CASE/0809/11/25

COMPLAINANT v CHIESI

Allegations about an online tool

CASE SUMMARY

This case was in relation to an online promotional material titled "Have you triple checked your patients with COPD" hosted on the Chiesi Air website. The complainant alleged that the first mention of Fostair (beclometasone/formoterol) did not include the non-proprietary name immediately adjacent to the brand name. The complainant further alleged that the material was misleading and not sufficiently complete because clinical efficacy data for Trimbow (beclometasone/formoterol/glycopyrronium) from its clinical studies was presented without safety outcomes information or reference to serious adverse events.

The outcome under the 2024 Code was:

Breach of Clause 12.4	**Failing to include the non-proprietary name of the medicine immediately adjacent to the first appearance 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 5.1 (x3)	**Requirement to maintain high standards at all times**
No Breach of Clause 6.1	**Requirement that information, claims and comparisons must not be misleading and that material must be sufficiently complete to enable recipients to form their own opinion of the therapeutic value of the medicine.**

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

COMPLAINT

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

> "Triple check tool hosted on a website promoting Trimbow has problematic compliance issues. The tool is described as a triple check tool to identify patients for escalation onto Trimbow [URL provided]. Webpage reference is UK-RES-2501714 - October 2025 The electronic Triple check tool - UK-TRI-2500084 June 2025, is available for download from the website provided on the link above. It contains 2 pages. The tool mentions Fostair at the beginning of the material on page 1 where the licensed indication for Fostair is given, but does not provide the generic name for Fostair. Considering the first mention of Fostair is at the beginning of the tool on page 1 where the license of Fostair is provided, no generic name provision is a direct breach of clause 12.4 and 5.1. On page 2 positive messaging around Trimbow is provided. This includes clinical outcome data from the Trilogy and Trinity studies. The claims present Trimbow reducing exacerbations compared to other inhalers. In both the Trilogy and Trinity studies, there were several serious adverse effects associated with Trimbow. These side effects included serious pneumonia, stroke, heart failure and cardiovascular death. No safety outcomes information about Trimbow from the studies is presented in this tool although clinical efficacy data is presented. The tool is severely misleading without the presentation of the side effect profile of Trimbow. The tool is not sufficiently complete to allow recipients to form their own opinion of the therapeutic value of the medicine. Lack of safety information is a material risk to patient safety considering the positive spin given on Trimbow clinical efficacy without any incorporation of safety reporting from Trilogy or Trinity studies. There is not a single mention of a side effect associated with Trimbow within this tool. Breaches of 6.1, 5.1 and Clause 2."

When writing to Chiesi, the PMCPA asked it to consider the requirements of Clauses 12.4, 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 26th November 2025 relating to a complaint you have received concerning allegations of missing information and misleading claims contained within an online tool.
>
> 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. <u>The Complaint</u>**
>
> The complainant, a contactable healthcare professional, alleges missing information and misleading claims contained within a two page piece of online material called the Triple Check Tool (the **Tool**), (UK-TRI-2500084) which was hosted on a Chiesi Limited (**Chiesi**) webpage [URL provided] (UK-RES-2501714, the **Webpage**) .

The complainant states that the Tool mentions Fostair (a Chiesi product) at the beginning of the Tool on page 1 where the licensed indication is given, but does not provide the generic name for Fostair, thereby breaching Clause 12.4 and 5.1 of the Code. The complainant also states that Trimbow safety data is missing from page 2 of the Tool, which the complainant alleges renders the material misleading and a breach of Clauses 6.1, 5.1 & 2 of the Code.

Chiesi accepts a breach of Clause 12.4 in relation to the first element of the complaint, but firmly refutes all other allegations and denies that any further 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 online tool and the hosting webpage .

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

[Table listing the names and qualifications of one medical signatory and one non-medical signatory]

We also enclose copies of the Summaries of Product Characteristics (SPCs) for Fostair and Trimbow, as further detailed in the appendix.

3. Details of how the material was used and the target audience

The Tool was housed on the ChiesiAir Webpage: [URL provided] (UK-RES-2501714) on the promotional, healthcare professional-facing page.

To access the promotional Webpage and the Tool a user must self-certify that they are a UK healthcare professional. A prominent disclaimer of '*For UK healthcare professionals only*' is also displayed at the top of the webpage banner.

