

COMPLAINANT v ORGANON

Allegations about certification of a slide deck for contraception webinars

CASE SUMMARY

This case was in relation to a webinar slide deck titled ‘Effective Contraceptive Counselling’, presented at a sponsored symposium, which had allegedly not been certified for promotional use although the slides themselves were promotional for Nexplanon (etonogestrel). The complainant further alleged that Organon had failed to disclose this error as a voluntary admission.

The outcome under the 2021 Code was:

Breach of Clause 8.1	Failing to certify promotional material
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 5.1	Requirement to maintain high standards at all times

**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 had sponsored [named clinical training organiser] for update on contraception webinars in 2023. There were several of these webinars in 2023 which Organon had sponsored. Organon had a slot on these webinars to promote the product Nexplanon. Organon had created a promotional slide deck for use at these webinars. The slide deck had the veeva code GB-XPL-115415 and was reviewed on veeva in January 2023. The slide deck was named as Effective contraceptive counselling slide deck. The slide deck was not certified for a promotional use although the slides themselves were promotional. Organon had failed to disclose this as a voluntary admission to the PMCPA despite the significant error. There were breaches of 8.1, 5.1 and 2.”

When writing to Organon, the PMCPA asked it to consider the requirements of Clauses 8.1, 5.1 and 2 of the 2021 Code, as cited by the complainant.

ORGANON'S RESPONSE

The response from Organon is reproduced below:

"We are writing in response to the complaint received under Case/0549/04/25 regarding our sponsorship of a symposium slot at the [named clinical training organiser] update on long-acting reversible contraception (LARC) webinars. We 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 Regarding the [named clinical training organiser] Symposium Sponsorship

[Named clinical training organiser] is a national provider of medical education to primary care healthcare professionals, established in 2007. Post-pandemic, they have been running an online webinar program using the Zoom platform. In 2023, Organon was approached by [named clinical training organiser] to sponsor a session at an educational meeting. [Named clinical training organiser] offered eight webinar events available for sponsorship in 2023, two of which Organon agreed to sponsor: on the 17th May 2023 and 28th June 2023.

Addressing the Complainant's Concerns

Upon agreeing to the sponsorship of the [named clinical training organiser] webinar, internal teams decided against conducting a promotional session. Instead, they opted for a non-promotional session focusing on 'Effective Contraceptive Counselling'. The session was led by a member of our medical department, a faculty registered trainer, working specifically within our Nexplanon Training Support Programme (NTSP) team; a team of non-promotional nurses (contracted via [named organisation]) who work on Organon's behalf to assist healthcare providers in becoming faculty registered trainers, ensuring the safe administration of the implant and to prevent complications such as neuromuscular injury or implant migration.

The slide deck used during the webinar symposium was certified for use by the NTSP team at non-promotional meetings. The objective of the slide deck was to provide a summary of contraception counselling techniques.

We acknowledge that, given the broad definition of promotion under the ABPI Code, and the findings from a previous complaint [AUTH/0233/07/24] this slide deck should have been classified as promotional and met promotional material requirements. Organon has accepted breaches for this oversight. However, despite this oversight, this slide deck did comply with the requirements of clause 8.1 and was certified by a Medical Signatory in its final form. Therefore, Organon denies breaches of clause 8.1.

With regards to voluntary admissions, Organon has accepted breaches for the misclassification of this slide deck and route of dissemination. There was an unfortunate oversight by the contracted Medical Signatory and internal employees regarding the broad definition of promotion in the ABPI code. However, Organon consistently strives to maintain high standards and believes that as ABPI members, they diligently work to uphold the industry's reputation and ensure confidence in their practices. Having accepted the breaches and an undertaking from case AUTH/0233/07/24 and AUTH/0531/03/25, Organon has withdrawn this slide deck and is in the process of looking at the NTSP Nurse job descriptions and their ways of working to avoid such breaches occurring again. Therefore, we deny breaches of clauses 5.1 and 2, as we are committed to ethical conduct and compliance, and any misstep was unintentional and not indicative of our overall approach. We have been implementing additional measures to prevent recurrence in the future, such as enhancing compliance education and training for all Organon employees by our in-house Medical Signatory."

