CASE/0627/06/25

COMPLAINANT v CONSILIENT HEALTH

Allegations about a promotional website

CASE SUMMARY

This case was in relation to a promotional website and video for Blissel (estriol). The complainant alleged that the non-proprietary name did not appear in immediate conjunction with the first mention of the brand name on the homepage of the website and that a description of Blissel as "well tolerated" on the website's efficacy page was misleading. The complainant also alleged that the prescribing information was displayed for an insufficient length of time at the end of the promotional video.

The outcome under the 2024 Code was:

Breach of Clause 5.1	**Failing to maintain high standards**
Breach of Clause 6.1	**Making a misleading claim**
Breach of Clause 6.2	**Making a claim that was incapable of substantiation**
Breach of Clause 12.4	**Failing to include the non-proprietary name of the medicine immediately adjacent to the first display of the brand name**

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 12.1	**Requirement to include prescribing information**

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 Consilient Health Ltd was received from an anonymous, non-contactable complainant who described themselves as a health professional.

COMPLAINT

The complaint wording is reproduced below:

> "Complaint Regarding Website and Video Content – [URL provided] I am writing to submit a formal complaint concerning the promotional website and associated materials for Blissel (estriol), found at [URL provided] and linked content. Please consider clauses 6.1, 6.2, 12.4 and 5.1. I believe the following aspects may constitute

breaches of the ABPI Code of Practice: Omission of the non-proprietary name: Throughout the homepage of the website, the brand name 'Blissel' is used prominently and repeatedly without being accompanied by the non-proprietary name, 'estriol,' in breach of Clause 12.4. The non-proprietary name only appears at the very bottom of the page, and not in immediate conjunction with the first mention of the brand. This undermines clarity and fails to meet the standards for transparency set by the Code. Insufficient prescribing information in promotional video: In the promotional video available at this link ([URL provided]), the prescribing information is shown for only approximately three seconds at the end. This duration is clearly insufficient for viewers to read and comprehend the required safety and prescribing details, and likely breaches Clause 12.1 and related guidance. Inappropriate claim of tolerability: On the website's efficacy page, the product is described as 'well-tolerated.' This blanket claim is misleading given the range of side effects listed in the product's own summary of product characteristics (SmPC), including local reactions and systemic estrogenic effects. The claim appears to downplay the potential risks and is likely in breach of Clauses 6.1 and 6.2, which require claims to be accurate, balanced, and not misleading, plus capable of substantiation. Taken together, these issues raise serious concerns about the responsible promotion of Blissel to patients and potentially to healthcare professionals. I respectfully request that the PMCPA investigates these matters and takes appropriate action in line with the ABPI Code of Practice."

When writing to Consilient Health, the PMCPA asked it to consider the requirements of Clauses 6.1, 6.2, 12.1, 12.4, 5.1 and 2 of the 2024 Code.

CONSILIENT HEALTH'S RESPONSE

The response from Consilient Health is reproduced below:

"Thank you for your letter of 23rd June 2025 regarding the above.

Consilient Health abides by the PMCPA Code of Practice as a non-member company.

We have reviewed the complaint and note the Clauses for consideration cited by PMCPA.

We do not believe that these items are in breach of the Code and will detail our reasons below.

Point 1: Non-proprietary name on website
On entering the healthcare professional (HCP) section of the [URL provided] website, the HCP is on the home page (UK-BLS-43a(2), date of preparation, March 2025). The home page has a large logo at the bottom which includes the non-proprietary name. We acknowledge that the page contains other mentions of the brand name without the non-proprietary name, however this logo with non-proprietary name is clearly the largest and most prominent mention of the brand name on the page.

Point 2: Prescribing information in promotional video
The promotional video (UK-BLS-291s; November 2023) is hosted on a video player platform and accessed by way of a link from the [URL provided] website. Of note, this

means that the video is operated by the HCP themselves, rather than being 'presented to a recipient' per 12.1 Si 'Clause 12.1 Provision of Prescribing Information'.

The video has standard online video control buttons, including play and pause, and a progress (or seek) bar with a screen preview, allowing the user to navigate to any point in the video at their discretion. Video controls such as these are ubiquitous across the internet and all HCPs viewing content online will be familiar with their use. It is therefore reasonable to expect that the HCP, having started the video playing, will also be able to pause the video when the PI is on the screen for as long as they need to enable it to be read. The PI provided on this video therefore fulfils the requirement of Clause 12 and is not in breach of clause 12.1.

