Medicines Australia
Better health through research & innovation

COMPLAINT OUTCOME

1176 - Promotional material related to UTROGESTAN

DETERMINATIONS OF THE MEDICINES AUSTRALIA CODE OF CONDUCT COMMITTEE

The administration of the Code is supervised by the Code of Conduct Committee. The Code of Conduct Committee has the power to make a determination as to a breach of the Code and impose sanctions. The right of appeal is available to both the Complainant and Subject Company. An appeal is heard by the Appeals Committee which has the power to confirm or overturn the decision and to amend or remove any sanctions.

The decisions of the Code of Conduct and Appeals Committees are relevant to the date of publication of the materials subject to complaint and approved Product Information (PI) at that time. A complaint is not deemed finalised until both parties have advised Medicines Australia that they will not appeal the outcome of the Code of Conduct Committee decision (following circulation of the Committee's Reasons) or, in the case of an appeal, the Appeals Committee Reasons have been provided to both parties.

This report is an extract of the 'Reasons for Decision' provided by the Code Committee. The complaint was heard on 17th February 2025.

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DOWNLOAD THE CODE

The Code of Conduct and all associated materials are available on the Medicines Australia website.

COMPLAINT 1176 Promotional material related to UTROGESTAN

SUBJECT COMPANY	PRODUCT	COMPLAINANT
Besins	UTROGESTAN (progesterone)	A healthcare professional (deidentified on request)

COMPLAINT

The complaint concerned an advertisement for UTROGESTAN, which the complainant alleged was misleading by inferring that the product could be used more broadly than the approved indication. Specifically, that the material implied that the product should be initiated for any patient experiencing such symptoms in the first trimester of pregnancy, without clarifying any limitations.

Concerns were also raised about the balance of the material. The complainant considered the material appeared to present benefits without adequately alerting prescribers to risks, including limitations in the indicated use, body of evidence supporting clinical benefit, and Special Warnings and Precautions for Use. In addition, the scientific validity of the material was questioned, with specific concern that the suggested benefits were not sufficiently qualified.

SECTIONS OF THE CODE (EDITION 19)

- **Overarching Principle 1**: All activities undertaken by Companies have the purpose of supporting the quality use of medicines.
- **Overarching Principle 3**: Companies are responsible for providing current, accurate, balanced, and scientifically valid information products to support their use.
- **Overarching Principle 7**: Information relevant to prescribing, in particular product and safety information, are clearly communicated in all promotional materials. Promotional materials are designed by Companies to not only create awareness of Therapeutic Goods Administration (TGA) approved medicines, but to support proper assessment of their risks and benefits.

RESPONSE TO THE COMPLAINT

Besins Healthcare Australia maintained that the material did not breach the Code. The Subject Company stated that the material—and the supporting website—were intended to promote the quality use of medicines for the relevant condition. The content aimed to raise awareness about the treatment of unexplained threatened miscarriage and directed healthcare professionals to further educational resources.

The Subject Company considered that information in the material was current, balanced, and accurate, was scientifically valid and backed by clinical data of the highest quality, which could be easily accessed for more in-depth reading by scanning the QR code and accessing the full Product Information.

The Subject Company also stated that the risks associated with the use of the product for this condition were minimal. Furthermore, it noted that the inclusion of Minimum Product Information—although not required under the Code—appropriately addressed important safety information, indications for use, and clearly outlined the patient group where treatment is of most benefit.

CODE COMMITTEE DECISIONS

The Code Committee considered the complaint and determined there were breaches of the Code. Sanctions were applied by the Code Committee. See the table of Committee Decisions below, and the Code Committee Reasons on pages 2-3.

Neither the Subject Company nor the Complainant appealed the Code Committee Decisions.

Area of the Code	Material	Sanctions
Pinciple 1	BREACH (unanimous)	• A single monetary fine of $100,000, and • Cessation of using the material in the future in its current form, noting the material has ceased being used on receipt of the complaint.
Principle 3	BREACH (unanimous)	
Principle 7	BREACH (unanimous)	

CONSIDERATION OF THE COMPLAINT by the CODE COMMITTEE

- The complaint concerned an advertisement for Besin's product Utrogestan, published in the Australian Journal of General Practice (AJGP) September 2024 issue.
- Utrogestan was recently approved for use in Australia for preventing miscarriage. The material was designed to raise awareness of the product and its indication so that primary care clinicians may increase their understanding of how to manage miscarriage and unexplained threatened miscarriage.
- The complainant considered that the material may be misleading, incomplete in its current form, and does not support the appropriate use of the product.
- Specifically, the complaint was separated into three separate but related concerns:
  (a) Broader use than approved indication
  (b) Balance of risks and benefits
  (c) Scientific Validity

Concern 1 – Broader use than approved indication

- The Committee formed the view that the statement "*Utrogestan should be initiated at the first sign of unexplained vaginal bleeding during the first trimester of pregnancy and continued to at least the 16th week of gestation*" implied that the product should be initiated for any patient experiencing such symptoms in the first trimester of pregnancy.
- Whilst this is extracted word-for-word from the Dose and Method of Administration section of the Product Information, the Committee determined that the way in which the material highlighted and presented this sentence gave an acute impression the product was indicated for any unexplained vaginal bleeding during the first trimester of pregnancy. This was amplified by the lack of clarity on its approved use.

