CASE/0387/12/24

COMPLAINANT v ASTRAZENECA

Allegation about a Symbicort promotional claim

CASE SUMMARY

This case was in relation to a promotional claim on the Symbicort website. The claim stated that BTS/NICE/SIGN recommended that all newly diagnosed asthma patients over 12 years of age should be prescribed first-line ICS-formoterol with AIR (anti-inflammatory reliever) therapy. The complainant alleged that the claim was incorrect as it did not reflect the national asthma guidance to which it referred.

The outcome under the 2024 Code was:

Breach of Clause 2	**Bringing discredit upon, and reducing confidence in, the pharmaceutical industry**
Breach of Clause 5.1	**Failing to maintain high standards at all times**
Breach of Clause 6.1	**Making a misleading claim**
Breach of Clause 6.2	**Making an unsubstantiated claim**

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

COMPLAINT

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

> "A promotional claim for Symbicort use in newly diagnosed asthma patients is incorrect as it does not reflect the national asthma guidance that the claim is referenced to. The claim is written out on the "why symbicort" page which can be found at [URL provided].
> At the top of the webpage below the images of the patients there are 3 promotional messages in 3 boxes. The last box message is written prominently as BTS/NICE/SIGN recommends all newly diagnosed patients (12+) should be prescribed first-line ICS-formoterol with AIR (anti-inflammatory reliever therapy). This promotional message is referenced to the BTS/SIGN/NICE asthma guidelines 2024. This promotional message is false as the BTS/SIGN/NICE asthma guidelines 2024 state that for newly diagnosed asthma in people aged 12 or over first line therapy if the patient is highly

symptomatic or there are severe exacerbations, low dose MART therapy should be offered. The use of ICS-formoterol with AIR is only for newly diagnosed patients who are not highly symptomatic or have severe exacerbations. MART and AIR are two different management methods and both are to be used for very defined newly diagnosed asthmatic patients as noted in the guidance. The guidance can be found at [URL provided]. By claiming all newly diagnosed patients should start ICS-formoterol AIR is a risk to patient safety and does not align with the guidance the claim is referenced to. It is very important those with exacerbations or symptomatic are initiated on MART and not AIR. One has to question how a signatory had enabled this claim in its current format and whether the process of review and approval are robust. Breaches of Clause 6.1 + 6.2 + 5.1 + 2."

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

ASTRAZENECA'S RESPONSE

The response from AstraZeneca is reproduced below.

"Thank you for your letter dated 9 December 2024, concerning a complaint from a healthcare professional (HCP) with respect to a promotional claim for Symbicort on the AZ Symbicort website. The complainant's allegations can be broken down as follows:

1. Promotional claim for Symbicort regarding use in newly diagnosed asthma patients is incorrect as it does not reflect the national asthma guidance that the claim is referenced to.
    a. At the top of [URL for the "Why Symbicort" webpage], there are 3 boxes and 3 promotional messages. The last box is written prominently as BTS/NICE/SIGN recommends all newly diagnosed patients (12+) should be prescribed first line ICS-formoterol with AIR (anti-inflammatory reliever therapy). This promotional message is false as the BTS/SIGN/NICE asthma guidelines 2024 state otherwise.
2. Claiming all newly diagnosed patients should start ICS-formoterol AIR is a risk to patient safety. It is important that those with exacerbations or symptomatic are initiated on MART and not AIR.
3. Questioned the robustness of the review and approval process.

AstraZeneca have been asked to consider clauses 2, 5.1, 6.1 and 6.2 of the 2024 ABPI Code. We will address each of the complainant's allegations according to the relevant clauses.

Background

On 27th November 2024, NICE, BTS and SIGN published new guideline for asthma diagnosis, monitoring and management (NG245). One of the significant changes is the treatment of newly diagnosed asthma in people aged 12 and over, which recommend low-dose ICS-formoterol combination inhaler as needed (anti-inflammatory reliever therapy, AIR) or low-dose maintenance and reliever therapy (MART) in patients who are highly symptomatic or have a history of severe exacerbations. This is a significant change from previous guidance, where short-acting beta agonist (SABA) inhaler monotherapy was the first-line treatment option. This new treatment pathway for NG245 can be found in 'Algorithm C: Pharmacological management of asthma in people aged 12 years and over'.

