

CASE AUTH/3739/2/23

COMPLAINANT v VALNEVA UK LIMITED

Allegations about the Valneva in Partnership website and a downloadable consumer awareness leaflet

CASE SUMMARY

This case was in relation to the Valneva in Partnership website and a consumer awareness leaflet about Japanese encephalitis. The complainant alleged the website was promotional and lacked prescribing information. The complainant alleged the leaflet was also promotional and made a number of allegations regarding the requirements for promotional material and certificate retention. The complainant further alleged that a form that was required to be completed in order to download the leaflet was against the General Data Protection Regulation (GDPR).

The Panel considered that the website promoted Valneva's Japanese encephalitis vaccine and ruled a breach of the following clause of the 2021 Code:

Breach of Clause 12.1	Failing to include prescribing information
------------------------------	---

The Panel considered, on balance, that the complainant had not established that the consumer awareness leaflet was promotional. The material was certified and the company had a copy of the certificate. The Panel ruled no breach of the following Clauses of the 2021 Code:

No Breach of Clause 8.1	Requirement to certify promotional material
No Breach of Clause 8.6	Requirement to preserve certificates
No Breach of Clause 12.1	Requirement to include prescribing information
No Breach of Clause 12.9	Requirement that all promotional material must include the prominent adverse event reporting statement
No Breach of Clause 15.6	Requirement that promotional materials and activities must not be disguised

The Panel had no evidence before it that a health professional had received a promotional email from Valneva without prior permission and, in the absence of a formal finding by a judicial authority or appropriate body charged with determining matters in relation to GDPR, the Panel ruled no breach of the following Clauses of the 2021 Code:

No Breach of Clause 5.1	Requirement that high standards must be maintained at all times
No Breach of Clause 15.5	Requirement that email must not be used for promotional purposes, except with the prior permission of the recipient

The Panel considered that the failure to include prescribing information on the website was sufficiently covered by the breach of Clause 12.1 and therefore ruled no breach of the following Clause of the 2021 Code:

No Breach of Clause 2	Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry
------------------------------	---

**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 from a contactable complainant, who described themselves as a health professional, about Valneva UK Limited.

COMPLAINT

The complainant stated that Valneva runs a Valneva in Partnership website. The complainant alleged that it was set up as a promotional website but there was no prescribing information on any product that was mentioned. On the resources page the complainant alleged that there was clear mention of indications for Valneva’s vaccines for which they were the sole ‘treatment’.

The complainant referred to a Japanese encephalitis consumer awareness leaflet available to download from the resources page of the website and noted the obligation [prior to downloading the material] to sign up for promotional emails. The complainant alleged this was against GDPR – where signing up should not be coercive – and failing to maintain high standards.

The complainant alleged that the leaflet did not state it was promotional, yet Valneva had the only treatment for this condition, thus making it promotional. The complainant claimed it was downloadable from a promotional website and the intent was clear. As such, the complainant alleged there was missing prescribing information, no adverse event statement, and that the leaflet had ‘probably’ not been adequately certified and the certificate not kept for the requisite length of time.

When writing to Valneva, the PMCPA asked it to consider the requirements of Clauses 2, 5.1, 8.1, 8.6, 12.1, 12.9, 15.5 and 15.6 of the Code.

RESPONSE

Valneva stated that it was committed to ensuring that all of its UK activities complied with the Human Medicines Regulations 2012 and were conducted in a legal and ethical manner. Valneva stated that its materials and activities were reviewed internally in line with Code requirements.

