CASE/0710/08/25

COMPLAINANT v ORGANON

Allegations about a Nexplanon website

CASE SUMMARY

This case was in relation to a promotional webpage on Organon's professional website (Organon Pro) that provided information about Organon's long-acting reversible birth control implant Nexplanon (etonogestrel). The complainant alleged that the webpage did not include the required prescribing information and that this was a patient safety risk.

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**

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:

> "Promotional page for Nexplanon has no prescribing information provided for Nexplanon. The competency of the individual who has approved this page is questionable as no provision of prescribing information is a patient safety risk + direct breach of ABPI code regulations [webpage provided]. Breaches of clauses 12.1 + 5.1 + 2"

When writing to Organon, the PMCPA asked it to consider the requirements of Clauses 12.1, 5.1 and 2 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/0710/08/25 regarding a Nexplanon webpage. 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**
>
> Organon has recently undergone a significant restructuring that includes the clustering of countries and resources. As part of this change, the digital team responsible for Organon Pro, Organon's promotional website, has transitioned from the UK to Portugal. This team is currently acclimating to the working practices of the UK. The webpage mentioned in the complaint pertains to a draft webpage currently in development.
>
> Although the team initially worked on this page within the live site, it was password protected, preventing access to anyone without the password. There were no links to this page from any other approved live pages.
>
> Regrettably, the webpage was unintentionally published online on August 26, 2025. Upon discovering this oversight, the page was reverted to its password-protected state on September 2. Despite being online, access to the draft page was limited; it could only be reached by searching for its specific/exact title in the Organon Pro website's search bar, or by entering the exact URL web address. This incident was due to human error, and the responsible teams have been informed. Corrective and preventative measures have been implemented to prevent recurrence. The risk of this unapproved content being easily accessible by the masses is minimal, ensuring that patient safety remains uncompromised.
>
> **Addressing the Complaint**
>
> **Clause 12.1:** Organon acknowledges that despite the draft page going live due to human error and having limited accessibility, it was still accessible, albeit without any prescribing information. Therefore, Organon accepts a breach of clause 12.1.

Clause 5.1 and 2: Organon believes that the initial intention was to ensure the draft page remained inaccessible from any approved pages and was password-protected. Upon identifying this human error, the page was restored to its password-protected state, and corrective and preventative actions were implemented to avoid recurrence. This approach ensures adherence to high standards and therefore Organon denies breaches of clauses 5.1 and 2.

The webpage was still in development and had not been completed or submitted for approval, therefore Organon is unable to supply the material, a certificate of approval or signatory details.

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

FURTHER INFORMATION FROM ORGANON

The case preparation manager asked Organon for the following further information:

1. Why/how did the webpage go live accidentally?
2. How did Organon become aware of the error?
3. The response refers to CAPAs - what were these? Please provide more detail.

The response from Organon is reproduced below:

"Apologies for not providing the requested information. Please see our responses to your questions below:

Why/how did the webpage go live accidentally?
As noted in our response dated 2 October, Organon has recently undergone a significant organisational restructuring, which included the clustering of countries and resources. As part of this transition, responsibility for Organon Pro, Organon's promotional website, shifted from the UK team to the team based in Portugal.

Unlike the UK team, the Portuguese digital team did not have access to a sandbox environment for webpage development. Consequently, web administrators and external agencies were required to build pages directly within the production (live) environment. To ensure Medical Affairs could review the content while restricting public access, pages were published with password protection. These pages are only accessible via a direct link or searching for them specifically and are not discoverable through any of the currently approved pages on the Organon Pro site.

The process of applying password protection involves manually selecting the "Publish – Password Protected" option during deployment. Both the activation of the page and the application of the password are manual steps carried out by the administrator. This approach is standard practice within the Portuguese team, which is why they have not historically used a sandbox environment.

Regrettably, due to human error, the password protection option was not selected during the development of this particular page, resulting in it being published live

unintentionally. It was never our intention for the page to go live prior to receiving medical approval.

How did Organon become aware of the error?
During this development stage, the links to these pages were sent from the digital team in Portugal to the marketing team working in the UK. Upon review of these links, the marketeer discovered that this page was not password protected and immediately asked for them to be password protected on the 2nd September.

The response refers to CAPAs - what were these? Please provide more detail.

- The Portuguese team and their supporting agency have been formally notified of the error and reminded of the importance of strict adherence to publishing standards. They have now been granted access to a sandbox environment and will work exclusively within it for all future webpage development, ensuring that no content is published live without appropriate review and approval.
- To strengthen oversight, a UK-based digital marketing manager has been assigned to review all webpages following medical approval. This additional layer of review will ensure that pages meet digital standards before being published.
- We are currently developing a formal guidance document to standardise this process across all teams. Once finalised, this will be rolled out through training sessions to both internal stakeholders and external agencies to ensure consistent understanding and implementation.
- We have emphasised the importance of attending internal Code Club sessions and Code Case Summary webinars, which are hosted by an external agency, to reinforce understanding of the ABPI Code and its application in digital materials.
- Additionally, we are in the process of organising bespoke ABPI Code training for all marketeers across the North West Europe cluster who work with the UK market, to ensure alignment with UK regulatory expectations and best practices.

