CASE AUTH/3913/5/24 ***NO BREACH OF THE CODE***

COMPLAINANT v IDORSIA

Allegations about misleading information on Idorsia website

CASE SUMMARY

This case was in relation to an Idorsia website. The complainant alleged that by directing users who selected "I am a member of the public" to a page of the Electronic Medicines Compendium (eMC) website, the Idorsia website was promoting Quviviq (daridorexant) to the public. The complainant also alleged that a statement on the webpage intended for health professionals was untrue. That statement related to NICE's recommendation of daridorexant.

The outcome under the 2021 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 (x2)	**Requirement to maintain high standards at all times**
No Breach of Clause 6.1	**Requirement that information, claims and comparisons must not be misleading**
No Breach of Clause 11.2	**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 its summary of product characteristics**
No Breach of Clause 26.1	**Requirement not to advertise prescription only medicines to the public**

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 Pharmaceuticals UK Ltd was received from an anonymous contactable complainant who described themselves as a concerned healthcare professional.

COMPLAINT

The complaint wording is reproduced below:

> "The following website has the initial page.

The ‘I am a member of the public’ just goes through to the product itself rather than providing information that would be suitable for the general public. In essence, they are promoting to the general public.

[Screenshot of landing page showing “Welcome to the Idorsia UK Healthcare Professional portal”, “This information is intended for UK Healthcare Professionals only. By entering this site you are confirming that you are a UK Healthcare Professional.”, and two buttons: “I am a UK healthcare professional” and “I am a member of the public”.]

[Screenshot showing “You are now leaving pro.idorsia.uk”, “You will now be redirected to an independent third party site that is maintained outside of this website, where all Idorsia Pharmaceuticals Ltd UK’s medicines can be found: the electronic Medicines Compendium (eMC)”, and one button: “Continue to medicines.org.uk”.]

[Screenshot of eMC webpage showing two Idorsia Pharmaceuticals UK Ltd products: Quviviq 25 mg film-coated tablets and Quviviq 50 mg film-coated tablets.]

The HCP section links to https://pro.idorsia.uk/?dct=SIMPLE&t=1

[Screenshot of top section of Quviviq webpage]

The top of this page mentions NICE recommends for chronic insomnia. This is untrue - NICE's recommendation is below:

1 Recommendations
1.1 Daridorexant is recommended for treating insomnia in adults with symptoms lasting for 3 nights or more per week for at least 3 months, and whose daytime functioning is considerably affected, only if:

cognitive behavioural therapy for insomnia (CBTi) has been tried but not worked, or

CBTi is not available or is unsuitable.

1.2 The length of treatment should be as short as possible. Treatment with daridorexant should be assessed within 3 months of starting and should be stopped in people whose long-term insomnia has not responded adequately. If treatment is continued, assess whether it is still working at regular intervals.

1.3 This recommendation is not intended to affect treatment with daridorexant that was started in the NHS before this guidance was published. People having treatment outside this recommendation may continue without change to the funding arrangements in place for them before this guidance was published, until they and their NHS clinician consider it appropriate to stop.

Given that this is more restrictive than the licenced indication, having the licenced indication present on the page doesn't help state what NICE's recommendation was.”

When writing to Idorsia, the PMCPA asked it to consider the requirements of the following clauses of the 2021 Code:

- Clauses 5.1 and 26.1 in relation to the allegation of promotion to the public,
- Clauses 5.1, 6.1 and 11.2 in relation to allegations relating to the healthcare professional page referenced by the complainant, and
- Clause 2 overall.

