CASE AUTH/3678/8/22

COMPLAINANT v ASTRAZENECA

Concerns about a Symbicort advertisement in MIMS

CASE SUMMARY

This case was in relation to an advertisement for Symbicort (budesonide, formoterol fumarate dihydrate) in MIMS placed by AstraZeneca.

The Panel ruled a breach of the following Clauses of the 2021 Code because:

- the advertisement did not include reference to where the prescribing information could be found on the page of the advertisement, it was not visible
- the advertisement misleadingly implied that all strengths of Symbicort could be prescribed for MART [maintenance and reliever therapy] when Symbicort 400/12 should be used as maintenance therapy only and the points in small font at the very bottom of the page in question were wholly insufficient to qualify the misleading impression given and use of the higher Symbicort dose (400/12) for reliever therapy had the potential to impact patient safety

Breach of Clause 2	**Bringing discredit upon, and reducing confidence in, the pharmaceutical industry**
Breach of Clause 5.1	**Failing to maintain high standards**
Breach of Clause 6.1	**Making a misleading claim**
Breach of Clause 6.2	**Making an unsubstantiated claim**
Breach of Clause 11.2	**Promotion inconsistent with the SPC**
Breach of Clause 12.7	**Failing to include on the pages of a printed journal advertisement where the prescribing information was not visible, reference to where it could be found**

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 from an anonymous, contactable complainant who described themselves as a health professional about an advertisement for Symbicort (budesonide, formoterol fumarate dihydrate) in MIMS placed by AstraZeneca.

COMPLAINT

The complainant stated that a Symbicort hard copy journal advertisement which featured in the June 2022 copy of MIMS placed by AstraZeneca did not meet the requirements of the Code. The advertisement (ref GB-35766, April 2022) featured on pages 293 and 294 of the hard copy

of MIMS. On page 293, the advertisement had a claim in big font at the top of the page 'for your eligible asthma [patients], prescribe maintenance and [reliever] therapy in one' and underneath the claim was a big Symbicort inhaler image (with no strength shown on the inhaler) and another statement under the image 'Think MART [maintenance and reliever therapy], Choose Symbicort'. The complainant alleged that this was a misleading advertisement as initial impressions for the health professional thought process would be that any strength of Symbicort turbohaler was suitable for MART. This was not the case as Symbicort came in various strengths and not all strengths were licensed for MART. The strength of Symbicort should have been made clear in the inhaler image or at the top of the claim for the strength that was licensed for MART. There would be a patient safety challenge if any strength of Symbicort was prescribed for MART based of this advertisement. The prescribing information was overleaf on page 294 but a statement on page 293 had not been included as to where prescribing information was available. Breaches of the following clauses were evident: 6.1, 6.2, 5.1, 11.2, 12.7 and 2.

When writing to AstraZeneca, the Authority asked it to consider the requirements of Clauses 2, 5.1, 6.1, 6.2, 11.2 and 12.7 of the 2021 Code as cited by the complainant.

RESPONSE

AstraZeneca stated that in its response to the complainant's allegations, it would establish that:

- the Symbicort Turbohaler advertisement in question was consistent with the marketing authorisation and was not misleading.

AstraZeneca regretted that the Prescribing Information (PI) was not visible from the first page of the advertisement in the MIMS Journal, and there was no reference on the first page to where PI could be found and accepted a breach of Clause 12.7.'

AstraZeneca addressed each of the complainant's allegations according to the relevant clauses of the Code.

Background

AstraZeneca explained that the advertisement subject to complaint was a promotional hardcopy advertisement, featuring the Symbicort Turbohaler, published in MIMS [June 2022].

Symbicort Turbohaler was indicated in the regular treatment of asthma where use of a combination (inhaled corticosteroid and long-acting β2 adrenoceptor agonist) was appropriate:

- Patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled short-acting β2 adrenoceptor agonists.
- Patients already controlled on both inhaled corticosteroids and long-acting B2 adrenoreceptor agonists.

The Symbicort Turbohaler device was available in three strengths; 100/6, 200/6 and 400/12.

For Symbicort there were two treatment approaches:

A. Symbicort maintenance therapy: Symbicort is taken as regular maintenance treatment with a separate rapid-acting bronchodilator as rescue.

B. Symbicort maintenance and reliever therapy: Symbicort is taken as regular maintenance treatment and as needed in response to symptoms.

The material subject to this complaint was certified by a senior nominated signatory from a third party agency that supported AstraZeneca with the review and approval of materials and activities. Nominated signatories employed by the agency were very experienced and dedicated their working days to Code Review and certification.

AstraZeneca Response

The Symbicort Turbohaler indication was clearly stated immediately below the Symbicort Turbohaler image. It was also made explicitly clear that Symbicort Turbohaler 100/6 and 200/6 could be used as MART therapy, whilst Symbicort Turbohaler 400/12 should be used as **maintenance therapy only**.

The strength was purposely not included in the Symbicort Turbohaler image because two strengths could be used for MART therapy and the indication information was clearly available below the image. Inclusion of one strength on the inhaler would not reflect the licensed indication and might give the wrong impression that only the included strength was licensed for MART.

Therefore, it was AstraZeneca's belief that the advertisement was **not** inconsistent with the marketing authorisation for Symbicort Turbohaler and was not in breach of the applicable alleged clauses of the Code.

AstraZeneca refuted the alleged breaches of Clauses 5.1, 6.1, 6.2, 11.2 and 2 of the Code.

AstraZeneca submitted that the advertisement was certified for publication in two journals (BMJ Thorax and MIMS) as a double-page spread and therefore the prescribing information would be visible from the first page without turning overleaf.

