CASE/0237/07/24 ***NO BREACH OF THE CODE***

COMPLAINANT v ORGANON

Allegations about a long-acting reversible contraception (LARC) discussion flow on Nexplanon

CASE SUMMARY

This case was in relation to a "Contraception LARC Discussion Flow" document produced by Organon for promotional use in relation to its Nexplanon (etonogestrel) implant. The complainant alleged that the document did not include specific information about blood pressure, diabetes and liver function monitoring, or a section about monitoring after use of Nexplanon.

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 6.1 (x2)	**Requirement that material must be sufficiently complete to enable recipients to form their own opinion of the therapeutic value of the 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 was received from a contactable complainant who described themselves as a health professional.

COMPLAINT

The complaint wording is reproduced below:

> "A contraception LARC discussion flow on Nexplanon had been created by Organon for HCP use (GB-XPL-115198, date of preparation – February 2022). The flow comprises of 6 sections. The 6 sections do not contain specific guidance around the need to refer to specialist treatment if there were significant acute or chronic liver disturbances using Nexplanon. No guidance was given on the need to discontinue Nexplanon if sustained blood pressure occurred. No specific information was provided on closer monitoring of diabetic woman due to effects on blood glucose tolerance that Nexplanon could cause. The flow asked HCPs to discuss benefits and dispel myths about Nexplanon but did not cover the specific patient safety requirements around

elevated blood pressure, diabetes or liver function monitoring. The flow did not have a section for monitoring after use of Nexplanon. The omission of specific information around blood pressure, diabetes and liver function monitoring, and monitoring needs after use is a risk to patient safety. (Breach of clauses 6.1, 5.1 and 2) The flow is not fully complete for a HCP to fully understand the therapeutic value of the medicine. (breaches of clauses 6.1, 5.1)"

When writing to Organon, the PMCPA asked it to consider the requirements of Clauses 6.1, 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/0237/07/24 regarding our contraception LARC discussion flow (GB-XPL-115198, February 2022). We take this complaint very seriously and appreciate the opportunity to address the complainant's 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 information disseminated to healthcare professionals meets the ABPI Code's requirements, thereby enabling informed prescribing decisions whilst also maintaining patient safety.

Background Regarding the LARC Discussion Flow (GB-XPL-115198)

The material in question was a LARC discussion flow (expired November 2022), developed to support HCPs in their discussions with patients. This generic counselling tool helped HCPs to consider the right questions to ask and what to discuss when speaking to women who have previously been prescribed contraception or who wanted to know more about their contraception options. It was not specific to Nexplanon, as indicated by the title "Contraception LARC Discussion Flow", and content. The document itself was split into 6 sections, and while the implant was briefly mentioned in the far-right hand column, it was also mentioned alongside intrauterine systems (IUS) and intrauterine devices (IUD) in the context of LARCs in general. As it was used for promotional purposes, the relevant requirements of the ABPI code were met, including the presence of the Nexplanon prescribing information on the second page of the PDF document.

Addressing the Complainant's Concerns

As previously mentioned, this LARC discussion flow was a generic counselling tool designed to help HCPs in their conversations with patients, ensuring they choose the

most appropriate contraceptive option in conjunction with their patients. Given the context and purpose of this tool, the discussion flow itself did not include special warnings and precautions. There is no explicit requirement in the ABPI code to include all special warnings and precautions in all promotional materials. The inclusion of such details relating to the safety of a medicine depends on various factors, including the material's content, layout, audience, and intended use, as noted in historic PMCPA code case AUTH/3633/4/22.

The material also highlighted in section 2, "How to decide, what's available," that HCPs should discuss contraindications, special warnings, and precautions with their patients. Information regarding considerations for patients with acute/chronic disturbances in liver function, sustained hypertension, and diabetic women was also included directly beneath the material in the Nexplanon prescribing information.

We believe the material maintained a high standard of ethical promotion and did not mislead or imply that Nexplanon can be used in all patient populations, regardless of their medical history. Importantly, we have not advocated the use of Nexplanon in the sub-populations mentioned in the special warnings and precautions, nor have we disregarded their importance. Given that the target audience of this material was HCPs, and there was a clear reference to the prescribing information within the document itself, we do not believe this material has compromised patient safety in any way.

Conclusion

Organon remains dedicated to maintaining a robust compliance culture and ensuring that all promotional material meets the ABPI code's requirements. On this occasion, we refute the allegations and, as a result, deny all breaches of clauses 6.1, 5.1, and 2.

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

PANEL RULING

The complaint related to a "Contraception LARC Discussion Flow" document produced by Organon for promotional use in relation to its Nexplanon (etonogestrel) implant.

The Panel noted that the document comprised two pages. The first page included the discussion flow, which was broken into six sections and consisted of lists of suggested questions to discuss with the patient. The second page of the document was the Nexplanon prescribing information.

The Panel noted that the only indirect mention of Nexplanon, other than in reference to the prescribing information, was in two points in the final section of the discussion flow:

> *"● Decide where the patient wants their implant/IUS* [intrauterine system]*/IUD* [intrauterine device] *fitted. Book the appointment there and then*
> *● Remember to set realistic expectations about what to expect following insertion of implant/IUS/IUD"*

The complainant alleged that the document did not include:

1. Specific information about blood pressure, diabetes and liver function monitoring (citing breaches of Clauses 6.1, 5.1 and 2), or

2. A section about monitoring after use of Nexplanon (citing breaches of Clauses 6.1 and 5.1).

Organon submitted that the discussion flow was developed to support health professionals in their discussions with patients. It was not specific to Nexplanon and was intended to help health professionals to consider the right questions to ask and what to discuss when speaking to women about contraception options.

