiate that 'chronic insomnia', defined by reputable clinical and scientific bodies, falls within the correct indication for daridorexant. Idorsia refutes breaches of Clauses 6.1 and 11.2 of the 2021 Code. Idorsia also refutes a breach of Clause 5.1, as high standards have been maintained at all times.

   The promotional (though highly educational) material appeared within an electronic banner advertisement hosted within the on-line General Practitioner resource. The intended audience were GP healthcare professionals. The intention was for an interested GP to click on the brief ~2 minute video to watch a clinical expert provide an explanation of the neuro-pathological role of the orexin signalling pathway as a cause of chronic insomnia, as well as its role in daytime functioning. We note that there was no comment by the complainant about the video content.

   The material was certified by [named medical signatory], a medical final signatory for Idorsia UK, registered as such through the PMCPA and MHRA.

   Idorsia UK believes that it has comprehensively addressed all of the points raised in your emailed letter of 22 November."

PANEL RULING

This complaint was about two advertisements by Idorsia that appeared on a UK news website for general practitioners. Both advertisements were related to Quviviq (daridorexant); a medicine used to treat insomnia.

The Panel noted that although the complaint included two advertisements, which were shared with the company by the case preparation manager, Idorsia referred only to Advertisement 1 (job code: UK-DA-00181) in its response. The Panel made its rulings with regard to each advertisement, as these formed part of the complaint.

Advertisement 1

Advertisement 1 (job code: UK-DA-00181) included a statement at the top, that it was promotional material from Idorsia Pharmaceuticals UK Ltd, and included a link to prescribing information and adverse event reporting, in small font. Beneath this was a prominent title "*Overactive signalling as a cause of Chronic Insomnia by* [named health professional]".

The body of the advertisement included a large image of a hand holding an iPad, with a picture of an adult man and woman, and a 'play' symbol in the centre of the picture. The prominent words "*2-MIN SUMMARY*" and a link to "*Watch now*" appeared adjacent to the image.

The bottom of the advertisement included a statement in small font that it was for UK healthcare professionals only, the date of preparation and the job code. The Panel noted Idorsia's submission that the advertisement included a link to a brief 2-minute video to watch a clinical expert provide an explanation of the neuro-pathological role of the orexin signalling pathway as a cause of chronic insomnia, as well as its role in daytime functioning.

Advertisement 2

Advertisement 2 (job code: UK-DA-00183) was titled "*Summary from two Phase 3 studies on efficacy and safety of daridorexant in patients with chronic insomnia*" and included a prominent link to download a 'plain language summary'.

The top of the advertisement included a statement in small font, that it was promotional material from Idorsia Pharmaceuticals UK Ltd and was for UK healthcare professionals only. This was followed by the date of preparation, the job code, and a link to prescribing information and adverse event reporting. The body of the advertisement contained an image of an adult man and two adult women.

The complainant's allegation was that "*the indication of this product is much more narrowly defined than merely 'chronic insomnia'"* and that *"as such, this product is being sold off licence*".

The Panel noted the content of the linked video in Advertisement 1; the Panel did not have a copy of the 'plain language summary' linked in Advertisement 2, before it. However, because the allegation was limited to the indication of the product "*as can be seen in the PI attached*" in relation to the term "*chronic insomnia*", which appeared on both advertisements, the Panel made its rulings on that basis.

The Panel noted the licensed indication for Quviviq as stated in its Summary of Product Characteristics (SPC): "QUVIVIQ *is indicated for the treatment of adult patients with insomnia characterised by symptoms present for at least 3 months and considerable impact on daytime functioning*".

The Panel noted Idorsia's submission with regard to the World Health Organisation (WHO) and National Institute for Health and Care Excellence (NICE) definitions of "*chronic insomnia*", both of which referred expressly to it comprising an effect on daytime functioning and it occurring for a duration of at least three months.

In the Panel's view, these definitions of the term "*chronic insomnia*" from well-established and authoritative health organisations, were consistent with the characterisation of chronic insomnia in the indication for Quviviq.

Conclusion

Based on the information before it, the Panel considered that the complainant had not established that Advertisement 1, which included the title "*Overactive signalling as a cause of Chronic Insomnia*" was misleading, nor that the promotion of Quviviq was inconsistent with the particulars listed in its SPC, and the Panel ruled **no breach of Clauses 6.1 and 11.2** accordingly.

The Panel considered that the complainant had not established that Advertisement 2, which included the title "*Summary from two Phase 3 studies on efficacy and safety of daridorexant in patients with chronic insomnia*" was misleading, nor that the promotion of Quviviq was inconsistent with the particulars listed in its SPC, and the Panel ruled **no breach of Clauses 6.1 and 11.2** accordingly.

Based on its rulings of no breach above, the Panel did not consider that Idorsia had failed to maintain high standards, and ruled **no breach of Clause 5.1**.

Complaint received **21 November 2023**

Case completed **18 February 2025**