Point 3: Claim of tolerability
The description of the tolerability profile of Blissel® on the Efficacy page of the website (UK-BLS-43d(3), March 2025) as 'well tolerated' is supported by the cited reference, Cano et al (Menopause. 2012 Oct;19(10):1130-9), and consistent with the product's Summary of Product Characteristics and therefore not in breach of Clauses 6.1 or 6.2.

Cano et al concludes *'Finally, 0.005% estriol vaginal gel was safe and well tolerated. The frequency and type of treatment-related AEs were similar between both the active and placebo groups, and most of these were mild in intensity. The observation of pruritus as the most frequent AE related to the study medication is concordant with the tolerability profile described for most estrogenic intravaginal products and may indicate a healing effect of the vaginal epithelium.'*

This is consistent with the Blissel® SPC which states: 'Undesirable effects from estriol are usually reported in 3-10% of those patients who are treated. They are often transient and of mild intensity' and that 'Blissel is a locally administered vaginal gel with a very low dose of estriol and self-limiting systemic exposure (shown to be almost negligible after repeated administration), and as such is highly unlikely to produce the more severe effects associated with oral estrogen replacement therapy.'

The materials do not claim that Blissel® has no side effects; a fact that healthcare professionals viewing this material will be aware of as being true for all medicines. The full list of adverse effects and precautions from the SPC are included on this page. The table of all Common, Uncommon and Rare undesirable effects from the SPC is below for ease of reference.

Organ System Class	**Common (≥1/100 to <1/10)**	**Uncommon (≥1/1,000 to <1/100)**	**Rare (≥1/10,000 to <1/1000)**
Reproductive system and breast disorders	Pruritus genital.	Pelvic pain, genital rash.	
General disorders and administration site conditions	Application site pruritus	Application site irritation	
Infections and infestations		Candidiasis	
Nervous system disorders		Headache	
Skin and subcutaneous tissue disorders	Pruritus	Prurigo	

While the complainant mentions patients, all of the material referred to by the complainant is clearly directed towards UK Healthcare professionals only, contained within the Healthcare Professional section of the website, and the information regarding tolerability from the SPC are clearly displayed. Therefore, high standards have been maintained and the website and video are not in breach of Clause 5.1 or Clause 2."

PANEL RULING

This case related to a promotional website for Consilient Health's product Blissel (estriol). The complainant made allegations relating to the location of the non-proprietary name; the duration that prescribing information was shown on a video; and the acceptability of the claim 'well-tolerated'.

Non-proprietary name

The complainant alleged that the brand name, Blissel, was used without the non-proprietary name throughout the homepage of the website. The complainant stated that the non-proprietary name was only present at the very bottom of the page and alleged that it was not in immediate conjunction with the first mention of the brand name.

Consilient Health acknowledged that the page contained mentions of the brand name without the non-proprietary name but submitted that the logo which included the non-proprietary name was the largest and most prominent mention of the brand name on the webpage.

For digital materials, Clause 12.4 required that the non-proprietary name must appear immediately adjacent to the brand name at its first appearance.

The Panel observed that the first appearance of the brand name on the homepage was in the navigation menu at the top of the page. The brand name appeared a further four times before the large logo (which included the non-proprietary name) at the bottom of the scrolling webpage.

The Panel noted that the first mention of the brand name on the homepage was not in a prominent location, with small white font over a light grey image. The complainant did not identify the location of the first mention of the brand name. The requirement of Clause 12.4 was clear, however, that, for digital materials, the non-proprietary name must be included at the first mention. The Panel noted that Clause 12.4 also required that the size and location of the non-proprietary name must be such that it was easily noticed and readable. There was nothing to prevent the non-proprietary name being included more than once and in the Panel's view, it would be good practice to also include the non-proprietary name alongside the first mention of the brand name within the substantive part of the webpage in question.

As the non-proprietary name had not been included immediately adjacent to the brand name at its first appearance on the homepage, the Panel ruled a **breach of Clause 12.4**.

Prescribing information

The complainant provided a link to a video and alleged that the prescribing information was only shown for approximately 3 seconds at the end of the video and that this was insufficient for viewers to read and comprehend the information.

