

COMPLAINANT v ORGANON

Allegations about a healthcare organisation webinar

CASE SUMMARY

This case was in relation to a webinar run by a healthcare organisation titled ‘Teenage pregnancies and the importance of LARC [long-acting reversible contraception]’. The webinar had been supported by Organon and featured, at the outset, a promotional video for its product; Nexplanon (etonogestrel). The complainant alleged that data on pregnancies in under-18s, and the benefits of LARC in this population, had been presented during the webinar meaning that Nexplanon had been promoted off label because it was not licensed for under-18s. The complainant further alleged that the webinar should not have been supported by Organon and that there was a risk to patient safety.

The outcome under the 2021 Code was:

Breach of Clause 2	Bringing discredit upon, and reducing confidence in, the pharmaceutical industry
Breach of Clause 5.1	Failing to maintain high standards
Breach of Clause 11.2	Promoting a medicine outside the terms of its marketing authorisation

**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 later became non-contactable) who described themselves as a health professional.

COMPLAINT

The complaint wording is reproduced below:

“Organon had supported a webinar titled teenage pregnancies and the importance of LARC. The webinar was run by [named healthcare organisation] on [date] February 2024 with 2 GPs. A promotional video was shown at the beginning of this webinar. It was presented during the webinar that according to ONS, 13.1 per 1,000 under-18s in England became pregnant in 2021 and that LARC has many benefits for this group. Organon product Nexplanon implant was a LARC product that was not licensed under 18 years of age. This webinar promoted off label use of the Nexplanon implant in under 18s. This was a risk to patient safety and the webinar should not have been supported

by Organon. It was disingenuous of the organon approver to allow the webinar to go ahead considering off-label promotion. Breaches of clauses 11.2, 5.1 and 2.”

When writing to Organon, the PMCPA asked it to consider the requirements of Clauses 11.2, 5.1 and 2 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/0262/08/24 regarding our sponsorship towards the [named healthcare organisation] webinar. We take all complaints very seriously and 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 are unwavering in our commitment to maintaining the highest standards of ethical conduct and regulatory compliance. We understand the importance of transparency and integrity, especially in our interactions with healthcare professionals and the public. We strive to ensure that all of our actions, including sponsorship of meetings, are conducted transparently and in full compliance with relevant guidelines and codes of practice.

Background

The [named healthcare organisation] is a membership organisation for primary care clinicians with an interest in women’s health. As part of their work, they arrange several educational/scientific events and provide sponsorship opportunities to the pharmaceutical industry in relation to such events.

Organon were approached by [named healthcare organisation] to sponsor several webinars in 2024 as per the attached invitation to support. The sponsorship of the webinars was a hands-off sponsorship such that Organon had no involvement or influence on the content or development of the events. This is clearly stated in the invitation to support under the sections ‘About [named healthcare organisation]’ and ‘Terms and Conditions’.

Following the request from [named healthcare organisation] a decision was made to sponsor the event and a sponsorship agreement signed by both parties.

Organon’s involvement in webinar

The webinar took place virtually on [date] February 2024 and as stated in the sponsorship arrangement Organon were asked to provide a short promotional video which was shown to the attendees before the start of the webinar. There was no

involvement of Organon in the webinar itself and no Organon employees were present during the meeting.

A recording of the webinar itself was posted to the [named healthcare organisation] website to be available on demand to [named healthcare organisation] members after the live stream of the event but this recording does not include the Organon video as this was not part of the webinar itself but was shown before the start of the webinar to those attendees who watched the live stream.

Material presented

The video presented was a promotional video for Nexplanon (etonogestrel). This video had been certified for use at virtual conferences for UK Healthcare Professionals. The video was certified by one of our signatories who is a UK registered pharmacist.

Addressing the Complainant's Concerns

We have reviewed the event at issue in this case and our involvement with the event and have found no evidence to support the allegations made by the complainant.

