

COMPLAINANT v ORGANON

Allegations about a Nexplanon promotional video

CASE SUMMARY

This case was in relation to a video for Nexplanon (etonogestrel), hosted on Organon’s promotional website. The complainant made several allegations including that the video made exaggerated claims, that it omitted any information regarding the medicine’s side effects, and that the activities of the woman depicted in the video were misleading and not representative of patients initiated on Nexplanon considering its common side effects.

The outcome under the 2024 Code was:

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 5.1	Requirement that companies maintain high standards at all times
No Breach of Clause 6.1 (x3)	Requirement that information/claims/comparisons must not be misleading
No Breach of Clause 6.3	Requirement that all artwork must conform to the letter and spirit of the Code

**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:

“A video which promotes Nexplanon [job code] has a video of females dancing and partying. The video is available to be watched on [link provided]. The video has claims of, ‘designed for her lifestyle’ and ‘wherever life takes her’, ‘plan on with Nexplanon’ which implies all females can use Nexplanon without any issues regardless of their lifestyle. These exaggerated claims and the video of females dancing and partying is inappropriate and misleading considering common side effects of Nexplanon include headache, dizziness and fatigue which would not allow for partying and dancing

portrayed in the video. A female being injected with Nexplanon also has the likelihood of injection site pain which would limit their movements significantly. All these side effects would not allow for females to behave as shown in the video. The video itself does not highlight any side effects and claims of designed for her lifestyle are wide of the mark considering not all females will be suitable for Nexplanon due to the side effects affecting their lifestyle. Overall the video and qualifying claims are not reflective of a patient initiated on Nexplanon considering the common side effects. The video fails to maintain high standards. There are breaches of clauses 6.1, 5.1 and 2.”

When writing to Organon, the PMCPA asked it to consider the requirements of Clauses 6.1, 6.3, 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/0707/08/25 regarding a Nexplanon promotional video.

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

The promotional video under discussion is designed to market Nexplanon to healthcare professionals (HCPs) via Organon's promotional website, Organon Pro. It is visually focused, aiming to capture attention and convey primary messages. Located in the Nexplanon section of Organon Pro, the video showcases a woman aged 18-30 engaged in typical activities for this demographic, such as studying with friends, partying, dancing, and traveling.

Addressing the Complaint

The video is hosted in the Nexplanon section of Organon Pro, specifically in a subsection called Nexplace. It opens with the complete Nexplanon indication, AE

reporting statement and references the prescribing information availability on the same webpage the video was hosted.

Two key claims are presented: Nexplanon is the sole sub-dermal contraceptive implant available in the UK, and it emphasizes the method's effectiveness, convenience and duration of use, substantiated and cited by the Nexplanon Summary of Product Characteristics (SmPC). The complainant has expressed concern that the advertisement "implies all females can use Nexplanon without any issues" and fails to mention "side effects," suggesting that "these side effects would not allow for females to behave as shown in the video." We contend that the concise information provided in the video fulfills its purpose without the necessity of explicitly referencing side effects or implying universal suitability for all females. Further explanation follows:

Clause 6.1 and 6.3: The ABPI Code of Practice does not mandate the inclusion of side effects in all promotional materials. The decision rests on factors such as the material's content, layout, audience, and intended use.

- o **Webpage video is hosted on:** The video is hosted on Organon's promotional site, specifically on the Nexplanon product page which hosts extensive information about Nexplanon. To access the video, HCPs need to navigate to the Nexplanon page, scrolling past the full indication, prescribing information, and contraindications. This ensures HCPs understand that Nexplanon is not suitable for all females [refer to the screenshot provided by the complainant].

- o **Full indication:** The video begins by displaying Nexplanon's full indication which demonstrates that Nexplanon is not appropriate for all patients: "Nexplanon (etonogestrel 68mg implant) is indicated for contraception. Safety and efficacy have been established in women between 18 – 40 years of age."

- o **Prescribing Information and SmPC availability:** The video begins with disclaimers directing HCPs to prescribing information on the webpage where the video is hosted and ends with a referral statement to the SmPC for more information. There are three easily accessible, one click away, links to prescribing information on the hosting website, along with a link to the SmPC at the bottom of the page [refer to the screenshot provided by the complainant].

