

CASE 0233/07/24

COMPLAINANT v ORGANON

Allegations about a Nexplanon webinar

CASE SUMMARY

This case was in relation to Organon's sponsorship of a symposium slot at a webinar that purported to be non-promotional. Organon's invitation to the webinar, and one of its slides in the presentation, referred to its product; Nexplanon.

The outcome under the 2021 Code was:

Breach of Clause 5.1	Failing to maintain high standards
Breach of Clause 12.1(x2)	Failing to include up-to-date prescribing information
Breach of Clause 12.3	Failing to include the non-proprietary name of the medicine immediately adjacent to the most prominent display of the brand name
Breach of Clause 12.9(x2)	Failing to include the prominent adverse event reporting statement
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 about Organon Pharma (UK) Limited was received from a contactable complainant who described themselves as a health professional.

COMPLAINT

The complaint wording is reproduced below:

"Organon had paid for a symposium slot at [named clinical training provider] update on LARC contraception webinar. The webinar took place on [named time and date] and was presented by a faculty registered trainer. The invite and agenda for this Organon symposium stated this symposium would be non-promotional. The symposium was titled as a Nexplanon training support programme. The agenda and invite did not have the generic name for Nexplanon even as the title on invite and agenda had Nexplanon written out. Adverse event reporting information and prescribing information for

Nexplanon were not provided on the agenda or invite for the symposium. Clauses 12.3, 12.1, 12.9, 5.1 and 2 were breached. The webinar symposium session did not provide the prescribing information or adverse event reporting even as Nexplanon was promoted as part of the content. Clauses 12.1, 12.9, 5.1, 2 were breached.”

When writing to Organon, the PMCPA asked it to consider the requirements of Clauses 12.1, 12.3, 12.9, 5.1 and 2 of the 2021 Code.

ORGANON’S RESPONSE

The response from Organon is reproduced below:

“We are writing in response to the complaint received under Case AUTH/0233/07/24 regarding our sponsorship of a symposium slot at the [named clinical training provider] update on long-acting reversible contraception (LARC) webinar. 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, our commitment to maintaining the highest standards of ethical conduct and regulatory compliance in all our activities is unwavering. We understand the importance of transparency and integrity, particularly in our interactions with healthcare professionals. We strive to ensure that all our actions are carried out transparently and in full compliance with relevant guidelines and codes of practice.

Background Regarding the [named clinical training provider] Symposium Sponsorship

[Named clinical training provider] is a national provider of medical education to primary care healthcare professionals. Post-pandemic, they have been running an online webinar program using the Zoom platform. In 2023, Organon was approached by [named clinical training provider] to sponsor a session at an educational meeting. [Named clinical training provider] offered eight webinar events available for sponsorship in 2023, one of which was the webinar in question, focused on providing an update on LARC contraception.

Addressing the Complainant’s Concerns

Upon agreeing to the sponsorship of the [named clinical training provider] webinar, internal teams decided against conducting a promotional session. Instead, they opted for a non-promotional session focusing on ‘Effective Contraceptive Counselling’ as per the invitation/agenda document. 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, which is a team of non-promotional nurses 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.

When preparing the slides for the session, information about the speaker's role at Organon was included. Consequently, the second slide of the webinar deck highlighted the purpose of NTSP to provide context on the speaker's background. This information was also included in the agenda/invitation document to clarify the speaker's identity and role at Organon, hence the inclusion of 'Nexplanon Training Support Programme'.

We acknowledge that, given the broad definition of promotion in the ABPI code, including 'Nexplanon' in the context of contraception on the agenda/invitation document, and slide deck rendered the materials promotional. Instead, the information provided on the speaker's role and background should have been more generic, without specific mention of 'Nexplanon'.

Upon investigation of this complaint, we found that only one document – a combined agenda and invitation, was sent to HCPs via [named clinical training provider], rather than two separate resources. Due to the understanding that the webinar was non-promotional in nature, the agenda/invitation document was not submitted for certification. As a result, it was not recognized that the inclusion of 'Nexplanon' made the document promotional, even though it was only intended to highlight the speaker's role. This combined invitation and agenda document was solely distributed by [named clinical training provider], not by Organon.

The slide deck used during the webinar symposium was an approved slide deck for use by the NTSP team at non-promotional meetings. However, the mention of 'Nexplanon' in the context of the NTSP on the second slide of the deck was an oversight and should not have been included, there were also other elements of the slide deck that had been overlooked by the medical signatory. These human errors were made by a previous medical signatory working on Organon's behalf.