These measures are intended to prevent recurrence and reinforce compliance with internal and regulatory standards.

Thank you for giving us the opportunity to further clarify our response."

PANEL RULING

This case was in relation to a webpage on Organon's professional website (Organon Pro) that provided information about Organon's long-acting reversible birth control implant Nexplanon (etonogestrel).

The complainant alleged that the webpage was a promotional page, yet it did not include prescribing information as required by Clause 12.1 of the Code. The complainant further alleged that this represented a patient safety risk and therefore was a breach of Clause 5.1 (for failing to maintain high standards) and Clause 2 (for bringing discredit upon, or reducing confidence in, the pharmaceutical industry).

In summary, Organon's response to the complaint was that:

1. the webpage was a draft page in development that was intended to be password-protected and inaccessible from any approved live pages,

2. following an organisational restructure, responsibility for Organon Pro (the website on which the webpage in question was hosted) had moved from a UK team to a team based in Portugal,

3. due to human error, the webpage was unintentionally published without password protection because the Portugal-based team built the webpage in the live environment without manually selecting "Publish – Password Protected",

4. the period during which the webpage was live was 26 August 2025 to 2 September 2025 ("the relevant period"),

5. the webpage could only be found by entering the exact URL or by searching for its specific title in the Organon Pro website search,

6. there were no links to the draft page from other approved live webpages, and

7. corrective and preventative actions (CAPAs) had been implemented, including obtaining a sandbox environment, additional review steps, and training.

Organon stated that it was unable to supply the material, a certificate of approval, or signatory details, because the webpage had not been completed or submitted for approval given it was still in development. Organon accepted a breach of Clause 12.1 on the basis that the webpage was accessible for a period without prescribing information. However, Organon denied breaches of Clauses 5.1 and 2, essentially because it submitted that this was an unintentional, isolated human error and because it had put effective CAPAs in place.

Failing to include prescribing information in promotional material (Clause 12.1)

Organon conceded that the webpage was unintentionally live during the relevant period, without prescribing information.

The Panel considered the content of the webpage, based on a screenshot taken by the case preparation manager. The Panel concluded that the webpage was clearly promotional for Nexplanon because:

1. it was hosted on Organon's promotional website for health professionals, and

2. it included promotional claims for Nexplanon, such as:

    a. "Longer acting methods such as implants like Nexplanon are more effective at preventing unwanted pregnancies than other methods of contraception, including condoms, the injection, or the pill", and

    b. "Over 99% effective contraception".

Notwithstanding Organon's explanation that this was a draft page that could only be found via specific search terms, the Panel considered that the page *had* been published and was accessible to health professionals for the relevant period, without the required prescribing information. The Panel therefore ruled a **breach of Clause 12.1**.

Failing to maintain high standards (Clause 5.1)

Organon conceded that the webpage had not been approved but argued that this was because it was still in development. The Panel accepted Organon's submission that the Clause 12.1 breach resulted from human error by a failure to manually select the password-protected option when publishing the webpage.

However, the Panel took account of the apparent lack of oversight by Organon of its website, and the failure to retain the staging site (or implement other robust processes to ensure effective Code compliance) when transferring responsibility for this work to the Portugal-based team. This had resulted in the omission of the prescribing information on a promotional webpage, which the Panel considered to be an important contributor to patient safety.

In light of these failings, the Panel concluded, on balance, that Organon had failed to maintain high standards in this case. The Panel ruled a **breach of Clause 5.1**.

Bringing discredit upon, or reducing confidence in, the pharmaceutical industry (Clause 2)

The Panel considered Clause 2 to be a sign of particular censure and reserved for the most serious matters.

The Panel took account of Organon's failings in this case and that prejudicing patient safety (of which the provision of prescribing information forms part) was an example, in the supplementary information to Clause 2, of an activity likely to result in a breach of that clause. However, the Panel also acknowledged the following mitigating factors in this case:

1. it involved an individual human error that was corrected within a relatively short period of 8 days,

2. the webpage was only accessible via a direct link or by using specific search terms within the Organon Pro website,

3. Organon had corrected the error on 2 September in advance of being notified of the complaint by the PMCPA on 3 September i.e. Organon had spotted the issue itself, and corrected it, and

4. the complainant had not provided any additional reasoning, or factors, that would warrant a Clause 2 breach in this case.

For these reasons, the Panel did not consider that the circumstances of this case met the threshold of bringing discredit upon, or reducing confidence in, the pharmaceutical industry. The Panel therefore ruled **no breach of Clause 2**.

Complaint received **28 August 2025**

Case completed **26 March 2026**