- The product is indicated for "*treatment of threatened miscarriage in women with a history of at least three or more previous miscarriages and women with less than three miscarriages who have a reduced chance of future pregnancy*". Because the statement lacked clarification on the limitations of its approved indication, it implied a broader use than its approved indication.
- The Committee acknowledged that the approved indication was included in the Minimum Product Information in the material, however, the font size rendered it practically illegible. The continuous block of text with no breaks or spacing contributed to it being unclear nor understood by the average reader. The Committee took the view that inclusion of the indication in the same font and size as the material's references contributed to a lack of prominence that meant it could not act, in practice, as a qualifier to the dominant parts of the material.
- While the inclusion of the Minimum Product Information in the material may have technically satisfied the requirement to provide information relevant to the appropriate assessment and use of the product, it was in fact ineffective due to difficulties in legibility.
- In contrast, the material contained bold and prominent information that highlighted the prevalence of threatened miscarriage alongside dosing information yet failed to adequately qualify or clarify the approved use of the product.
- The Committee determined the overall effect of the material's messaging and presentation in the material did not support the approved use of the product.

Concern 2 – Balance of risks and benefits

- The Committee considered that displaying a brand name alongside the statement '*how you can help*' and a directive to initiate patients on the treatment implied a potential benefit, thereby necessitating the inclusion of relevant risk information in the piece.
- In relation to whether the material included adequate information on the risks of the product, the Committee acknowledged that risks were included in the Minimum Product Information in the material, however, it was practically illegible and lacking in prominence as per above.
- Because of this, the Committee considered that the material did not sufficiently alert healthcare professionals to the product's risks (for example, Special, Warnings and Precautions for Use). Considering ectopic pregnancy is listed as a contraindication, the Committee cautioned against downplaying risks even if sources suggest there is minimal risk and there is no black box warning.
- The Committee determined the information relevant to prescribing was not clearly communicated in conjunction with the statements on product use and does not support proper assessment of the risks and benefits.

Concern 3 – Scientific Validity

- The Committee considered the complainant's view that the material should have explicitly stated the lack of evidence for women without a history of miscarriage, as well as the reduced benefit for those with fewer than three miscarriages, as outlined in the approved indication.
- The Committee accepted that the body of evidence only supports a clinical benefit in some (but not all) women experiencing threatened miscarriage in the first trimester. However, the Committee did not consider it to be essential for this information to be included in the material given the absence of explicit promotional claims.
- Overall, the Committee considered that, had the material clearly outlined the approved indications and their limitations, the relevance of referencing the broader body of evidence would have been less significant.

RELEVANT PRINCIPLES AND PROVISIONS OF THE CODE

In light of the reasons set out above, the Committee determined unanimously on all counts that the promotional material comprised a breach of the following principles and provisions of the Code:

- **Principle 1:** the material does not support the quality use of medicines because it selectively omits key qualifying information on the use of the product, and implies the product is beneficial for a use broader than its approved indication.
- **Principle 3:** the material does not support the appropriate use of the product by failing to qualify or clarify the statement on the use of the product, and misleading healthcare professionals with the implication of broader use than indicated.
- **Principle 7:** information relevant to prescribing is not clearly communicated in conjunction with the statements on product use and therefore does not support proper assessment of the risks and benefits.

SANCTIONS

- The Committee considered that the material implied a broad call to action—encouraging prescribing of the product at the first sign of unexplained vaginal bleeding during the first trimester of pregnancy—without adequately reflecting the limitations in the approved indication. The Committee discussed the potential impact of this messaging on prescribing practices and patient safety, noting that these considerations were relevant to assessing the nature of the breach and determining appropriate sanctions. The Committee determined that the messaging could result in prescribing being prioritized over investigating the underlying cause of the bleeding.
- On balance, the Committee determined that the primary impact would likely be commercial— probably causing increased prescribing of the product—rather than presenting a direct risk to patient safety. The Committee was satisfied that the claim was likely to influence prescribing behaviour within the medical profession, and accordingly, the breach was classified as moderate.
- The Committee determined that a fine was appropriate, at the low end of the moderate category threshold (as guided by the Code). The Committee imposed the following sanctions:

    1. A single monetary fine of $100,000, and
    2. Cessation of the material in the future, noting the material has been withdrawn from circulation.

- The Committee did not impose corrective action, determining that a monetary fine coupled with the withdrawal and cessation sanction would be adequate.

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