CASE/0801/11/25 ***NO BREACH OF THE CODE***

COMPLAINANT v CHIESI

Allegations regarding misleading claims on a website

CASE SUMMARY

This case was in relation to two claims on a Chiesi website which were alleged to be misleading and to have promoted its medicine, Clenil (beclometasone dipropionate), outside the terms of its marketing authorisation.

The outcome under the 2024 Code was:

No Breach of Clause 2 (x2)	**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 information/ claims/ comparisons must not be misleading**
No Breach of Clause 11.2	**Requirement not to promote a medicine for an unlicensed indication**

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 was received about two claims on a Chiesi website from a contactable complainant who described themselves as a health professional.

COMPLAINT

The complaint wording is reproduced below with some typographical errors corrected:

> "There are uncompliant claims on a promotional website promoting the Chiesi Inhalers portfolio. The evidence for this is [URL provided]. There is a section titled equipping and empowering patients underneath which there are misleading claims. There is a claim that is provided as - We know what our Chiesi Air Medicines can mean to people affected by asthma and COPD. The page has Atimos, Fostair, Trimbow and Clenil at the origin of the page. Clenil is not licensed for COPD so to claim the Chiesi Air medicines can mean to people with asthma and COPD is misleading and is off-label promotion for Clenil considering the products license is limited for Asthma management. The licenced indications for the products are not written out on the page to qualify the claim compounding the misleading claims in respect of immediate impressions to the reader. This is a breach of clause 11.2 & 6.1 & 5.1 & 2. A further claim states Our research and

resulting portfolio have been carefully designed to meet patient needs, including offering device flexibility and extrafine formulations in our latest products (references 6–15). References 6-15 include Clenil which is not available as an extrafine formulation or available as a dry powder inhaler yet the claim incorrectly specifies device flexibility and extrafine formulations and the claim references Clenil directly (reference 6-9). There are breaches of clause 6.1 & 5.1 & 2. It is concerning that the review of such promotional material had not been carried out with complete diligence by the medical review team considering the nature of the misleading claims and off-label promotion."

When writing to Chiesi, the PMCPA asked it to consider the requirements of Clauses 2, 5.1, 6.1, 11.2 of the 2024 Code.

CHIESI'S RESPONSE

The response from Chiesi is reproduced below:

"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 misleading claims on a Chiesi Limited (Chiesi) webpage introducing Chiesi Air (the Webpage).

The complainant, a contactable healthcare professional, alleges that a section of the website titled *'Equipping and empowering patients'* contains two misleading claims, specifically:

a) ***'We know what our Chiesi Air Medicines can mean to people affected by asthma and COPD'.***

The complainant states that the Webpage lists Atimos, Fostair, Trimbow and Clenil at the top of the page. As Clenil is not licensed for the treatment of COPD, the complainant considers that presenting these medicines on the same page as the statement above could be interpreted as suggesting they are all indicated for both Asthma and COPD, which is therefore misleading and off-label promotion of Clenil. The complainant alleges that the licensed indications for the products are not presented on the page, which, according to the complainant, compounds the misleading claim in respect of immediate impressions given to the reader. The complainant alleges breaches of Clauses 11.2, 6.1, 5.1 & 2 of the Code.

b) ***'Our [Chiesi] research and resulting portfolio have been carefully designed to meet patient needs, including offering device flexibility and extrafine formulations in our latest products (references 6-15)***

The complainant alleges that references 6-15 include references to Clenil Summary of Product Characteristics (SPC), and as Clenil is not available as an extrafine formulation

or available as a dry powder inhaler, the claim is misleading. The claimant alleges breaches of clause 6.1, 5.1 & 2 of the 2024 ABPI Code.

Chiesi firmly refutes all the allegations relating to both claims 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: [signatory names and qualifications listed].

We also enclose copies of the SPC 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 *'Our product portfolio for respiratory'* 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 misleading claim *'We know what our Chiesi Air Medicines can mean to people affected by asthma and COPD' (Claim 1)*.