Valneva set out its response to the matters raised in the complaint below:

- Valneva stated that the Valneva in Partnership website was aimed at UK healthcare professionals only. The website was accessed via the landing page which required users to select whether they were a UK healthcare professional or a patient/member of the public. Valneva stated that, if the user selected that they were a patient/member of the public, they were redirected to the main Valneva website which contained non-promotional material suitable for patients/members of the public. If the user selected that they were a UK healthcare professional, they were asked to confirm that they were a healthcare professional by way of a pop-up box. If the user confirmed they were a healthcare professional, they were directed to the Valneva in Partnership website homepage. Valneva submitted that the landing page displayed adverse event reporting information.
- Valneva stated that the website was intended to support healthcare professionals who wished to set up a travel health service and included training and operational support on that topic. Valneva submitted that the homepage contained a single general reference to vaccines but did not mention any specific vaccine or other medicinal product and therefore Valneva had not provided prescribing information for its individual products.
- Valneva submitted that the leaflet referred to in the complaint was only downloadable from the 'Resources' page of the Valneva in Partnership website and was described clearly as a 'consumer awareness leaflet'. Valneva stated that the 'Resources' page could be accessed by selecting 'Resources' from the menu at the top of the Valneva in Partnership homepage or by scrolling down the homepage to the link to 'Resources'. Valneva submitted that its involvement in the leaflet was clearly stated on the leaflet as 'Sponsored and developed by Valneva UK Limited'.
- Valneva submitted that the leaflet was disease awareness material that was intended to help raise public awareness of the disease Japanese encephalitis and to provide information about the steps that travellers can take to reduce their risk of contracting this disease. Valneva submitted that the leaflet provided factual and balanced educational information about the disease and preventative steps. It did not promote Valneva's products, did not refer to vaccination generally or to any vaccines by brand or non-proprietary name, and did not encourage members of the public to ask their doctors or other prescribers to prescribe a specific prescription only medicine. Valneva submitted that the leaflet was not a vaccination campaign as suggested by the complainant.
- Valneva submitted that, in developing and approving the leaflet, it followed the MHRA Blue Guide Disease Awareness Campaign Guidelines. In line with these guidelines, the content of the material related to the condition and preventative steps, with details of where to get appropriate advice.
- Valneva noted that the complainant alleged that the leaflet was promotional simply by virtue of the fact that Valneva had the only vaccine for this disease (which, Valneva noted, for completeness, was a vaccine and not a treatment as referred to by the complainant). Valneva submitted, however, that the fact that a company had the only vaccine for a disease did not automatically mean that all materials were promotional – otherwise it would not be possible for any company to provide disease awareness materials for any disease where there was only one authorised treatment or vaccine.

Rather, the MHRA Blue Guide and Code provide that particular care needs to be taken. Valneva stated that it took particular care in creating the leaflet, including by not featuring any reference to vaccination or vaccine and instead directing the public to speak to their healthcare professional for advice. Valneva, therefore, did not agree that the leaflet in question was promotional.

- Valneva stated that, in line with Clause 26.2 of the Code, non-promotional information could be made available to the public via healthcare professionals.

In relation to the specific clauses of the Code referenced by the case preparation manager, Valneva submitted the following:

- **Clauses 8.1 and 8.6:** As explained above, Valneva considered the leaflet was not promotional material. Valneva stated it was certified in advance as non-promotional disease awareness material in accordance with Clause 26.2 and the reference number was clearly stated on the leaflet (UK-JE-2200002). One of the signatories, [name provided], was a GMC registered medical practitioner. Valneva submitted that certificates were preserved within its Veeva system for at least three years after the date of final use of the material, in accordance with the Code and Valneva's internal SOP on certification.
- **Clauses 12.1 and 12.9:** Valneva submitted that the leaflet was not promotional material and therefore no prescribing information or adverse event information needed to be provided in relation to the leaflet. Valneva submitted that an adverse event statement was provided on the landing page of the website. There was no mention of any of its vaccine products on the website and therefore it had not provided prescribing information for those products.
- **Clause 15.5:** Valneva submitted that, by choosing to download the leaflet, users did give permission to be contacted by digital communications for promotional purposes. Users could choose not to download the leaflet if they did not wish to give permission for such communications. On this basis, Valneva submitted that the leaflet download wording was not contrary to Clause 15.5.
- However, Valneva acknowledged that, in error, no opt-out was included to the obligation to sign up for promotional emails when downloading the leaflet. While Valneva's privacy policy, which applied to the personal data collected via the sign up, contained confirmation that data subjects had the right to restrict or object to processing of their data, Valneva acknowledged that the wording used was inconsistent with the Information Commissioner's Office's guidance on direct marketing. Valneva stated that it had now amended this so that healthcare professionals could simply download the leaflet without providing contact details. Valneva confirmed that, in practice, the data collected in connection with the leaflet had not been used to send promotional materials to healthcare professionals.
- **Clause 15.6:** Valneva submitted that the leaflet was not promotional and therefore was not disguised promotional material.
- **Clauses 2 and 5.1:** Valneva submitted that the leaflet was compliant with the Code. Valneva submitted that the user download language had been amended and, while not