- o **Side effects:** The video does not suggest an absence of side effects related to Nexplanon. There is no implication within this video that women should engage in the depicted activities immediately after insertion or that she should engage in these activities at all. The first claim notes that Nexplanon provides contraception for up to three years, reinforcing that the depicted behaviour could occur over this duration if the women choose too, not straight after insertion.

- o **Target Audience:** The target audience of this video would be healthcare professionals working within contraception. They would be aware of guidelines and likely to exercise caution by referring to the appropriate product information such as the SmPC or PI before prescribing contraceptives such as Nexplanon.

Clause 5.1 and Clause 2: The material in question refers the HCP to consult the full information (PI) and Summary of Product Characteristics (SmPC), providing one-click access to all relevant safety information, including side effects on the web page the video was hosted.

Clause 2: We believe the advertisement maintains a high standard of ethical promotion and does not mislead or imply that Nexplanon can be used in all females. Importantly, Organon has not implied that Nexplanon does not have any side effects. Therefore, we believe there is no requirement to include side effects in this video. Furthermore, given that the target audience of the advertisement is healthcare professionals, and there is a clear reference to and availability of the SmPC and PI, we do not believe that this advertisement has compromised on patient safety in any way.”

PANEL RULING

This case was in relation to a promotional video for Nexplanon (etonogestrel), hosted on Organon’s promotional website.

The video was 1 minute 47 seconds in duration and began with a title frame which was present for approximately 12 seconds. The frame included the licensed indication, (*“Nexplanon (etonogestrel 68 mg implant) is indicated for contraception. Safety and efficacy have been established in women between 18 and 40 years of age”*) together with:

- signposting to where prescribing information could be found,
- a statement that the video was intended to be viewed online and for UK health professionals only,
- adverse event reporting information,
- a declaration that the video had been paid for and developed by Organon & Co,
- the material unique identifier and date of preparation.

For the final 3 seconds of the opening frame, the question *“Is she being offered contraception that is right for her lifestyle?”* (emphasis as it appeared in the video) was displayed.

The substantive content of the video featured a young woman participating in studying, partying and travelling. Text was overlaid throughout the video and included the following claims (emphasis as it appeared in the video):

- *“Nexplanon (etonogestrel) offers her **over 99% effective** contraception and up to **3 years of protection**”;*
- *“During the clinical studies no pregnancies were observed during 35,057 cycles of exposure; the Pearl index observed is 0.00 (95% confidence limits:0.00-0.14). However, it must be realised that in practice no method can be considered 100% effective”;*
- *“And as the UK’s only contraceptive implant for women ages 18-40, NEXPLANON gives you the choice of a **minimally-invasive, non-uterine insertion**”;*
- *“Working **behind the scenes** so she can focus on ... what **matters to her**”.*

The Panel interpreted the complainant’s concerns to be that:

1. The video contained exaggerated claims which implied that Nexplanon could be initiated for all women, regardless of their lifestyle
2. The video was inappropriate and misleading because the activities depicted in the video were not reflective of patients initiated on Nexplanon, given its common side effects
3. The video did not highlight any side effects of Nexplanon

The Panel addressed each in turn.

1. Exaggerated claims

The complainant's allegation of exaggerated claims specifically related to the statements "*designed for her lifestyle*" and "*wherever life takes her, plan on with Nexplanon*", which, in the complainant's view, implied that all women can use Nexplanon "*without any issues regardless of their lifestyle*".

The Panel noted that these claims appeared towards the end of the video, following the depiction of the young woman's lifestyle and activities. "*Wherever life takes her, plan on with Nexplanon*" appeared on a frame displaying the Nexplanon logo and a reference to consult the summary of product characteristics (SPC) for further information. The subsequent frame included the statement "*Explore Nexplace to learn more about how Nexplanon is designed for her lifestyle*".

The Panel considered the claims formed part of the overall messaging of the video, which it understood to relate to claims of convenience associated with Nexplanon. The Panel considered that Nexplanon was a long-acting hormonal contraceptive and that a single implant was to be inserted subdermally and left in place for three years.

