CASE/0761/10/25 *NO BREACH OF THE CODE*

COMPLAINANT v CHIESI

Allegations about pre-licence promotion and misleading claims

CASE SUMMARY

This case was in relation to a webpage on Chiesi's promotional website for health professionals. The complainant alleged that the webpage promoted Chiesi's new propellant formulation for its respiratory portfolio, which amounted to pre-licence promotion and that the webpage included a claim which misleadingly implied the Chiesi inhaler portfolio was available in a range of devices, when Atimos (formoterol fumarate dihydrate) and Clenil (beclomethasone dipropionate) were only available as pMDI (pressurised metered-dose inhaler) devices.

The outcome under the 2024 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 3.1	**Requirement that a medicine must not be promoted prior to the grant of its marketing authorisation**
No Breach of Clause 5.1	**Requirement for companies to maintain high standards at all times**
No Breach of Clause 6.1	**Requirement that claims must not be misleading**

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 Chiesi Limited was received from a contactable complainant who described themselves as a health professional.

COMPLAINT

The complaint wording is reproduced below:

> "There is pre-licence promotion of a new formulation for Chiesi pMDI inhalers. The evidence for this is on the page [URL provided] UK-RES-2401893 November 2024 Chiesi pMDI inhaler products currently in the marketplace include Trimbow pMDI, Fostair pMDI, Atimos pMDI and Clenil pMDI, these products are promoted at the top of the page in the header. The propellant within these inhalers currently is HFA-134a. Chiesi are promoting their new propellant formulation on the page by calling it a[n] environmentally friendly propellant and stating there is completion of clinical

development by end of 2025. This would require a new marketing authorisation as the new propellant would replace the old propellant in the current inhaler products rendering Chiesi inhalers new formulations when a new propellant is added. The page itself claims that subsequent introduction of the new propellant to UK market will take place following regulatory approval, validating that the page is blatant pre-licence promotion. There are fu[r]ther claims on the page about the new propellant which include 'waiting for introduction of low carbon pMDIs to our inhaler portfolio has potential to reduce carbon emissions'. Such claims are evidence that Chiesi are wanting to promote their new propellant further although the low carbon inhalers as claimed have not had regulatory approval. Further down on the same page there is a concerning claim which reads as 'with the only carbon neutral portfolio of respiratory products available in a range of devices and strengths'. This is a misleading claim as both Atimos and Clenil are only available as pMDI devices and no other devices so it cannot be claimed the Chiesi inhaler portfolio is available in range of devices. Pre-licence promotion and misleading claims directly breach regulatory standards equating to breaches of 3.1, 6.1, 5.1 and clause 2 of the ABPI code 2024."

When writing to Chiesi, the PMCPA asked it to consider the requirements of Clauses 3.1, 6.1, 5.1 and 2 of the 2024 Code.

CHIESI'S RESPONSE

The response from Chiesi is reproduced below:

"We write in response to your letter dated 8th October 2025 relating to a complaint you have received concerning allegations about pre-license promotion in association with misleading claims.

We take alleged breaches of the ABPI Code of Practice (Code) very seriously and welcome the opportunity to respond in an open and transparent manner. We are committed to maintaining the highest standards of clinical accuracy, integrity and compliance across all our activities.

1. The Complaint

The complaint concerns alleged pre-licence promotion and misleading claims on a Chiesi Limited (Chiesi) webpage about environmentally friendly propellants for its pMDI inhalers [URL provided] (UK-RES-2401893) (the Webpage).

The complainant, a contactable healthcare professional, alleges the Webpage promotes a new propellant formulation before regulatory approval, and that the inclusion of product names within the standard prescribing information website header constitutes pre-licence promotion of new formulations of existing Chiesi pMDI inhaler products, being Trimbow, Fostair, Atimos and Clenil.

The complainant also alleges that the statement describing Chiesi as having 'the only carbon neutral portfolio of respiratory products available in a range of devices and strengths,' is misleading since Atimos and Clenil are only available as pMDIs.