PANEL RULING

This case was in relation to a webinar slide deck titled 'Effective Contraceptive Counselling', presented at a sponsored symposium, which had allegedly not been certified for promotional use although the slides themselves were promotional for Nexplanon (etonogestrel). The complainant further alleged that Organon had failed to disclose this error as a voluntary admission.

The Panel noted that the slides at issue were the same as those in Case/0233/07/24 and Case/0531/03/25. In Case/0531/03/25, the Panel determined that the material was promotional for two Organon medicines, Nexplanon and NuvaRing (ethinylestradiol, etonogestrel), for the following reasons:

- Slide 2 included the Nexplanon brand name six times, the non-proprietary name and its indication.
- Slide 8 was titled "Contraceptive efficacy" and included a graphic with different types of contraceptives and the incidence of unintended pregnancy within first year of typical use.

This graphic included the “Ring”, defined in a footnote on the slide as being ‘NuvaRing’, and its effectiveness data.

- The graphic on Slide 8 also included the “Subdermal Implant” with data showing that it was associated with the lowest incidence of unintended pregnancy.
- Slide 14 contained screenshots of, and a link to, an Organon-funded website, including specifically the section of the website titled “Implant” and “Implant key facts” and what appeared to be an image of, and information about, the Nexplanon subdermal implant

Promotional material must be certified as required by the Code. Organon submitted that the slide deck used during the symposium was certified for use by the Nexplanon Training Support Programme team at non-promotional meetings but acknowledged that, given the broad definition of promotion in the ABPI Code and findings in Case 0233/07/24, the slide deck should have been classified as promotional. However, Organon denied a breach of Clause 8.1 as the slide-deck was certified by a medical signatory in its final form.

The Panel noted that the material at issue had been certified by a medical signatory in its final form. However, the certificate was titled “Non-Promotional Material Certificate” and the signatory statement, which appeared under a “Non-Promotional Material Statement – Signatory” heading, reflected the wording required for Clause 8.3 (non-promotional material).

The Code stated that the certificate for promotional material must certify that the signatory has examined the final form of the material to ensure that in their belief it is:

- in accordance with the requirements of the relevant regulations relating to **advertising** and the Code (emphasis added)
- not inconsistent with the marketing authorisation and the summary of product characteristics
- a fair and truthful presentation of the facts about the medicine.

The Panel considered that the material at issue could not be seen as anything other than promotional and that certification of the material under Clause 8.1 was therefore required. The Panel determined that the signatory had certified the material in question as non-promotional and therefore they had reviewed and approved the material without any consideration for the obligatory requirements of the Code in relation to promotional material. On that basis, the Panel considered that the promotional material at issue had not been certified as required by the Code and ruled a **breach of Clause 8.1**.

The Panel took into account that the material at issue had been reviewed and approved by a medical signatory in its final form and that this same material had been ruled in breach of the Code (including breaches of Clause 5.1) in two other cases (0233/07/24 and 0531/03/25) for lack of obligatory information as required for promotional material. While the PMCPA Constitution and Procedure encouraged voluntary admissions, that a company did not make a voluntary admission was not in itself necessarily a breach of the Code as alleged by the complainant. Bearing in mind the specific allegation in relation to certification in this current case, and the breaches of Clause 5.1 in Cases 0233/07/24 and 0531/03/25, the Panel considered that an additional breach of Clause 5.1 for the same material would be disproportionate and therefore it ruled **no breach of Clause 5.1**.

Clause 2 was a sign of particular censure and reserved for such use. The Panel did not consider that the matter in relation to certification of the material at issue had brought discredit

upon, or reduced confidence in, the pharmaceutical industry and it ruled **no breach of Clause 2** accordingly.

Complaint received **12 April 2025**

Case completed **6 March 2026**