The Tool is an electronic consultation guide to provide healthcare professionals with the rationale to review moderate to severe COPD patients who are inadequately treated with an inhaled corticosteroid (ICS) + long-acting beta-agonist (LABA) combination with a separate long-acting muscarinic antagonist (LAMA) inhaler or ICS/LABA combination for step-up to single inhaler triple therapy with Trimbow. Both treatment initiation strategies are consistent with the Trimbow licensed indication described in the SPC.

4. Response to the Allegations

(a) Generic name not next to the first mention of PI

The complainant states that the Tool references Fostair at the outset of the material on page 1, where the licensed indication is provided, but omits the generic name for Fostair, thereby constituting a breach of Clause 12.4 and 5.1 of the Code.

Chiesi takes all alleged breaches of the Code extremely seriously and is committed to maintaining the highest standards of accuracy, integrity, and compliance across all activities. Upon receipt of the complaint, we conducted an internal investigation, which confirmed that the omission of the generic name adjacent to the first mention of Fostair in the Triple Check Tool was the result of an isolated human error, and not any systemic failing or intent to mislead.

Accordingly, Chiesi accepts a breach of Clause 12.4 in relation to the Triple Check Tool. Immediate corrective action was taken:

- the Tool was withdrawn from use, and an updated version is currently undergoing approval to ensure full compliance;
- we have revisited the material with the relevant teams and individuals, using this case as a critical learning point, reflecting our culture of continuous improvement and accountability.

However, Chiesi firmly refutes that this isolated omission also constitutes a breach of Clause 5.1. The generic name for Fostair was included in the material, positioned alongside the most prominent (and the second) mention of the brand name on page 2. This placement ensured that healthcare professionals accessing the material were provided with the necessary information in a clear and identifiable manner. The error did not result in any inaccuracy, nor did it compromise the overall clarity or integrity of the material. The presence of the generic name elsewhere in the material, and the immediate steps taken to correct the omission, underscore our dedication to maintaining the high standards expected under the Code. Chiesi's processes and culture are designed to ensure compliance with the Code, and this incident is not indicative of any broader issue with Chiesi's compliance framework.

In summary, while Chiesi acknowledges and has rectified the breach of Clause 12.4, we are of the firm view that the circumstances do not amount to a breach of Clause 5.1, as all relevant information was ultimately present and accessible, and there was no intent to mislead or diminish the high standards expected under the Code.

(b) No discussion of side-effect profile of Trimbow

The complainant alleges Trimbow safety data is missing from page 2 of the Tool, rendering the material misleading and a breach of Clauses 6.1, 5.1 and 2 of the Code.

Chiesi strongly refutes this allegation. There is no explicit requirement within the ABPI Code of Practice to provide the side-effect profile of a medication within the body of promotional material. The inclusion of such detail is context-dependent, taking into account the intended audience, the nature of the material and its intended use. In this case, the Tool is housed on the healthcare professional section of ChiesiAir, accessible only to UK healthcare professionals who must self-certify before entry. The Webpage itself contains an evidence section immediately below the Tool, providing comprehensive information about Trimbow's clinical trials and safety profile for those seeking further detail. Safety information is also located one-click away within the static header of the page, being the Prescribing Information banner.

Moreover, within the Tool itself, safety information is readily accessible one-click away within the Prescribing Information, which is clearly signposted at the base of page 1 and clearly positioned on page 2 of the document. This ensures that healthcare professionals have immediate access to the relevant safety data, inline with industry standards and regulatory requirements.

Chiesi maintains that it not necessary to include detailed safety information within the material itself, particularly as the material does not present detailed clinical data.

Chiesi believe that healthcare professionals do not rely solely on electronic leavepieces, without further research, when making prescribing decisions for patients and therefore would not be misled by the Tool.

This position is supported by PMCPA precedent, notably CASE 3905/5/24 (Complainant v Organon) where the Panel concluded that detailed safety information is not always required on promotional material, and that it depends on the context which is in line with Chiesi's perspective above: '*The Panel considered that, provided the material complied with the Code and was not misleading, it was not always necessary to include detailed safety data in an advertisement.'* In the case of the Tool, the complainant has not provided any evidence to suggest that the material is misleading or that the absence of side-effect data within the Tool itself has resulted in any risk to patient safety or breach of the Code.

