

## **COMPLAINANT v ALMIRALL**

### **Allegation regarding a dermatology website**

#### **CASE SUMMARY**

**This case was in relation to an Almirall dermatology website. The complainant alleged that one of the four product tiles on the homepage promoted Wyznora (betamethasone dipropionate 0.5mg/g, calcipotriol 50micrograms/g) off license due to the absence of the full indication.**

**The outcome under the 2021 Code was:**

<b>No Breach of Clause 5.1</b>	<b>Requirement to maintain high standards at all times</b>
<b>No Breach of Clause 6.1</b>	<b>Requirement that information, claims and comparisons must not be misleading</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 its summary of product characteristics</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 Almirall Ltd from an anonymous, contactable complainant.

#### **COMPLAINT**

The complaint wording is reproduced below:

“Dear PMCPA,

On the following website [link provided] there is the below:

[Screenshot of webpage at issue]

You will note that three of the four specify who the product can be used in (either adult or 12+). The fourth one would lead one to think that there is no age restriction. The licenced indication is:

Wyznora is indicated for topical treatment of mild to moderate psoriasis vulgaris, including scalp psoriasis, in adults.

In essence, it is therefore being promoted off licence.

Please investigate."

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

## **ALMIRALL'S RESPONSE**

The response from Almirall is reproduced below:

"Thank you for your letter of 15th August advising a complaint had been made about the Almirall owned website [named Almirall website].

The complainant alleged that one of the four product tiles in the index section titled "Realising the ambition" promoted Wyzora (betamethasone dipropionate 0.5mg/g, calcipotriol 50micrograms/g) off licence through the statement on the tile that read "The first and only CAL/BDP cream that treats mild to moderate psoriasis vulgaris on the body and scalp", without the information that the product was indicated for treatment in adults.

After a thorough review of the material, we believe it meets the requirements of the ABPI 2021 Code of Practice, including Clauses 5.1, 6.1 and 11.2.

The website in question is intended for UK healthcare professionals and requires affirmation of such capacity to allow the reader to proceed and access its content. The first header on the website homepage is clear dark grey text on a white background states that "Prescribing Information and adverse event reporting can be found at the bottom of the page." Wyzora's prescribing information clearly shows that Wyzora is indicated for topical treatment of mild to moderate psoriasis vulgaris, including scalp psoriasis, in adults.

The section at issue is under the subheading "Realising our ambition" in which the sub header text immediately under the title states "Please click below if you would like more information on our products." Four separate tiles are provided with a short sentence about each prescription-only medicine represented. The intent of each tile is to move the reader to further information on the medicine of interest, and not to enable a prescribing decision at this point in the reader journey. Each tile is clickable and contains a clear text in a green box on white background that states "Discover more >" which leads the reader to a page with further information about the medicine.

We understand the complainant believes the tile promoted Wyzora off licence by leading the reader to think there was no age restriction and thus understand that the complainant believes the information promoted use of Wyzora in children (under 18 years of age). The text offers a general statement about the medicine being the first and only CAL/BDP cream. We do not believe the sentence promotes the use of Wyzora in children. Furthermore, the image provided in the tile is of an adult female pictured at a distance wearing casual clothes of long trousers and a long-sleeved top.

It is our understanding that the promotion of Wyzora is being made in accordance with the terms of its marketing authorization and is not inconsistent with the particulars listed in its Summary of Product Characteristics. We believe that the information on the tile in

question, along with the Prescribing Information being one click away from this page meets the requirements of clause 6.1 and clause 11.2 in so far as these clauses apply. In this regard, we refute the allegations of breaches of these clauses.

The website has been appropriately certified and all requirements including the provision of obligatory information and appropriate signposting to the reader have been provided. We believe that high standards have been maintained and, along with the information above, refute a breach of clause 5.1.

The certified webpage and Wynzora Prescribing Information including the electronic certificates of approval, along with details of how the website was used, the signatory's qualifications and the Wynzora Summary of Product Characteristics are attached with this response.”

