CASE/0217/06/24 ***NO BREACH OF THE CODE***

COMPLAINANT v ORGANON

Allegations about a leaflet

CASE SUMMARY

This case was in relation to a three-page leaflet produced by Organon titled "What are my contraceptive options?". The complainant alleged that, by advertising the advantages of the implant as a contraceptive option, the leaflet constituted promotion of Organon's Nexplanon (etonogestrel) implant to the public. The complainant also alleged that not discussing the risks of complication of insertion of the implant and the recurrence of thrombotic risks after insertion was misleading with regard to patient safety.

The outcome under the 2021 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 (x2)	**Requirement to maintain high standards at all times**
No Breach of Clause 26.1	**Requirement not to advertise prescription only medicines to the public**
No Breach of Clause 26.2	**Requirement that information about prescription only medicines which is made available to the public must be factual, balanced, must not raise unfounded hopes of successful treatment or encourage the public to ask their health professional to prescribe a specific prescription only medicine**

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 an anonymous, contactable complainant who described themselves as a health professional. The complainant later became non-contactable.

COMPLAINT

The complaint wording is reproduced below:

> "Organon had created a what are my contraceptive options leaflet (job code - GB-NON-110185 and date of preparation September 2021) for patients. Leaflet showed different

types of contraceptives with benefits and drawbacks. Organon manufactured implant contraceptive product Nexplanon and the benefits of implant was discussed. On the leaflet there was a drawbacks section of the implant product but this did not discuss the risks of complication of insertion of the implant and the reoccurrence of thrombotic risks after insertion. Advertising the advantages of implant as a contraception option on the leaflet which Organon manufacture is promotion to the public and not providing all the drawbacks with the implant was misleading towards patient safety. Clauses 26.1, 26.2, 5.1 & 2 are in breach."

When writing to Organon, the PMCPA asked it to consider the requirements of Clauses 26.1, 26.2, 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/0217/06/24 concerning a leaflet titled "What are my contraceptive options?" (GB-NON-110185, September 2021). At Organon, we are committed to the highest ethical and regulatory standards, and patient safety is at the core of everything we do. We take this complaint very seriously and appreciate the opportunity to address these concerns.

We have conducted a thorough internal review to fully understand the complaint and ensure our response is comprehensive and accurate.

Commitment to Ethical Standards

Organon is dedicated to upholding the highest level of ethical and regulatory standards. We are deeply committed to earning and maintaining the trust of our patients and healthcare professionals. We take any complaints, especially those involving patient safety, extremely seriously. As ABPI members, our goal is to ensure that all of the information disseminated by us meets the relevant regulatory requirements.

Background and context for the leaflet

The leaflet in question formed part of a non-promotional contraception awareness campaign intended for members of the public. The campaign aimed to raise awareness, empower, and educate women about the full range of contraceptive options, supporting them in their conversations with healthcare professionals. This initiative was launched in response to the fact that 45% of pregnancies in England are either unplanned or associated with feelings of ambivalence. All methods of contraception were included in the leaflet, from medicinal options to non-medicinal methods such as sterilisation and natural methods, ensuring comprehensive and balanced information.

The leaflet was approved for distribution on the 22nd of October 2021 and was subsequently withdrawn on the 11th of October 2023. It is no longer in circulation and nor is the corresponding website which also formed part of the awareness campaign, "Contraceptive Match". The leaflet was accessible as a download on this website. The

leaflet aimed to support women in their discussions with healthcare professionals by providing general information about the full range of contraceptive methods.

Addressing the Complainant's Concerns

Clause 26.1

We maintain that the leaflet was non-promotional in nature. The leaflet provided balanced and general information on the full range of contraceptive options, including non-medicinal methods, and was designed to support informed discussions between patients and healthcare professionals. The goal was to educate and empower women about their contraceptive choices without promoting a specific product over another. Advantages were indeed listed for the implant on the leaflet but were also included for every other method of contraception, to ensure a balanced presentation. Efforts were made to ensure that the content was factual and that there was consistency in the content within the advantages section for all methods. The contraceptive categories and options were also listed in alphabetical order, and this was stated on the leaflet.

According to the MHRA Disease Awareness Guidelines in Appendix 7 of the Blue Guide:

"Campaigns which aim to stimulate demand by the public for a specific medicine or specific medicines, are likely to be considered promotional, falling within scope of Part 14 of the Regulations."

"A DAC (disease awareness campaign) may make reference to the availability of treatment options (which may include medicines as part of a range of possible management options) but this should not be of such a nature that an individual would be encouraged to approach a prescriber to request a particular medicinal option".

We had kept these guidelines in mind while developing the leaflet and campaign.