IDORSIA'S RESPONSE

The response from Idorsia is reproduced below:

> "Thank you for your letter of 03 June 2024 (the **Letter**), enclosing a redacted copy of an anonymous complaint to the PMCPA, from a contactable person describing themselves as a concerned healthcare professional, alleging breaches of the ABPI Code of Practice (the **Code**) by Idorsia.
>
> Idorsia is committed to following both the letter and the spirit of the Code and all other relevant regulations and took this complaint very seriously.
>
> We understand that the PMCPA has received allegations regarding a website owned and controlled by Idorsia (the **Idorsia Website**), which can be found at the URL https://pro.idorsia.uk. We understand that these allegations can be briefly summarised as follows:
>
> 1. An allegation that the content which is made available to members of the public who try to access the Idorsia Website and are directed away from the Healthcare Professional Page constitutes promotion of a prescription-only medicine to the general public (**Allegation 1**); and
> 2. An allegation that certain content (regarding a NICE recommendation) is untrue. This information is made available to healthcare professionals (**HCPs**) who access the Idorsia Website and are directed to a page intended for HCPs only (the **Healthcare Professional Page**) (**Allegation 2**).
>
> Further detail in relation to each of Allegations 1 and 2 is provided in our detailed responses to each of the Allegations below.
>
> We note that the PMCPA has asked Idorsia to consider:
>
> 1. the requirements of Clauses 5.1 and 26.1 in relation to Allegation 1 concerning promotion to the public;
> 2. the requirements of Clauses 5.1, 6.1 and 11.2 in relation to Allegation 2 concerning the Healthcare Professional page; and
> 3. Clause 2 overall.
>
> We understand that the ABPI Code 2021 is applicable to this complaint and interpret these clause references accordingly.
>
> Idorsia is confident that its materials are fully compliant with the Code and refutes breaches of Clauses 2, 5.1, 6.1, 11.2 and 26.1.
>
> We start by responding to the additional questions posed by the PMCPA in the Complaint Letter as our responses provide contextual background on how users may access and interact with the Idorsia Website.

1) *To whom was each section of the webpage directed: patients for whom the medicine was prescribed, members of the public or health professionals?*

When the Idorsia Website is accessed by a user for the first time, the landing page is entitled 'Welcome to the Idorsia UK Healthcare Professional Portal'. It is clear from the outset that the intended audience of the Idorsia Website is exclusively UK Healthcare Professionals. To reiterate this point, beneath this heading, there is further text prominently stating 'This information is intended for UK Healthcare Professionals only. By entering this site you are confirming that you are a UK Healthcare Professional.'

Beneath this text, there are two self-selection buttons. These buttons are clearly labelled 'I am a UK healthcare professional' and 'I am a member of the public'.

If the user clicks on the button labelled 'I am a UK healthcare professional', they are taken to the Healthcare Professional Page.

If the user clicks on the button labelled 'I am a member of the public', they are directed away from the Idorsia Website to a webpage containing content appropriate for the general public.

2) *How was the intended audience made aware of the webpage?*

There is no active promotion of the Idorsia Website to the public. Idorsia has not undertaken any search engine optimisation of the Idorsia Website. Members of the public will only arrive at the Idorsia Website if they deliberately choose to follow links marked for HCPs. It is also possible that a member of the public could accidentally arrive at the Idorsia Website, for instance by typing in the URL or by using an internet search engine.

In any event, any user who arrives at the Idorsia Website for the first time will be shown the landing page referred to in our response to question 1, which clearly directs members of the public away from promotional content which is intended for HCPs only.

Idorsia UK promotes the Idorsia Website in HCP-facing assets, such as leave pieces, stands at HCP congresses, and on adverts placed on HCP closed websites, such as [examples provided]. All relevant materials have been reviewed and certified as promotional material, and clearly state that they are intended for UK healthcare professionals.

3) *Could the webpage at any time since its creation be accessed by individuals who were not part of the intended audience, if so, how?*

As referred to in our response to question 1 above, the landing page of the Idorsia Website requires the user to select the section of the website which is appropriate to them by declaring whether or not they are a UK healthcare professional.

If the user clicks on the button labelled 'I am a UK healthcare professional', they are taken to the Healthcare Professional Page, which contains content appropriate for UK HCPs.

