CASE/0678/07/25

COMPLAINANT v CHIESI

Allegations about the balance of clinical trial data presented regarding Fostair

CASE SUMMARY

This case was in relation to a Fostair (beclometasone dipropionate/ formoterol fumarate dihydrate) for COPD webpage on a website for health professionals. The complaint alleged that outcome information from a COPD clinical trial comparing Fostair pMDI 100/6 with formoterol was not presented in a balanced way as it failed to include side effect data for Fostair.

The outcome under the 2024 Code was:

Breach of Clause 6.1	**Failing to provide balanced information that is sufficiently complete to enable recipients to form their own opinion of the therapeutic value of the medicine**
Breach of Clause 5.1	**Failing to maintain high standards**

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 Chiesi from an anonymous, contactable complainant who described themselves as a health professional.

COMPLAINT

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

> "Outcomes from a COPD clinical trial over 48 weeks comparing Fostair pMDI 100/6 to formoterol were provided in the evidence section referenced to a Wedzicha et al publication. In this clinical trial there had been several side effects reported. This included 106 serious adverse events, 42 adverse drug reactions and 75 severe adverse events all in the Fostair arm. Endpoint data for Fostair respiratory outcomes were given for the trial but no Fostair side effects data were given so the information is not balanced as total data including side effect data is needed to assess the balanced use of Fostair. ABPI code breaches of 6.1, 5.1 and 2. [link provided]"

When writing to Chiesi, the PMCPA asked it to consider the requirements of Clauses 5.1 and 6.1 of the 2024 Code. The case preparation manager determined that Clause 2 was not warranted in this case therefore Chiesi was not required to respond to this clause. The complainant consented to this approach. The case preparation manager initially asked Chiesi to respond to the complaint under the abridged complaints' procedure, however upon receipt of the company's response, determined that the complaint should be progressed through the full complaints' procedure.

CHIESI'S RESPONSE

The response from Chiesi is reproduced below with some typographical errors corrected:

> "Thank you for your letters dated 4 August 2025 and 18 September 2025 regarding the above case, and for your subsequent correspondence on 23 September 2025 clarifying the PMCPA's decision to progress this matter through the full complaints procedure. We also appreciate the PMCPA's decision, communicated on 4 August 2025, not to pursue a Clause 2 allegation in this case.
>
> As set out in our communication of 26 August 2025, Chiesi Limited (Chiesi) accepts that, in this instance, the material at issue did not meet the standards required by the ABPI Code. We therefore admit a breach of Clauses 6.1 and 5.1.
>
> We understand that the decision to progress the complaint through the full complaints procedure reflects the Panel's view that the assessment of balance in the presentation of clinical trial data is inherently subjective and merits detailed consideration. Notwithstanding our admission of breach, and our confirmation on 26 August 2025 that our internal investigation did not identify any systemic compliance issues, Chiesi remains fully committed to cooperating with the PMCPA and to providing all information required under the full procedure. Our full response, therefore, is set out below.
>
> **1. The Complaint**
>
> The complaint relates to the presentation of clinical trial data for Fostair pMDI 100/6 on our UK healthcare professional website [link provided], being Chiesi's UK "Fostair for COPD" page (the Webpage).
>
> Specifically, the allegation concerns the omission of adverse event and side effect data presented in the Wedzicha *et al.* study (the Wedzicha Study) from the Webpage, which the complainant alleges resulted in an imbalance in the information provided on the Webpage regarding the use of Fostair in the treatment of COPD.
>
> **2. PMCPA's request for information/documentation**
>
> **(i) Documents**
>
> As requested, we enclose:
>
> - A copy of the Webpage, together with the associated approval certificate
> - the Wedzicha Study

- Summary of Product Characteristics for Fostair pMDI 100/6

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

[table including the name, job title, qualifications and registration number of a nominated medical signatory who was no longer working for Chiesi at the time of the complaint, and a second named nominated signatory, with their job title and qualifications]

The Webpage was within its two-year approval cycle, having been approved on 25 June 2024, with an expiry date of 25 June 2026.

(ii) How the material was used

The content on the Webpage is expressly targeted to UK healthcare professionals, not the general public, with visitor access gated by an HCP confirmation. The Webpage is intended to provide clinical, prescribing-level information about the product, its mechanism, device options and indication, and includes links to prescribing information and adverse event reporting. The purpose is to support informed medical decision-making and product awareness among clinicians, while ensuring regulatory compliance through disclaimers, version control, and oversight under the company's certification and medical-review processes.

