CASE/0531/03/25

COMPLAINANT v ORGANON

Allegations about a symposium

CASE SUMMARY

This case was in relation to a sponsored webinar titled 'Effective Contraceptive Counselling' presented by a member of the Organon medical department. The complainant alleged that this session was promotional for Nexplanon (etonogestrel) and NuvaRing (ethinylestradiol, etonogestrel) and should not have been delivered by an Organon speaker who was not a sales representative. The complainant also alleged that prescribing information was not provided for the two products.

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 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 9.4	**Requirement that representatives take an appropriate examination within their first year of employment as a representative and pass it within two years of starting such employment**

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 with some typographical errors corrected:

> "[Clinical training organiser] had organised a promotional online educational webinar symposium for HCPs [health professionals] on 28th June 2023 with Organon. The session was titled effective contraceptive counselling. An Organon employee [named] delivered the session. The Organon employee was not a sales representative but the content delivered during the online webinar promoted use of Nexplanon and NuvaRing, both Organon products for contraception. The presentation did not provide prescribing

information for NuvaRing and Nexplanon. The Organon employee should not have delivered the promotional session as they are not a sales representative. Organon had acted inappropriately in allowing a non-sales representative employee to promote Organon medicines at this symposium. Clause 9.4, 12.1 (twice breached as 2 product prescribing informations not provided), 5.1 and Clause 2 were breached."

When writing to Organon, the PMCPA asked it to consider the requirements of Clauses 12.1, 9.4, 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/0531/03/25 regarding our sponsorship of a symposium slot at the [clinical training organiser] 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, 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

[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 [clinical training organiser] to sponsor a session at an educational meeting. [Clinical training organiser] 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 [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, [name], a faculty registered trainer, working specifically within our Nexplanon Training Support Programme (NTSP)

team; a team of non-promotional nurses (contracted via [third-party agency]) 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. Due to the non-promotional nature of [their] role, [name] had not conducted the ABPI representative examination.

The slide deck used during the webinar symposium was approved 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. One of the slides highlights the various forms of contraception available, including the 'subdermal implant' and the 'vaginal ring'. The intent of this slide was to support patient counselling by clearly outlining the range of contraceptive options available.

However, we acknowledge that, given the broad definition of promotion under the ABPI Code, and the findings from a previous complaint [Case/0233/07/24] which classified this slide deck as promotional for other reasons, the content would be considered promotional. As the slide deck was intended to be non-promotional, the associated promotional requirements were not fulfilled. This oversight resulted from human error by the medical signatory acting on behalf of Organon at the time. Accordingly, Organon accepts that prescribing information should have been included when referencing the contraceptive methods.

Clause 9.4

As previously mentioned, the webinar symposium was presented by a member of our non-promotional NTSP (medical) team, a faculty registered trainer. [Name] was selected due to [their] extensive experience in women's health and [their] deep knowledge in the field. The intention was to deliver a non-promotional session hence why a non-promotional team member delivered this slide deck. Given that the slide deck is deemed promotional but delivered by a member of the medical team who has not completed the ABPI representative examination, Organon accepts a breach of Clause 9.4.

Conclusion

To conclude, Organon accepts breaches of Clauses 12.1 and 9.4 regarding this 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. Having accepted the breaches and an undertaking from Case/0233/07/24, 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.

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

FURTHER INFORMATION FROM ORGANON

Organon's response to a request from the Panel for further information is reproduced below:

"Please see the requested information below and attached.

- Please see attached a copy of the job description of the speaker, [named], at the time of the webinar at issue (28 June 2023)

- Details of any relevant objectives for [named speaker] (for example, regarding speaking at meetings sponsored or organised by Organon in 2023)
    - No KPIs [key performance indicators], speaking objectives or activity-based targets were set for any NTSP nurse in 2023, including [named speaker].
    - Organon-organised meetings (NTSP/"Fitters Forum") were at the time designed and classified as non-promotional patient-safety follow-ups to support competence in implant fitting and removal. Attendance was reactive and based on prior participation in the training pathway.
    - For meeting sponsored by Organon, any (at the time) non-promotional presenting was considered case-by-case, and not part of any objectives or KPIs.

- The date that [named speaker] first started presenting at meetings sponsored or organised by Organon where Organon products were proactively discussed
    - 17th May 2023

- The number of such proactive meetings that [named speaker] presented at in 2023
    - Two sponsored meetings delivered; two additional meetings were arranged but cancelled by HCPs

- Details of any internal assessment of whether the requirements of Clause 9.4 were relevant to the role that [named speaker] would perform at Organon
    - No Clause 9.4 assessment was performed at the time because the activities were incorrectly classified as non-promotional. Organon accepts and acknowledges that this was an error as stated in previous complaint Case/0233/07/24
    - Following complaints and a change in management, NTSP activities were reclassified in early 2025, and current NTSP nurses have been required to complete the ABPI Advanced Professional Programme (in progress). These steps form part of Organon's strengthened compliance controls to prevent recurrence.
    - We have withdrawn the material, re-evaluated NTSP roles and ways of working, and enhanced compliance training for relevant personnel. These corrective and preventive actions reflect Organon's commitment

to ethical conduct, patient safety, and robust, sustainable compliance with the ABPI Code."