If the user clicks on the button labelled 'I am a member of the public', they are shown an interstitial which states 'You are now leaving pro.idorsia.uk. You will now be redirected to an independent third party site that is maintained outside of this website, where all Idorsia Pharmaceuticals Ltd UK's medicines can be found: the electronic Medicines Compendium (eMC)'. The user is not automatically redirected to the electronic Medicines Compendium. The user must click a button labelled 'Continue to medicines.org.uk'.

If the user chooses to click the button labelled 'Continue to medicines.org.uk', the user is redirected to the following webpage: https://www.medicines.org.uk/emc/company/4255 (the **eMC Webpage**). The eMC Webpage is an independent third party website which contains non-promotional reference information concerning Idorsia's products, namely the Summary of Products Characteristics (**SPC**) and the Patient Information Leaflet (**PIL**).

In our experience, this is a common approach for pharmaceutical companies seeking to make reference information available as regards their medicines (which the Code considers to be good practice).

4) *How did Idorsia satisfy itself that the webpage was accessed by an appropriate audience?*

Please refer to the answers to the questions above. The Idorsia Website is not promoted to the general public. The Healthcare Professional Page is only accessible by a user who confirms that they are a UK HCP. Members of the public who arrive at the Idorsia Website are redirected to non-promotional reference information concerning Idorsia's products.

Allegation 1 – Promotion to public on the public section of the website: Clauses 5.1, 26.1

The complainant alleges that, by directing users of the Idorsia Website to the eMC Webpage when those users identify themselves as members of the public, Idorsia is promoting a prescription-only medicine to the general public. This is not correct.

As described above, the eMC Webpage only contains non-promotional reference information concerning Idorsia's products, namely the SPC and the PIL for QUVIVIQ. Clause 26.2 of the Code is clear that information concerning prescription-only medicines can be made available to the general public, provided that it is factual, balanced and non-promotional. The Supplementary Information to Clause 26.2 further explains that companies can make available reference information on their websites (or on third party websites) to act as a non-promotional library resource for the general public. Such reference information can include the SPC and the PIL for prescription-only medicines. Similar guidance is provided in the MHRA Blue Guide at Section 7.5 (Company internet sites).

Further, we note that the PMCPA Panel has accepted in multiple previous cases that it is appropriate and non-promotional for companies to redirect members of the public to reference information found on the electronic Medicines Compendium, when those members of the public attempt to access a webpage intended for HCPs only. We refer to the following cases in this regard:

- AUTH/3329/3/20 - Complainant v Boehringer Ingelheim
- AUTH/3204/6/19 - Anonymous pharmaceutical employee v GlaxoSmithKline

As explained in our responses to the PMCPA's questions, Idorsia does not promote the Idorsia Website to the general public. It also does not encourage the general public to access the eMC Webpage, except where users have arrived at the Idorsia Website and indicated that they are a member of the general public on the landing page. Idorsia only provides the general public with access to non-promotional reference information by way of the eMC Webpage. Idorsia does so to discourage the general public from accessing the Healthcare Professional Webpage which contains content intended for HCPs only.

We refute the allegation that Idorsia has promoted a prescription-only medicine to the public and thus breached clause 26.1 or clause 5.1.

Allegation 2 – 'Untrue' information in the Healthcare Professional Page: Clauses 5.1, 6.1 and 11.2

The complainant points to a statement at the top of the Healthcare Professional Page which concerns Idorsia's product QUVIVIQ (INN-daridorexant). This statement reads: 'NICE recommended for chronic insomnia' (the **NICE Recommendation Statement**). The NICE Recommendation Statement is followed by a reference to footnote 12, which directs the user to the corresponding NICE Technology Appraisal Guidance TA922 which contains the recommendation for daridorexant.

