CASE AUTH/3319/3/20 *NO BREACH OF THE CODE*

COMPLAINANT v ASTRAZENECA

Concerns about promotion of Symbicort on a website

A complainant who described him/herself as a concerned UK health professional, complained about promotional material for Symbicort (budesonide/formoterol) created by AstraZeneca UK Ltd and hosted on the Guidelines in Practice website. Symbicort was variously indicated for use in the treatment of asthma and/or chronic obstructive pulmonary disease (COPD) according to the strength and formulation used.

The complainant was concerned that the prescribing information which was available on a downloadable formulary decision guide was out-of-date as there had been two updates since it was created. The complainant noted that Section 4.4, Special warnings and precautions for use, of the summary of product characteristics (SPC) had had the following text added 'Complete withdrawal of inhaled corticosteroids should not be considered unless it is temporarily required to confirm diagnosis of asthma'.

The complainant alleged that the omission of that statement could be a patient safety issue, especially as the material at issue was to help guide formulary decisions and treatment algorithms.

The detailed response from AstraZeneca is given below.

The Panel noted that the formulary decision guide in question clearly related to the use of Symbicort in the treatment of COPD. The complainant had drawn attention to a statement included in Section 4.4, Special warnings and precautions for use, of the Symbicort SPC ie 'Complete withdrawal of inhaled corticosteroids should not be considered unless it is temporarily required to confirm diagnosis of asthma'. AstraZeneca submitted that this warning was specific to the treatment of asthma and thus did not need to be included in COPD prescribing information.

On the basis of the information before it, the Panel considered that there was no evidence that the warning in question should have been included in the COPD prescribing information and so in that regard it ruled no breach of the Code.
The complainant gaveno reasons for his/her concern regarding patient safety and had not explained how and why omission of the warning would, as implied, hinder rational formulary decisions or treatment algorithms. The Panel noted that the prescribing information in the formulary decision guide for Symbicort in COPD included the statement, under 'Warnings and Precautions', 'Treatment should not be stopped abruptly without supervision by a physician'. Readers were also advised to consult the SPC before prescribing which the Panel considered they would do before making any formulary decisions or treatment algorithms.

The Panel considered that the complainant had not established that AstraZeneca had failed to maintain high standards and no breach of the Code was ruled. It also ruled no breach of Clause 2.

A complainant who described him/herself as a concerned UK health professional, complained about promotional material for Symbicort (budesonide/formoterol) created by AstraZeneca UK Ltd and hosted on the Guidelines in Practice website. Symbicort was variously indicated for use in the treatment of asthma and/or chronic obstructive pulmonary disease (COPD) according to the strength and formulation used.

COMPLAINT

The complainant stated that he/she was concerned that the prescribing information which was available on a downloadable formulary decision guide was out-of-date as there had been two updates since it was created. The complainant noted that Section 4.4, Special warnings and precautions for use, of the summary of product characteristics (SPC) had had the following text added 'Complete withdrawal of inhaled corticosteroids should not be considered unless it is temporarily required to confirm diagnosis of asthma'.

The complainant submitted that the omission of that statement could easily be a patient safety issue, especially as the material at issue was to help guide formulary decisions and treatment algorithms.

When writing to AstraZeneca, the Authority asked it to consider the requirements of Clauses 2, 4.1, 4.2 and 9.1 of the Code.

RESPONSE

AstraZeneca noted that the complainant alleged that the material in question which related to the use of Symbicort in COPD included out-of-date information, specifically that a warning for asthma ('Complete withdrawal of inhaled corticosteroids should not be considered unless it is temporarily required to confirm diagnosis of asthma') was not included in the prescribing information, following an update to the SPC in August 2019.

AstraZeneca noted that Clause 4.2, specifically, parts iv and v, required prescribing information to be relevant to the indications in the advertisement and in that regard noted that Symbicort was indicated for patients with asthma and/or COPD depending on the type of device and strength of the medicine. The company had long maintained that for a product with more than one indication, it was permissible and indeed more clinically appropriate, to separate prescribing information by indication. As such, AstraZeneca maintained two versions of the prescribing information for Symbicort, one for asthma and one for COPD and both versions were accurate and up-to-date. Each relevant prescribing information was incorporated into promotional materials depending on which indication was promoted.

The warning cited by the complainant was specific to the asthma indication only and so it was not included in the COPD prescribing information as it was not relevant to the treatment of that patient population. AstraZeneca confirmed that the warning was included in the latest asthma prescribing information, which was refreshed when the SPC was last updated.

Given the above, AstraZeneca maintained that the prescribing information for Symbicort was correct and up-to-date and it therefore refuted any breach of Clauses 2, 4.1, 4.2 or 9.1.

AstraZeneca noted that the material referenced by the complainant explicitly referred to the use of Symbicort in COPD. The webpage included the most up-to-date Symbicort COPD prescribing information. The warning referred to by the complainant exclusively applied to the use of Symbicort in patients with asthma and therefore it was not relevant to the COPD prescribing information. A summary of SPC and prescribing information updates for Symbicort was provided.

AstraZeneca submitted that it had maintained high standards and had ensured that both versions of the Symbicort prescribing information were accurate and up-to-date. The warning in question was specific only to the asthma indication and was therefore not included in the COPD prescribing information as it was not relevant to the treatment of that patient population. AstraZeneca strongly refuted any suggestion that Clauses 2, 4.1, 4.2 and 9.1 had been breached or indeed that a risk to patient safety existed as a result of the prescribing information for Symbicort.

PANEL RULING

The Panel noted that the formulary decision guide in question clearly related to the use of Symbicort in the treatment of COPD. The complainant had drawn attention to a statement included in Section 4.4, Special warnings and precautions for use, of the Symbicort SPC ie 'Complete withdrawal of inhaled corticosteroids should not be considered unless it is temporarily required to confirm diagnosis of asthma'.

AstraZeneca had submitted that the warning was specific to the treatment of asthma and thus did not need to be included in COPD prescribing information and confirmed that the warning was included in the latest asthma prescribing information.

Clause 4.1 required the prescribing information listed in Clause 4.2 to be provided on all promotional material. Clause 4.2 listed the components of prescribing information. It was not possible to breach Clause 4.2; failure to provide the required information would be a breach of Clause 4.1. The Panel noted that Clause 4.2 required prescribing information to include a succinct statement regarding precautions relevant to the indication in question. On the basis of the information before it, the Panel considered that there was no evidence that the warning in question should have been included in the COPD prescribing information and so in that regard it ruled no breach of Clause 4.1.

The complainant suggested that the omission of the warning from the prescribing information on the COPD formulary decision guide was prejudicial to patient safety but had given no reasons for his/her concerns in that regard and had not explained how and why omission of the warning would, as implied, hinder rational formulary decisions or treatment algorithms. The Panel noted that the prescribing information in the formulary decision guide for Symbicort in COPD included the statement, under 'Warnings and Precautions', 'Treatment should not be stopped abruptly without supervision by a physician'. Readers were also advised to consult the SPC before prescribing which the Panel considered they would do before making any formulary decisions or treatment algorithms.

The Panel considered that the complainant had not established that AstraZeneca had failed to maintain high standards and no breach of Clause 9.1 was ruled.

The Panel noted its rulings above and ruled no breach of Clause 2.

Complaint received **10 March 2020**

Case completed **1 July 2020**