Consilient Health submitted that the video, which was a total of 1 minute 51 seconds long, was hosted on a video player platform and operated by the health professional themselves which allowed the user to play, pause and navigate to any point in the video. Consilient Health submitted that the viewer could, therefore, pause the video for as long as they needed to enable the prescribing information to be read.

Clause 12.1 required that prescribing information must be provided in a clear and legible manner in all promotional material. The supplementary information provided that when prescribing information is included as text in promotional material presented to a recipient, either in person or remotely, it must be of sufficient duration so that it is easily readable.

The Panel noted that when the video provided by Consilient Health was played at its pre-set speed the prescribing information appeared to be visible for more than the three seconds referred to by the complainant and was of sufficient duration such that the viewer would be able to recognise that the slides at issue contained prescribing information and decide whether to control the video themselves, including the use of pause and play back. In the Panel's view this fulfilled the requirements of Clause 12.1 and the Panel accordingly ruled **no breach of Clause 12.1**.

Claim of 'well-tolerated'

The complainant alleged that the description of Blissel as "well-tolerated" on the website's efficacy page was misleading given the range of side effects listed in the SPC, including local reactions and systemic estrogenic effects. The complainant alleged that the claim appeared to downplay potential risks of the product.

Consilient Health submitted that the wording was supported by the cited reference and was consistent with the SPC. Consilient Health submitted that there was no claim that Blissel had no side effects and that the full list of adverse effects and precautions from the SPC was included on the webpage.

The efficacy page of the website featured a large picture of a woman across the top of the page followed by the heading "Give her effective vaginal atrophy treatment with Blissel". The wording at issue appeared beneath this, in the first of three lines of text in smaller font, alongside a smaller image:

> "Blissel is well-tolerated and effective in the treatment of postmenopausal vaginal atrophy.[1]
>
> Blissel allows you to treat vaginal atrophy whilst limiting systemic exposure to estrogens
>
> Low dose estriol formulations, such as Blissel, have significantly lower systemic absorption than higher dose medications.[2]"

The first sentence was referenced to Cano A et al. (2012) which evaluated the efficacy and safety of the product.

Beneath this text was an embedded video, then a box with information about efficacy in vaginal dryness and improvements in changes due to vaginal atrophy, followed by another embedded video.

A heading, “Administration”, was followed by a box that included a small amount of text, an image of the product and a link to a ‘how to use’ guide. This was followed by a heading, “Precautions” and two boxes side by side. The box on the left contained four bullet points reproducing information from the Special warnings and precautions for use section of the SPC and an instruction to the reader to refer to the SPC for full information. The box on the right contained a table of common and uncommon undesirable effects, corresponding to the table in section 4.8 of the SPC. Both boxes contained an icon in the top left corner of an exclamation mark in a triangle, which the Panel considered was to draw a reader’s attention to the information.

The rest of the webpage included a box with information on how to book a visit, links to other sections of the website, a large logo and strapline (“Release her confidence from within.”), a link to prescribing information and the adverse event reporting statement.

Clause 6.1 required information, claims and comparisons to be accurate, balanced, fair, objective and unambiguous, whilst Clause 6.2 required that any information, claim or comparison must be capable of substantiation. The Panel noted Consilient Health’s submission that the claim was supported by the cited reference, quoting:

> “Cano et al concludes *‘Finally, 0.005% estriol vaginal gel was safe and well tolerated. The frequency and type of treatment-related AEs were similar between both the active and placebo groups, and most of these were mild in intensity. The observation of pruritus as the most frequent AE related to the study medication is concordant with the tolerability profile described for most estrogenic intravaginal products and may indicate a healing effect of the vaginal epithelium’.”*

The Panel considered that there was a difference between wording that might be used in a peer-reviewed article and the requirements of the Code in relation to wording used in company material within the scope of the Code. Clause 6.4, for example, required that the word “safe” must not be used without qualification.

The Panel noted Consilient Health’s submission that the claim was consistent with the product’s SPC. The Panel took into account the content of the SPC, including:

From Section 4.4 Special warnings and precautions for use:

> “For the treatment of postmenopausal symptoms, local estrogen therapy should only be initiated for symptoms that adversely affect quality of life.
>
> In all cases, a careful appraisal of the risks and benefits should be undertaken at least annually and HRT should only be continued as long as the benefit outweighs the risk.
>
> Blissel 50 micrograms/g vaginal gel must not be combined with estrogen preparations for systemic treatment, as there are no studies of safety and rusks with estrogen concentrations attained in combination treatment.
>
> Intravaginal applicator may cause minor local trauma, especially in women with serious vaginal atrophy.”