Given the overall context, the safeguards in place, and accessibility of safety information, Chiesi is of the firm view that the Tool is in full compliance with Clauses 6.1, 5.1 and 2. The material is accurate, substantiated and presented in a manner that does not mislead. There are no patient safety implications, and nothing in the content could reasonable be considered to bring discredit upon or reduce confidence in the pharmaceutical industry.

Accordingly, Chiesi respectfully invites the Panel to find that no breach of Clauses 6.1, 5.1 or 2 has occurred.

5. Conclusion

- **Clause 12.4 -** For the reasons set out above, Chiesi accepts that the omission of the generic name for Fostair adjacent to the first mention of the brand name in the Triple Check Tool constitutes a breach of Clause 12.4 of the Code.

- **Clause 5.1 -** However, as the generic name was included adjacent to the most prominent mention of Fostair's brand name elsewhere in the material, and given the isolated nature of this error, Chiesi denies that this constitutes a breach of Clause 5.1 in relation to the Tool.

With regard to the other allegations concerning the absence of detailed safety data, Chiesi maintains that the material is fully compliant with the Code:

- **Clause 6.1 -** The material is consistent with the related product SPCs. There are no inaccuracies, all required information is included and all statements are accurate, substantiated and presented in a manner that does not mislead.

- **Clause 5.1 -** Chiesi has acted responsibly, ensured factual accuracy and maintained high standards throughout the development and approval of the material.

- **Clause 2 -** There are no patient safety implications, all relevant reference materials is included, and 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 online tool falls well below that threshold.

Accordingly, Chiesi firmly asserts that, aside from the admitted breach of Clause 12.4 in relation to the omission of the generic name in the Tool at the first mention, there has been no breach of Clause 5.1 in relation to the Tool, or any breach of Clauses 6.1, 5.1, or 2 in relation to the allegations regarding safety data, Chiesi respectfully invites the Panel to rule accordingly."

PANEL RULING

This case was in relation to an online promotional material titled "Have you triple checked your patients with COPD" hosted on the Chiesi Air website. The complainant alleged that the first mention of Fostair (beclometasone/formoterol) did not include the non-proprietary name immediately adjacent to the brand name. The complainant further alleged that the material was misleading and not sufficiently complete because clinical efficacy data for Trimbow (beclometasone/formoterol/glycopyrronium) from its clinical studies was presented without safety outcomes information or reference to serious adverse events.

Chiesi submitted that the material, referred to as the triple check tool, was an electronic consultation guide intended to provide health professionals with the rationale to review moderate to severe COPD patients who are inadequately treated with an inhaled corticosteroid (ICS) + long-acting beta-agonist (LABA) combination with a separate long-acting muscarinic antagonist (LAMA) inhaler or ICS/LABA combination for step-up to single inhaler triple therapy with Trimbow.

The first page of the material, headed "Have you triple checked your patients with COPD", included the Chiesi and Trimbow logos at the top and reproduced the licensed indications for Trimbow and Fostair. Beneath this was a box headed *"Optimise care for your adult patients with moderate to severe COPD"* which referred to the GOLD recommendations and the importance of regularly monitoring patients. The page then included a box presenting "*The triple check system"* which provided a graphic for identifying which patients receiving ICS/LABA or ICS/LABA plus LAMA therapy might benefit from escalation to single inhaler triple therapy. The framework prompted whether symptoms were adequately controlled, whether adherence was affecting treatment outcomes and whether the patient was using the most suitable inhaler device. The first page concluded with the statement, "Choose Trimbow, in either a pMDI or NEXThaler (DPI), for your appropriate adult patients with moderate to severe COPD", alongside images of the Trimbow inhalers.

