

CASE/0480/02/25

COMPLAINANT v ORGANON

Allegations about declaration of involvement and promotion of prescription only medicines to the public

CASE SUMMARY

This case was in relation to a report published by an advisory group that was funded by Organon. The complainant alleged that the declaration of involvement was not provided “from the outset of the report” and that, as the implant was discussed in the report and Nexplanon (etonogestrel) was the only contraceptive implant in England, the report promoted a prescription only medicine to the public.

The outcome under the 2024 Code was:

Breach of Clause 5.1	Failing to maintain high standards
Breach of Clause 5.6	Failing to be sufficiently clear as to the company's role and involvement
No Breach of Clause 2 (x2)	Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry
No Breach of Clause 5.1	Requirement for companies to maintain high standards at all times
No Breach of Clause 26.1	Requirement not to advertise prescription only medicines to the public

**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 a named, contactable complainant who described themselves as a member of the public.

COMPLAINT

The complaint wording is reproduced below:

“The [named advisory group] are funded by Organon. The [advisory group] had created a report on inequalities in access to contraception in England. Within the report the declaration of Organon involvement was not provided from the outset of the report. The reader of such reports which include members of the public needed to know pharmaceutical company involvement from the beginning especially as pages 1 and 2

provided a summary. Breach of clauses 5.6, 5.1 and 2. On page 9, the implant was discussed within a bar chart titled awareness of contraceptive methods. This was promoting a POM to members of the public as there was only one contraceptive implant in England, Nexplanon, a Organon product. The report was open access for members of the public. Breach of clauses 26.1, 5.1 and 2. The Organon signatory should have challenged and prevented this non-compliant report from release. A link to the report is available at [URL provided]"

When writing to Organon, the PMCPA asked it to consider the requirements of Clauses 5.6, 5.1 and 2 of the 2024 Code in relation to the declaration of involvement, and Clauses 26.1, 5.1 and 2 of the 2024 Code in relation to the allegation about promotion of a prescription only medicine to members of the public.

ORGANON'S RESPONSE

The response from Organon is reproduced below:

"We are writing in response to the complaint received under Case AUTH/0480/02/25 regarding our sponsorship of the [named advisory group]. 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 advisory group] is an expert advisory group of leading clinicians and advocacy groups who have come together to discuss and make policy recommendations concerning the contraceptive needs of women of all ages and from all backgrounds.

Organon has supported the work of the [advisory group] for a number of years and were approached by [named healthcare consultancy] (who act as a secretariat for [advisory group]) to provide sponsorship for secretariat services to support the running of the AGC for the 12 months between 1 March 2024 and 28 Feb 2025. Sponsorship of £[redacted] was requested as per the request.

Following the request a decision was made to sponsor the organisation and a sponsorship agreement signed by both parties.

Clause 5.6

Declaration of sponsorship

The [advisory group] website ([URL provided]) includes a clear statement on the homepage referring to all their sponsors, as evidenced by the enclosed screenshot. The sponsorship statement is clear and transparent about the nature of the support received and the logos of the sponsoring companies are clearly displayed; we note that there is one other company sponsoring the website as well as ourselves currently, but we believe that there was an additional sponsoring company at the time this report was written based on the sponsorship statement mentioned below.

The [advisory group] report

The [advisory group] report called “Breaking barrier: Inequalities in access to contraception in England,” dated August 2024, was funded by three companies (Organon, [named pharmaceutical company] and [named pharmaceutical company]) who had purchased sponsorship packages as presented by [the sponsorship request document]. There was a statement at the bottom of page 3 within the report in a different coloured font stating the company’s declaration of sponsorship:

“Support for the [advisory group] is provided by [pharmaceutical company], Organon and [pharmaceutical company], who fund [advisory group] meetings, activities and the [advisory group] secretariat, delivered by [healthcare consultancy]. Sponsor organisations have no influence or input in the selection or content of [advisory group] projects or communications. Members of the [advisory group] receive no payment from [pharmaceutical company], Organon and [pharmaceutical company] for their involvement in the group, except to cover appropriate travel costs for attending meetings.”

Whilst this statement is not on the first page of the report, readers could only access this report through the [advisory group] website which does include Organon’s sponsorship statement on the home page. They would therefore be aware of Organon’s involvement in the materials on the website.

Clause 5.1 and Clause 2

Organon consider that sponsorship of this organisation is clearly indicated on the home page and is stated within the report. The wording of the declaration is unambiguous and accurately reflects the extent of our involvement as required by the Code, and therefore Organon deny any breach of Clauses 5.1 and 2.

Clause 26.1

Organon is unable to comment on the content of the report due to their lack of involvement in it. Organon’s sole involvement in the report was to provide an arm’s length sponsorship which was clear from the declaration of sponsorship. The report was written and controlled by [advisory group] to an audience with an interest in sexual and reproductive health and woman’s health. Organon therefore cannot be held responsible for the content which may or may not have mentioned their products or

who/how the content is disseminated. Therefore, Organon denies a breach of clauses 26.1, 5.1 and 2.”

PANEL RULING

This complaint related to a report published by an advisory group that was funded by Organon. The complainant alleged that the declaration of involvement was not provided “from the outset of the report” and that, as the implant was discussed in the report and Nexplanon was the only contraceptive implant in England, the report promoted a prescription only medicine to the public.

While the report was dated August 2024, the Panel noted that the case preparation manager had asked Organon to respond in relation to the requirements of the 2024 Code because the report was available online at the time of the complaint in February 2025. The Panel therefore ruled on the relevant clauses of the 2024 Code.

