

**CASE AUTH/3731/1/23**

**COMPLAINANT v CONSILIENT HEALTH**

**Concerns about a journal advertisement**

**CASE SUMMARY**

This case was in relation to an advertisement in the printed edition of the British Medical Journal (BMJ) placed by Consilient Healthcare.

The Panel ruled a breach of the following Clauses of the 2021 Code as the advertisement stated without qualification that contraceptive pills ‘help with skin related conditions, balancing hormones and managing menstrual cycles’ which misleadingly implied that they were licensed for such use, which was not so and because the prescribing information was illegible:

<b>Breach of Clause 6.1</b>	<b>Making a misleading claim</b>
<b>Breach of Clause 12.1</b>	<b>Failing to include up-to-date prescribing information in a clear and legible manner</b>
<b>Breach of Clause 5.1</b>	<b>Failing to maintain high standards</b>

**This summary is not intended to be read in isolation.  
For full details, please see the full case report below.**

**FULL CASE REPORT**

A contactable complainant who described themselves as a health professional complained about an advertisement in the printed edition of the British Medical Journal (BMJ) placed by Consilient Healthcare.

**COMPLAINT**

The complainant referred to an advertisement in the BMJ dated 21 January 2023 between pages 51 and 52 (copy provided). The complainant noted that the advertisement stated that contraceptive pills ‘help with skin related conditions, balancing hormones and managing menstrual cycles’ which they alleged was misleading, particularly in terms of ‘balancing hormones’. The complainant further alleged that the full page ‘abbreviated’ prescribing information was virtually illegible and defeated the object of the requirement.

When writing to Consilient, the Authority asked it to consider the requirements of Clauses 5.1, 6.1 and 12.1 of the Code.

**RESPONSE**

Consilient Health stated that the company was not an ABPI member company, however, it did agree to abide by the Code of Practice and took its obligations very seriously.

Consilient Health confirmed that no Consilient Health products were mentioned in the article, and that some women accessed contraceptives for conditions other than for contraception.

The article in the BMJ referred to a patient survey of 150 women taking the oral contraceptive in the UK that was carried out in 2021. This survey was not intended for Consilient Health products alone, however, instead was a survey of women on any oral contraceptive. In the UK there were more than 50 oral contraceptive products available. The article was presented as an 'infographic' so that the main points of the patient survey could be presented. The full report consisted of 24 slides and a copy was provided.

The aim of the patient survey was to assess women's perceptions on the accessibility of oral contraceptive pills. The study aimed to gain an insight into why the recent introduction of OTC (over the counter) contraceptive pills had led to a low uptake, and how women were currently sourcing their contraceptive pills, and the key factors that would influence the transition from GP to Pharmacist prescribing.

The objectives of the research were:

- 1 To explore women's attitudes towards the access to oral contraceptive pills in the UK.
- 2 To gain insight into the preferred methods of obtaining contraception.
- 3 To explore women's attitudes towards pharmacists and their increasing responsibility to provide contraceptive services.
- 4 To collect sound bites from health professionals who delivered contraceptive services.

The attached report for the patient survey included the methodology, demographics, as well as the survey results. An infographic was created from this report so that health professionals would be able to see the key results in an easy-to-read manner. The infographic was approved as a 2-page print article in the BMJ in the November and January editions.

The infographic that was the subject of this complaint included how women described what they used the contraceptive pill for. For some of these women, the survey showed that they sometimes used the contraceptive pill for skin-related conditions and managing menstrual cycles. The women stated that regulating/balancing of hormones was important to them, and this has been represented on the infographic. As the infographic was a summary of the patient survey results, and the information in the infographic could be substantiated from the full report of the patient survey, this was therefore not a breach of Clause 6.1.

The infographic at the outset stated prominently 'Survey was initiated and funded by Consilient Health' and 'Based on the data from 150 women in the UK currently taking an oral contraceptive pill' so it was clear to a health professional, even a busy health professional, that the advertisement related to a patient survey that had been initiated and funded by Consilient Health ensuring that health professionals were aware of Consilient Health involvement (initiated

and funded) and left no doubt in the health professional's mind that this was an industry-funded survey. The statement at the outset that the survey was based on 150 women on an oral contraceptive pill in the UK meant that the health professional could take this into account when reading the results that followed. Both of these statements were intentionally placed at the top of the advertisement so that Consilient Health was being open and transparent about Consilient Health involvement and the demographics that the survey related to. The prescribing information was found on the next page of the advertisement, and this was stated on page 1 of the advertisement so it was clear to the health professional where it could be found. If the health professional wanted further information on the survey, a statement was included on the advertisement that they should contact Consilient Health to obtain the full report. No requests for the full report had been received. For these reasons, Consilient Health believed that high standards had been maintained, and there was no breach of Clause 5.1 of the Code.