3. Admission of Breach

Chiesi takes alleged breaches of the ABPI Code of Practice (Code) very seriously and is committed to maintaining the highest standards of accuracy, integrity, and compliance across all activities. Following our internal review, we acknowledge that the Webpage did not include the relevant safety data detailed alongside the efficacy outcomes detailed in the Wedzicha Study, and therefore did not fully meet the requirements of Clauses 6.1 and 5.1 of the 2024 Code.

As you are aware, Clause 6.1 of the 2024 ABPI Code states that:

"Information, claims and comparisons must be accurate, balanced, fair, objective and unambiguous and must be based on an up-to-date evaluation of all the evidence and reflect that evidence clearly. They must not mislead either directly or by implication, by distortion, exaggeration or undue emphasis. Material must be sufficiently complete to enable recipients to form their own opinion of the therapeutic value of the medicine."

Chiesi recognises that the provision of balanced and comprehensive clinical data is essential to supporting informed decision-making by healthcare professionals and safeguarding patient safety. In this instance, the omission of adverse event and side-effect data meant the material was not sufficiently complete to allow healthcare professionals to form their own opinion of the medicine's therapeutic value, as required by the Code.

This incident has reinforced the importance of presenting both efficacy and safety information transparently and consistently across our materials. On that basis, Chiesi voluntarily admits a breach of Clauses 6.1 and 5.1 of the 2024 Code.

4. Internal Investigation and Remedial Actions

As part of our internal investigation, the follow remedial actions have been initiated:

- The content at issue was removed from our website by 6 August 2025, within 48 hours of receiving the complaint

- We have engaged the services of a third-party signatory consultant to undertake a comprehensive audit of all Chiesi Air website content to ensure compliance with the Code

- The Air Marketing Team has recently appointed two dedicated content managers for Asthma and COPD-related content on the Chiesi Air website, with accountability for continuous content review being at the core of their responsibilities. One individual started in July 2025, and the other started in September 2025

- Our Medical and Compliance teams are jointly preparing a “retrospectives” training session for all medical and business signatories across the UK business, using this case as a critical learning point to reinforce the importance of balanced presentation of clinical data.

These remedial actions will further bolster our existing compliance framework. Chiesi strives to uphold the principles and practice of compliant activity and has long invested in, and maintains, a robust, systematic compliance infrastructure, including:

- companywide SOPs governing the development, certification and ongoing monitoring of materials
- a comprehensive mandatory training programme for all relevant staff, including modules on:
    - ABPI Code compliance
    - SOP application and governance workflows
    - material content generation, approval and maintenance
- continuous monitoring of PMCPA Code cases, subscriptions to publications that discuss recent cases, and regular meetings with both internal and external experts to discuss the Code, its interpretation and rulings
- monthly online Code case reviews, delivered to the entirety of the Chiesi head office function in the UK by an external training provider, and quarterly in-person Legal & Compliance training sessions with all head office staff covering recent Code developments, guidance and case rulings
- a structured review cycle for all assets and materials, including maintaining live trackers of content which are under constant review and update, with teams working cross functionally to consider content and update requirements
- the issue to all content owners of frequent reminders at timed intervals regarding upcoming content expiry dates along with a requirement to review content and submit it for re-approval or withdrawal it before its expiry.

The above activities are then monitored and controlled by the Legal & Compliance Department.

The existence and operation of these controls demonstrate that the breach of Clauses 6.1 and 5.1 occurred despite Chiesi's established systems, not because of their absence or failure. The remedial measures outlined above are intended not only to address the specific issue identified in this case, but also to further strengthen our governance framework. By enhancing oversight, reinforcing accountability, and embedding continuous review into our processes, we are confident that these steps will minimise the risk of recurrence and ensure that all future materials consistently meet the highest standards of accuracy, balance, and integrity.

5. Conclusion and Assurance

In conclusion, we:

- admit a breach of Clauses 6.1 and 5.1
- have taken prompt remedial action, including removal of the Webpage, appointment of dedicated content managers, a full content audit, and enhanced training for signatories
- confirm that no systemic compliance issue has been identified and that Chiesi maintains a robust compliance framework."

