

## **COMPLAINANT v VALNEVA**

### **Allegations about a website**

#### **CASE SUMMARY**

This case was in relation to a promotional webpage for Valneva's chikungunya vaccine, IxchIQ. The complainant alleged that there was no clear signposting to where the prescribing information and adverse event reporting statement could be found and that the link to prescribing information was not clear and prominent. The complainant also alleged that when the user clicked to view further content, a pop-up appeared which also did not include mention of where the prescribing information could be accessed from.

The outcome under the 2024 Code was:

<b>Breach of Clause 12.3</b>	<b>Failing to include a clear, prominent statement as to where prescribing information could be found</b>
<b>Breach of Clause 12.6</b>	<b>Failing to include a clear, prominent statement as to where the adverse event reporting statement could be found</b>
<b>No Breach of Clause 5.1</b>	<b>Requirement for companies to maintain high standards at all times</b>
<b>No Breach of Clause 12.1</b>	<b>Requirement to include prescribing information</b>
<b>No Breach of Clause 12.3</b>	<b>Requirement to include a clear, prominent statement as to where prescribing information could be found</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 about Valneva was received from a named, contactable complainant who described themselves as a member of the public.

#### **COMPLAINT**

The complaint wording is reproduced below with some typographical errors corrected:

"Valneva's webpage for their chikungunya vaccine (IxchIQ) has PI and AE reporting information appearing in the footer of their website (please see attached screengrab). However, there is no clear signposting as to where this can be found. Clause 12.1 (part ii) states that for electronic media access by an individual on their own device, the PI should be accessible 'by way of a clear and prominent, direct, single click link'. I

would argue that the link is neither clear nor prominent. This issue persists when a user clicks into further content, whereupon a pop-up swipes in from the right-hand portion of the screen, filling it, and also containing no mention of where prescribing information can be accessed from.”

When writing to Valneva, the PMCPA asked it to consider the requirements of Clauses 12.1, 12.3, 12.6, 5.1 of the 2024 Code.

## VALNEVA’S RESPONSE

The response from Valneva is reproduced below:

“We are writing in response to the above complaint received regarding Valneva UK Ltd.’s promotional healthcare professional webpage for Ixchiq® ▼ (powder and solvent for solution for injection Chikungunya vaccine (live)).

Our understanding of the allegations is as follows. The complainant alleged that:

- 1) prescribing information (PI) and the adverse event (AE) reporting box on our Ixchiq promotional webpage was in the footer of our website which was not prominent,
- 2) there was no clear signposting to where PI and AE reporting can be found, and
- 3) this issue also persisted once a pop-up is clicked on the webpage. Therefore, the complainant alleged breaches of Clauses 12.1, 12.3, 12.6 and 5.1 of the 2024 ABPI Code of Practice (the “Code”).

We have reviewed the Ixchiq® webpage in question and conducted a thorough investigation in order to respond to these allegations. Following such investigation, Valneva UK Ltd. acknowledges breaches of Clause 12.3 and 12.6 because the webpage for Ixchiq® ([URL provided]) did not contain a clear prominent statement signposting at the top of the webpage as to where prescribing information and adverse event reporting can be found. However, we refute the alleged breaches for the pop-ups and do not accept the pop-ups in question are in breach of these clauses for the reasons described in further detail below.

### Alleged breach of Clause 12.3 and Clause 12.6- Prominent statement to where PI/AE can be found on pop-up

Valneva UK Ltd. has taken immediate action to correct the webpage lacking a prominent statement signposting where PI and AE reporting is found on the website. The webpage now complies fully with Clauses 12.3 and 12.6. We thank the complainant for bringing this to our attention.

The Code does not however explicitly require for us to signpost to PI and AE statement on pop-ups as they are not standalone webpages. We would not expect to be required to add PI and AE statements on every single pop-up on a website as pop-ups are an integral part of each webpage (and where the webpage contains a prominent statement signposting where PI and AE reporting is found). Further, we do not believe adding PI and AE statements to pop-ups is standard practice across the industry.

#### Alleged breach Clause 12.1- Prescribing information (PI)

Valneva UK Ltd. strongly denies that breach of Clause 12.1 has occurred.

Clause 12.1 states PI must be provided in a clear and legible manner in all promotional materials for a medicine. On the promotional webpage in question, we fulfil this requirement: we have PI available above our footer and reference section in a larger font (compared to references), on a white background and hyperlinked to a single click link directly to our PI. The complainant alleged that the PI was in the footer of the webpage; however, the footer only contains our job bag number, date of preparation, transparency, privacy policy, cookies policy and cookies preferences. Above this footer, we have our webpage itself (please see attached the webpage). Our PI is clear, prominent, and not located in the footer, and it is accessible via a direct single click link. Therefore, we reject the suggestion that we have breached Clause 12.1, as the link meets both the letter and spirit of the Code.

#### Alleged breach Clause 5.1- Maintaining high standards

Valneva UK Ltd. strongly denies that breach of Clause 5.1 has occurred.

Clause 5.1 states that companies must maintain high standards at all times and the supplementary information to Clause 5.1 explains that companies should have “policies or similar to clearly communicate corporate standards, expectations and behaviours, and should provide appropriate training”.

Valneva UK Ltd. upholds the highest standards in all aspects of its operations within the pharmaceutical industry, including policies and standard operating procedures relating to development and approval or promotional materials, and training on such policies and procedures. It is important to note that the webpage in question (and website as a whole) is intended for HCPs only and is clearly signposted as such. It has a two-step self-declaration, with exit ramps for the public before access to promotional content. The complainant, identified as a member of the public, should not have accessed this HCP-designated content. The Code’s requirements must be interpreted in the context of the intended audience, and we maintain that the site’s structure and content are appropriate and compliant for professional users.