AstraZeneca Response to the Allegations

1. *Promotional claim for Symbicort regarding use in newly diagnosed asthma patients is incorrect as it does not reflect the national asthma guidance that the claim is referenced to. At the top of [URL provided] webpage, there are 3 boxes and 3 promotional messages. The last box is written prominently as BTS/NICE/SIGN recommends all newly diagnosed patients (12+) should be prescribed first line ICS-formoterol with AIR (anti-inflammatory reliever therapy). This promotional message is false as the BTS/SIGN/NICE asthma guidelines 2024 state otherwise.*

As per the treatment algorithm, there are 2 treatment options for newly diagnosed asthma patients aged 12 and over, depending on whether the patient presenting is highly symptomatic/severe exacerbations or not.

[screenshot of relevant section of treatment algorithm]

Therefore, we agree that the claim '*BTS/NICE/SIGN recommends all newly diagnosed patients (12+) should be prescribed first line ICS-formoterol with AIR (anti-inflammatory reliever therapy)'* does not accurately reflect the full BTS/NICE/SIGN guideline, which was an unintentional error. Although the majority of newly diagnosed asthma patients presenting in primary care will be eligible for an ICS-formoterol as AIR (aligned with the claim), we acknowledge that there will be a small proportion of highly symptomatic patients who should be offered low-dose MART in the first instance, in line with the guidelines.

Based on this, we regrettably accept breach of clause 6.1 and 6.2 of the Code regarding this allegation.

2. *Claiming all newly diagnosed patients should start ICS-formoterol AIR is a risk to patient safety. It is important that those with exacerbations or symptomatic are initiated on MART and not AIR.*

The majority of newly diagnosed asthma patients will be prescribed AIR (ICS/formoterol as needed). A smaller proportion of highly symptomatic newly diagnosed patients should be prescribed MART (ICS/formoterol twice daily + as needed).

We do not believe that this error would have constituted a patient safety risk:

1. If a highly symptomatic, newly diagnosed, asthmatic patient were to have been erroneously prescribed AIR, they would have been instructed to self-administer ICS/formoterol as needed in response to symptoms, and if their symptoms persisted, then to self-administer additional inhalations until either symptom control was restored or to seek medical attention.
2. Symbicort is licensed for both AIR and MART. The maximum daily dose of Symbicort 200/6 is the same for both MART and AIR, and thus there is no theoretical risk that a patient wrongly prescribed AIR could receive an overdose of Symbicort.

3. As per usual practice, the patient would be told to seek further medical advice if their current therapy is inadequate to control their symptoms. If this occurs, they would be considered for another treatment.

In summary, we think that it is reasonable to expect that, even if a patient was erroneously prescribed ICS/formoterol using AIR posology, that they would self-administer a total daily dose of ICS/formoterol commensurate with the severity of their asthma, or to seek attention from an HCP and therefore that patients were not put at risk.

It is pertinent to note that directly underneath the claim, there is a prominent link to the guideline and treatment algorithm as shown in the screenshot below. Therefore, the HCP would have had direct access to the full guideline and treatment algorithm which includes both recommended treatment options for newly diagnosed asthma patients.

[Screenshot of webpage]

In addition, there is a clear link to the prescribing information (PI) for Symbicort at the top of the webpage in the same view. At the top of the PI there is the prominent statement **"Consult Summary of Product Characteristics before prescribing"**.

[screenshot of top section of Symbicort prescribing information - asthma]

Due to the reasons outlined above, we do not agree that this claim would impact patient safety, and thus refute breach of clauses 5.1 or 2 of the Code in regard to this allegation.

3. Questioned the robustness of the review and approval process.

AZ have a robust process for review and approval of materials in line with our Approval Management SOP, and Signatory training and validation. All Nominated Signatories complete a validation before they can work as a Nominated Signatory for AZ and are re-validated each year thereafter. They participate in monthly Code review forums where we discuss recent PMCPA cases, Nominated Signatory forums where we discuss unusual situations, and they receive regular training in response to the training needs of the team. The Nominated Signatory reviews and certifies every promotional material in line with the Code and the AZ Materials Management SOP. Based on this, we disagree that the company has not maintained high standards and refute breach of clause 5.1.

