CASE/0245/07/24

COMPLAINANT v ORGANON

Allegations regarding a Nexplanon Fitters Forum Meeting

CASE SUMMARY

This case was in relation to an online meeting organised by Organon. The complainant alleged that, although the invite stated that the meetings were non-promotional and intended to educate and support Nexplanon fitters, the invite was promotional as was the meeting itself. As a result, the complainant alleged that prescribing information and adverse event information was missing from the invite and the slides, neither was certified and the suggestion by Organon that the meeting was non-promotional was misleading.

The outcome under the 2021 Code was:

Breach of Clause 5.1	**Failing to maintain high standards**
Breach of Clause 6.1	**Making a misleading claim**
Breach of Clause 8.1(x2)	**Failing to certify promotional material**
Breach of Clause 12.1	**Failing to include up-to-date prescribing information**

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 12.1	**Requirement to include up-to-date prescribing information**
No Breach of Clause 12.9(x2)	**Requirement that all promotional material must include the prominent adverse event statement**

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 complainant who described themselves as a health professional. The complainant has since become non-contactable.

COMPLAINT

The complaint wording is reproduced below:

> "To the PMCPA An online meeting organised by Organon on [date] 2021 at 7pm-8.30pm was named as Nexplanon Fitters Forum meeting. The meeting invite stated that the meetings were non promotional, held to educate and support Nexplanon fitters. The meeting invite was promotional and the meeting contents were promotional as there was extensive discussion on Nexplanon. Organon had misleadingly claimed the Nexplanon Fitters forum meeting on [date] 2021 was non-promotional which was a breach of clause 6.1 and 5.1. Prescribing information and adverse event information were not provided on the invite or on the slides presented at the online meeting which were breaches of clauses 8.1, 12.1, 12.9, 5.1 and 2."

When writing to Organon, the PMCPA asked it to consider the requirements of Clauses 2, 5.1, 6.1, 8.1, 12.1 and 12.9 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/0245/07/24 regarding the online meeting organised by Organon on the [date] 2021, named the Fitters Forum meeting. We appreciate the opportunity to address the complainant's concerns.
>
> We have conducted a thorough internal review to fully understand the complaint and ensure our response is comprehensive and accurate.
>
> **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 of our interactions, whilst also meeting the relevant requirements of the ABPI code of practice.
>
> **Context for the Complaint**
>
> For context, it is essential to understand our Nexplanon Training Support Programme (NTSP) and the way in which it was previously classified. Historically, there were reported cases of neurovascular injury and migration of the Nexplanon implant from the insertion site within the arm. In rare instances, the implant migrated into the pulmonary artery. This is believed to be associated with the deep or incorrect insertion of the Nexplanon implant.
>
> To mitigate this risk and as a condition of our approval, outlined in the risk minimisation plan for Nexplanon, the following measures have been implemented:
>
> **Routine Risk Minimisation Measures (RMM)**
>
> - Relevant Label Wording: The Summary of Product Characteristics (SPC) strongly recommends that Nexplanon is inserted and removed only by healthcare professionals (HCPs) who have completed specific training.

- Provision of Training Materials: Training materials and voluntary sessions on implant insertion and removal are provided.

Additional Risk Minimisation Measures (RMM)

- Patient Alert Card
- Online Training Videos: Accessible for HCPs.
- Dear Healthcare Professional (DHCP) Letter: Sent post-approval to outline risks and precautions.

HCPs can become 'faculty registered trainers' by completing a series of training modules, as dictated by the Faculty of Sexual and Reproductive Healthcare (FSRH). Upon completion, the FSRH provides a letter of competence for subdermal contraceptive implant techniques (insertion and removal), known as the LoC SDI-IR. While the FSRH does not conduct the training itself, it supports HCPs in finding a registered trainer responsible for ensuring the completion of relevant assessments, allowing an HCP to apply for their LoC SDI-IR.

As part of the voluntary sessions on implant insertion and removal mentioned in the routine RMM (above), the Nexplanon Training Support Programme (NTSP) was created and has been instrumental in addressing and minimising patient harm for several years. This programme featured a non-promotional team of [named] third-party nurses who supported HCPs to achieve their LoC SDI-IR by ensuring they meet the FSRH's training requirements and standards. The NTSP fell under the remit of Organon's medical department and was non-promotional in nature. It was also reactive; training was provided in response to unsolicited requests from HCPs.

It's important to note that Organon is not the sole provider of this training. Many NHS trusts and private sexual health clinics also offer similar training. However, the key difference is that Organon's programme is free of charge, reflecting Organon's commitment to patient safety.

