CASE/0765/10/25

COMPLAINANT v ORGANON

Allegations about off-licence promotion

CASE SUMMARY

This case was in relation to a healthcare organisation's website which had received sponsorship from Organon. The complainant alleged that the website promoted Organon's migraine product, Emgality (galcanezumab), outside the terms of its marketing authorisation and that Organon should not have sponsored off-label content.

The outcome under the 2024 Code was:

Breach of Clause 5.1	**Failing to maintain high standards**
Breach of Clause 11.2	**Promoting a medicine for an unlicensed indication**

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 11.2	**Requirement not to promote a medicine for an unlicensed indication**

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 Organon Pharma (UK) Limited from a contactable complainant who described themselves as a health professional.

COMPLAINT

The complaint wording is reproduced below:

> "Organon have sponsored content on an organisation website and the organisation are promoting organon migraine product (Emgality- Galcanezumab) for off-label use. [Named healthcare organisation] are located in [named county], there is a UK nexus as Organon are sponsoring the content of UK based organisation [URL provided]. Organon promote Galcanezumab which is licensed for migraine prophyalxis only in the UK. The following section of the website contains information on Galcanezumab which is off-label [URL provided]. The following text on this page is in breach as Galcanezumab is not licensed for episodic cluster headache. "The CGRP monoclonal antibody, Emgality (galcanezumab), was approved for the prevention of migraine in adults in September 2018 and, in June 2019, became the first and only

anti-CGRP therapy to be approved for the prevention of episodic cluster headache in adults." The website also contains several studies related to Galcanezumab within the clinical trials section which discuss ongoing trials in areas that the product currently does not have a licence in. This is further off-label promotion for a product with a migraine license in the UK. Organon should not have sponsored content which is off-label promotion for Organon migraine product. It is concerning Organon did not refuse the sponsorship request from [named healthcare organisation] located in the UK in respect of the off-label content. This is a serious matter that needs investigation with breaches of clauses 5.1 & 11.2 & 2 of the code."

When writing to Organon, the PMCPA asked it to consider the requirements of Clauses 11.2, 5.1 and 2 of the 2024 Code.

ORGANON'S RESPONSE

The response from Organon is reproduced below:

"We are writing in response to the complaint received under Case AUTH/0765/10/25 regarding off-license promotion. We take all complaints very seriously and appreciate the opportunity to address these concerns thoroughly and transparently.

After a comprehensive internal review to fully understand the complaint, we aim to provide a clear and accurate response.

Commitment to Ethical Standards

At Organon, we uphold the highest standards of ethical conduct and regulatory compliance. We strive to ensure our materials and activities provide healthcare professionals (HCPs) with accurate and essential information, maintaining transparency and integrity in all our interactions whilst also meeting the relevant requirements of the ABPI code of practice. As ABPI members, our goal is to ensure that all of the information disseminated by us meets the relevant regulatory requirements. We take this complaint very seriously and appreciate the opportunity to address the healthcare professional's concerns.

Background

The [named healthcare organisation] is a unique, independent, global, expert-led initiative providing clinicians worldwide with free-access, peer-reviewed, international resource focused on CGRP. It was established by an international group of clinicians and researchers, providing healthcare professionals free access to independent news, information and resources. It is aimed at physicians, physician specialists, nurse practitioners, pharmacists, health economists, service providers and payers worldwide.

Organon received a request for sponsorship on the 18th June 2025 from the Director of the [named healthcare organisation] seeking funding to further develop its e-platform/website so that clinicians fully understand the implications of latest research for optimising patient care in their daily practice. Organon agreed to support the development of the e-platform via an arm's length sponsorship for the duration of 12 months at a value of [amount] from 2025-2026. A sponsorship agreement was signed by both parties.

Addressing the Complainant`s Concerns

We have reviewed the material at issue in this case and our involvement with the organisation and have found no evidence to support the allegations made by the complainant.