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 (the PI Banner). This is a fixed, standardised header consistently present across all Chiesi Air website content pages. The PI Banner's 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.

It should also be noted that PI hyperlinks within the PI Banner are displayed in nondescript black font on a grey 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 visitor would therefore most likely view the PI Banner 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 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 PI Banner could reasonably be interpreted as promotion of every product listed within it, whether on this Webpage or elsewhere on the Chiesi Air site. Excluding PI Banner 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 PI Banner is therefore a necessary, compliance-driven, functional website element, and not intended as promotional material for the Webpage in question or otherwise.

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

It is Chiesi's position that Claim 1 relates to the Chiesi Air medicines as a whole and is not applicable to all the individual medicines within the Chiesi portfolio or any specific one of them. Aside from the PI Banner, and reference to the SPCs in the footnotes, the Webpage content contains no direct or indirect reference to any individual Chiesi medicine or brand.

Furthermore, the positioning of the PI Banner is clearly separate from the wording of Claim 1 and is not sufficiently proximate to the reference to *'asthma and COPD*' within Claim 1 to create any link between those therapeutic indications and the products listed within the PI Banner. The design and placement make it evident that the PI Banner serves as a compliance function, not a promotional one.

On the basis of the points set out in paragraphs i. and ii. above, Chiesi firmly believes that nothing in the Webpage content would lead a healthcare professional to conclude or infer that any specific Chiesi product is being described or promoted by virtue of the present of the PI Banner and / or Claim 1. Such an interpretation is highly unlikely given the layout and wording of the Webpage content and the clear purpose of the PI Banner.

Accordingly, Chiesi maintains there is no breach of Clauses 11.2 or 6.1. Consequently, there are no additional breaches of Clause 5.1 or Clause 2. Chiesi stands by its position that the Webpage is fully compliant with the Code and applicable legal requirements.

b) Alleged misleading claim 'Our research and resulting portfolio have been carefully designed to meet patient needs, including device flexibility and extrafine formulations in our latest products (references 6-15)' (Claim 2).

The complainant alleges that including the references 6-15 at the end of Claim 2 is misleading because references 6-9 relate to Clenil SPCs and Clenil is not available as an extrafine formulation or as a dry powder inhaler.

i. Claim 2 relates to the Chiesi inhaler portfolio as a whole

The definition of portfolio is '*a range of products [or services] offered by an organisation*'. In this instance Claim 2 clearly relates to Chiesi's respiratory portfolio as whole and not the individual products within it.

The first limb of the statement ***'Our research and resulting portfolio have been carefully designed to meet patient needs'*** refers to the characteristics of the portfolio taken collectively, which includes products across different device types, strengths and formulations. The statement does not assert, nor imply, that each individual product is available in more than one device type and formulation. The wording is clearly framed at portfolio level, highlighting the availability of both pMDI and DPI devices within the portfolio, rather than suggesting device interchangeability for each individual product. On that basis, the first limb of Claim 2 is not misleading.

ii. Claim 2 is factually correct

The second limb of Claim 2, ***'including offering device flexibility and extrafine formulations in our latest products',*** refers specifically to Chiesi products Fostair and Trimbow – the most recent (i.e. latest) additions to Chiesi's respiratory portfolio. Both products are available in pMDI and DPI formats and are characterised by extrafine formulations. On that basis, the second limb of Claim 2 is factually correct and therefore not misleading in any way.

iii. Referencing is a compliance requirement of the Code, not promotional

The Code requires all claims to be referenced. In line with this requirement, the SPCs for all products constituting the Chiesi inhaler portfolio are listed at the bottom of the page. There is **no obligation** under the Code for the full content of every reference cited to align with every element of the claim, provided their only mention is a number to depict the reference the claim can be referred to. Furthermore, the use of a reference does not equate to the entire content of that reference being used in a promotional context.

This distinction is critical because clinical studies and publications often include data which is broader than the licensed population. To say that practice was a breach of the Code would then prohibit such data's use to support claims for which elements of the data is on license.