The second page was titled *"Think triple (ICS/LABA/LAMA), Think Trimbow"* and it included three boxes on the page which containing promotional claims as follows:

- Box 1 - *"Extrafine formulation like Fostair® (beclometasone/formoterol)[1–4]"*

- Box 2 – *"Choice of device to help meet your patients' needs[1,2]*
  The Click of Confidence with NEXThaler for you and your patients who need a DPI[2,8]
    - *Confidence for your patients through confirmed dose delivery[2,8]*

  A familiar pMDI device for your patients who need it[1,9,10]"

- Box 3 – *"Trimbow pMDI 87/5/9 demonstrated:*
    - *Similar rates of moderate to severe exacerbations vs. multiple inhalers (Fostair pMDI 100/6 + Spiriva® HandiHaler® [RR 1.01]) – secondary endpoint[1,11]*
    - *Reduction in moderate to severe exacerbations vs. ICS/LABA (Fostair pMDI 100/6) – secondary endpoint[1,12*]"*

Non-proprietary name

The first allegation concerned the omission of the non-proprietary for Fostair at the first mention of the brand name.

Clause 12.4 included that, for digital materials, the non-proprietary name of the medicine or the list of active ingredients must appear immediately adjacent to the brand name at its first appearance.

The Panel noted that the guide was hosted on Chiesi's website and that the first mention of the Fostair brand name appeared within the indication at the top of the first page, where the non-proprietary name (beclometasone/formoterol) was not stated. The Panel therefore ruled a **breach of Clause 12.4**, as acknowledged by Chiesi.

The Panel nonetheless observed that the non-proprietary name appeared adjacent to a subsequent mention of the Fostair brand name, towards the top of the second page. In the Panel's view, the omission was adequately covered by its ruling under Clause 12.4. The Panel did not consider that the complainant had established that the matter amounted to a failure to maintain high standards. The Panel therefore ruled **no breach of Clause 5.1** in this regard.

Safety information

The complainant's concerns in relation to the second part of the complaint appeared to primarily relate to the omission of side effects. The complaint also referred to the absence of safety outcomes information. Whilst it was not entirely clear whether this constituted a separate allegation, the Panel interpreted this aspect of the complaint as two related, but distinct, allegations.

The Panel took into account that secondary endpoint efficacy claims, relating to exacerbation rates for Trimbow compared to multiple inhalers and ICS/LABA alone, were presented on the second page amongst Trimbow promotional messaging and were referenced to the TRILOGY and TRINITY studies. No further information from those clinical studies, including safety outcome data, was presented.

The Panel first considered the complainant's allegation regarding the omission of specific adverse events. The Panel considered whether contraindications, special warnings or adverse events needed to be highlighted within a particular section of promotional material, depended on

a consideration of all the circumstances including the nature of that information and the content, layout, audience and intended use of the material.

The complainant referred to serious adverse events including pneumonia, stroke, heart failure and cardiovascular death but had not stated why these adverse events required specific inclusion within the material. In the circumstances of this case, the Panel did not consider that it had been established that omission of those specific adverse events rendered the material misleading and therefore ruled **no breach of Clause 6.1** in relation to this aspect of the allegation.

The Panel then considered whether the absence of safety outcomes information for Trimbow, despite the presentation of clinical efficacy data from the TRILOGY and TRINITY studies, meant that the tool was not sufficiently complete to allow recipients to form their own opinion of the medicine.

Clause 6.1 of the Code required that material must be sufficiently complete to enable recipients to form their own opinion of the therapeutic value of the medicine.

The Panel noted that it was not necessarily unacceptable to include comparative efficacy data without including comparative safety data as long as the material complied with the Code. Consideration should be given to all of the circumstances including the nature of the information, the therapy area and the content, context and layout of the material.

The Panel noted that the complainant had not identified what safety outcomes information ought to have been included from the studies and why this rendered the tool as not sufficiently complete. The complainant bore the burden of proof; it was not for the Panel to infer detailed reasons to support an allegation on behalf of the complainant. The Panel, therefore, considered that the complainant had not made out their complaint with respect to this allegation and ruled **no breach of Clause 6.1**.

Given its rulings of no breach of the Code above in relation to the safety information allegations, and without any further allegations or evidence regarding this, the Panel considered that Chiesi had not failed to maintain high standards. The Panel ruled **no breach of Clause 5.1**.

Clause 2 was a sign of particular censure and was reserved for such use. The Panel did not consider that it had been established, in the circumstances of this case, that the matters before it amounted to activity that brought discredit upon, or reduced confidence in, the pharmaceutical industry. The Panel considered its concerns had been adequately covered by its rulings above and ruled **no breach of Clause 2**.

Complaint received **24 November 2025**

Case completed **05 August 2026**