in-line with the ICO guidance, healthcare professionals still had the option not to download the leaflet and to contact Valneva for a copy if they did not wish to provide permission to be contacted in this way. Valneva, therefore, believed this did not warrant a finding of breach of Clause 2 or 5.1.

Valneva stated that at the date of the complaint the only downloadable material on the resources page was the leaflet and a poster. At the date of Valneva's response, three other downloadable materials were now available on the resources page.

PANEL RULING

The Panel noted Valneva's submission that changes had been made to the website since the receipt of the complaint. The Panel therefore made its rulings in relation to the material as provided by the complainant and as captured by the case preparation manager at the time of the complaint.

The Valneva in Partnership website

The Panel noted the complainant's allegation that the Valneva in Partnership website was promotional and lacked prescribing information for any Valneva product that was mentioned.

The Panel noted that the Valneva in Partnership website landing page required users to select whether they were a health professional or a patient/member of the public. Patients/members of the public would be redirected to the main Valneva website, while health professionals proceeded through to the Valneva in Partnership website.

The Panel noted that the complainant provided two weblinks: one that led to the Valneva in Partnership homepage (after selecting 'I am a health professional') and the other to the resources webpage for health professionals within the Valneva in Partnership website. The leaflet referred to by the complainant could be downloaded by health professionals from the resources webpage. The Panel therefore restricted its consideration to the homepage and the resources webpage as referred to by the complainant.

The Panel noted Valneva's submission that the Valneva in Partnership website was 'intended to support healthcare professionals who wish to set up a travel health service and included training and operational support ...'. The Panel noted that the homepage included a navigation bar at the top with links named 'Home', 'Resources' and 'Contact us'. The top of the homepage included the text 'Working with you to create the best travel health service for you and your customers'. There was a video titled 'The Valneva in Partnership (VIP) programme', which the Panel was not provided with. Beneath this were sections on 'Training', with a link to register for an online learning platform and reference to 'injection technique training', 'Ongoing Support', with a link to place an order for vaccines, and 'Promotion', with a link to find out more about Valneva's 'Beware of the Bugs' website and the option to register the user's travel clinic on that customer-facing website. This was followed by a section listing available 'clinic support and disease awareness materials' including 'Japanese encephalitis patient poster' and 'Japanese encephalitis patient leaflet' which health professionals could download from the Resources webpage, and a link to that webpage. Towards the bottom of the homepage was a 'Get in Touch' section, and the page footer, which referred to Valneva as an established global vaccine company providing products to help protect travellers.

Valneva submitted that the homepage contained a single general reference to vaccines but did not mention any specific vaccine or other medicinal product. The Panel accepted that there was no named specific vaccine or medicinal product on the homepage; however, contrary to Valneva's submission, the Panel considered that vaccines were mentioned twice on the homepage:

- in the 'Ongoing Support' section: 'You can also order vaccines directly from the Valneva UK website.'
- in the page footer: 'Valneva is an established global vaccine company providing products to help protect travellers.'

The Panel noted that there were multiple uses of the words 'travel health clinic' or 'travel health service' throughout the homepage and that the 'Ongoing Support' section included an offer of ongoing support from the Valneva Travel Services Development Manager.

The 'Resources' webpage also referred to a 'travel health clinic' and included the Japanese encephalitis patient materials referred to above along with the same page footer as the homepage, which mentioned 'vaccine'.