The complaint alleges breaches of Clauses 3.1, 6.1, 5.1 and 2 of the 2024 ABPI Code. Chiesi firmly refutes the allegations and denies that any breaches of the Code have occurred. Our detailed response is below.

2. PMCPA request for documentation and signatory details

As requested, we enclose a copy of the approval certificate for the Webpage.

The following signatories were involved with the approval of the Webpage:

[Details of signatories provided]

We also enclose copies of the summaries of product characteristics for each of Atimos, Clenil, Fostair and Trimbow, as further detailed in the appendix.

3. Details of the Webpage and its intended audience

The Webpage forms part of the sustainability section of the ChiesiAir website and is intended for UK healthcare professionals only. It can only be accessed after self-certification of UK healthcare professional status.

4. Response to the Allegations

a. Alleged, '*pre-licence promotion of a new formulation of Chiesi pMDI inhalers.*'

The complainant has alleged that the Webpage content, combined with the reference to the Chiesi products Trimbow, Fostair, Clenil and Atimos across the top of the Webpage, amounts to pre-licence promotion of a new formulation of Chiesi pMDI inhalers.

i. Presence of a standardised header:

At the top of the Webpage is a standardised header providing 'one click away' hyperlinks to prescribing information for Chiesi's inhaler portfolio. This is a fixed, standardised header consistently present across all Chiesi Air website content pages. Its purpose is to provide helpful hyperlinking to the prescribing information for all Chiesi respiratory inhalers should a healthcare professional wish or need to view such whilst browsing website content. This is reflective of industry standard practice.

Save for this standardised header, there is no other mention of a specific Chiesi medicine on the Webpage.

It should also be noted that PI hyperlinks are displayed in nondescript black font on a grey banner background and are adjacent to a 'Contact Us' tab with no logos, imagery or product branding present. This design contrasts clearly with the Webpage body, which uses a white background, coloured and varied font, and supporting imagery. A reasonable visitor would therefore view the header as a separate, functional element rather than as part of the Webpage content. This distinction is critical and any

alternative interpretation would set PMCPA case precedent with consequent implications for:

- the statutory requirement that prescribing information must be readily accessible under The Medicines (Advertising) Regulations 1994 (SI 1994/1932);
- the requirements [of] Clause 12 of the Code that such information must be positioned for ease of reference and be by way of a clear and prominent, direct, single click link; and
- the ability of HCPs to efficiently navigate a site to locate the relevant information as effectively as possible during clinical decision making.

On that basis, we strongly dispute that the presence of this fixed header could reasonably be interpreted as promotion of every product listed within it, whether on this Webpage or elsewhere on the Chiesi Air site. Excluding the header would, in fact, compromise both legal accessibility of prescribing information and the user experience for HCPs, undermining Chiesi's compliance with statutory and Code requirements. The header is therefore a necessary, compliance-driven, functional website element, not promotional material.

ii. No direct or indirect reference to any Chiesi product or therapeutic indication

Aside from the functional header, the Webpage contains no direct or indirect reference to any Chiesi medicine, brand, or therapeutic indication and there is no language used within the Webpage which could be attributed to or be construed as relating to therapeutic indications or clinical claims. Nothing in the content would enable a reasonable healthcare professional to identify or infer that a specific Chiesi product is being described or promoted. The material is limited to high-level environmental messaging and corporate sustainability commitments, none of which relate to a particular medicinal product.

Accordingly, no element of the Webpage constitutes promotion within the meaning of the Code, and there is no breach of Clause 3.1.

iii. Distinction between medicines and propellants

It is important to distinguish clearly between a medicinal product and its excipients. An inhaler propellant is listed as an excipient within the Summary of Product Characteristics (SmPC) and does not constitute a medicine in its own right. While the future introduction of a low-carbon propellant would require the appropriate regulatory approval as an excipient variation, this does not convert the propellant into a medicinal product. Clause 3.1 governs the promotion of a medicine prior to the grant of the relevant marketing authorisation; it does not extend to the discussion of excipients that may form part of a future regulatory submission.