The complainant alleges that 'this webinar promoted off label use of the Nexplanon implant in under 18s'. Organon is unable to comment on the content of the webinar due to their lack of involvement in the content of the webinar. Organon's sole involvement in the webinar was to provide an arm's length sponsorship and to supply a promotional video to be shown before the start of the event. The video itself clearly reflects the Nexplanon licence, there is a clear statement (at 29 sec) of the age range (18-40) the product is licenced for and the images within the video are clearly of women within this age range.

The webinar was organised and controlled by a bone fide healthcare organisation with scientific/educational content to an audience of primary care healthcare professionals with an interest in women's health.

Organon remains dedicated to maintaining a robust compliance culture and ensuring that all activities meet the ABPI code's requirements.

On this occasion, Organon consider that their sponsorship of the event and the material they were accountable for in relation to the event is in line with the requirements of the Code and therefore deny any breach of Clauses 11.2, 5.1 and 2.

We are unable to provide copies of the slides presented at the meeting as Organon was not involved with the content of the webinar other than in relation to the promotional video referred to earlier in our response.

We appreciate the opportunity to clarify our position and thank you for bringing this matter to our attention."

PANEL RULING

This case related to a webinar run by a healthcare organisation titled ‘Teenage pregnancies and the importance of LARC [long-acting reversible contraception]’, which had been supported by Organon, and featured a promotional video for Nexplanon (etonogestrel) at the beginning. The complainant stated that data on pregnancies in under-18s and the benefits of LARC in this population had been presented during the webinar and alleged that this meant that Nexplanon had been promoted off label, as it was not licensed for individuals under 18 years of age. The complainant further alleged that the webinar should not have been supported by Organon and that there was a risk to patient safety.

Organon submitted that:

1. it had been approached by the healthcare organisation to sponsor several webinars in 2024,
2. the sponsorship of these webinars was a “hands-off sponsorship”,
3. it had no involvement or influence on the content or development of the webinars, and
4. it had been asked to provide a short promotional video which was shown to attendees before the start of the webinar.

Organon provided a copy of the slides presented during the webinar which it had sourced from the healthcare organisation. The Panel noted that the slides included information on LARC treatments, including Nexplanon.

Firstly, the Panel had to decide what aspects of the webinar Organon was responsible for under the Code. The Panel noted that the Code did not prohibit a company from sponsoring third party material which mentioned the company’s products. However, a company would be liable under the Code for the content of the material unless there had been a strictly arm’s length arrangement between the parties. The arrangements must ensure that the pharmaceutical company cannot exert any influence or control over the final content of the material. Factors which might mean there had not been a strictly arm’s length arrangement would include where the pharmaceutical company:

- initiates the material, or the concept for it,
- influences the content/balance/scope of the material,
- choose and/or pays the authors of the material, and
- influences the list of persons to whom the material is sent.

In relation to material/activities aimed at health professionals, case precedent states that the content would be subject to the Code if it was promotional in nature or if the company had used the material for a promotional purpose. Even if neither of these applied, the company would be liable if it had been able to influence the content of the material in a manner favourable to its own interests.

The Panel noted that the healthcare organisation’s invitation to Organon, to support the webinars, clearly outlined the topics that the webinars would cover. One of those topics was “Teenage pregnancies, and the importance of LARC” which the Panel noted was the title for the webinar in question. The invitation further stated under ‘About [named healthcare organisation]’: *“Should the [named healthcare organisation] receive grants from industry, these are received at arms-length, control remains with the [named healthcare organisation] at all times and organisations are not involved in the development of content”*. There was no mention within the invitation about the provision of a promotional video.

However, the sponsorship agreement between Organon and the healthcare organisation stated in 'Background': *"[Named healthcare organisation] hands off sponsorship of 3 webinars including playing our short promotional video at the beginning of the webinar. Organon logo will be shown as sponsor"*. The agreement also specified the titles of the three webinars which had previously been set out as topics.