Declaration of sponsorship

The [named healthcare organisation] website [URL provided] includes a clear statement at the top of the homepage referring to all their sponsors along with a link to their 'Educational Partners and Supporters' page [URL provided] and at the bottom of the page, as evidenced by the enclosed screenshot submitted by the complainant. The sponsorship statement is clear and transparent about the nature of the support received and the logos of the sponsoring companies are clearly displayed; we note that there are two other companies sponsoring the website as well as ourselves.

Clause 11.2

Organon cannot comment on the website's content, as it had no involvement in its development or editorial process. The company's only role was to provide an arm's length sponsorship and to ensure that the declaration of sponsorship was clear from the outset. The funding supported the costs associated with platform development activities only such as website functionality, content development, copyright permissions, platform management, and audience engagement. Organon had no prior knowledge that off-licence use of its medicine would be included. Therefore, Organon denies any breach of Clause 11.2.

Clauses 5.1 and 2

Organon considers the sponsorship to be clearly arm's length, as demonstrated by the unambiguous declaration and documentation submitted which is in line with the PMCPA definition. The company had no prior visibility of the website's content, as confirmed in the Letter of Request, and was unaware that off-licence use of Galcanezumab would be featured. Organon maintains that it has upheld high standards throughout and cannot be held responsible for the content published on the website. Accordingly, Organon denies any breach of Clauses 5.1 or 2.

Organon is unable to provide an original or high-quality colour copy of the material in question, details of how the material was used, or a certificate approving the material, as the company was not involved in its creation, approval, or dissemination."

PANEL RULING

This case was in relation to a healthcare organisation's website which had received sponsorship from Organon. The complainant alleged that the website promoted Organon's migraine product, Emgality (galcanezumab), outside the terms of its marketing authorisation and that Organon should not have sponsored off-label content.

At the time of the complaint, Emgality was, in accordance with its UK Summary of Product Characteristics (SPC), licensed *"for the prophylaxis of migraine in adults who have at least 4 migraine days per month."*

The complainant referred to two aspects of the website which allegedly constituted off-label promotion of galcanezumab.

The complainant firstly provided a screenshot of a webpage titled "Galcanezumab" which displayed a prominent image of a title slide from a slide set which featured the name of the healthcare organisation, "EMGALITY (GALCANEZUMAB)" and "FOR MIGRAINE PREVENTION". Beneath the image appeared the following text which the complainant alleged to be off-label, accompanied by a link to download the slide set:

> *"The CGRP [*calcitonin gene-related peptide] *monoclonal antibody, Emgality (galcanezumab), was approved for the prevention of migraine in adults in September 2018 and, in June 2019, became the first and only anti-CGRP therapy to be approved for the prevention of episodic cluster headaches in adults. These approvals were supported by data including the results of the EVOLVE 1 and 2 trials in episodic migraine, the REGAIN trial in chronic migraine and a Phase 3 study in cluster headache. The CONQUER trial investigated the efficacy of galcanezumab in patients with migraine who had failed on 2-4 previous preventative therapies."*

The complainant further referred to the clinical trials section of the website which the complainant stated contained several studies related to galcanezumab which discussed ongoing trials in areas that the product was not currently licensed in.

Organon submitted that it had received a request for sponsorship from the healthcare organisation in June 2025 to further develop its e-platform/website. Organon submitted:

- it agreed to support the development of the e-platform via an arm's length sponsorship for 12 months,
- it could not comment on the website's content, as it had no involvement in the development or editorial process,
- it had no prior knowledge that off-licence use of its medicine would be included.

Before considering the sponsorship arrangements and whether Organon was responsible for the website content under the Code, the Panel first considered the complainant's assertion that there was a UK nexus because the healthcare organisation being sponsored by Organon was based in the UK.