Clause 26.2

We assert that the leaflet did not breach Clause 26.2. The information provided about prescription-only medicines was factual, balanced, and presented in a way that did not mislead with respect to safety. The leaflet included both advantages and drawbacks for each contraceptive method, ensuring that the presentation was balanced. The section addressing drawbacks was focused on general considerations such as administration method and menstrual impact, rather than exhaustive medical details, to avoid overwhelming the reader and to encourage professional medical consultation. As this is not a promotional material intended for healthcare professionals, but simply a resource to provide generic top-line information to members of the public, detailed information around complications associated with insertion of the implant and thrombotic event recurrence (which is only specific to women with a history of thromboembolic disorders), were not included.

Information about previous medical history, concomitant medication, and specific risks associated with administering any of the products should be a conversation that takes place between a healthcare professional and the patient before a prescribing decision

is made. The MHRA Disease Awareness Guidelines in Appendix 7 of the Blue Guide states:

"The appropriate treatment for each disease is for the HCP to decide in consultation with the patient."

The leaflet directed individuals to speak with their doctors or nurses for more detailed information and to visit the corresponding Contraceptive Match website, which was also certified separately as a non-promotional resource. The aim was to provide support for conversations between patients and healthcare providers, ensuring that any decisions regarding prescription-only medicines were made within the context of professional medical advice.

Clause 5.1

Organon maintains high standards for material review and compliance with the ABPI Code. The leaflet was reviewed and certified by a medical signatory with the necessary qualifications (see below). Our review process ensures that all materials are thoroughly evaluated for accuracy and compliance with regulatory requirements before distribution. This rigorous review process ensures that all materials distributed by Organon meet the highest standards of ethical and professional conduct.

Clause 2

We assert that the leaflet has not brought discredit upon or reduced confidence in the pharmaceutical industry. The leaflet was part of a responsible, non-promotional campaign aimed at providing general information about contraceptive options to support informed discussions between patients and healthcare providers. The material itself has not prejudiced patient safety or public health, as it directed individuals to consult their healthcare providers for more detailed information. The content was carefully curated to ensure it was educational and supportive, without being misleading or promotional.

Conclusion

Organon remains dedicated to maintaining a robust compliance culture and ensuring that all promotional materials meet the ABPI Code's requirements. The material was intended to provide general information to support informed discussions between patients and healthcare providers, not to promote specific products. On this occasion, we refute the allegations and as a result, deny breaches of clauses 26.1, 26.2, 5.1, and 2."

PANEL RULING

This complaint related to a three-page leaflet produced by Organon titled "What are my contraceptive options?".

The first two pages provided information on 12 different contraceptive options, organised into five categories (long acting, natural, permanent, short acting, and spontaneous), and the third page consisted of a list of references. For each contraceptive option, there was a short

description, an illustration depicting the option, a list of “Advantages” and a list of “Drawbacks”. The leaflet stated that the categories and options were listed alphabetically.

The complainant alleged that:

1. By advertising the advantages of “implant” as a contraceptive option, the leaflet constituted promotion of Organon’s Nexplanon (etonogestrel) implant to the public.

2. Not discussing the risks of complication of insertion of the implant and the recurrence of thrombotic risks after insertion was misleading with regard to patient safety.

Organon submitted that the leaflet formed part of a non-promotional contraception awareness campaign intended for members of the public. The aim of the campaign was “to raise awareness, empower, and educate women about the full range of contraceptive options, supporting them in their conversations with healthcare professionals.” Organon submitted that the leaflet was available as a download from the campaign website and provided “general information about the full range of contraceptive methods”. The Panel did not have a copy of the content on the campaign website at the time of the complaint and neither party made any submission in this regard.

Allegation 1: Promotion to the public

The supplementary information to Clause 26.2 stated that particular care must be taken (in disease awareness or public health campaigns) where the company’s product, even though not named, is the only medicine relevant to the disease or symptoms in question. In the Panel’s view, although Organon had the only contraceptive implant available in the UK at the time of the complaint, this did not necessarily prohibit the company from conducting an awareness campaign about options for pregnancy prevention, provided that the materials in no way promoted the use of a specific medicine; the content and balance of the material would be important considerations in this regard.

The Panel took account of the following factors:

- Neither the brand name, Nexplanon, nor the non-proprietary name, etonogestrel, were included in the leaflet

- “Implant” was one of 12 contraceptive options, including non-hormonal and non-medicinal methods, presented within the leaflet; the full range of available contraception options was included

- “Implant” was the first contraceptive option detailed on the first page of the leaflet as it was first alphabetically within the “long acting” category:
    - implant,
    - injection,
    - IUD or coil [intrauterine device], and
    - IUS [intrauterine system])

- The information provided for each contraceptive option fell into the same categories and was presented in the same format; the information generally included:
    - typical and perfect use effectiveness

- comments on insertion/administration method
- the return of fertility levels after stopping use
- potential changes to menstrual patterns
- duration of the contraceptive method
- whether the method involved hormones.