The complainant alleges that the NICE Recommendation Statement is untrue in that it does not refer to the full wording of NICE's recommendation for daridorexant, which is as follows:

> *'1.1 Daridorexant is recommended for treating insomnia in adults with symptoms lasting for 3 nights or more per week for at least 3 months, and whose daytime functioning is considerably affected, only if:*
>
> - *cognitive behavioural therapy for insomnia (CBTi) has been tried but not worked, or*
> - *CBTi is not available or is unsuitable.*
>
> *1.2 The length of treatment should be as short as possible. Treatment with daridorexant should be assessed within 3 months of starting and should be stopped in people whose long-term insomnia has not responded adequately. If treatment is continued, assess whether it is still working at regular intervals.*
>
> *1.3 This recommendation is not intended to affect treatment with daridorexant that was started in the NHS before this guidance was published. People having treatment outside this recommendation may continue without change to the*

funding arrangements in place for them before this guidance was published, until they and their NHS clinician consider it appropriate to stop.'

Idorsia considers that NICE's recommendation can be accurately summarised as a recommendation for the use of QUVIVIQ for chronic insomnia, and that accordingly the NICE Recommendation Statement is not untrue.

Adjacent to the NICE Recommendation Statement regarding NICE on the Healthcare Professional Page, is a clear statement of the approved indication for QUVIVIQ as per its Marketing Authorisation. The statement clearly states that QUVIVIQ should only be used for adult patients who have had insomnia for at least three months, which is significantly impacting their daytime functioning.

With reference to 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...'.

Similarly, in the definition section of the recently published NICE CKS on Insomnia (April 2024), Insomnia is defined as 'a persistent difficulty with getting to sleep, maintaining sleep, or quality of sleep, which occurs despite adequate opportunity and circumstances for sleep, and results in impaired daytime functioning', and chronic insomnia is defined as 'Insomnia symptoms occurring on at least 3 nights per week for 3 months or more'.

In other words, an adult who experiences insomnia symptoms lasting for 3 nights or more per week for at least 3 months, and whose daytime functioning is considerably affected, can be accurately described as someone suffering from chronic insomnia. Accordingly, it is correct to say that NICE has recommended daridorexant for the treatment of chronic insomnia.

Further, the NICE Recommendation Statement prominently refers to footnote 12, which directs the HCP to the relevant NICE guidance containing the terms of the recommendation. Idorsia considers that the presence of this prominent footnote reference clearly substantiates the NICE Recommendation Statement and helpfully makes the relevant NICE guidance available to an HCP who may be considering whether to prescribe QUVIVIQ.

<u>Clause 2</u>

As per the 2021 edition of ABPI Code of Practice, Clause 2 relates to 'Activities or materials must never be such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry', and 'a ruling of a breach of this clause is a sign of particular censure and is reserved for such circumstances. Examples of activities that are likely to be in breach of Clause 2 include prejudicing patient safety and/or public health, excessive hospitality, inducements to prescribe, unacceptable payments, inadequate

action leading to a breach of undertaking, promotion prior to the grant of a marketing authorisation, conduct of company employees/ agents that falls short of competent care and multiple/ cumulative breaches of a similar and serious nature in the same therapeutic area within a short period of time'.

Regarding Allegation 1, we have explained that Idorsia has not promoted a prescription-only medicine to the public, and has adhered to the principles of Clause 26.2 of the Code and section 7.5 of the MHRA Blue Guide by providing non-promotional reference information to the general public on a third party website, namely the electronic Medicines Compendium. This is consistent with industry standard practice which the PMCPA Panel has previously held not to constitute a breach of the Code on multiple occasions.

Regarding Allegation 2, that the NICE Recommendation Statement is untrue, we have provided evidence that NICE has indeed issued guidance (TA922) recommending daridorexant (to which guidance the NICE Recommendation Statement refers) and that this recommendation is for use in the condition 'chronic insomnia'. Accordingly we do not consider the NICE Recommendation Statement to be untrue or to otherwise constitute a breach of the Code.

We therefore strongly refute the possibility of a breach of Clause 2.

The relevant materials were signed off by two Signatories registered with both the MHRA and PMCPA. [details provided]

Idorsia UK believes that it has comprehensively addressed all of the points raised in the Letter. If you require any further information or need any further clarification, please do not hesitate to contact us."

