CASE/0596/05/25

COMPLAINANT v ORGANON

Allegations about the use of Nexplanon on an agenda

CASE SUMMARY

This case was in relation to the agenda for a healthcare organisation's study day at which Organon had sponsored a symposium slot in which the 'Nexplanon training support programme' would be discussed. The complainant alleged that the agenda did not comply with the Code as the generic name, adverse event reporting information and prescribing information for Nexplanon were not provided.

The outcome under the 2024 Code was:

Breach of Clause 5.1	**Failing to maintain high standards**
Breach of Clause 12.1	**Failing to include up-to-date prescribing information**
Breach of Clause 12.3	**Failing to include a clear, prominent statement as to where prescribing information could be found**
Breach of Clause 12.4	**Failing to include the non-proprietary name of the medicine immediately adjacent to the most prominent display of the brand name**
Breach of Clause 12.6	**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 was received from an anonymous, contactable complainant who described themselves as a health professional.

COMPLAINT

The complaint wording is reproduced below with some typographical errors corrected:

> "Agenda for Organon session at [named healthcare organisation study day] is not compliant. A link to the page can be found at – [URL provided] The agenda for 10:10-10:40 with [named speaker] is titled 'Effective contraceptive counselling' and on the page

states a session sponsored by Organon will discuss the Nexplanon training support programme. No generic name is given after Nexplanon. No prescribing information or adverse event reporting for Nexplanon is provided. Considering this was a promotional session with Nexplanon product mention and multiple references to contraception and efficacy, the content is promotional. An Organon signatory should have ensured this content was appropriate for promotion but has allowed the uncompliant material to be published. Breaches of clauses 12.1, 12.3, 12.4, 12.6, 5.1 and clause 2."

When writing to Organon, the PMCPA asked it to consider the requirements of Clauses 2, 5.1, 12.1, 12.3, 12.4, and 12.6 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/0596/05/25 regarding our sponsorship of a symposium slot at the [named healthcare organisation study day]. 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
[Named healthcare organisation study day] is a dedicated event or session designed to provide healthcare professionals, especially those working in primary care settings, with specialized education and training on women's health issues. These study days are organized to improve knowledge, clinical skills, and the overall quality of care provided to women in the community.

Organon agreed to sponsor the [named healthcare organisation study day] through the purchase of a sponsorship package which included a 30-minute sponsored slot on the agenda as referred to by the complainant. A certified promotional slide deck was presented by a contracted speaker for this session. The agenda was solely distributed by the [named healthcare organisation] not by Organon.

Addressing the complaint

Having reviewed the agenda, Organon acknowledge that, given the broad definition of promotion in the ABPI code, including “Nexplanon” in the context of contraception on the agenda renders the materials promotional. The agenda was not certified and as a result, it was not recognized that the inclusion of “Nexplanon” made the document promotional therefore not meeting the promotional materials requirements. As a result, Organon accepts breaches of clauses 12.1, 12.3, 12.4 and 12.6.

Organon recognises that there has been a lack of oversight with sponsorships. Following the panel ruling for AUTH/0233/07/24 in April 2025, where Organon accepted similar breaches, we have put in corrective and preventative measures in place including reviewing our SOPs, incorporating additional due diligence steps to mitigate the risks of similar issues occurring again. This sponsorship occurred before these measures were put in place and therefore whilst we accept breaches of promotional requirements not being met for the agenda, they were met for the slide deck presented. Organon feels that we have maintained high standards once the issue was brought to our attention. Therefore, Organon denies breaches of clause 5.1 and clause 2.

Medical Signatory details for the slide deck:
[named signatory]

We appreciate the opportunity to clarify our position and trust that this response addresses the concerns raised.”

PANEL RULING

This case was in relation to the agenda for a healthcare organisation’s study day at which Organon had sponsored a symposium slot in which the ‘Nexplanon training support programme’ would be discussed. The complainant alleged that the agenda did not comply with the Code as the generic name, adverse event reporting information and prescribing information for Nexplanon were not provided.

Organon submitted that it had agreed to sponsor the healthcare organisation’s study day through the purchase of a sponsorship package which included a 30-minute symposium slot on the agenda. Organon also submitted that a certified promotional slide deck was presented by a contracted speaker for this session, but that the agenda was distributed solely by the healthcare organisation; not Organon.

<u>The agenda</u>

The complainant alleged that the agenda should have included:

1. Prescribing information (Clause 12.1)
2. A clear prominent statement as to where the prescribing information can be found (Clause 12.3)
3. The generic name of the medicine (Clause 12.4)
4. An adverse event reporting statement (Clause 12.6)

The complainant further stated that *“Considering this was a promotional session with Nexplanon product mention and multiple references to contraception and efficacy, the content is promotional.”*

The Panel considered that it was possible to have non-promotional materials (e.g. an agenda) that related or referred to a promotional symposium. The content and context of each individual material would need to be considered.

The agenda webpage had the name of the event, date and location at the top of the page, and then detailed the programme for the day. The session that was the subject of the complaint was titled 'Effective Contraceptive Counselling' under which the following was stated:

> *"The slides are to enable attendees to effectively counsel women on a range of contraceptive options to ensure they are given an informed choice of method. [Named speaker] will cover the following in [their] presentation which will help HCPs be more confident in their contraceptive knowledge as well as discuss what is required to become an implant fitter.*
>
> - *The Contraceptive Landscape*
> - *Efficacy*
> - *Counselling*
> - *UKMEC*
> - *Nexplanon Training Support Programme"*

The Panel considered the following and concluded that the agenda itself was promotional:

1. The broad definition of promotion in Clause 1.17 of the Code
2. The reference to the brand name and 'implant' in the context of a session around contraceptives (Nexplanon was indicated for contraception and was the only implant available in the UK at the time).

Organon acknowledged that the agenda itself was promotional and therefore should have included obligatory information. It accepted breaches in relation to the Clause 12 allegations.

The Panel agreed and ruled **breaches of Clauses 12.1, 12.3, 12.4 and 12.6**.

Clause 5.1 and 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).

The Panel noted Organon's submission that although the promotional requirements were not met for the agenda, they had been met for the slide deck that was presented, a copy of which had been provided to the Panel.

The Panel considered that there were significant similarities between this case and Case/0233/07/24 but acknowledged that the ruling in that case had not been provided to Organon prior to the date of the activity involved in this current case.

However, the Panel observed that whilst Organon submitted that the agenda was solely distributed by the healthcare organisation, the session description, as it appeared on the agenda, *had* been provided to the healthcare organisation by an Organon employee. This was evidenced by email correspondence Organon had provided as part of its response to the complaint. The Panel considered that Organon should have been aware that any material in which this description appeared, would likely have been rendered promotional and therefore Organon should have taken the necessary steps to ensure the material complied with the Code.

This lack of oversight had resulted in promotional material being distributed without important patient safety information (prescribing information and adverse event reporting statement). 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 that the breaches above adequately covered the matter and that the circumstances of this case did not meet the threshold of bringing discredit upon, or reducing confidence in, the pharmaceutical industry. The Panel therefore ruled **no breach of Clause 2**.

Complaint received **27 May 2025**

Case completed **12 November 2025**