## PANEL RULING

This complaint about Almirall was received from an anonymous, contactable complainant. The complaint related to an Almirall dermatology website. The complainant alleged that one of the four product tiles on the homepage promoted Wynzora (betamethasone dipropionate 0.5mg/g, calcipotriol 50micrograms/g) off license through the statement on the tile that read “*The first and only CAL/BDP cream that treats mild to moderate psoriasis vulgaris on the body and scalp*”, without the information that the product was indicated for treatment in adults, and therefore it “*would lead one to think there was no age restriction*”.

The Panel noted that the webpage at issue included a statement at the top, against a slim, grey banner, that read “This site is only for UK healthcare professionals and contains promotional information”. This was followed by the statement: “Prescribing information and adverse event reporting can be found at the bottom of the page.” Beneath this appeared a large, prominent colourful banner stating “Welcome to Almirall”, and four boxes overlaying the bottom of the banner, containing brand names and logos for Klisyri, Wynzora, Ilumetri and Ebglyss. Text below the banner discussed the company's philosophy regarding its approach to patient care, including an infographic illustrating the company's therapeutic focus on atopic dermatitis, actinic keratosis and psoriasis and a further banner with a button to “Discover more” about up-to-date developments in dermatology. The footer of the webpage included links to prescribing information for each of the above products mentioned on the webpage.

The section of the webpage, “Realising the ambition”, which was the subject of the complaint, appeared underneath. This section included four individual tiles for Klisyri, Wynzora, Ilumetri and Ebglyss respectively. Each tile included a different image. The tiles for Klisyri, Ilumetri and Ebglyss included the indication on each tile and a prominent green button to “Discover more”. Each indication was referenced to the respective summary of product characteristics (SPC) for the products.

The Panel observed that the text on the tile for Wynzora stated “The first and only CAL/BDP cream that treats mild to moderate psoriasis vulgaris on the body and scalp”, and included a prominent, green button to “Discover more”. This statement was referenced to the Wynzora SPC and a clinical paper.

The Panel noted that Wynzora was indicated for topical treatment of mild to moderate psoriasis vulgaris, including scalp psoriasis, in adults.

The Panel took into account Almirall's submission that the subheading "Realising our ambition" included the text "Please click below if you would like more information on our products." immediately underneath the subheading, and that the intent of each tile was to move the reader to further information on the medicine of interest, and not to enable a prescribing decision at this point in the reader journey. The Panel further noted Almirall's submission that the image provided in the Wyznora tile was of an adult female pictured at a distance wearing casual clothes of long trousers and a long-sleeved top.

The Panel considered the content, layout and impression created by the webpage as a whole; it determined that its purpose was to enable health professionals to discover more information about the company's dermatology portfolio via the homepage.

Noting the context of the webpage, the Panel considered the inclusion of the text "Please click below if you would like more information on our products" beneath the "Realising the ambition" subheading, sufficient to alert prescribers that more information was available for the prescribers' consideration before determining the suitability of the product for an individual patient.

The Panel considered that a health professional may only look at the homepage of the website and therefore the claims on the homepage should be capable of standing alone. However, in the Panel's view it was clear that the webpage was not intended to be a source of complete prescribing information for Wyznora, and the Panel considered it was highly unlikely that health professionals would rely solely on the brief information stated about each product on their respective tiles to inform prescribing decisions.

The Panel noted that the website metadata submitted by Almirall stated that the website was intended for UK health professionals with information about Almirall medicines. The intended audience was dermatologists, general practitioners, healthcare providers and other medical specialists.

The Panel considered the overall impression of the webpage including the text of the Wyznora tile and the accompanying image of an adult woman. In the Panel's view, while it would have been helpful to include the full indication for Wyznora on its tile, the Panel did not consider that the complainant had established that the absence of the full indication for Wyznora, including that it was for use only in adults, meant that Wyznora had been promoted outside the terms of its marketing authorisation, or that the statement on the Wyznora tile was misleading. The Panel therefore ruled **no breach of Clauses 11.2 and 6.1**.

Based on its ruling of no breaches of the Code above, the Panel did not consider that it had been established that Almirall had failed to maintain high standards. The Panel ruled **no breach of Clause 5.1**, accordingly.

**Complaint received**      **5 August 2024**

**Case completed**      **4 November 2025**