PANEL RULING

This complaint related to an Idorsia website. Idorsia submitted that, when the website was accessed by a user for the first time, they would be met with a landing page with two self-selection buttons: "I am a UK healthcare professional" and "I am a member of the public". If the user clicked the button for health professionals, they would be taken to the healthcare professional webpage; if they clicked the button for members of the public, they would be directed away from the Idorsia website to a page of the Electronic Medicines Compendium (eMC) website.

Alleged promotion to the public (Clauses 26.1 and 5.1)

In relation to the complainant's first allegation, the Panel noted that the complainant had provided screenshots of the landing page of the Idorsia website. The complainant alleged that in directing non-health professionals to a webpage on the eMC website, rather than to "information that would be suitable for the general public", Idorsia was "promoting to the public".

The Panel noted that Idorsia and the complainant had provided different screenshots of the self-selection buttons on the landing page. The complainant's version had a more recent date of preparation and the Panel therefore ruled on the basis of the complainant's screenshots.

The Panel noted the supplementary information to Clause 16.1, which stated: "Unless access to promotional material about prescription only medicines is limited to health professionals and other relevant decision makers, a pharmaceutical company website or a company sponsored website must provide information for the public as well as promotion to health professionals with the sections for each target audience clearly separated and the intended audience identified. This is to avoid the public needing to access material for health professionals unless they choose to."

The Panel further noted that Clause 26.1 prohibited the advertising of prescription only medicines to the public. Clause 26.2 permitted information to be supplied directly or indirectly to the public but such information had to be factual and presented in a balanced way. The supplementary information to Clause 26.2, Information to the Public, stated that this clause allowed "for the provision of non-promotional information about prescription only medicines to the public" including "reference information made available by companies on their websites or otherwise as a resource for members of the public". It also stated that "Such information must not be presented in such a way as to be promotional in nature … but it is considered good practice to provide as a minimum the regulatory information comprising the:

- summary of product characteristics (SPC)
- the patient information leaflet which is included in the pack (PIL)
- and the public assessment report (PAR) (UK or European) where such a document exists."

The Panel noted that the website at issue was primarily aimed at health professionals. The Panel took into account Idorsia's submission that, while members of the public could access the website, there was no active promotion of the website to the public. The Panel considered that the landing page clearly separated the link intended for health professionals from the link intended for members of the public. The link for members of the public took the user to an eMC webpage listing two Idorsia Pharmaceuticals UK Ltd products: Quviviq 25 mg film-coated tablets and Quviviq 50 mg film-coated tablets. The Panel understood that, from here, the user would be able to access the summary of product characteristics and patient information leaflet for each product.

In the Panel's view, the link to the eMC webpage fell within the definition of reference information in the supplementary information to Clause 26.2. The Panel considered that the complainant had not discharged their burden of proof that the information provided for members of the public constituted the promotion of Quviviq to the public, or that Idorsia had failed to maintain high standards in this regard. The Panel ruled **no breach of Clause 26.1** and **no breach of Clause 5.1**.

Allegations relating to the health professional webpage (Clauses 6.1, 11.2 and 5.1)

The complainant's second allegation related to the webpage intended for health professionals. The complainant alleged that a statement near the top of the webpage was untrue.

The statement at issue was "NICE recommended for chronic insomnia". The NICE Technology Appraisal, Daridorexant for treating long-term insomnia, was cited as a reference for this statement, the list of references appearing towards the bottom of the webpage.

The statement appeared in a box in the top right corner of the webpage (below the navigation bars). Also in the top section of the continuous scroll webpage was:

- The statement “For patients with chronic insomnia”
- An image of a woman, with the words “Night-time sleep” and “Daytime functioning” overlaid
- The Quviviq indication:
  “QUVIVIQ™▼ (daridorexant) 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 statement “Prescribing information can be accessed using the PI button at the side. This information is intended for healthcare professionals.”
- The adverse events reporting statement
- A button labelled “PI & AE”

The Panel noted the content of the full webpage.