PANEL RULING

The complaint related to a Fostair (beclometasone dipropionate/ formoterol fumarate dihydrate) for COPD webpage on a website for health professionals and alleged that outcome information from a COPD clinical trial comparing Fostair pMDI 100/6 with formoterol, was not presented in a balanced way as it failed to include side effect data for Fostair.

The Panel noted that the webpage at issue included information on Fostair inhalers for COPD. The first part of the webpage included three boxes with the following:

1. the indication for Fostair and a link to 'find out more'
2. useful links for the Summary of Product Characteristics (SPC) and patient information leaflet
3. downloadable patient resources such as Fostair Patient User Guides and a COPD Action Plan.

The Panel did not have the content of the links to "learn more" about Fostair in COPD or the Fostair Patient User Guides and COPD Action Plan before it.

The first part of the webpage described above was followed by several sections: "Fostair for COPD: Overview", "Evidence", "Molecules and devices", "How to prescribe", "Patient support" and "Cost".

The complainant referred to the Evidence section.

The Panel noted this section included the prominent claim, "The extrafine particles of Fostair are designed to reach the large and small airways" followed by two boxes which contained trial information for Fostair pMDI 100/6 (the first box) and Fostair NEXThaler 100/6 (the second box).

The allegation was specifically in relation to the first box, which was referenced to Wedzicha *et al* and the Fostair pMDI 100/6 SPC.

The information in the first box stated:

> "Fostair pMDI 100/6. Over a 48-week period in patients with severe COPD aged 55-73 years (N=1,199), Fostair pMDI 100/6 demonstrated:
>
> Significant improvement in lung function (change in pre dose morning FEV_1) vs formoterol* after 12 weeks of treatment (co-primary endpoint). Adjusted mean difference: 69 mL ($p<0.01$).
>
> Significant reduction in the mean number of exacerbations per patient/year vs formoterol* (co-primary endpoint). Adjusted mean rate: Fostair 0.80 vs formoterol* 1.12 (adjusted ratio 0.7, $p<0.001$).
>
> Significantly prolonged the time to first exacerbation vs formoterol (secondary endpoint; HR** 0.8; P=0.010).
>
> *Formoterol 12 mcg pDMI (1 inhalation b.d.)
>
> **Hazard ratio"

The positive clinical claims were in a prominent pink font. The Panel noted that references to the medicine's extrafine formulation appeared throughout the page including immediately beneath the page heading 'Fostair.'

Chiesi submitted that the content of the webpage was expressly targeted to UK health professionals, and was intended to provide clinical, prescribing-level information about the product, its mechanism, device options and indication, and included links to prescribing information and adverse event reporting.

The Panel was concerned that the webpage did not include any safety information, or information regarding adverse reactions.

The Panel noted that Wedzicha *et al* reported pneumonia in 3.8% of patients in the Fostair 100/6 arm versus 1.8% in the formoterol arm. The most commonly reported adverse reaction was oral candidiasis, which the Panel noted was listed as a common adverse reaction in the SPC, as was pneumonia in COPD patients. Two adverse reactions (one in each treatment arm) were considered serious (atrial fibrillation). The Panel noted that cardiac events and pneumonia were included in the Special warnings and precautions for use section in the Fostair SPC which stated that Fostair should be used with caution in patients with cardiac arrhythmias and that an increase in the incidence of pneumonia, including pneumonia requiring hospitalisation, has been observed in patients with COPD receiving inhaled corticosteroids.

The Panel acknowledged that links to the SPC and patient information leaflet were included towards the beginning of the scrolling webpage, however these links were not referred to within the context of the reader seeking safety information, nor were they either sufficiently close to the trial information at issue in the first box or signposted from the trial information. In any event the Panel considered that the webpage should be capable of standing alone in relation to the

requirements of the Code. As the webpage referred to positive clinical data without any reference to Fostair's safety profile, the Panel considered that the trial information was neither balanced nor complete, as sufficient information had not been provided to enable recipients to form their own opinion of the therapeutic value of the medicine. The webpage was therefore misleading, and the Panel ruled a **breach of Clause 6.1**, as acknowledged by Chiesi.

The Panel noted its concerns about the absence of safety information and further noted that the material had been certified in the absence of such information. The Panel considered that the failure to include or refer to such information reflected poor governance and meant that Chiesi had failed to maintain high standards in this regard, and the Panel ruled a **breach of Clause 5.1** as acknowledged by Chiesi.

Complaint received **29 July 2025**

Case completed **3 March 2026**