The Webpage contains only high-level environmental information regarding propellants in development and makes no reference to any one product, formulation, therapeutic indication, or clinical attribute. As the introduction of a new propellant will not alter the licensed indication or posology of any inhaler, the content does not enable a

reasonable healthcare professional to identify any specific future medicinal product or variation.

Accordingly, this non-product-specific discussion of excipient characteristics falls outside the scope of pre-licence promotion under Clause 3.1.

iv. Environmental and sustainability messaging

Chiesi asserts that use of the words '*environmentally friendly*' to describe the new propellant, and '*potential to reduce emissions*' in relation to a future inhaler portfolio containing low carbon pMDIs, does not constitute pre-licence promotion. The Webpage contains no reference so a specific medicine, efficacy or therapeutic indication that could link these statements to an identifiable product.

Rather, this language forms part of Chiesi's corporate sustainability communications. It reflects Chiesi's commitment to support the NHS in achieving its carbon reduction goals, as well as Chiesi's contribution to the wider global net-zero commitment. This is particularly relevant to communicate to the NHS given its target of reaching net zero by 2040 for direct emissions and 2045 for emissions the NHS can influence (see *Delivering a net zero NHS* from NHS England [copy provided]). Such stakeholders expect transparent communications from suppliers regarding their environmental impact.

The material therefore remains non-product-specific, does not include any claims relating to clinical performance, efficacy or therapeutic indication and falls within legitimate corporate reporting. As such, it does not amount to promotion of a medicinal product for the purposes of the Code, including Clause 3.1.

v. Non-identifiability of any specific future propellant or product

Inhalers account for approximately 3% of NHS carbon emissions (see *NHS England: Improving health outcomes for respiratory patients while reducing carbon emissions* [copy provided]). The transition of current pMDIs from high to low GWP propellants is excepted to reduce their carbon footprints by >90% (see *Jeswani HF and Azapagic A*., *Life Cycle Environmental Impact of Inhalers* [copy provided], and *Hargreaves C et al, A new medical propellant HFO-1234ze(E): reducing the environmental impact of inhaled medicines* [copy provided]). Two environmentally friendly propellants are currently in development by the pharmaceutical industry, being HFO1234ze and HFA-152a. While the complainant correctly states that propellant within Chiesi's current pMDI portfolio is HFA-152a, the Webpage makes no reference to any specific propellant and therefore a visitor would be unable to determine which propellant Chiesi may choose to progress.

For content to constitute pre-licence promotion under Clause 3.1, it must enable the reader to identify, directly or indirectly, a specific medicine. As there is more than one environmentally friendly propellant in development across the industry, and the Webpage makes no specific mention of HFA-152a or any Chiesi product or any therapeutic indication, then no such identification is possible.

Accordingly, Chiesi strongly asserts there has been no pre-license promotion of any specific medicine and therefore no breach of Clause 3.1.

b. Alleged misleading claims regarding carbon neutral portfolio of respiratory products

It is alleged that the statement '…*With the only carbon neutral portfolio of respiratory products available in a range of devices and strengths…'* is a misleading claim on the basis that Atimos and Clenil are only available as pMDIs. Chiesi does not accept this interpretation.

Chiesi's portfolio of carbon neutral respiratory products comprises Clenil 50, 100, 200 and 250mcg pMDIs, Atimos 12mcg pMDI, Fostair 100/6 and 200/6 pMDIs and Trimbow 87/5/9 and 172/5/9mcg pMDIs, as well as Fostair NEXThaler 100/6 and 200/6mcg (DPI) and Trimbow NEXThaler 88/5/9mcg (DPI). This represents a broad portfolio of inhaler therapies across multiple molecules, strengths and two device types (pMDI and DPI).