Allegation 1: Omission of information about blood pressure, diabetes and liver function monitoring

The Panel noted the following information from the Nexplanon SPC.

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 Liver Disease, Section 4.4 stated:

> *"When acute or chronic disturbances of liver function occur the woman should be referred to a specialist for examination and advice."*

In relation to Elevated Blood Pressure, Section 4.4 stated:

> *"If a sustained hypertension develops during the use of Nexplanon, or if a significant increase in blood pressure does not adequately respond to antihypertensive therapy, the use of Nexplanon should be discontinued."*

In relation to Carbohydrate Metabolic Effect, Section 4.4 stated:

> *"The use of progestagen-containing contraceptives may have an effect on peripheral insulin resistance and glucose tolerance. Therefore, diabetic women should be carefully monitored during the first months of Nexplanon use."*

The Panel acknowledged that Clause 6.1 of the Code did not require expressly for special warnings and precautions for use to be included in materials. However, Clause 6.1 did require, among other things, that material must be sufficiently complete to enable recipients to form their own opinion of the therapeutic value of the medicine.

The Panel considered that whether a warning or precaution needed to be highlighted within the main body of promotional material, in addition to the requirement for it to be included within the prescribing information, depended on a consideration of all the circumstances, including the therapy area, the nature of the warning, and the content, layout, audience and intended use of the material.

The Panel took into account the following factors:

- The second section of the discussion flow ("How to decide, what's available") included the discussion point "Discuss contraindications, special warnings and precautions".

- The fourth section of the discussion flow ("Inform and advise") included the discussion point "Discuss possible adverse events and any concerns they have".

- The only mention of Nexplanon was in the context of "implant/IUS/IUD", as described above.

- The Nexplanon prescribing information was included on page 2 of the document and included a 'Precautions' section, which included information on liver disease, elevated blood pressure, and monitoring women with diabetes.

The Panel accepted Organon's submission that the discussion flow document was a generic counselling tool designed to help health professionals in their conversations with patients, ensuring they choose the most appropriate contraceptive option in conjunction with their patients. The Panel considered that, on the balance of probabilities, the target audience would be familiar with the well-defined guidelines which existed for prescribing contraceptives and aware that all contraceptives had contraindications and special warnings. The Panel did not consider that the discussion flow was likely to be viewed by health professionals as a comprehensive prescribing guide.

Having carefully considered the material before it, the Panel concluded that the content of the document did not misleadingly imply that there were no warnings or precautions to be considered in relation to the use of Nexplanon. In the Panel's view, the complainant had not established that the absence of the information about blood pressure, diabetes and liver function monitoring in the body of the discussion flow made the document misleading or incomplete. The Panel ruled **no breach of Clause 6.1** accordingly.

Taking into account its ruling of no breach of Clause 6.1, 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 Clauses 5.1 and 2**.

<u>Allegation 2: Omission of a separate section about monitoring after use of Nexplanon</u>

The complainant's second allegation was that the discussion flow was not fully complete for a health professional to fully understand the therapeutic value of the medicine because it did not include a section for monitoring after use of Nexplanon.

Clause 6.1 required, among other things, that material must be sufficiently complete to enable recipients to form their own opinion of the therapeutic value of the medicine.

The Panel took into account the following factors:

- The only mention of Nexplanon was in the context of "implant/IUS/IUD", as described above.

- The final section of the discussion flow ("Establish where and who to fit") included the discussion points:
    - "Remember to set realistic expectations about what to expect following insertion of implant/IUS/IUD"
    - "Counsel patient around bleeding changes"
    - "In the event of any side effects, patients should speak to their doctor, pharmacist, or nurse".

- The Nexplanon prescribing information was included on page 2 of the document and included the instruction to "Refer to Summary of Product Characteristics (SmPC) before prescribing".

The Panel accepted Organon's submission that the Nexplanon implant was only mentioned alongside intrauterine systems and intrauterine devices in the context of LARCs in general. In the Panel's view, the discussion flow document was designed to help health professionals in their conversations with patients about contraceptive options, giving examples of the types of questions to ask and points to discuss. The Panel considered that, on the balance of probabilities, the target audience would be familiar with the well-defined guidelines which existed for prescribing contraceptives and would be unlikely to view the discussion flow as a comprehensive prescribing guide.

In the Panel's view, the monitoring requirements for different forms of LARC were likely to be different. The discussion flow document appeared to be focused on LARC as a general concept, rather than focused on the Nexplanon implant specifically. The Panel considered that the particular monitoring requirements would be relevant once the contraceptive option had been chosen and, most likely, at the appointment at which the implant (or other LARC) was fitted. In the Panel's view, a health professional was unlikely to refer solely to the discussion flow document at that time.

Having carefully considered the material before it, the Panel concluded that the omission of a specific section on monitoring within the discussion flow document did not misleadingly imply that there were no monitoring requirements associated with the use of Nexplanon. In the Panel's view, the complainant had not established that the document was not sufficiently complete to enable recipients to form their own opinion of the therapeutic value of the medicine or that Organon had failed to maintain high standards in this regard. The Panel therefore ruled **no breaches of Clauses 6.1 and 5.1**.

Complaint received **18 July 2024**

Case completed **24 April 2025**