

CASE AUTH/3734/2/23

COMPLAINANT v VALNEVA

Allegations about a webpage and video on YouTube

CASE SUMMARY

This case related to Valneva's participation in a pharmacy organisation's training webinar for pharmacy staff setting up or running a travel health service.

The outcome under the 2021 Code was:

Breach of Clause 5.1	Failing to maintain high standards
Breach of Clause 8.1	Failing to certify promotional material
Breach of Clause 12.9	Failing to include a prominent adverse event reporting statement
Breach of clause 15.6	Disguised promotion

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 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

COMPLAINT

The complaint wording is reproduced below:

'The following video is on youtube - and therefore available to the general public.: [link provided]

It is also linked from [pharmacy organisation's] website where they state their relationship with Valneva – [link provided]

It does not make clear Valneva's involvement with [pharmacy organisation], and the page itself does not appear to have been reviewed by Valneva although it contains the link to the video where their staff are an invited speaker.

In the video, which is aimed at Pharmacists (although available to the general public) does not specifically state that is promotional. But as can be heard the Valneva staff lists the vaccines that they have and also that they are in many cases the only vaccine available for this indication. This clearly then meets the criteria for promotion. [Their] role appears to be to work with Pharmacists to spread patient awareness to get vaccines. This does not appear to be a campaign signed off by the Department of Health, so such collusion with Pharmacists is not allowed.

No prescribing information is available for any of the three products. There is no obligatory yellow card information to report adverse events. Although there is a code on some of the slides presented, there is not on many of the others. Hence, I question whether the entire presentation has been reviewed, certified and indeed, the certificates kept for the required length of time. This clearly fails to meet high standards, and potentially brings the industry into disrepute.

Whether this is an isolated case, or whether "index case" or whether there is a more widespread systemic effort to work with pharmacists in a way that is not in line with the Code also needs to be checked. Given there appear to be staff who are on film stating that this is their role, the latter seems likely.'

When writing to Valneva, the Authority asked it to consider the requirements of Clauses 2, 5.1, 8.1, 12.9, 15.6 and 26.1 of the Code.

RESPONSE

The response from Valneva is reproduced below:

'We are committed to ensuring that all of our UK activities comply with the Human Medicines Regulations 2012 and are conducted in a legal and ethical manner. While Valneva UK is not a member of the ABPI, we voluntarily follow the standards set out in the ABPI Code of Practice. Our materials and activities are reviewed internally in line with ABPI Code requirements.

We have set out our response to the matters raised in the complaint below.

- The complaint relates to a [pharmacy organisation's] website and a video recording of a [pharmacy organisation's] webinar. [Pharmacy organisation] provides support and resources to independent pharmacies. [Pharmacy organisation] offers membership which is paid, open only to healthcare professionals and provides various benefits to its member including training webinars. [Pharmacy organisation] developed an online training webinar to provide information on setting up and running a travel health and vaccination services. As part of that offering, Valneva provided a presentation on practical aspects of setting up a travel health service in a pharmacy.

The invitation and agenda for the webinar made clear that the webinar featured a guest speaker employed by Valneva with the inclusion of the statement "The

speakers providing the 'Travel Health – Consolidation' training are provided by Valneva UK Ltd and are employed by Valneva UK Ltd.” The content of Valneva’s presentation was reviewed by Valneva in advance as shown by the enclosed certificate. The transcript of the webinar is provided below as requested. The invitation, agenda and presentation did not refer to Valneva’s vaccine products and therefore no adverse event reporting or prescribing information was included.

- The complainant alleges that the webpage in the screen shot does not make clear Valneva’s involvement with [pharmacy organisation]. However, the webpage clearly states “Working in partnership with Valneva...” and as described above the involvement of a Valneva employee was also made clear in the invite and agenda.
- Following the webinar, [pharmacy organisation] uploaded a video recording of the webinar to the members areas of [pharmacy organisation’s] website. The video recording was accessible only to [pharmacy organisation] members who had logged in to [pharmacy organisation’s] website and then navigated to the video via the member benefits tab.
- The video was hosted on the YouTube platform but was not as alleged by the complainant available on YouTube to the general public. The video was “unlisted” which means that it cannot be found by the general public when searching through Google or on YouTube and can only be accessed via the unique URL. Confirmation of the “unlisted” status of the video can be seen in the lower left hand corner of the screenshot provided by the complainant (under the wording “Travel Health & Vaccination Service Webinar”).
- Following the migration of the [pharmacy organisation] website to a new platform in 2022 it became technically possible for a member who had logged in to the [pharmacy organisation] members area to copy and share the link if they wished to. The ability for members to do this has now been removed.
- Based on the above, the video was not accessible by the general public on YouTube and therefore was not promotion of prescription medicines to the public.

In relation to the other specific clauses of the Code referenced in your letter:

- **Clauses 8.1:** The presentation was certified in advance as indicated by the reference on the slides and we enclose a copy of the certificate. One of the signatories, [name], is a GMC registered medical practitioner. Certificates are preserved within our Veeva system for at least three years after the date of final use of the material in accordance with the Code and our internal SOP on certification.
- **Clauses 12.9:** While the meeting invite, agenda and presentation did not contain any reference to any of Valneva’s medicinal products, from the transcript of the presentation there is a single mention of our products Ixiaro, Rabipur and

Dukoral . We acknowledge that adverse event reporting and prescribing information should therefore have been provided.

- **Clause 15.6:** The video is not a disguised promotional material as the involvement of Valneva was made clear in the invitation, agenda, webinar and webpage. The purpose of the material was to provide information on setting up a travel vaccination service and not to promote Valneva's products.
- **Clauses 2 and 5.1:** The video as certified was compliant with the Code but we acknowledge that the single reference to our products in the commentary provided by the presenter meant that adverse event reporting and prescribing information should therefore have been provided. We do not believe that this warrants a finding of a breach of Clause 2 or 5.1.'