Addressing the Complainant's Concerns

The Fitters Forum meeting was a non-promotional event that formed part of the NTSP programme, introduced for the purpose of patient safety. Those attending the meeting had reactively signed up to take part in the training programme and had agreed to participate in follow-up meetings at 1, 3, and/or 6 months, with the 6-month follow-up being the 'Fitters Forum' meeting. The purpose of the meetings was to ensure that HCPs were still indeed competent with regards to the fitting and removal of the implant and was an opportunity to address any concerns. We believe the initiative was truly non-promotional, and the content within the slide deck during this meeting was also non-promotional, focusing solely on the safety aspects of administering the Nexplanon implant. Neither the invitation or slides included any product claims or other information intended to promote the prescription or use of Nexplanon.

Regarding the invitation for this meeting, it was sent only to those who had reactively requested to participate in the NTSP training. A written agreement was also developed between each HCP that signed up and [named third party nurses], highlighting the relevant follow-up training meetings, including the Fitter Forum meeting. The invitation

was intended to be non-promotional in nature. However, it mistakenly contained prescribing information and met some other aspects of the promotional requirements in the ABPI code. This oversight occurred during the transition period when Organon spun off from MSD in 2021. During this time, Organon was being set up, and final medical signatory contractors were in use who did not have sufficient understanding of the NTSP programme and its classification. Since then, on a separate note, with the help of third-party compliance experts, we reclassified the NTSP programme as a package deal in Q1 2024, to which we have robust procedures in place to ensure compliance with the ABPI code under the new classification.

Conclusion

In conclusion, regarding the meeting itself, due to the unsolicited, reactive nature of the programme, we believe the meeting was indeed non-promotional and the information presented was accurate, balanced, fair, and objective. We therefore deny a breach of clause 6.1.

Regarding the slide deck used in the meeting, we maintain that it was indeed non-promotional content, and therefore the relevant requirements for promotion did not need to be met, so we deny breaches of clauses 8.1, 12.1, and 12.9. As for the invitation, we deny a breach of clause 8.1 due to the reactive nature of the programme, this was intended to be non-promotional. The invitation, although mistakenly, contained prescribing information and adverse event reporting. On this technicality, we deny breaches of 12.1 and 12.9 as it did include these relevant aspects.

There was an unfortunate oversight by the medical signatory contractor, resulting in the inclusion of prescribing information and other promotional elements in the material. Despite this error, Organon consistently strives to maintain high standards and diligently works to uphold the industry's reputation and ensure confidence in our practices as ABPI members. Therefore, we deny breaches of clauses 5.1 and 2. This historical oversight due to the use of an external contractor does not reflect our overall approach and is certainly not indicative of our current practices.

Given the above, we consider that there is no prima facie case to answer under the ABPI Code and respectfully request that the case preparation manager does not refer this complaint for adjudication by the Panel."

ORGANON'S FURTHER RESPONSE

The Panel requested further information from Organon. The Panel's requests are in bold below with the response from Organon underneath:

You refer to the invite being sent to HCPs in response to "unsolicited requests" and that "Those attending the meeting had reactively signed up to take part". Please provide more details as to how, in the context of obtaining their LoC SDI-IR, consents were provided to you in relation to your "fitter's forum" invitation and/or what requests were made for such training.
When a request for training is submitted to NTSP from various sources, it undergoes a structured process to ensure compliance and alignment with the HCP's commitment:

- Initial Request and Explanation of Commitment: Once a request for training is received, the commitment required for the training process is explained to the HCP (by a member of the NTSP team) to allow them to decide if they wish to continue. This includes the need to pay £85 and study for and pass the Faculty of Sexual and Reproductive Health (FSRH) OTA (Online Training Assessment) exam before live training (organised by Organon) can commence. The HCP must confirm their agreement to undertake this preparation as part of the process.
- Completion of FSRH OTA Exam: The HCP signs up with the FSRH to study for the OTA exam. Passing this exam is a prerequisite for proceeding to the live training stage.
- Coordination with FRT for Live Training: Once the HCP has successfully passed the OTA exam and subsequently obtaining their LoC SDI-IR, they notify the NTSP Team. The request is forwarded to the Faculty Registered Trainer (FRT) team (part of the NTSP team) to arrange live training sessions. At this stage, the logistics for the training are planned, and the HCP's participation is scheduled.
- Contractual Agreement: Before the live training can be organized, a detailed contract is signed by the HCP undertaking the training and, in most cases, by the Practice Manager (PM). This contract outlines the full training package, including the commitments of all parties involved. The terms are thoroughly discussed to ensure mutual understanding. The HCP can then decide to continue or not.
- Explanation of Training and Follow-Ups: As part of the agreement, we provide a clear explanation of the training package, which includes:
  o The live training session including insertions and sign off
  o A one-month follow-up to review progress – a phone call from the NTSP team to check in with HCP and answer any questions they may have
  o A three-month follow-up involving a clinic session – a face-to-face visit from an FRT in clinic to observe their technique and fine tune if required
  o A six-month follow-up that includes an invitation to attend the "fitter's forum." – optional invitation only to those who have partaken in the NTSP training. A forum to discuss best practice and another opportunity to ask questions.
- HCP and PM Agreement: By signing the contract, the HCP and the PM consent to the entire training package, including the follow-up schedule and participation in the "fitter's forum."