It was clear to the Panel that Organon was fully aware of the title of the webinars before deciding whether to provide sponsorship to the healthcare organisation. It was the Panel's view that prior awareness that the material would discuss the company's medicine might undermine the spirit of arm's length arrangements. The Panel considered that from the title of the webinar in question ('Teenage pregnancies, and the importance of LARC'), on the balance of probabilities, Organon would have been aware that the content of the webinar would very likely include mention of its product; Nexplanon. Nexplanon was a LARC treatment and the only implant available in the UK.

In relation to the video, individuals who attended the live-stream webinar about teenage pregnancies and LARC treatments would have been shown a promotional video for Nexplanon, a LARC treatment. The Panel noted that the opening title slide at the webinar included the following disclaimer *"This webinar has been supported by Organon. Organon has had no involvement in, or influence over the content. There will be a promotional video shown at the beginning of this webinar"*. It was not clear to the Panel whether this disclaimer slide had been shown before or after the promotional video. Either way, the Panel considered the final two sentences of the disclaimer to contradict each other. In the Panel's view, it was not possible to state that there had been no involvement or influence by Organon, but to then state that an Organon promotional video will be shown.

The Panel disagreed with Organon's submission that the promotional video was not part of the webinar itself. The sponsorship agreement expressly stated that a promotional video would be played at the beginning of the webinar. The Panel considered that the video could not be seen as anything but part of the webinar. The fact that the promotional video did not form part of the on-demand webinar did not negate this view.

The Panel considered that as the promotional video formed part of the webinar, Organon had influenced the balance and scope of the webinar. Whilst it was clear from the documentation that the intent of Organon and the healthcare organisation was for this to be an arm's length arrangement, in the Panel's view, this influence meant that this was not the case. There had not been a strictly arm's length arrangement between the parties and as such Organon was liable for the content of the webinar under the Code.

Off Label Promotion

The complainant alleged that the webinar promoted off label use of the Nexplanon implant in women under 18 years of age, as the webinar referred to pregnancies and the many benefits of LARC, in this group.

The Summary of Product Characteristics (SPC) for Nexplanon, in place at the time of the webinar, stated in section 4.1, Therapeutic indications: *"Safety and efficacy have been established in women between 18 and 40 years of age"*. Further to this, section 4.2, Posology

and method of administration stated under the heading 'Paediatric population': *"The safety and efficacy of Nexplanon in adolescents under the age of 18 have not been established"*.

The webinar at issue was titled 'Teenage Pregnancies and the Importance of LARC'. The presentation comprised 43 slides in total, divided into the following sections:

- Title slides, faculty, and disclosures (6 slides)
- Speaker 1 slides (17 slides) which appeared to focus on the progress made in reducing teen pregnancies, consequences of teenage pregnancy and how to counsel teenage patients.
- Speaker 2 (16 slides) which appeared to present data on the use of LARC and the different LARC options
- Q&A/Thank you slide, slides related to healthcare organisation (4 slides)

Organon had provided a copy of the promotional video which was shown at the beginning of the webinar. As mentioned above, it was not clear to the Panel exactly when this video had been shown, before or after the title slides. The video was approximately 2 minutes long and featured a young female adult. The video featured the following claim *"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**"* (emphasis present in video) which appeared approximately 25 seconds into the video. The only other reference to the licensed age range appeared within the prescribing information shown at the end of the video. *"Safety and efficacy have been established in women between 18 and 40 years of age"* appeared in small font within the 'Uses' section of the prescribing information and again at the bottom of the prescribing information.

On reviewing the slide presentation, the Panel noted that whilst the majority of slides referred to teenage pregnancy in general, a number of slides specifically referred to and presented data on pregnancies in women under 18 years of age, including conception, maternity and abortion rates in this group and risk factors associated with pregnancy at this age.

The presentation also featured four specific slides on the implant (slides 29-32). One slide was titled 'Nexplanon' and featured a pack shot, bullet points summarising the product and its contraindications. The following slide was titled 'Contraceptive Implant' and again featured a pack shot of Nexplanon and bullet points summarising the 'Pros', 'Cons' and 'Common side effects' with the implant. The following two slides discussed bleeding patterns and problems with the implant and how these can be managed. The Panel understood that Nexplanon was the only contraceptive implant on the market in the UK at the time and these references to 'implant' corresponded to Nexplanon. The Panel noted that there was no reference to the licensed age range for Nexplanon on any of these slides.