The Panel noted the signed sponsorship agreement included the named healthcare organisation, with its registered address in the UK, and Organon Pharma (UK) Limited as the parties. The Panel further noted that the request letter from the healthcare organisation stated the website would be available to clinicians worldwide and did not state or indicate that access would be restricted to, nor targeted at, a UK audience.

Taking these factors into consideration, the Panel concluded that there was sufficient UK nexus to bring the matter within the scope of the Code.

The Panel then considered whether Organon was responsible for the content of the website under the Code or whether the arrangements constituted a strictly arm's length sponsorship.

The Panel considered it was possible for a company to sponsor materials and activities in which its own products were mentioned and not be liable under the Code for its contents, but only if there had been a strictly arm's length arrangement with no input and no use by the company. In practical terms, the arrangements must be such that the pharmaceutical company cannot exert any influence or control over the final content of the material. Factors which might mean there had not been a strictly arm's length arrangement would include, but not be restricted to:

- Initiation of the material, or concept for it, by the pharmaceutical company.
- Awareness by the company prior to funding that the material would mainly discuss the company's medicine and/or positively position it above other treatments.
- Awareness by the company prior to funding that the material would likely discuss the company's medicine off-label or pre-licence (a company should not sponsor an activity that it could not perform itself under the Code).
- Influence from the pharmaceutical company on the content/balance/scope of the material.
- Choice and/or direct payment of the authors/speakers by the pharmaceutical company.
- Influence from the pharmaceutical company on the list of persons to whom the material is sent.
- Receipt by the pharmaceutical company of a benefit in return for the funding, for example, detailed reports from the organisation.

The Panel noted that the request letter from the healthcare organisation, which had been incorporated into the signed sponsorship agreement, set out the activities to which Organon's sponsorship contribution would be used towards. These included website functionality, content development, copyright permissions, platform management, and audience engagement.

The request letter expressly described the website as providing clinicians worldwide with resources focused on *"prevention and treatment of migraine, prevention of cluster headache and other potential indications".* Examples of resources included, among other things:

- "…summaries of *recently completed and ongoing clinical trials of anti-CGRP [calcitonin gene-related peptide] therapies in multiple indications",*
- *"…news and meeting reports of latest findings from pre-clinical, clinical, patient-focused and health economic research on anti-CGRP treatment and other advances in understanding of migraine and its co-morbidities and novel therapies"*
- *"…regularly updated online interactive guide to the regulatory status of anti-CGRP therapies worldwide including approvals and indications"*
- *"Backgrounders and slide decks on migraine, CGRP and key clinical trials supporting regulatory approval of anti-CGRP therapies"*

The Panel noted that the webpage provided by the complainant stated *"The CGRP monoclonal antibody, Emgality (galcanezumab), was approved for the prevention of migraine in adults in September 2018 and, in June 2019, became the first and only anti-CGRP therapy to be approved for the prevention of episodic cluster headaches in adults."*

The Panel considered the prevention of episodic cluster headaches did not form part of the UK marketing authorisation for Emgality, which was licensed for the prophylaxis of migraine. It therefore appeared that galcanezumab was licensed for episodic cluster headaches outside of the UK.

The Panel accepted there was no evidence that Organon had initiated the website, selected authors, or influenced the content, balance, scope or dissemination of the website. However, the Panel considered that the descriptions in the request letter made clear that the website would discuss anti-CGRP therapies across a range of indications, including indications beyond those licensed in the UK. The Panel particularly noted that the request letter stated the website would include "*CGRP research focused on…prevention of cluster headache…*" along with other potential indications for anti-CGRP therapies.

In the context that Emgality was an anti-CGRP therapy that appeared to have been approved for the prevention of episodic cluster headaches outside the UK, the Panel considered that Organon should have reasonably foreseen, prior to entering the sponsorship arrangement, that galcanezumab would likely be discussed outside the terms of its UK marketing authorisation.

