CASE/0443/01/25 ***NO BREACH OF THE CODE***

COMPLAINANT v ORGANON

Allegations about the promotion of NuvaRing to the public

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 listing advantages of the contraceptive vaginal ring as a contraceptive option, the leaflet constituted promotion of Organon's NuvaRing (etonogestrel/ethinyl estradiol) vaginal ring to the public. The complainant also alleged that Organon should have self-reported this as a breach of the Code.

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 3.4	**Requirement that companies must comply with all applicable codes, laws and regulations to which they are subject**
No Breach of Clause 5.1	**Requirement 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 Pharma (UK) Limited was received from a contactable complainant who described themselves as a health professional.

COMPLAINT

The complaint wording is reproduced below:

> "Organon had produced a material with the title what are my contraceptive options? This material is aimed at members of the public. Job code – GB-NON-110185. Date of preparation – September 2021. Organon manufactured NuvaRing which is a contraceptive vaginal ring. On this material advantages of the contraceptive vaginal ring were given including effectiveness rates and how the nuvaring is not affected by vomiting and diarrhoea. This was directly promoting to the public. Promoting to the public is unlawful. Medical reviewers for this material should not have approved the

content and Organon had not self reported the compliance breach. Breaches of clause 3.4, 26.1, 5.1, 2."

The complainant's response to a request for further information by the case preparation manager is reproduced below, with some typographical errors corrected:

> "You asked for further information regarding Organon complaint. Below are answers to your points.
> 1. I do not have copy of material to share. It is titled what are my contraceptive options? It is 3 pages long with the first 2 pages describing different contraceptive options and their advantages and disadvantages. Advantages and disadvantages of the vaginal ring are given on page 2. The material states to talk to your doctor or nurse for more information on contraceptive choices. The wording throughout the material was aimed at patients. The unique code and date of preparation for the item were provided in initial complaint email.
> 2. The material was shown to me by a young female patient asking for prescription of the vaginal ring as she had seen the advantages of the vaginal ring on this material. The only vaginal ring available is the Organon NuvaRing.
> 3. Clause 3.4 raised as UK law does not allow promotion to the public. If you do not feel this is appropriate can leave out but 3.4 does cover law which Organon would be subject to?"

When writing to Organon, the PMCPA asked it to consider the requirements of Clauses 3.4, 26.1, 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/0443/1/25 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 listed for the vaginal ring 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.

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 information provided in the leaflet 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. It is mentioned clearly at the top of the leaflet that the advantages and disadvantages listed was not exhaustive and that if more information was required, they were to speak to their doctor or nurse. 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 3.4 & 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.

We take compliance with all applicable laws and regulations very seriously and as a company, we are committed to operating ethically, transparently, and responsibly in all our activities.

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 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, 3.4, 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 listing advantages of the contraceptive vaginal ring as a contraceptive option, the leaflet constituted promotion of Organon's NuvaRing (etonogestrel/ethinyl estradiol) vaginal ring to the public, which is unlawful.

2. Organon did not self-report this alleged breach of the Code.

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 vaginal ring 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, NuvaRing, nor the non-proprietary name, etonogestrel/ethinyl estradiol, were included in the leaflet

- "Vaginal ring" 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

- "Vaginal ring" was the tenth contraceptive option listed, appearing halfway down the second page of the leaflet, as the fourth option within the "short acting" category:
    - combined pills,
    - patch,
    - progestogen-only pills, and
    - vaginal ring

- 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 vaginal ring section of the leaflet was no more prominent than any of the other contraceptive options presented within the leaflet.

The "advantages" listed for the vaginal ring were:

"● Typical effectiveness: 91%; perfect use effectiveness: 99%
● Only needs to be replaced once a month (one week following removal)
● Not affected by vomiting and diarrhoea"

The "drawbacks" listed for the vaginal ring were:

"● Need to learn how to insert, a doctor or nurse can show you how to put it in
● Oestrogen component may not be suitable for some women depending on medical history"

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 NuvaRing. 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 comply with all applicable codes, laws and regulations to which it was subject. The Panel therefore ruled **no breach of Clause 3.4**.

Allegation 2: Not self-reporting a breach of the Code

The Panel noted that the PMCPA Constitution and Procedure encouraged companies to make voluntary admission by advising the PMCPA where they consider that they may have breached the Code.

Taking into account its rulings of no breach of the Code above, 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**.

Clause 2

Taking into account its rulings of no breaches of Clauses 26.1, 3.4 and 5.1, the Panel considered that the complainant had not established that Organon had brought discredit upon, or reduced confidence in, the pharmaceutical industry. The Panel therefore ruled **no breach of Clause 2**.

Complaint received **20 January 2025**

Case completed **4 July 2025**