Can you confirm whether there were any alternative implants on the market at the time of this complaint?
There are no alternative contraceptive implants on the market. Nexplanon (etonogestrel) is the only implant available.

If any of your risk minimisation material was approved by the MHRA, please provide evidence.
Please find email MHRA approvals attached:

- Patient Alert Card (PAC) from Oct 2022 where MAH name/address change was MHRA approved
- PAC from Dec 2024 where MAH address change to Cramlington was MHRA approved
- Video Transcripts from Dec 2021 where MHRA approved the last updates
- For the DHPC from 2020:
  - MHRA agreed to retire this in October 2022

- DHPC approval from Dec 2019 from the previous MAH entity

PANEL RULING

This case related to an online meeting organised by Organon in November 2021 titled the "Fitters Forum Meeting". The complainant alleged that, although the invite stated that the meetings were non-promotional and intended to educate and support Nexplanon fitters, the invite was promotional as was the meeting itself. As a result, the complainant alleged that prescribing information and adverse event information was missing from the invite and the slides, neither was certified and the suggestion by Organon that the meeting was non-promotional was misleading.

Organon's product, Nexplanon (etonogestrel), is a contraceptive implant and the only one available on the market. Organon in its response, explained that due to previous concerns about deep or incorrect insertion of the Nexplanon implant and the impact on patients, Risk Minimisation Measures ("RMMs") were put in place, some of which were approved by MHRA. These included, among other measures, the provision of training materials and voluntary sessions for health professionals on the safe insertion and removal of Nexplanon.

Training on the insertion and removal of Nexplanon was provided by Organon through its Nexplanon Training Support Programme ("NTSP"). Organon accepted in its submissions that the NTSP was created as part of the RMMs and included a team of third-party nurses who supported health professionals with training following unsolicited requests for such training. Health professionals who signed up for the training could pay to complete an online training assessment exam with the Faculty of Sexual and Reproductive Healthcare, becoming 'Faculty Registered Trainers' and receive a letter of competence for subdermal contraceptive implant techniques (insertion and removal), known as the LoC SDI-IR. There was no requirement for those health professionals who successfully passed the exam to attend the live training provided by Organon and there were other training providers available. When a health professional agreed to the live training with Organon, they also received a follow up review with the NTSP at one, three and six months. At the six month follow up, they received an invitation to the Fitters Forum Meeting, attendance at which was optional.

During the Panel's consideration of this case, Organon was asked to provide further information about MHRA approval of its RMMs. Although there were RMMs approved by MHRA at the time of the meeting, the Panel was not provided with any evidence that the invitation and slides for the Fitters Forum Meeting formed material approved by MHRA as RMMs. As such, the material was not excluded from the broad definition of promotion as set out in Clause 1.17 of the Code.

<u>The invitation</u>

The invitation, which was shared with those health professionals who had signed up to the Organon training programme at six months, contained the following information:

- The top banner contained the Organon and NTSP logos at either end and the statement "*Organon non-promotional material*" in the middle of the banner with text that this was for UK health professionals and a hyperlink for prescribing information and adverse event reporting.
- The words "*Calling all implant fitters!*" appeared in large text followed by a picture of two women alongside two questions posed to the reader.

"Do you have concerns regarding women's limited choice and access to Long-Acting Reversible Contraception (LARCs)?
Do you have concerns or questions you would like to ask around fitting implants?"

- The next block of text stated,
  "If you do…why not attend a remote Nexplanon (etonogestrel) Fitters Forum Meeting?"
  Followed by information about the purpose of the meetings including,
  "*These meetings are non-promotional, held to educate and support Nexplanon fitters who inset and remove implants*."
- Further information below included a bullet point agenda, dates and times of the meetings, a 'Register now' button which was hyperlinked to an Organon non-promotional website, and an adverse events reporting statement.

The invitation was certified by Organon as non-promotional material.

The Panel noted that the invitation mentioned both the brand and non-proprietary name of the medicine, as well as the indication. Although the intention of the meeting was to support health professionals in the safe use of the product, the Panel was concerned that this invitation contained information which was clearly promotional. The persuasive language and overall tone and impression was to encourage health professionals to attend a meeting about the use of an Organon product. The use of the medicine names and indication, as well as an adverse event reporting statement and link to prescribing information, all suggested to the Panel that this was promotional material and related solely to the use of this single product.