The Panel noted the complainant's allegation that there was no prescribing information for 'any product that was mentioned'. The Panel noted that the complainant did not name any specific product in their complaint but stated that there was 'clear mention of indications' for Valneva's vaccines on the resources webpage for which the complainant asserted Valneva had the only 'treatment' and in that regard the complainant referred to a leaflet about Japanese encephalitis. The Panel therefore determined that the allegation regarding prescribing information related to Valneva's vaccine for Japanese encephalitis, Ixiaro.

The Panel noted that the homepage and resources webpage Veeva Vault certificates referred to the material as 'Promotional'. The Panel understood that Valneva had the only vaccine for Japanese encephalitis available in the UK at the time of the complaint.

The Panel noted that while there were no product names explicitly stated on the homepage and the resources page, both webpages referred to 'vaccine', 'Japanese encephalitis' and 'travel health clinic'.

The Panel noted the broad definition of promotion under Clause 1.17 of the Code. The Panel considered that it was a well-established Code principle that a medicine could be promoted without its name being mentioned. The Panel considered that in referring to Japanese encephalitis and vaccines, in which Valneva had the only licensed vaccine in the UK, alongside references to health professionals setting up travel health clinics, including with ongoing support from Valneva, meant that the Valneva in Partnership website, on the balance of probabilities, promoted Valneva's vaccine for Japanese encephalitis, Ixiaro. The Panel noted Valneva's submission that the website did not contain prescribing information and the Panel therefore ruled **a breach of Clause 12.1**.

The Japanese encephalitis leaflet

The Panel noted the complainant's allegation that the leaflet on Japanese encephalitis available to download from the Valneva in Partnership website was promotional because Valneva had the

'only treatment' [sic] for this condition. The Panel also noted the complainant's comment that the leaflet was downloadable from a promotional website.

The Panel noted that the leaflet in question (UK-JE-2200002) had been certified by Valneva as non-promotional disease awareness material. The Panel noted Valneva's submission that the leaflet did not feature any reference to vaccination or vaccine and instead directed the public to speak to their health professional for advice.

The Panel noted the content of the leaflet, which was available to download from the 'Resources' page of the Valneva in Partnership website with the heading 'Consumer Awareness Leaflet (Japanese Encephalitis)'. The leaflet referred to preventative measures including avoiding mosquito bites, using a recommended insect repellent, wearing appropriate clothing and using mosquito nets, and encouraged the reader to 'Talk to your healthcare professional about a full travel health risk assessment before travelling'. The leaflet also provided other information about Japanese encephalitis, including symptoms and countries where the disease is present. The Panel noted that the body of the leaflet made no reference to vaccination but encouraged the reader to talk to their health professional or visit bewareofthebugs.com to start an online consultation. The Panel did not have a copy of the content on the bewareofthebugs.com website at the time of the complaint and neither party made any submission in this regard. The Panel noted that there was one reference to 'vaccination' in the references section of the leaflet, which was in small font, and was a published article reference.

The supplementary information to Clause 26.2 stated that particular care must be taken (in disease awareness or public health campaigns) where the company's product, even though not named, is the only medicine relevant to the disease or symptoms in question. In the Panel's view, although Valneva had the only vaccine for Japanese encephalitis available in the UK at the time of the complaint, this did not necessarily prohibit the company from conducting disease awareness; the content and balance of the material would be important considerations in this regard. The Panel noted that the leaflet referred to a number of different types of preventative measures to reduce risk of infection, including non-medicinal preventative options, and insect repellent, and encouraged the reader to talk to their health professional. There was no specific reference to vaccination in the body of the material. The material also provided general information about Japanese encephalitis symptoms and risk areas/countries. The Code did not prohibit companies providing non-promotional material to health professionals that was intended to be passed on to their patients; that such material was available for health professionals to download from a promotional website did not mean that the material itself was necessarily promotional. Taking everything into consideration, the Panel considered, on balance, that the complainant had not established that the leaflet in question promoted Ixiaro.

The Panel noted the complainant's specific allegations regarding the lack of prescribing information and the adverse events reporting statement on the leaflet in question. Having determined that the leaflet was not promotional material, the Panel subsequently ruled **no breach of Clause 12.1 and Clause 12.9**.