- At the start of the leaflet, the following statement was included:
  "Contraceptive methods suitability will depend on your medical history.
  The advantages and drawbacks listed for each method are not exhaustive, talk to your doctor or nurse for more information."

In the Panel's view, the implant section of the leaflet was no more prominent than any of the other contraceptive options presented within the leaflet – except that it appeared in the top left alphabetically.

The "advantages" listed for the implant were:

"● Typical and perfect use effectiveness: over 99%
● Fertility should return to levels expected for you after removal"

The Panel considered that these points were consistent with the type of information provided for the other contraceptive options. The number of advantages and disadvantages listed for the implant was consistent with those listed for the other contraceptive options.

Taking everything into consideration, the Panel determined that the complainant had not established that the leaflet in question promoted Nexplanon. 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. The Panel therefore ruled **no breach of Clause 5.1**.

Allegation 2: Providing misleading information regarding patient safety

The Panel noted the following information from the Nexplanon summary of product characteristics.

Section 4.4, Special Warnings and Precautions for Use, listed various warnings and precautions, and stated:

> *"If any of the conditions / risk factors mentioned below is present, the benefits of progestagen use should be weighed against the possible risks for each individual woman and discussed with the woman before she decides to start with Nexplanon. In the event of aggravation, exacerbation or first appearance of any of these conditions, the woman should contact her HCP. The HCP should then decide on whether the use of Nexplanon should be discontinued."*

In relation to Thrombotic and Other Vascular Events, Section 4.4 stated (among other things):

> *"Women with a history of thromboembolic disorders should be made aware of the possibility of a recurrence. The implant should be removed in the event of a thrombosis."*

In relation to Complications of Insertion, Section 4.4 stated:

> *"There have been reports of migration of the implant within the arm from the insertion site, which may be related to a deep insertion (see section 4.2 How to insert Nexplanon), or external forces (e.g. manipulation of the implant or contact sports). There also have been rare postmarketing reports of implants located within the vessels of the arm and the pulmonary artery, which may be related to deep insertions or intravascular insertion. In cases where the implant has migrated within the arm from the insertion site, localisation of the implant may be more difficult and removal may require a minor surgical procedure with a larger incision or a surgical procedure in an operating room. In cases where the implant has migrated to the pulmonary artery endovascular or surgical procedures may be needed for removal (see section 4.2 How to remove Nexplanon). If at any time the implant cannot be palpated, it should be localised and removal is recommended as soon as medically appropriate. If the implant is not removed, contraception and the risk of progestagen-related undesirable effects may continue beyond the time desired by the woman.*
>
> *Expulsion may occur especially if the implant is not inserted according to the instructions given in section 4.2 How to insert Nexplanon, or as a consequence of local inflammation."*

The Panel acknowledged that Clause 26.2 of the Code did not require expressly for all special warnings and precautions to be included in materials made available to the public. However, Clause 26.2 did require that, among other things, information about prescription only medicines which is made available to the public must not be misleading with respect to the safety of the product. The Panel considered that whether a special warning/precaution needed to be highlighted within material for the public depended on a consideration of all the circumstances – this would include taking account of the therapy area, the nature of the warning/precaution, as well as the content, layout and intended use of the material.

The Panel took into account the following factors:

- At the start of the leaflet, the following statement was included:
  "Contraceptive methods suitability will depend on your medical history.
  The advantages and drawbacks listed for each method are not exhaustive, talk to your doctor or nurse for more information."

- At the bottom of each page of the leaflet, the following statement was included:
  "To find out more about your contraceptive options speak to your doctor/nurse or visit [Organon's campaign website]*"*

- The information provided for each contraceptive option fell into the same categories and was presented in the same format; the information generally included:
  - typical and perfect use effectiveness
  - comments on insertion/administration method
  - the return of fertility levels after stopping use
  - potential changes to menstrual patterns

- duration of the contraceptive method
- whether the method involved hormones

- Organon's submission that the section addressing drawbacks was focused on general considerations, rather than exhaustive medical details, to avoid overwhelming the reader and to encourage professional medical consultation.

The "drawbacks" listed for the implant were:

"● Women may have changes in menstrual patterns (periods)
● Insertion and removal must be performed by trained healthcare professionals"

The Panel considered that these points were consistent with the type of information provided for the other contraceptive options.

Having carefully considered the material before it, the Panel concluded that the content of the leaflet did not misleadingly imply that there were no warnings or precautions to be considered in relation to the use of Nexplanon. The reader was encouraged to speak to a health professional for more information about the contraceptive options listed.

In the Panel's view, the complainant had not established that the absence of information about the risks of complication of insertion and the recurrence of thrombotic events made the leaflet misleading. The Panel ruled **no breach of Clause 26.2** accordingly.

Taking into account its ruling of no breach of Clause 26.2, 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 **25 June 2024**

Case completed **23 June 2025**