Declaration of involvement

The report at issue was a 28-page report titled “Breaking barriers: Inequalities in access to contraception in England”. The Panel observed that the first page of the report included a foreword and contents list; the second page presented the executive summary; and the third page contained the ‘introduction’ section of the report.

The Panel observed that there was no mention of Organon involvement on either page 1 or page 2 of the report. At the very bottom of page 3 and page 28, the following text was present in a different colour and slightly smaller font than the main content of the report:

“Support for the [advisory group] is provided by [pharmaceutical company], Organon and [pharmaceutical company], who fund [advisory group] meetings, activities and the [advisory group] secretariat, delivered by [healthcare consultancy]. Sponsor organisations have no influence or input in the selection or content of [advisory group] projects or communications. Members of the [advisory group] receive no payment from [pharmaceutical company], Organon and [pharmaceutical company] for their involvement in the group, except to cover appropriate travel costs for attending meetings.”

Clause 5.6 required that material relating to medicines and their uses, whether promotional or not, and information relating to human health or diseases which is sponsored by a pharmaceutical company or in which a pharmaceutical company has any other involvement, must clearly indicate the role of that pharmaceutical company. The supplementary information to that clause stated that the declaration of sponsorship must be sufficiently prominent to ensure that readers of sponsored material are aware of it at the outset.

Organon submitted that, while the declaration of involvement was not on the first page of the report, readers could only access the report through the advisory group’s website, which included Organon’s sponsorship statement on the homepage. In the Panel’s view, however, it was likely that some readers would arrive at the report having not first landed on the homepage. The complainant had provided a direct URL link to the report, and it also appeared that the report could be downloaded and therefore shared and circulated offline. The Panel considered that the report should be able to stand alone in terms of the requirements of the Code, irrespective of whether readers had first landed on the home page.

In the Panel's view, including the declaration of involvement statement on pages 3 and 28 of the report did not fulfil the requirement for it to be sufficiently prominent to ensure that readers were aware of it at the outset. There was a significant amount of information on pages 1 and 2, including an executive summary, which might be all that some readers read. The Panel ruled a **breach of Clause 5.6**.

Although no specific allegation was raised in relation to the written sponsorship agreement, the Panel was concerned that the agreement did not set out the requirement for a declaration of involvement to be included on any materials and activities related to the agreement. The Panel considered that, based on the evidence before it, Organon had failed to take steps to ensure that an appropriate declaration of involvement would be included in an appropriate location in the materials and activities developed as a result of the agreement. While the report did contain a declaration of funding, the Panel considered that Organon had failed to maintain high standards in this regard. The Panel ruled a **breach of Clause 5.1**.

The Panel did not consider that the particular circumstances of this case warranted a breach of Clause 2, which was reserved to indicate particular censure. The Panel ruled **no breach of Clause 2**.

Promotion to the public

The complainant alleged that a prescription only medicine had been promoted to the public because:

- the contraceptive implant was discussed on page 9 of the report,
- there was only one contraceptive implant in England: Nexplanon, an Organon product, and
- the report was open access for members of the public.

Organon submitted that it could not be held responsible for the content of the report or to whom or how the content was disseminated because its sole involvement was to provide an arm's-length sponsorship.

The Panel noted that it was possible for a company to provide funding for activities or materials produced by an independent organisation which mentioned its own products and not be liable under the Code for its contents, but only if there had been a strictly arm's-length arrangement between the parties.

The Panel noted the content of the sponsorship request document and the sponsorship agreement. The Panel took particular account of the following points:

- The sponsorship request made no reference to specific forms of contraception
- Organon was not the sole sponsor of the advisory group's activities
- The sponsorship agreement included the following wording:
"The Institution declares that the Program is not intended and will not promote or discuss specific pharmaceutical products, so as to suggest any endorsement or preference for any specific Organon pharmaceutical product."

In the Panel's view, there was no evidence before it that the arrangement between the advisory group and Organon did not meet the requirements of an arm's-length arrangement. Noting, in addition, Organon's submission that it had no involvement in the report, the Panel considered that, other than ensuring an appropriate declaration of sponsorship, Organon was not responsible for the content of the report.

The Panel also took note of the content of the report. As alleged by the complainant, the contraceptive implant was mentioned in a bar chart on page 9 of the report. The Panel made the following observations:

- Neither the brand name, Nexplanon, nor the non-proprietary name, etonogestrel, were included in the report
- "Implant" was the fourth of nine contraceptive methods presented in the bar chart and this was the only reference to the implant in the report
- The bar chart included a comprehensive range of contraceptive options, including natural family planning
- The bar chart was titled "Awareness of contraceptive methods" and compared awareness of the different methods in "Marginalised groups" and "Non-marginalised groups"

In the Panel's view, the implant was no more prominent than any of the other contraceptive methods presented, and there were no claims or positive statements made about the implant. The inclusion of the term "implant" had been used in the context of communicating the awareness of different contraceptive methods within the population measured. In the Panel's view, the report was not promotional for Nexplanon.

Having satisfied itself that the sponsorship was an arm's-length arrangement, accepting Organon's submission that it had no involvement in the content of the report, and also that, in any event, the report did not promote Nexplanon, the Panel determined that the report did not promote a prescription only medicine to the public. The Panel ruled **no breach of Clause 26.1**.

Taking into account its ruling of no breach of Clause 26.1, the Panel considered that, in this regard, the complainant had not established that Organon had failed to maintain high standards or had brought discredit upon, or reduced confidence in, the pharmaceutical industry. The Panel therefore ruled **no breach of Clause 5.1** and **no breach of Clause 2**.

Complaint received **11 February 2025**

Case completed **8 September 2025**