The Panel further took into account that Organon were entitled to a number of benefits as outlined in the request letter. These included:

- *"Reciprocal weblinks to relevant educational material on sponsor websites at the discretion of the [healthcare organisation] Steering Committee"*
- *"Inclusion of information on sponsor's forthcoming educational events with contact details at the discretion of the [healthcare organisation] Steering Committee"*
- *"Upload and hosting of up to two educational webcasts/symposia (provided the content remains fair balance and is approved by the [healthcare organisation] Steering Committee) supplied conforming to the site's technical specifications"*
- *"Opportunity for dissemination of information regarding clinical trial enrollments or other important announcements on the [healthcare organisation] website, e-alerts and news updates with approval from the [healthcare organisation] Steering Committee"*
- *"Access to all materials and reports related to the [healthcare organisation] website which may be used, reproduced, disseminated and hosted subject to an acknowledgement of Ownership of Work"*
- *"Two registrations will be made available for sponsor representatives to attend any Closed Scientific Expert Meetings as observers"*

The Panel considered that these benefits went beyond an acknowledgement of sponsorship or confirming appropriate use of funds for due diligence purposes.

Taking all the above circumstances into consideration, the Panel considered that Organon UK, on the balance of probabilities, should have anticipated discussion of its medicine outside the terms of its UK marketing authorisation and that it stood to derive meaningful benefits from the arrangements. The Panel therefore concluded that the arrangements between the healthcare organisation and Organon could not be classed as being strictly arm's length. On that basis, the Panel determined that Organon was responsible for the content of the website under the Code.

Off-label promotion (Clause 11.2)

Clause 11.2 of the Code stated that the promotion of a medicine must be in accordance with the terms of its marketing authorisation and must not be inconsistent with the particulars listed in its SPC.

As referred to above, the Panel noted that the webpage stated that galcanezumab was approved for the prevention of episodic cluster headache in adults which did not form part of the

UK marketing authorisation for galcanezumab. Galcanezumab was only licensed for the prophylaxis of migraine in the UK.

As the Panel had determined that there was no strictly arm's length arrangement, it concluded that Organon were responsible for the content of the webpage which promoted galcanezumab outside of the terms of its marketing authorisation. The Panel ruled a **breach of Clause 11.2** in this regard**.**

The Panel noted that the complainant had also alleged that the website contained several studies relating to galcanezumab within the clinical trial section which discussed ongoing trials in areas that the product was not licensed for. However, the complainant had failed to provide any evidence to support this allegation. The Panel concluded that the complainant had failed to discharge their burden of proof and the Panel therefore ruled **no breach of Clause 11.2** in relation to this aspect of their complaint.

High standards (Clause 5.1)

The Panel noted its determination above that the arrangements for the sponsorship of the website were not strictly arm's length and that, on the balance of probabilities, Organon would have foreseen that galcanezumab was likely to be discussed outside of the terms of its marketing authorisation. The Panel queried whether it would ever be acceptable for a pharmaceutical company to sponsor an activity which it could not do itself. In the Panel's view, high standards had not been maintained, and a **breach of Clause 5.1** was ruled.

Upholding confidence in the industry (Clause 2)

Clause 2 was a sign of particular censure and reserved for such use.

The Panel noted with concern that Organon had considered the arrangements to be arm's length, which was not so, and that it was found responsible for the promotion of galcanezumab outside the terms of its marketing authorisation.

However, the Panel took account of the broader context including that the website covered a range of other topics and medicines, and that content relating to galcanezumab did not appear to form a significant proportion of the website. The Panel further took into account that Organon was one of a number of organisations providing funding for the website. It had not been established that Organon had initiated the website or influenced its content in any manner.

The Panel did not consider, on balance, that it had been established, in the circumstances of this case, that the matters before it amounted to activity that brought discredit upon, or reduced confidence in, the pharmaceutical industry. The Panel considered its concerns had been adequately covered by its rulings above and ruled **no breach of Clause 2**.

Complaint received **8 October 2025**

Case completed **3 July 2026**