Chiesi's entire range of inhalers was certified as carbon neutral in 2023 in accordance with the requirements of PAS 2060, an internationally recognised and externally assessed and validated standard for carbon neutrality (see Chiesi press release: *Chiesi announces carbon neutral respiratory portfolio* [copy provided]). PAS 2060 certification is achieved through a documented, audited and verified carbon-management plan covering defined reduction measures and the purchase and retirement of verified carbon removal credits. Since certification, Chiesi has continued to apply the reduction measures and carbon-credit approach established through that plan. The claim that the portfolio is carbon neutral is therefore fully substantiated.

The claim refers to the characteristics of the portfolio taken collectively, which includes products across different device types and strengths. The statement does not assert, nor imply, that each individual product is available in more than one device type. In the context of the Webpage, the wording is clearly framed at portfolio level, reflecting the availability of both pMDI and DPI devices within the overall range rather than suggesting device interchangeability for each product.

Given that:

- Chiesi's portfolio of inhalers was certified as carbon neutral under PAS 2060 in 2023;
- the portfolio contains both pMDIs and DPIs in more than one strength; and
- the claim refers to the characteristics of the portfolio collectively, not each individual product,

Chiesi does not believe that this claim is misleading. On the contrary, it is factually accurate, substantiated and does not mislead a reasonable healthcare professional. Chiesi therefore maintains that there is no breach of Clause 6.1.

5. Conclusion

For the reasons set out above, Chiesi maintains that the Webpage complies fully with the Code. In particular:

- **Clause 3.1**
  There is no direct or indirect reference to any Chiesi medicine or therapeutic indication; the propellant discussion is non-product specific and does not identify any medicinal product, and the standard PI header is a functional, compliance-driven website element included to meet statutory and Code obligations, not promotional content;
- **Clause 6.1**
  The carbon-neutral portfolio claim is accurate and substantiated by PAS 2060 certification, clearly refers to the portfolio as a whole and would not mislead the reasonable healthcare professional;
- **Clause 5.1**
  Chiesi has acted responsibly, ensured factual accuracy and substantiation and maintained high standards throughout;
- **Clause 2**
  The material consists solely of sustainability information, an accurate description of Chiesi's carbon-neutral respiratory portfolio, together with the standardised PI header. There are no product references, no promotional intent, and no patient safety implications. Nothing in the content could reasonably be considered to bring discredit upon or reduce confidence in the pharmaceutical industry. Clause 2 is reserved for only the most serious breaches, and the Webpage falls well below that threshold.

Accordingly, Chiesi firmly asserts there has been no breach of clauses 3.1, 6.1, 5.1 or 2 and respectfully invites the Panel to rule the same.

We trust that the evidence and rationale provided in this response address all points raised. Should the PMCPA require any further clarification or supporting documentation, we would be pleased to provide it."

PANEL RULING

This case was in relation to a webpage on Chiesi's promotional website for health professionals, Chiesi Air. The complainant alleged that this webpage promoted Chiesi's new propellant formulation for its respiratory portfolio, which amounted to pre-licence promotion. The complainant further alleged the webpage included a claim which misleadingly implied the Chiesi inhaler portfolio was available in a range of devices, when Atimos (formoterol fumarate dihydrate) and Clenil (beclomethasone dipropionate) were only available as pMDI (pressurised metered-dose inhaler) devices.

The webpage was titled "Environmentally-friendly propellants" and was housed within the 'Sustainability' section of the Chiesi Air website. The website header, appearing at the very top of the webpage, included links to the prescribing information for Trimbow, Atimos, Clenil and Fostair on a grey background. It appeared to the Panel that this header was a static component appearing across the whole of the Chiesi Air website. At the top of the webpage itself was a 'hero section' with the company logo, navigation menu, the page title ("Environmentally-friendly propellants"), an image and a button to "Learn more". The rest of the webpage consisted of three sections: "Supporting the planet, patients and the NHS", "Patient Control" and "Providing choice and flexibility in respiratory care". A banner with a link to more information about Chiesi's respiratory portfolio appeared at the bottom of the webpage.