The Panel acknowledged that other LARC options were discussed in the presentation (copper intrauterine devices and intrauterine systems) with 'Pros' and 'Cons' also discussed for these options (slides 33-38). The final content slide of the presentation (slides 39) featured a table comparing the different options which was titled 'Comparison of Various LARC Options in Teenage **Girls**' (emphasis added by the Panel). The table featured three columns titled

'Implant', 'IUD' and 'IUS'. The last bullet point in the implant column stated: "*Most effective LARC (failure rate extremely rare)*".

In deciding whether Nexplanon had been promoted outside of its marketing authorisation, the Panel took account of the following:

1. The webinar was titled 'Teenage Pregnancies and the Importance of LARC'. The Panel understood the definition of teenage pregnancy to be pregnancy in women within the ages of 13-19. The webinar included specific data on pregnancies in girls under 18 years of age.
2. The webinar featured a promotional video for Nexplanon. Nexplanon was only licensed for women between 18 and 40 years of age. Safety and efficacy had not been established in women outside of this age range.
3. The only reference to the licensed age range for Nexplanon outside of the prescribing information, was as part of a longer claim within the promotional video. Other parts of the claim had been emboldened to draw the viewers' attention, meaning the age range may easily have been overlooked in the context of a teenage pregnancy webinar.
4. The webinar featured specific slides on Nexplanon as a LARC option with no reference to the suitable age range. Nexplanon (implant) was described as the "*most effective LARC*" in a table comparing LARC options for teenage girls, which in the Panel's view pointed towards a younger age group.

Taking all the above into account, the Panel considered that the overall impression given by the title and content of the webinar was that Nexplanon was a suitable treatment for preventing *all* teenage pregnancy. There was no clear mention that safety and efficacy had not been established in women under 18 years of age, nor that Nexplanon was not licensed for that age group.

In the Panel's view, the small reference to Nexplanon being licensed for ages 18-40 in the promotional video at the start of the webinar did not negate the misleading impression given that Nexplanon was a suitable option for preventing all ages of teenage pregnancy. Therefore, the Panel considered that the webinar had promoted Nexplanon outside of the terms of its marketing authorisation. As there had not been a strictly arm's length arrangement between Organon and the healthcare organisation, Organon was liable for the content, therefore the Panel ruled **a breach of Clause 11.2**.

Overall

The Panel's overall impression of the webinar was that Nexplanon was suitable for preventing all teenage pregnancy. However, it was clear from the licensed indication that safety and efficacy of Nexplanon had not been established in women under 18 years of age. Given the Panel's conclusion that Organon was responsible for this webinar (because Organon had not established a genuine arm's length arrangement), the Panel concluded that Organon had failed to maintain high standards and ruled **a breach of Clause 5.1**.

The supplementary information to Clause 2 listed prejudicing patient safety as an activity likely to lead to a breach of this clause. Given the fact that the safety of Nexplanon in women under 18 years of age had not been established, as per its marketing authorisation, the Panel

considered that implying that Nexplanon was suitable for this age group could have prejudiced patient safety, especially given the potential vulnerability of this age group.

The Panel noted with concern that Organon had submitted that the sponsorship was an arm's length arrangement and that its only involvement had been to supply a promotional video. Organon had failed to appreciate that by influencing the content of the webinar (with the provision of its video), the arrangements had not been strictly arm's length and it would be liable under the Code for the webinar's contents. In the Panel's view, the failure to recognise this demonstrated a lack of awareness of the Code.

Taking into account its findings above, the Panel considered that the promotion of Nexplanon outside its marketing authorisation in a potentially vulnerable patient group including children, in which safety and efficacy had not been established fell short of competent care. The Panel concluded that this brought discredit upon, and reduced confidence in, the pharmaceutical industry and therefore ruled **a breach of Clause 2**.

Complaint received **06 August 2024**

Case completed **28 August 2025**