Summary of AstraZeneca's position

In summary:

- We regrettably accept that the claim in question is not representative of the full BTS/NICE/SIGN guideline. However, it is important to note that there was a link to the full guidelines directly underneath and PI was available from outset.
- The error in the claim was an honest mistake.
- AZ has a robust review and approval process as outlined in our Materials Management SOP. Our Nominated Signatory team undergo thorough and continuous training to ensure they are up to date and suitably qualified.

AstraZeneca takes its responsibilities under the Code very seriously. Based on the above detailed response, **we regrettably accept breach of clauses 6.1 and 6.2 of the Code**.

However, we do not agree that patient safety has been jeopardised, and maintain that our company processes and training is robust. **We therefore refute breach of Clause 5.1 and 2 of the Code.**

After receiving the complaint and conducting our investigation, the webpage with the claim '*BTS/NICE/SIGN recommends all newly diagnosed patients (12+) should be prescribed first line ICS-formoterol with AIR (anti-inflammatory reliever therapy)'* was removed immediately and updated to accurately reflect the wording of the guidelines."

PANEL RULING

This case was in relation to a promotional claim for the use of Symbicort (budesonide/formoterol) in newly diagnosed asthma patients, which appeared on an AstraZeneca webpage. The complainant alleged that the claim was incorrect as it did not reflect the national asthma guidance to which it referred.

The Panel noted the layout of the webpage in question; the headline banner stated "Why does Symbicort® (budesonide/formoterol) Turbohaler® make sense?" and included images of three adults of varying ages who could be eligible asthma patients. Directly below were three boxes placed horizontally which each contained a claim for Symbicort. The third box contained the claim at issue "BTS/NICE/SIGN recommends all newly diagnosed asthma patients (12+) should be prescribed first-line ICS-formoterol with AIR (anti-inflammatory reliever) therapy" and cited the BTS, NICE and SIGN 2024 Asthma: diagnosis, monitoring and chronic asthma management guideline as the reference.

Underneath the three boxes there were links to the Symbicort Turbohaler indication, the new BTS, NICE and SIGN [NG245] guideline and treatment algorithm for the pharmacological management of asthma in people aged 12 years and over.

Clause 6.1

Clause 6.1 of the Code required claims to be "accurate, balanced, fair, objective and unambiguous", that "they must not mislead either directly or by implication, by distortion, exaggeration or undue emphasis" and that they "must be sufficiently complete to enable recipients to form their own opinion of the therapeutic value of the medicine".

The Panel noted the treatment algorithm stated that low-dose maintenance and reliever therapy (MART) should be offered to newly diagnosed asthma patients aged 12 years and over, who were highly symptomatic or had severe exacerbations. In other words, such patients should not be offered anti-inflammatory reliever (AIR) therapy. Therefore the Panel considered that the claim at issue (that "all newly diagnosed asthma patients (12+) should be prescribed … AIR therapy" (Panel's emphasis) was factually incorrect and incapable of substantiation. Accordingly the Panel ruled **breaches of Clauses 6.1 and 6.2**, as acknowledged by AstraZeneca.

Clause 5.1

Noting the complainant also alleged the claim constituted a risk to patient safety the Panel considered the immediate and overall impression of the webpage to a busy health professional. Context and layout were important in this regard. The claim at issue was positioned prominently,

appearing within the first field of view alongside two other boxed claims that “Symbicort Reliever Therapy (Turbohaler 200/6) is the **FIRST ICS/LABA INHALER** licensed as a **RELIEVER** for patients (≥12 years) with **MILD ASTHMA**” and “Symbicort Turbohaler is now indicated **ACROSS** all **ASTHMA SEVERITIES**” [emphasis as it appeared on the webpage].

Below the boxed claims there were links to the Symbicort Turbohaler indication statement, the BTS, NICE and SIGN Guideline [NG245] and treatment algorithm. The continuously scrolling page also included sections titled “Why does Symbicort Turbohaler make sense for your patients?” and “Why does Symbicort Turbohaler make sense for you?” which included, among other things, information about how Symbicort Turbohaler fitted into various national and international guidelines, namely the BTS/NICE/SIGN [NG245] Guideline, the Primary Care Respiratory Society (PCRS) Guide, the Global Initiative for Asthma (GINA) Guideline and the European Respiratory Society Task Force Guideline. This section included two infographics: the first outlined treatment algorithms for the new and the previous BTS/SIGN guidelines; the second illustrated steps 1 to 5 for treatment with low-dose ICS-formoterol as a reliever, per the GINA and PCRS guidelines.