The Panel noted that NICE’s recommendations in the Technology Appraisal were set out in three parts: Paragraphs 1.1 to 1.3. Paragraph 1.1 stated:

> “Daridorexant is recommended for treating insomnia in adults with symptoms lasting for 3 nights or more per week for at least 3 months, and whose daytime functioning is considerably affected, only if:
>
> - cognitive behavioural therapy for insomnia (CBTi) has been tried but not worked, or
> - CBTi is not available or is unsuitable.”

Paragraph 1.2 of the NICE recommendation was related to the duration of treatment. Paragraph 1.3 was regarding treatment that started before the guidance was published.

The complainant did not make clear which of these three paragraphs of the NICE recommendation they were referring to. The allegation was that the statement “NICE recommended for chronic insomnia” was untrue. Having quoted the NICE recommendation, the complainant alleged that as it was “more restrictive than the licensed indication”, having the licensed indication present on the page did not help state what NICE’s recommendation was. It was not for the Panel to make out the complaint. The Panel therefore limited its consideration to Paragraph 1.1 of the NICE recommendation: the Panel did not consider Paragraphs 1.2 or 1.3 of the recommendation wording directly relevant to the claim “NICE recommended for chronic insomnia”.

The Panel noted Idorsia’s submission with regard to the World Health Organization and 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. The Panel had regard to the similar complaint in Case AUTH/3856/11/23, and concluded that these definitions of the term ‘chronic insomnia’ were consistent with the indication for Quviviq and the NICE recommendation. The Panel considered that there was no evidence that Quviviq had been promoted outside the terms of its marketing authorisation and ruled **no breach of Clause 11.2**.

The Panel noted that the NICE recommendation also included criteria relating to cognitive behavioural therapy. There was no mention of cognitive behavioural therapy on the webpage at issue.

In determining whether the statement “NICE recommended for chronic insomnia” was accurate and not misleading, the Panel took into account the following points:

- The statement was referenced to the full NICE Technology Appraisal document, with the URL provided in a list of references towards the bottom of the webpage.
- NICE Technology Appraisals determine whether or not a medicine should be funded by the NHS: because the process involves assessment of cost-effectiveness, the recommendation may include criteria that are not present in the licensed indication.
- According to the NICE Technology Appraisal, cognitive behavioural therapy is the standard first treatment for people with long-term insomnia after sleep hygiene advice is offered.

In the Panel’s view, it was not unusual for NICE guidance to recommend non-pharmacological approaches as first-line treatments for various conditions. The Panel considered that users of this website (health professionals) would be likely to be familiar with NICE recommendations and the likelihood of additional criteria being included alongside the product’s licensed indication.

While the Panel considered that it may have been helpful for Idorsia to have included a link or some sort of encouragement for the reader to consult the full NICE Technology Appraisal document, the Panel noted that a reference had been provided, albeit at the bottom of a long continuous scroll webpage.

However, in the context of this complaint, the Panel considered that the statement at issue was not likely to mislead the reader. In addition, the complainant’s allegation that it was “untrue” to state that Quviviq was NICE recommended was not a well-founded complaint, in the view of the Panel. NICE *had* recommended daridorexant for use in patients with chronic insomnia, albeit with some caveats around the requirement for non-pharmacological management. The Panel therefore ruled **no breach of Clause 6.1**.

The Panel noted its rulings that the statement was not misleading and did not promote Quviviq outside the terms of its marketing authorisation. The Panel considered the complainant had not discharged their burden of proof that Idorsia had failed to maintain high standards in this case. The Panel ruled **no breach of Clause 5.1**.

Clause 2

Clause 2 was a sign of particular censure and reserved for such use. In light of its findings above, the Panel ruled **no breach of Clause 2**.

Complaint received **28 May 2024**

Case completed **8 April 2025**