Section 4.4 further stated that during treatment periodic check-ups are recommended with a frequency and nature adapted to the individual woman and in addition listed thirteen conditions which if present required the patient to be closely supervised.

Section 4.8 Undesirable effects stated:

> "Undesirable effects from estriol are usually reported in 3-10% of those patients who are treated. They are often transient and of mild intensity."

This was followed by further text about local irritation at the start of treatment. The table of undesirable effects listed pruritus genital, application site pruritus and pruritus as common undesirable effects and pelvic pain, genital rash, application site irritation, candidiasis, headache, and prurigo as uncommon undesirable effects. No rare undesirable effects were listed. Underneath the table it stated:

> "Blissel is a locally administered vaginal gel with a very low dose of estriol and self-limiting systemic exposure (shown to be almost negligible after repeated administration), and as such is highly unlikely to produce the more severe effects associated with oral estrogen replacement therapy. However, other very rare adverse reactions have been reported with higher dose systemic estrogen/progestin therapy. These are:
>
> - Estrogen-dependent neoplasms benign and malignant, e.g. endometrial cancer and breast cancer (see also section 4.3 Contraindications and 4.4. Special warnings and precautions for use)
>
> - Venous thromboembolism, i.e. deep leg or pelvic venous thrombosis and pulmonary embolism, is more frequent among hormone replacement therapy users than among non-users. For further information, see section 4.3 Contraindications and 4.4. Special warnings and precautions for use
>
> - Myocardial infarction and stroke
>
> - Gall bladder disease
>
> - Skin and subcutaneous disorders: chloasma, erythema multiforme, erythema nodosum, vascular purpura
>
> - Probable dementia"

The Panel considered the immediate and overall impression of the efficacy page and noted that the positive and unqualified claim that Blissel was well tolerated was positioned near the top of the page and that a user would have to scroll over halfway down the page, past videos and links to other information, to reach the information about precautions and undesirable effects.

The Panel was mindful that the patient population for this product comprised older women and therefore was likely to include patients on an estrogen or other hormone preparation; the Panel considered that the warning against combination treatment with estrogen preparations for systemic treatment information within the Precautions section was of particular importance. The Panel acknowledged the information in various parts of the SPC that Blissel is a locally acting, low dose, estriol preparation with self-limiting systemic exposure. Nonetheless the Panel bore in mind that Blissel was a hormone therapy and noticed the caution reflected in the SPC in this regard. The Panel was therefore concerned that the phrase 'well-tolerated' was not qualified and would be read in light of the positive claims within its immediate visual field which referred to 'limiting systemic exposure' and 'lower systemic absorption'. The Panel considered that the relevant section of the webpage was not sufficiently complete to enable readers to form their own opinion in relation to the claim 'well-tolerated.' Overall, the Panel considered that the unqualified nature of the claim was such that it was not a fair reflection of the SPC and was

misleading in this regard. The Panel ruled a **breach of Clause 6.1**. The Panel further considered the unqualified nature of the claim was such that it was not capable of substantiation and therefore the requirements of Clause 6.2 had not been met and ruled a **breach of Clause 6.2**.

High standards

The complainant alleged that, taken together, the issues they had complained about raised serious concerns about the responsible promotion of Blissel to health professionals. The Panel was concerned that Consilient Health's response in relation to the requirements of Clause 12.4 demonstrated a misunderstanding of the requirements of the Code and queried the robustness of the review processes in relation to the breaches ruled on the two webpages at issue. The Panel considered that Consilient Health had failed to maintain high standards and ruled a **breach of Clause 5.1**.

The Panel recognised that Clause 2 was a sign of particular censure for cases where a company had brought discredit upon, or reduced confidence in, the pharmaceutical industry. The Panel took into account that the efficacy page did contain some safety information towards the bottom of the webpage and directed the reader to the SPC. The Panel did not consider that Consilient Health had prejudiced patient safety and thereby brought discredit upon, or reduced confidence in, the pharmaceutical industry. The Panel therefore ruled **no breach of Clause 2**.

Complaint received **18 June 2025**

Case completed **17 February 2026**