AstraZeneca submitted that the majority of newly diagnosed asthma patients will be prescribed AIR (ICS/formoterol as needed) and a smaller proportion of highly symptomatic newly diagnosed patients should be prescribed MART (ICS/formoterol twice daily + as needed). AstraZeneca further submitted that patient safety would not be at risk even if these patients were prescribed Symbicort AIR therapy because Symbicort Turbohaler was licensed for both AIR and MART with both indications having the same maximum daily dose, therefore there was no theoretical risk of overdose, and because patients were instructed to seek medical advice if their current therapy did not adequately control their symptoms. The Panel noted AstraZeneca’s submission that there was a clear link to the prescribing information for Symbicort at the top of the webpage and a prominent statement to consult the summary of product characteristics before prescribing.

The Panel disagreed with AstraZeneca’s position for the following reasons:

- the prominence and strength of the claim at issue made in the first field of vision misleadingly implied that readers could prescribe Symbicort Turbohaler for all newly diagnosed asthma patients over 12 years, which was not so, and this impression was reinforced by the adjacent claim which referred to use of Symbicort Turbohaler for all severities of asthma,
- the strength of Symbicort Turbohaler indicated in AIR therapy for newly diagnosed asthma patients over 12 years who were not highly symptomatic was not included in the claim, nor provided in close proximity to it, despite three different strengths of Symbicort Turbohaler being available (100/6, 200/6 and 400/12), and
- the volume of intervening material on the continuously scrolling webpage before readers would reach information regarding the strength of Symbicort Turbohaler licensed for AIR therapy (Symbicort Turbohaler 200/6). The Panel noted the BTS/NICE/SIGN guideline and treatment algorithm did not mention products by brand name or include a specific strength but referred to low dose ICS/formoterol combination inhaler.

In the Panel’s view, inclusion of the first infographic illustrating the difference between the new and the previous BTS/SIGN guidelines did not negate the misleading impression created by the incorrect claim at issue, and the Panel was concerned to note the other issues with the webpage outlined above, which reinforced this misleading impression. The Panel queried the robustness of the review and approval process in relation to the webpage at issue and

considered that AstraZeneca had failed to maintain high standards in this regard. The Panel ruled a **breach of Clause 5.1**.

Clause 2

A breach of Clause 2 was a sign of particular censure and was reserved for such use. However, prejudicing patient safety was cited in the supplementary information to Clause 2, as an example of an activity that was likely to be in breach of this clause.

The Panel was concerned that the claim "BTS/NICE/SIGN recommends all newly diagnosed patients (12+) should be prescribed first-line ICS-formoterol with AIR (anti-inflammatory reliever) therapy", alongside the claim "Symbicort Turbohaler is now indicated ACROSS all ASTHMA SEVERITIES" created the misleading impression that Symbicort Turbohaler with AIR therapy was suitable for all asthma patients, which was not so. The Panel was concerned that newly diagnosed asthma patients who were highly symptomatic or had severe exacerbations might inadvertently be prescribed AIR therapy, resulting in poor symptom control and/or persistent exacerbations, which are potentially serious. In the Panel's view, such patients were being directed away from MART (regular dosing once or twice a day plus as required in response to symptoms) and towards potentially unsuitable AIR (with dosing only as required in response to symptoms) which was a genuine patient safety concern.

The Panel did not accept AstraZeneca's submission that a newly diagnosed asthma patient (who would have no prior experience of inhaler-use) could be expected to self-administer additional inhalations until symptom control was restored. Similarly, the Panel did not consider AstraZeneca's submission that these patients could "seek further medical advice if their current therapy is inadequate" to be an acceptable justification.

Having considered its rulings and comments above, the Panel considered that the failings in this case were such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry. The Panel ruled a **breach of Clause 2**.

Complaint received **6 December 2024**

Case completed **12 September 2025**