The complainant had raised Clauses 12.1 and 12.9 however the Panel noted that an adverse event reporting statement was in fact included in the invitation and therefore ruled **no breach of Clause 12.9**. Similarly, the Panel also noted that a direct single click link was provided to the prescribing information at the top of the invitation, which fulfilled the requirements of Clause 12.1. The Panel ruled **no breach of Clause 12.1**.

The complainant also alleged that the invitation had not been certified as promotional material in line with the requirements of Clause 8.1. Organon confirmed that the invitation was intended to be non-promotional and therefore although it had been certified, it was not certified as promotional material. Having found the invitation to be promotional, the Panel considered that it should have been certified in line with the requirements of Clause 8.1 and therefore ruled a **breach of Clause 8.1**.

<u>The slide deck</u>

The Panel was provided with a copy of the slide deck used for the Fitters Forum Meeting which contained 26 slides and was titled "Implant Fitters Forum (etonogestrel) Nexplanon Training Support Programme". The slides included question polls, implant update, insertion and removal videos, good practice points, case studies and scenarios, training and support, and question and discussion time.

The slides related solely to Nexplanon and its use and was aimed at providing information around the safe use of Nexplanon in line with Organon's RMMs. The Panel noted the broad definition of promotion in Clause 1.17 of the Code and was concerned that, although the intention was to improve safety, the slides contained information which was promotional in nature. The slides provided information, support and guidance to health professionals regarding

the insertion and removal of Nexplanon and contained phrases such as “ensure the implant available in pharmacy/practice’ and “missed opportunities” which were indicative of the overall promotional tone of the slides. The Panel considered the aim of such material to be intended to increase attendees’ confidence in administering Nexplanon thereby increasing their willingness to prescribe it to patients.

Having concluded that the slides were promotional, the Panel considered that prescribing information and an adverse reporting statement should have been included. An adverse event reporting statement appeared on slide 15 of the deck, between slides on good practice and training and revalidation. Although the Panel queried whether this was sufficiently prominent, the Panel based its ruling on the actual allegation which, in this case, was that there *was* no adverse event reporting statement. Given that allegation was unfounded, the Panel ruled **no breach of Clause 12.9.** However, there was no prescribing information or link to prescribing information contained anywhere within the slides and the Panel ruled a **breach of Clause 12.1**.

Organon in its response confirmed that the slides had been certified as non-promotional. The Panel, having concluded that the slides were promotional, considered that they should have been certified in line with the requirements of Clause 8.1 and therefore ruled a **breach of Clause 8.1**.

Misleading information

The complainant also alleged that Organon had misleadingly claimed the Fitters Forum meeting was non-promotional which was a breach of Clauses 6.1 and 5.1. Clause 6.1 stated that information must be accurate, balanced, fair, objective and unambiguous. At the very top of the invitation in the banner heading were the words “Organon non-promotional material” in bold. The Panel considered that attendees could have been under the impression that they were invited to a non-promotional meeting which the Panel considered to be inaccurate and misleading. Although not intended as such, this was a promotional invitation for a promotional event and on that basis, the Panel ruled a **breach of Clause 6.1**.

Clause 5.1 and Clause 2

The Panel was concerned that both the invitation and slides had been certified as non-promotional material despite the repeated mention of the medicine by name, the indication, adverse event statement and prescribing information being presented and the general promotional tone and impression to a viewer. Organon in its response detailed the changes that were being made to the structure of the company at the time of the event which meant that final medical signatory contractors were used, who were not familiar with the NTSP and its classification. Although Organon referred to improvements it had made to its compliance programme since the time of the complaint, the Panel did not accept that structural changes within a company could justify failures in relation to Code compliance. The Panel was concerned that there were obvious indicators in both materials to suggest they were promotional and that these had been overlooked. The Panel considered there was a lack of oversight and Code compliance in relation to this matter. Although the intention was to improve safety in line with RMMs, providing inaccurate information which misled potential attendees was a concern to the Panel and, in its view, amounted to a failure to maintain high standards. The Panel ruled a **breach of Clause 5.1**.

Although the complainant appeared to raise two breaches of Clause 5.1, the Panel considered that the arguments in relation to each were the same. Having regard to the overriding objective, the Panel concluded that one ruling of a breach of Clause 5.1 in relation to both the invitation and slides adequately covered the allegations in this complaint.

Clause 2 was reserved for cases of particular censure which the Panel considered was not the case here and therefore ruled **no breach of Clause 2**.

Complaint received **25 July 2024**

Case completed **8 August 2025**