Alleged pre-licence promotion (Clause 3.1)

The complainant alleged that Chiesi was promoting its new propellant formulation on the webpage and, as this formulation would require a new marketing authorisation, the webpage amounted to pre-licence promotion.

The complainant pointed to several statements that appeared on the webpage that they considered promotional:

- *"Environmentally-friendly propellants"*
- *"We are on track to complete the clinical development of our environmentally-friendly propellant by the end of 2025"*
- *"Waiting for the introduction of low carbon pMDIs to our inhaler portfolio has the potential to reduce carbon emissions…"*

Clause 3.1 of the Code stated that a medicine must not be promoted prior to the grant of the marketing authorisation which permits its sale or supply.

Chiesi submitted that, apart from the functional header containing links to prescribing information, the webpage contained no direct or indirect reference to any Chiesi medicine, brand or therapeutic indication. It further submitted that an inhaler propellant is an excipient, and that a future introduction of a low-carbon propellant would require the appropriate regulatory approval as an excipient variation, but that Clause 3.1 governs the promotion of a medicine prior to the grant of a relevant marketing authorisation and does not extend to excipients.

Chiesi further submitted that the webpage contained only high-level environmental information regarding propellants in development and contained no reference that could link these statements to an identifiable product.

The Panel observed that the links to prescribing information in the website header were in significantly smaller font than the body of the webpage. There was also a colour difference, with the website header appearing on a darker grey background compared to the white background of the rest of the webpage. In the Panel's view, the website header appeared visually separate to the main body of the webpage, appearing above elements such as the company logo and the navigation menu. The Panel considered the prescribing information links in the website header were sufficiently distinct from the content about new propellants on the webpage itself.

The Panel had some concerns about the appropriateness of language used in relation to products that were not yet available (e.g. "*Our environmentally-friendly propellant has the potential to reduce the carbon footprint of pMDIs by up to 90%...*").

The Panel noted, however, the complainant's narrow allegation that, as a new propellant formulation would require a new marketing authorisation, the webpage amounted to pre-licence promotion.

The Panel noted that Chiesi intended to seek regulatory approval of the new propellant via excipient variations to the existing marketing authorisations. In the Panel's view, a health professional would likely associate the statements about the new propellant with Chiesi's existing pMDIs, which had all been granted marketing authorisations, rather than with any new medicine that might be in development.

Based on the narrow allegation, the Panel considered that the webpage did not constitute promotion of a medicine prior to the grant of its marketing authorisation and ruled **no breach of Clause 3.1**.

Alleged misleading claim (Clause 6.1)

The complainant alleged that the claim "*With the only carbon neutral portfolio of respiratory products available in a range of device and strengths…*" was misleading as Atimos and Clenil were only available as pMDI devices.

Clause 6.1 of the Code stated, amongst other things, that information, claims and comparisons must not mislead directly or by implication.

Chiesi submitted that its entire range of inhalers was certified as carbon neutral in 2023 and the claim referred to the characteristics of the portfolio taken collectively, which included products across different device types and strengths.

The Panel noted the narrow allegation raised by the complainant, that the claim was misleading as Atimos and Clenil were only available as pMDI devices. The Panel considered that it was clear that the claim referred to the respiratory portfolio as a whole and that it did not misleadingly imply that every medicine in the portfolio was available in different device types and strengths. The Panel ruled **no breach of Clause 6.1**.

Overall

The complainant cited a breach of Clauses 5.1 and 2 in regard to these allegations. The Panel noted its rulings of no breach above and, in the absence of any other allegations, the Panel concluded it had not been established that there had been a failure to maintain high standards nor that discredit had been brought upon the industry. The Panel therefore ruled **no breach of Clauses 5.1 and 2**.

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During the consideration of this case, the Panel queried whether the webpage was consistent with the particulars listed in the SPCs for Chiesi's respiratory range. The Panel asked that Chiesi be made aware of its concerns.

Complaint received **7 October 2025**

Case completed **17 June 2026**