The advertisement was printed in this format in the BMJ Thorax Journal; a photograph of which was uploaded to attachments of the job for the Nominated signatory to check final form.

Although print of the advertisement over a double-page spread was agreed with MIMS, the two-page advertisement was actually printed on consecutive pages but with the prescribing information overleaf. MIMS had acknowledged that this happened by mistake and had assured AstraZeneca that it was putting a process in place to avoid such mistakes in the future. The magazine was printed for distribution before AstraZeneca could check the final form of the advertisement. The AstraZeneca Materials Management SOP stated that where magazine preview from the publisher was not possible, the medical nominated signatory would certify based on the proof version. If the document owner noticed a mistake once the advertisement was published, an unplanned deviation was raised internally.

AstraZeneca stated that it regrettably acknowledged that the location of the prescribing was not visible from the first page of the advertisement, as it was placed overleaf and there was no reference to where the prescribing information [was] present on the first page.

Therefore, AstraZeneca accepted a breach of Clause 12.7.

Summary of AstraZeneca's position

It was AstraZeneca's position that this Symbicort advertisement was consistent with the marketing authorisation and therefore was not misleading to health professionals. Therefore, AstraZeneca believed that the company was not in breach of Clauses 6.1, 6.2, 11.2 and 2 of the Code. AstraZeneca regretted that the position of the prescribing information was not consistent with the certified material, and therefore AstraZeneca accepted a breach of Clause 12.7. This was a result of miscommunication with the publishing journal, and AstraZeneca was taking steps to ensure this did not happen again.

AstraZeneca submitted that it subscribed fully to the high ethical and moral spirit of the Code and took its responsibilities under the Code very seriously.

PANEL RULING

The Panel noted that the first page of the advertisement in question included the claim 'For your eligible asthma patients, prescribe **Maintenance** and **Reliever** therapy in one' in large font above an image of a Symbicort turbohaler which included the name Symbicort but no strength.

The Panel disagreed with AstraZeneca's submission that it was made explicitly clear that Symbicort Turbohaler 100/6 and 200/6 could be used as MART therapy, whilst Symbicort Turbohaler 400/12 should be used as **maintenance therapy only**. The Panel noted that below the image it stated 'Think **MART**. Choose **Symbicort**.' again in large font. The Panel noted that below this in very small font in comparison to the claims above, it stated:

> 'MART = maintenance and reliever therapy
> **Symbicort® Turbohaler** is indicated for adults, adolescents 12 years and older and children aged 6 years and older (100/6 Turbohaler only) for the regular treatment of asthma where use of a combination (inhaled corticosteroid and long-acting β2 adrenoceptor agonist) is appropriate:
>
> - Patients not adequately controlled with inhaled corticosteroids and "as needed" inhaled short-acting β2 adrenoceptor agonists
> - Patients already adequately controlled on both inhaled corticosteroids and long-acting β2 adrenoceptor agonists
>
> **Symbicort Turbohaler** 400/12 should be used in asthma as Maintenance Therapy only.
> **Symbicort MART**: Regular maintenance doses of Symbicort Turbohaler and in addition taken as needed in response to symptoms'.

The Panel considered the immediate and overall impression to a busy health professional. Context and layout were also important in this regard. In the Panel's view, the advertisement misleadingly implied that readers could prescribe Symbicort regardless of strength as MART therapy and the final points in small font at the very bottom of the page in question were wholly insufficient to qualify the misleading impression given. The Panel thus ruled **breaches of Clauses 6.1 and 6.2**. The Panel considered that the advertisement implied that all strengths of Symbicort, including Symbicort 400/12, could be used as MART therapy which was not so.

Section 4.2 Posology and method of administration of the Symbicort 400/12 Symbicort SPC stated 'Symbicort 400/12 should be used as Symbicort maintenance therapy only. Lower strengths are available for the Symbicort maintenance and reliever therapy regimen (200 micrograms/6 micrograms/inhalation and 100 micrograms/6 micrograms/inhalation)'. In the Panel's view, the points in small font at the very bottom of the page in question was wholly insufficient to qualify the immediate impression given which was inconsistent with the particulars listed in the Symbicort 400/12 SPC and a **breach of Clause 11.2** was ruled. The Panel considered that high standards had not been maintained in this regard and a **breach of Clause 5.1** was ruled.

The Panel noted that the restrictions of the use of Symbicort 400/12 as MART therapy had not been prominently stated in the advertisement. The Panel noted that it was crucial that health professionals and others could rely upon the industry to provide them with robust and accurate information to aid their decision making. The Panel noted its comments above and considered that the advertisement encouraged the use of Symbicort 400/12 for MART therapy for patients when it should be used as maintenance therapy only. In the Panel's view, the use of the higher Symbicort dose (400/12) for reliever therapy had the potential to impact patient safety. The Panel considered that the material brought discredit upon, and reduced confidence in, the industry and a **breach of Clause 2** was ruled.

Clause 12.7 states that in a printed journal advertisement the prescribing information must appear on at least one of the pages. The pages where the prescribing information is not visible must include a reference on the outer edge of the page as to where the prescribing information can be found in a type size such that a lower case 'x' is no less than 2mm in height. The Panel noted AstraZeneca's submission that although print of the advertisement over a double-page spread was agreed with MIMS journal, the two-page advertisement was actually printed on consecutive pages. AstraZeneca acknowledged that the location of the prescribing information was not visible from the first page of the advertisement as it was placed overleaf and there was no reference to where the prescribing information was present on the first page. The Panel therefore ruled a **breach of Clause 12.7** as acknowledged by AstraZeneca.

Complaint received **1 August 2022**

Case completed **4 July 2023**