Since the intention of both the slide deck and invitation/agenda document was not to promote Nexplanon, neither resource met the relevant ABPI code requirements for promotional materials. We therefore accept breaches of Clauses 12.1, 12.3, and 12.9 regarding the single agenda/invitation document and Clauses 12.1 and 12.9 regarding the webinar symposium.

As previously mentioned, the webinar symposium was presented by a member of our non-promotional NTSP (medical) team, a faculty registered trainer. This person was selected due to her extensive experience in women's health and her deep knowledge in the field. A briefing document was deemed unnecessary since the speaker was regarded as an internal Organon employee.

Conclusion

To conclude, we accept breaches of Clauses 12.1, 12.3, and 12.9 regarding the single agenda/invitation document and Clauses 12.1 and 12.9 regarding the webinar symposium.

There was an unfortunate oversight by the final 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. 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 will be implementing additional measures to prevent recurrence in the future, such as enhancing compliance education and training for all Organon employees."

PANEL RULING

This case was in relation to Organon's sponsorship of a symposium slot at a webinar. The webinar was intended to provide an update on long-acting reversible contraception. Organon had arranged for one of its faculty registered trainers (from its non-promotional Nexplanon Training Support Programme) to provide a presentation. The invitation for the webinar included the agenda, which described this as a non-promotional session.

However, as accepted by Organon, the "Nexplanon Training Support Programme" was named in:

1. the agenda contained within the invitation, and
2. the second slide of the speaker's 16 slide presentation.

The Panel noted that the second slide of the presentation went further in highlighting the purpose of the Nexplanon Training Support Programme as a way of detailing the speaker's background. In this context, the second slide did refer to the non-proprietary name of Nexplanon (etonogestrel) as part of citing its indication.

The complainant alleged that the inclusion of the name "Nexplanon" in the invitation and in the second slide meant this was promotional material and therefore should have included certain information under Clause 12. Organon agreed and accepted breaches in relation to the Clause 12 allegations.

The Panel acknowledged that the second slide was the only slide that referred to Nexplanon. However, the Panel considered the following and concluded that the invitation, combined with the slides, meant that this was a promotional meeting:

1. the broad definition of promotion in paragraph 1.17 of the Code,
2. the prominent references on the second slide to the brand name, non-proprietary name and indication,
3. the overall impression given by the invitation, combined with the slides, and
4. the mention of the brand name and details of the product would likely solicit questions about it from the attendees.

The invitation

The complaint alleged that the invitation should have included:

1. Prescribing information (Clause 12.1)
2. The non-proprietary name of the medicine (Clause 12.3)
3. An adverse event reporting statement (Clause 12.9)

The Panel agreed and ruled **breaches of Clauses 12.1, 12.3 and 12.9**, as acknowledged by Organon.

The second slide

The complaint alleged that the second slide of the presentation should have included:

1. Prescribing information (Clause 12.1)
2. An adverse event reporting statement (Clause 12.9)

The Panel agreed and ruled **breaches of Clauses 12.1 and 12.9**, as acknowledged by Organon.

Clause 5.1 and Clause 2

The complainant also alleged that this complaint amounted to a breach of high standards (Clause 5.1) and brought discredit upon the pharmaceutical industry (Clause 2).

As part of its response to the complaint, Organon did not accept a breach in relation to these clauses.

The Panel noted that the above rulings of breaches of Clause 12 arose from the inclusion of the name of the medicine. In the context of the slide, the Panel accepted that the indication and purpose of the Nexplanon Training Support Programme was relevant to the content of the presentation on women's contraception. However, Organon had failed to include important safety requirements under Clause 12. The Panel observed that the slides had been certified by a final medical signatory and, although the intended purpose of the webinar was non-promotional, the Panel was concerned that multiple references to the name of the medicine in the second slide had been overlooked. In addition to the second slide, the Panel took account of the fact that Organon had also included a reference to Nexplanon in the invitation. The Panel therefore determined that there had been a failure to maintain high standards and ruled a **breach of Clause 5.1**.

The Panel considered the breaches above adequately covered the matter and that the circumstances of this case did not meet the threshold for a breach of bringing discredit upon the industry. The Panel therefore ruled **no breach of Clause 2**.

Complaint received 10 July 2024

Case completed 2 April 2025