Referencing such material in this manner does not equate to endorsing or promoting off-label elements; rather, it reflects standard practice to ensure transparency and is in line with the spirit and the letter of the Code.

The Webpage utilises the Vancouver referencing style, widely recognised in medical and scientific writing. In-text citations are numerical and correspond to a reference list. As the sentence did not include any direct quotes or author names, it was appropriate to place the references at the end of the sentence, in line with standard Vancouver practice. It is also standard to include all the refences relevant for the entire sentence, which in this case means SPCs for the entire Chiesi respiratory portfolio. This approach is both appropriate and compliant.

iv. Additional context for HCPs

Should a healthcare professional visiting the Webpage wish to view further information regarding the prescribing of products within the Chiesi respiratory portfolio, they are able to (and it is reasonable to infer they are likely to) click on the hyperlink [URL provided] embedded within the 'Equipping and empowering patients' section of the Webpage. This would navigate the healthcare professional to a further webpage entitled '*Introducing Chiesi Air medicines*'. This section specifically relates to the different products within the Chiesi respiratory portfolio as a whole. It contains images of the four products, clearly indicating the device type in which each medicine is available, and the information for each product comprehensively states each product license(s). This resource displays each product with its device type and licensed indications, ensuring transparency and ease of access.

For the reasons stated in paragraph 4b)i) to 4b)0) above, Chiesi firmly believes that Claim 2 is not in any way misleading. On the contrary, it is factually accurate, substantiated and presented in a manner consistent with the Code and accepted scientific referencing standards. The refences cited in the allegation are relevant to the portfolio as a whole and do not imply off-label promotion. Should an HCP wish to gain more information regarding prescribing of specific medicines within the Chiesi Respiratory portfolio the embedded hyperlink would take them to an appropriately comprehensive resource. Accordingly, the claim is not misleading and does not constitute a breach of Clause 6.1. Consequently, Chiesi asserts there are no additional breaches of Clause 5.1 or Clause 2.

5. Conclusion

For the reasons set out above, Chiesi maintains that the claims highlighted in the complaint fully comply with the Code. Specifically:

- **Clause 11.2**
  No product is promoted outside of its license indications.
- **Clause 6.1**
  All statements are accurate, substantiated and presented in a manner that does not mislead. The content reflects portfolio-level characteristics and factual product attributes.

- **Clause 5.1**
  Chiesi has acted responsibly, ensured factual accuracy and maintained high standards throughout.

- **Clause 2**
  The material consists of references to the Chiesi portfolio as a whole and a standardised PI Banner designed for compliance. There are no inaccuracies, all relevant reference material is included and there are 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 11.2, 6.1, 5.1, or 2 and respectfully invites the Panel to rule accordingly."

PANEL RULING

This complaint related to two claims on a Chiesi website which were alleged to be misleading and to have promoted its medicine, Clenil (beclometasone dipropionate), outside the terms of its marketing authorisation.

The webpage at issue was titled “Introducing Chiesi Air” and included two key sections “What do we do” and “How do we do it”. The claims referred to by the complainant appeared within the latter section, beneath the heading “Equipping and empowering patients”. The section included the text:

> *“We know what our Chiesi Air medicines can mean to people affected by asthma and COPD.*
>
> *Clear product information and condition management guidance can transform outcomes – these are areas we continue to learn about and invest in.[4,5] Our research and resulting portfolio have been carefully designed to meet patient needs, including offering device flexibility and extrafine formulations in our latest products.[6-15]*
>
> *We know that our medicines alone are not enough. People also need guidance and the right tools to get optimal results from their treatment.[16,17]*
>
> *At every step, we try to ask ourselves what services and guidance can empower people to feel in control of their condition; to live life the way they want, with the support they need.”*

The Panel noted the header contained the statement *“for UK healthcare professionals only. Contains promotional material”* and included a hyperlink to adverse event reporting information along with hyperlinks to the prescribing information for Chiesi’s inhaler portfolio: Trimbow (beclometasone/formoterol/glycopyrronium), Fostair (beclometasone/formoterol), Clenil (beclomethasone) and Atimos (formoterol). Chiesi submitted that the header was fixed and standardised throughout the Chiesi Air website.