In the Panel's view, neither of the statements highlighted, nor the activities of the young woman in the video, amounted to exaggerated claims such that they misleadingly implied that Nexplanon could be used by all women without restriction, as alleged. The Panel ruled **no breach of Clause 6.1**.

2. Inappropriate and misleading

The complainant alleged that the video was inappropriate and misleading because the activities depicted in the video were not reflective of people initiated on Nexplanon, given the medicine's common side effects. The complainant stated that Nexplanon "*would not allow for partying and dancing*" because of its common side effects, including headache, dizziness, fatigue and injection site pain.

The Panel noted that it was a well-established principle that images and videos could constitute claims and that companies had to consider carefully whether they were appropriate, ensuring that they were not inconsistent with the summary of product characteristics or likely to create a misleading impression.

Clause 6.1 of the Code required, among other things, that information must not be misleading directly or by implication. The supplementary information to Clause 6.3 stated that care must be taken to ensure that artwork does not mislead as to the nature of the medicine or any claim or comparison and that it does not detract from any warnings or contraindications.

The Panel noted that Section 4.8 of the Nexplanon SPC (Undesirable effects) listed a range of adverse reactions across multiple system organ classes. Headache was listed as a very common adverse reaction ($\geq 1/10$) and dizziness, fatigue and implant site pain were listed as common adverse reactions ($\geq 1/100$ to $< 1/10$). The Panel further noted that additional very common and common reactions were also listed in the SPC but not cited by the complainant.

The Panel considered the adverse reactions highlighted and considered that their duration and severity would vary between individuals.

The Panel took into account that Nexplanon was a long-acting hormonal contraceptive, inserted as a single implant for subdermal use and intended to be left in place for three years. The video depicted a range of activities, but the Panel did not interpret the video as suggesting when, in relation to the time of insertion, they took place. There was no suggestion that the young woman was carrying out the activities very soon after having the implant.

In the Panel's view, the activities depicted in the video were not unusual for eligible women aged 18 to 40, as per the licensed indication for Nexplanon. The Panel considered that the nature, frequency, severity or duration of the adverse events highlighted by the complainant were not such that women administered Nexplanon would be unable to engage in the activities depicted in the video.

The Panel therefore considered that it had not been established that the video was misleading or inappropriate as alleged, nor that the imagery was inconsistent with, or detracted from any of the warnings in, the Nexplanon SPC. The Panel ruled **no breaches of Clause 6.1 and Clause 6.3**.

3. Omission of side effects

The Panel interpreted the complainant's concern, that the video did "*not highlight any side effects*", to raise the question of whether the video was sufficiently complete.

The Panel considered that whether a contraindication, special warning or adverse event needed to be highlighted within a particular section of promotional material, depended on a consideration of all the circumstances including the nature of that information and the content, layout, audience and intended use of the material.

The Panel noted Organon's submission that the video was hosted within the Nexplanon section of its promotional website and that users would have to scroll past the full indication, prescribing information and contraindications. The introduction to the video similarly included the indication and reference to where the prescribing information could be found. Organon further submitted that the target audience for the video was health professionals working within contraception who would be aware of the guidelines and likely to consult product information before prescribing.

The Panel had concluded above that the adverse reactions highlighted by the complainant (including headache, dizziness, fatigue and injection site pain) did not mean that the activities depicted in the video were inappropriate or misleading. The Panel further considered it was unclear whether the complainant believed that additional adverse events should have been highlighted, and, if so, why. It was not for the Panel to infer reasons to support a complaint.

The video was short in duration and, taking into account the context in which it appeared, and its content, the Panel did not consider it had been established that the omission of side effects within the video rendered it misleading or insufficiently complete. The Panel therefore ruled **no breach of Clause 6.1**.

High standards and bringing discredit upon the pharmaceutical industry

The complainant also alleged a breach of Clauses 5.1 and 2 but provided no further information. Given its rulings of no breaches above and, in the absence of any other allegations, evidence or factors, the Panel concluded it had not been established that there had been a failure to maintain high standards nor that discredit had been brought upon the industry. The Panel therefore ruled **no breaches of Clause 5.1 and Clause 2.**

Complaint received **26 August 2025**

Case completed **24 April 2026**