The Ixchiq® webpage was developed under strict medical, legal, and regulatory oversight, with compliance embedded throughout the approval process. The website has been reviewed and certified through Valneva’s internal processes – it is intended for access by healthcare professionals and has been approved as such. While promotional, the website presented safety information in a place of prominence, with the required prescribing information and adverse event report information.

The breaches that Valneva UK Ltd. has accepted are due to human error and not related to any deficiencies in company procedures and processes. Valneva UK Ltd. has taken prompt action to rectify the situation in line with the requirements of the Code. The suggestion that the webpage falls short of Clause 5.1 is unfounded and does not reflect the diligence and integrity with which this webpage was approved and certified.”

## PANEL RULING

The complaint was about a promotional webpage for Valneva's chikungunya vaccine, Ixchiq. The complainant alleged that there was no clear signposting to where the prescribing information and adverse event reporting statement could be found and that the link to prescribing information was not clear and prominent. The complainant also alleged that when the user clicked to view further content, a pop-up appeared which also did not include mention of where the prescribing information could be accessed from.

The webpage consisted of a header with the statement "This is a promotional website intended for UK Healthcare Professionals (HCPs) only" and a navigation bar. There was a large image at the top of the main body of the webpage with the product name. Below the image was the indication and, in smaller font, an instruction to the reader to read the MHRA drug safety update and noting that the vaccine was temporarily paused in people aged 65 and over.

Beneath this were three colourful boxes that the reader could click on to obtain more information about "IXCHIQ overview", "Clinical data" and "Dosing and administration". Each included an image and some text inviting the reader to learn more.

Beneath the three colourful boxes were three links – one to view prescribing information, one to the summary of product characteristics and one to the patient information leaflet. Beneath these was a button to "Place an order", a references list with one item (the summary of product characteristics) and, finally, the adverse event reporting statement in a grey box. The webpage footer included the job code, date of preparation, copyright year and links to the privacy policy and such like.

Clause 12.3 required that, where not immediately apparent, promotional material must include a clear, prominent statement as to where the prescribing information can be found. Clause 12.6 required the same for the adverse event reporting statement. Given their location towards the bottom of the webpage, the Panel considered that neither the prescribing information nor adverse event reporting statement were immediately apparent. The webpage at issue did not include such a signpost near the top of the page to indicate that the prescribing information and adverse event reporting statement could be found further down the page. The Panel therefore ruled a **breach of Clause 12.3** and a **breach of Clause 12.6**, as acknowledged by Valneva.

While the complainant described the prescribing information link as appearing in the footer of the website, the Panel observed that it was actually towards the bottom of the main body of the webpage. The link was in a medium-sized font (compared to the other content on the webpage) and was blue on a white background, with plenty of white space surrounding it. In the Panel's view, the link was sufficiently clear and prominent. The Panel ruled **no breach of Clause 12.1**.

The complainant described how a "pop-up" swiped in from the right of the screen when the user clicked into further content. Valneva provided screenshots of the website as part of its submission, from which the Panel could see that there were three of these pop-ups that corresponded to the three colourful boxes described above. It appeared to the Panel from the complainant's description and from the screenshots that each "pop-up" was a click-triggered, full-screen overlay that appeared when the user clicked on one of the colourful boxes on the main webpage. It appeared likely that the large pop-up would cover the content of the main webpage until it was dismissed by the user clicking on the "x" button to close it. The Panel noted that the pop-up elements did not have their own URLs, distinct from that of the main webpage,

and had not been certified separately to the rest of the webpage. The Panel noted Valneva's submission that the pop-ups were an integral part of the webpage.

The complainant alleged that one of the pop-ups contained no mention of where prescribing information could be accessed from. The complainant did not specify which of the three pop-ups they were referring to, but the Panel noted that all three were similar in function and none contained a signpost to where prescribing information could be found. It was for the Panel to decide whether each of the pop-ups should be treated as a "promotional material" in its own right for the purposes of Clause 12.3.

The Panel observed that the pop-ups were large and contained content that could alternatively have been hosted on a separate webpage. If that were the case, the Panel noted that the separate webpages would each need to comply with the requirements of Clause 12.3. The Panel concluded, on balance, that the pop-ups in this case technically formed part of the main webpage and were not considered promotional material in their own right with regard to the requirements of Clause 12.3. The Panel took into account that the pop-up elements did not have their own URLs and, as such, they could not be accessed without the user first accessing the main webpage. The Panel concluded that the pop-ups did not require an additional signpost to where the prescribing information could be found; the requirements of Clause 12.3 would have been met by a signpost being in place on the main webpage. The Panel therefore ruled **no breach of Clause 12.3** in relation to the pop-ups.

Notwithstanding this conclusion, the Panel noted that the three pop-ups did each include the adverse event reporting statement and a link to prescribing information at the bottom of the content. The Panel considered that it might be good practice to also include signposting to these elements at the top of each pop-up.

Valneva submitted that it had taken prompt action to rectify the error in not including the signposts to prescribing information and the adverse event reporting statement on the webpage at issue. Noting that, although not signposted, the prescribing information and adverse event reporting statement were present, the Panel considered that the complainant had not established that Valneva had failed to maintain high standards. The Panel ruled **no breach of Clause 5.1**.

**Complaint received**      **12 August 2025**

**Case completed**        **20 February 2026**