Claim 1

The first claim, “We know what our Chiesi Air Medicines can mean to people affected by asthma and COPD”, was alleged to be misleading and promote Clenil outside the terms of its marketing authorisation. The Panel understood the complaint to be that the inclusion of Clenil within the webpage header, together with the absence of any qualification regarding licensed indications, meant that the claim created the misleading impression that Clenil was licensed for both asthma and COPD, when Clenil was only licensed in the management of asthma.
Chiesi submitted that the claim related to Chiesi Air medicines as a whole and that aside from the header and reference to SPCs in the footnotes, the webpage contained no reference to any individual Chiesi medicine.

The Panel considered that the claim referred to “Chiesi Air medicines” collectively for people “affected by asthma and COPD”. The Panel further considered the context in which the claim appeared, on a webpage titled “Introducing Chiesi Air” and within a section discussing Chiesi’s respiratory portfolio and patient management more broadly.

The Panel did not consider it had been established that the claim stated or implied that each medicine within the Chiesi Air portfolio, as listed in the header, was licensed for both asthma and COPD. In the Panel's view, the claim conveyed that Chiesi Air medicines were used collectively across the management of patients affected by asthma and/or COPD, rather than that every medicine within the portfolio was licensed for both conditions.

Accordingly, the Panel did not consider that the claim misleadingly implied that Clenil was licensed for COPD, which fell outside the terms of its marketing authorisation. The Panel further considered that it had therefore not been established that the claim required qualification by the inclusion of the licensed indications of each individual medicine. The Panel ruled **no breach of Clause 6.1 and 11.2**.

Claim 2

The second claim at issue was "Our research and resulting portfolio have been carefully designed to meet patient needs, including device flexibility and extrafine formulations in our latest products[6-15]".

The complainant highlighted that references 6–9 related to Clenil, which was not available as an extrafine formulation or as a dry powder inhaler. The Panel understood the complaint to be that the claim therefore misleadingly implied that the features referred to in the claim, namely device flexibility and extrafine formulations, applied to Clenil.

The Panel noted Chiesi's submission that the first part of the claim referred to its respiratory portfolio collectively and that the claim did not imply that every product within the portfolio possessed each of the characteristics referred to in the claim. Chiesi further submitted that the phrase, "our latest products" referred specifically to Fostair and Trimbow, which were the latest additions to its portfolio, available in both pressured metered-dose inhalers and dry powder inhaler formats.

The Panel took into account that the cited references appeared at the bottom of the page and that references 6-9 related to the SPC for four strengths of Clenil.

The Panel considered the immediate and overall impression created by the full claim. It accepted Chiesi's submission that the start of the claim referred to its portfolio collectively. It further noted that reference to "device flexibility and extrafine formulations" appeared to have been qualified by the phrase "in our latest products", albeit with no particular medicines mentioned. The Panel further considered the context in which the claim appeared, on a webpage titled "Introducing Chiesi Air" and within a section discussing Chiesi's respiratory portfolio and patient management more broadly.

In the circumstances of this case, the Panel did not consider it had been established that the citation of references relating to Clenil for the broad claim, which appeared at the bottom of the webpage, implied that the features referred to in the claim applied to Clenil. The Panel therefore concluded that it had not been established that the claim was misleading in this regard and ruled **no breach of Clause 6.1.**

High standards and disrepute

The complainant cited a breach of Clauses 5.1 and 2 in relation to each claim with regard to their allegations of misleading and off-label promotion. The Panel noted its rulings of no breach above and, in the absence of any other allegations, evidence or factors in relation to allegation 2, 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 in this regard. The Panel therefore ruled **no breaches of Clause 5.1 and Clause 2** in relation to each claim**.**

Complaint received **11 November 2025**

Case completed **08 July 2026**