PANEL RULING

The complaint was about a sponsored webinar titled 'Effective Contraceptive Counselling' presented by a member of the Organon medical department. The complainant alleged that this session was promotional for Nexplanon (etonogestrel) and NuvaRing (ethinylestradiol, etonogestrel) and should not have been delivered by an Organon speaker who was not a sales representative. The complainant also alleged that prescribing information was not provided for the two products.

The Panel noted that the webinar at issue was one of a series of webinars sponsored by Organon and that other complaints had been received about these webinars. The Panel observed that the slides presented at the webinar at issue in this case were the same as those in Case/0233/07/24.

Organon submitted that the session on 'Effective Contraceptive Counselling' was intended to be non-promotional.

The Panel noted that slide 2 stated that "The Nexplanon Training Support Programme is offered as part of the Organon risk minimisation plan for Nexplanon." The Panel had no evidence before it that the slide-deck at issue had been approved by the MHRA as part of Organon's risk minimisation materials; as such, it was not excluded from the broad definition of promotion as set out in Clause 1.17. Organon acknowledged that, given the broad definition of promotion and the Panel's previous ruling (Case/0233/07/24), this slide deck was promotional.

The complainant alleged that the webinar was promotional for NuvaRing and Nexplanon and that prescribing information should have been provided.

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. The Panel observed that this graphic included the "Ring", defined in a footnote on the slide as being 'NuvaRing'. The Panel considered that the presence of the brand name combined with its effectiveness data constituted promotion of NuvaRing and therefore prescribing information should have been provided. The Panel ruled a **breach of Clause 12.1**, as acknowledged by Organon.

Consistent with its previous ruling in Case/0233/07/24, the Panel determined that the webinar slides were also promotional for Nexplanon. The Panel took into account the following content from the slide deck:

- Slide 2 included the Nexplanon brand name six times, the non-proprietary name and indication.
- The graphic on Slide 8 (described above) 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.

Prescribing information for Nexplanon was not provided. The Panel therefore ruled a **breach of Clause 12.1**, as acknowledged by Organon.

Clause 9.4 required that representatives must take an appropriate examination within their first year of employment as a representative and must pass it within two years of starting such employment. Clause 1.19 defined a representative as someone calling on members of the health professions and other relevant decision makers in relation to the promotion of medicines.

In the Panel's view, presenting at one promotional symposium did not necessarily mean that an individual was a representative as defined in the Code. Whether an individual was considered a representative as defined in Clause 1.19 would be assessed on a case-by-case basis, taking into account multiple factors including their activities, responsibilities, job description and objectives.

The Panel noted that the individual in question's job description referred to carrying out training interactions to develop health professionals' knowledge and to provide continual support to health professionals through a variety of channels before and after training including but not limited to face-to-face support visits and email/telephone contact. The job description did not refer to this being in response to unsolicited requests only; therefore, it appeared this was not a reactive only service.

The Panel took into account Organon's submission that the individual in question had presented at two sponsored meetings in 2023 and had been scheduled to speak at two further proactive meetings that year where Organon products were to be discussed. The Panel considered such meetings were promotional.

Taking everything into account, it appeared to the Panel that the individual was required to repeatedly participate in promotional meetings and thus could be considered as someone calling on members of the health professions and other relevant decision makers in relation to the promotion of medicines. The Panel therefore considered that the individual met the definition of a representative.

The supplementary information to Clause 9.4 stated that prior to passing an appropriate examination, representatives may be engaged in such employment for no more than two years, whether continuous or otherwise and irrespective of whether with one company or with more than one company.

Organon submitted that the individual in question first started presenting at meetings sponsored/organised by Organon where Organon products were proactively discussed on 17 May 2023. The Panel had no information before it about this individual's employment history prior to this date. Therefore, on the information before it, the Panel considered that the individual in question first commenced work as a representative on 17 May 2023.

The Panel considered that the complainant's allegation solely related to the symposium on 28 June 2023. Bearing in mind the requirements of Clause 9.4 as stated above, the Panel considered that at the time of the symposium on 28 June 2023, the individual in question still had time to attempt and pass the examination. The Panel therefore ruled **no breach of Clause 9.4**.

The Panel was, however, concerned that, at the time in question, Organon had done no assessment of the individual's role in relation to the requirements of Clause 9.4. The Panel further considered that the promotion of two Organon medicines at the sponsored symposium without the required prescribing information was such that Organon had failed to maintain high standards. The Panel ruled a **breach of Clause 5.1** accordingly.

Clause 2 was a sign of particular censure and was reserved for such use. The Panel considered that the matters in this case were adequately covered by its rulings above and it therefore ruled **no breach of Clause 2**.

Complaint received **29 March 2025**

Case completed **23 February 2026**