Consilient Health noted that the complainant alleged that the prescribing information was virtually illegible. However, it was presented on a full page (page 2 of the article) with the intention that the health professional was able to easily read it, which was the mandatory information as required by Clause 12.1 of the Code.

The job bag was electronically certified on 14 November 2022 and the hard copy certified on 17 November 2022 by a medical signatory. The prescribing information was checked by the medical signatory for legibility and the printed copy was deemed to be legible. Inspection of the published BMJ dated 21 January 2023, page 51 showed that the prescribing information was legible and compliant with Clause 12.1 of the Code, and a copy of the BMJ was provided. Consilient Health therefore believed there was no breach of Clause 12.1 of the Code.

## PANEL RULING

The Panel noted that Gedeon Richter was listed as the marketing authorisation holder in the summaries of product characteristics (SPCs) provided by Consilient Health for Gedarel (ethinylestradiol and desogestrel), Millinette (ethinylestradiol and gestodene), Cerelle (desogestrel), Lucette (ethinylestradiol and drospirenone), Rigevidon (levonorgestrel and ethinylestradiol), and Triregol (ethinylestradiol and levonorgestrel) tablets. It appeared that Gedeon Richter had, in February 2023, after receipt of the complaint, acquired full marketing and distribution rights to all of Consilient Health's contraceptive range. Consilient Health made no mention in this regard within its response.

The Panel noted that the BMJ article, which was certified by Consilient Health as a promotional advertisement and included prescribing information for the above mentioned products was titled '*Access to oral contraception: the female perspective Based on the data from 150 women in the UK currently taking oral contraceptive pill*'. Below the title it stated that the survey was initiated and funded by Consilient Health. It explained that the survey set out to explore how women currently accessed their oral contraceptive pills, how likely they were to make the move from GP to Pharmacist and then detailed results from the survey, the first being:

*'91% - For 91% of the women in our research, the oral contraceptive pill is the first choice and the most preferred method of contraception, with many referring to "its convenience" and "ease of use" as key factor for its popularity. For many women, the contraceptive pill is more than just birth control. It helps with skin-related issues, balancing hormones and managing menstrual cycles. Control over these can have a profound impact on women.'*

The Panel noted Consilient Health's submission that the infographic that was the subject of this complaint included how women described what they used the contraceptive pill for, and for some of these women, the survey showed that they sometimes used the contraceptive pill for skin-related conditions and managing menstrual cycles and stated that regulating/balancing of hormones was important to them which was represented on the infographic. The Panel, however, noted that Consilient Health was responsible for the advertisement and any information included within it must comply with the requirements of the Code. The Panel noted that, according to the SPCs for the Consilient Health products (when the article was published): Gedarel, Millinette, Cerelle, Lucette, Rigevidon, Triregol, and Cilique (norgestimate and ethinylestradiol) tablets, all were licensed for oral contraception, contraception or hormonal contraception only. The Panel noted that it was not necessarily unacceptable to refer to the secondary benefits that might flow from using a medicine for its licensed indication provided that such benefits were unambiguously placed within the context of the medicine's licensed indication and the material did not imply that the medicine was licensed to treat such secondary benefits and otherwise complied with the Code. The Panel considered that the phrase '*For many women the contraceptive pill is more than just birth control*' implied that women were prescribed the contraceptive pill for reasons other than contraception. Whilst this might be so, the Panel considered that stating without qualification that contraceptive pills '*help with skin related conditions, balancing hormones and managing menstrual cycles*' misleadingly implied that they were licensed for such use, which was not so. The Panel therefore ruled **a breach of Clause 6.1**.

The Panel noted that the line length of the prescribing information, which was combined for all of the above-mentioned medicines within the hard copy BMJ, was approximately 186 characters including spaces. The Panel considered that was excessive and made the prescribing information difficult to read, as alleged. **A breach of Clause 12.1** was ruled.

The Panel noted its comments and rulings above and considered that Consilient Health had failed to maintain high standards and **a breach of Clause 5.1** was ruled.

**Complaint received**      **24 January 2023**

**Case completed**        **18 September 2023**