PANEL RULING

The Panel noted the complaint concerned a [pharmacy organisation] training webinar about setting up a travel health and vaccination service in a pharmacy which had been uploaded to [pharmacy organisation's] member website and hosted on YouTube. [Pharmacy organisation] was a membership organisation supporting independent pharmacy businesses and thus the Panel understood the intended audience would be pharmacists and pharmacy staff.

The Panel noted as part of the online training webinar, Valneva provided a presentation on the practical aspects of setting up a travel health service in pharmacy; the presentation was titled 'Starting you on your travel health service journey'

The Panel noted the invite appeared to have been sent out from [pharmacy organisation] and stated:

'[Pharmacy organisation] have partnered with Valneva UK* to bring you a free and interactive webinar designed which has been designed to support managers, pharmacists and business owners to explore how to start or reignite an effective and profitable travel service in your pharmacy.

During this 90 minute Webinar, [pharmacy organisation] will cover the following:

- The commercial and healthcare benefits of a travel service
- Engaging your team with new services
- Engaging with local stakeholders
- [Pharmacy organisation] support

Getting started with Travel Health provided by Valneva will cover:

- Travel health update
- What is a risk assessment?
- Setting up an effective travel health service in COVID times.
- Overcoming barriers
- Marketing your travel service

*The speakers providing the "Getting started with Travel Health" training are provided by Valneva UK Ltd and are employed by Valneva UK Ltd.'

The Valneva presentation covered the benefits to pharmacies, travellers and the NHS of a travel service along with pharmacy's role in increasing awareness of travel health risks, improving access to travel health advice and the provision of travel health services including vaccination. It provided guidance on the steps to be undertaken to set up a travel health service in a pharmacy.

The Panel noted there was no reference to any medicine in the presentation slides, which had been reviewed and approved internally prior to the webinar as evidenced by Valneva. However, the Panel noted Valneva's acknowledgement that from the transcript of the presentation there was a single mention of its products Ixiaro, Rabipur and Dukoral. In this regard, the Panel noted the speaker highlighted Valneva's vaccines in the context of their indications and there being 'no competitors in the market'.

The Panel, noting reference to Ixiaro, Rabipur and Dukoral Valneva's products, considered the webinar was promotional.

Clause 12 of the Code set out the requirements for inclusion of prescribing information, adverse event reporting statement and other obligatory information in promotional material.

Noting its finding that the video was promotional material, the Panel ruled **a breach of Clause 12.9** in relation to the absence of adverse event reporting information. Clause 12.1 had not been raised by the case preparation manager in relation to the complainant's allegation that the material did not contain prescribing information for any of the three products. The Panel therefore determined that this matter would be dealt with under Clause 5.1 noting that the absence of prescribing information for Ixiaro, Rabipur and Dukoral amounted to a failure to maintain high standards. The Panel ruled **a breach of Clause 5.1**.

The Panel noted Valneva provided a copy of its certificate in relation to Valneva's slides. The Panel noted the complaint related to the video recording of the webinar which consisted of the slides and accompanying voiceover. The Panel considered that the video was promotional material and therefore needed to be certified. The Panel had no evidence that the video had been certified as promotional material in its own right before being hosted on the [pharmacy organisation] website and therefore ruled **a breach of Clause 8.1**.

The Panel noted the allegation that Valneva's involvement with [pharmacy organisation] was not clear and it was not clear that the video was promotional.

In this regard, the Panel noted the [pharmacy organisation] webpage was titled 'Travel Health and Vaccination Service', directly beneath which was the statement 'Working in partnership with Valneva UK, we will provide an overview on how to set up and run an effective and profitable Travel Health and Vaccination Service in your pharmacy'. Below this was a list of the areas covered in the webinar and a link to the video recording appeared at the bottom of the page. In addition, the Panel noted Valneva's submission that its involvement in the [pharmacy organisation] webinar was also stated in the invitation and agenda.

In the Panel's view, whilst Valneva's involvement in the webinar was made clear, the matter regarding disguised promotion was relevant noting the Valneva speaker's reference to its medicines rendered the webinar promotional.

The Panel, noting the contents of the invitation/agenda, webpage, presentation slides and video transcript, considered there was no indication that the webinar would include information about Valneva's medicines. The Panel accordingly ruled **a breach of Clause 15.6**.

In relation to the allegation that the video on YouTube was available to the general public, the Panel noted Valneva's submission that the video recording was accessible only to [pharmacy organisation] members who had logged in to their website. Valneva submitted the video was 'unlisted' and thus could not be found by searching through Google or on YouTube and could only be accessed via the unique URL. In this regard, the Panel noted that the screenshot of the YouTube video provided by the complainant included the 'Unlisted' icon.

Noting the complainant bore the burden of proof, the Panel considered the complainant had not established that the webinar recording was accessible by members of the public and accordingly ruled **no breach of Clause 26.1**.

The Panel noted the complainant's assertion that the role of the speaker, who was a Valneva employee, appeared 'to be to work with pharmacists to spread patient awareness to get vaccines' and that such collusion was not allowed. They requested PMCPA investigate if this was a more widespread systemic effort to work with pharmacists in a way that was not in line with the Code. Noting contents of the video and that the PMCPA was not an investigatory body, the Panel considered that the complainant had not established their complaint in this regard. Whilst the Panel noted its ruling of breaches above in relation to promotion, the Panel noted that Clause 2 was used as a sign of particular censure and reserved for such use. The Panel did not consider that the circumstances in this particular case warranted a ruling of a breach of **Clause 2** and therefore **no breach** was ruled.

Complaint received **10 February 2023**

Case completed **4 June 2024**