The Panel noted the complainant's allegation that the leaflet did not state that it was promotional. Having determined that the leaflet was not promotional, it could not be disguised promotion, and therefore the Panel ruled **no breach of Clause 15.6**.

The Panel noted the complainant's allegations that the leaflet 'has probably not been adequately certified' and that the certificate 'has not been kept for the requisite length of time'.

The Panel noted that Clause 8.1 related to the certification of promotional material; the material in question was considered by the Panel to be non-promotional disease awareness material that required certification under Clause 8.3. The Panel therefore considered that Clause 8.1 was not relevant to the material at issue. Furthermore, the material appeared to have been certified as non-promotional disease awareness material in September 2022 and the company was able to provide the PMCPA with a copy of the certificate in March 2023; the Panel therefore ruled **no breach of Clauses 8.1 and 8.6** accordingly.

The user download language

The Panel noted the screenshot provided by the complainant of the form that appeared when a user clicked to obtain the leaflet.

The form required the health professional to enter their name and email address and included the text:

'By registering to download these materials, I declare that:
I hereby agree to the collection and processing of my personal data by Valneva UK Ltd. and/or any of its affiliates ("Valneva") in order to be contacted via email for the promotional related purposes and services in general as described in detail in the Privacy Policy.
I have read and understood the terms and conditions applicable to the processing of my Personal Data, for the purposes set out in the Privacy Policy [hyperlink] [unticked checkbox].'

The Panel noted the complainant's allegation that, in order to access the leaflet, there was an obligation to consent to receiving promotional emails and that this was against the General Data Protection Regulation (GDPR) and indicated a failure to maintain high standards.

The Panel noted Valneva's submission that users could choose not to download the leaflet and, instead, contact Valneva for a copy. The Panel noted, however, that there was no wording to this effect included on either the 'Resources' page of the website or the pop-up form.

The Panel noted that, in Valneva's opinion, the wording used was inconsistent with guidance from the Information Commissioner's Office (ICO). Valneva stated that it had since amended the website to enable the leaflet to be downloaded by health professionals without the requirement for contact details.

The Panel noted that its sole role was to rule in relation to the Code.

Clause 15.5 stated that '... email ... and other digital communications must not be used for promotional purposes, except with the prior permission of the recipient.' The Panel noted the wording of the form that appeared when a user tried to download the leaflet, as provided in the complainant's screenshot, and the fact that the checkbox did not appear to be pre-ticked. The Panel considered that by ticking the checkbox to download the leaflet, the user was taking positive action to consent to receive promotional emails. The Panel further noted Valneva's submission that, in practice, the data collected in connection with the leaflet had not been used to send promotional materials to healthcare professionals. The Panel had no evidence before it that a health professional had received a promotional email from Valneva without prior permission and, in this regard, the Panel ruled **no breach of Clause 15.5**.

The Panel noted the complainant's concern that the obligation to sign up for promotional emails in order to download the leaflet was 'against GDPR' because it was 'coercive', and therefore that it was 'failing to maintain high standards'. While the Panel was concerned that health professionals would feel obliged to consent to receiving promotional emails in order to download the leaflet (particularly in the absence of wording to indicate that they could request it via an alternative route), the Panel considered that the complainant's allegation was narrow and specific to GDPR.

The Panel noted that there did not appear to have been any formal finding by any judicial authority or appropriate body charged with formally determining matters in relation to GDPR. The Panel considered that in the absence of such a formal finding the complainant, who bore the burden of proof, had not established that Valneva's activities had breached GDPR. Accordingly, the Panel ruled **no breach of Clause 5.1**.

Overall

Clause 2 was a sign of particular censure and reserved for such use. The Panel considered that the failure to include Ixiaro prescribing information on the Valneva in Partnership website was sufficiently covered by the breach of Clause 12.1 ruled above. The Panel therefore ruled **no breach of Clause 2**.

* * * * *

Complaint received **13 February 2023**

Case completed **6 March 2024**