Case AUTH/3817/9/23 ***NO BREACH OF THE CODE***

COMPLAINANT v ASTRAZENECA

Alleged lack of prescribing information and adverse event reporting statement on AstraZeneca's SENTINEL plus website

CASE SUMMARY

This case related to allegations regarding AstraZeneca's SENTINEL Plus website which included information about Maintenance and Reliever Therapy (MART).

The outcome under the 2021 Code was:

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	**Requirement to maintain high standards**
No Breach of Clause 12.1	**Requirement to provide prescribing information in promotional material**
No Breach of Clause 12.9	**Requirement to include the prominent adverse event reporting statement**

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 about AstraZeneca UK Limited.

COMPLAINT

The complaint wording is reproduced below:

> "There were multiple implied mentions of a product (by usage of the word MART [Maintenance and Reliever Therapy] in the context of increasing MART prescribing) on the SENTINEL plus website but prescribing information and adverse event reporting was not provided [web link provided]. On this page, the following mentions of MART were written: The SENTINEL project developed an intervention to implement the local asthma guideline which has a focus on reducing short-acting beta agonist (SABA) over-reliance and using Maintenance and Reliever Therapy (MART) for appropriate patients. Pilot data from the SENTINEL project has demonstrated that implementation of a MART focussed asthma guideline can substantially reduce SABA prescribing and reduce the proportion of all inhaled therapies that are a SABA [web link provided]. On this aims and objectives page, it was made clear Aim 1 was to implement appropriate MART based treatment strategy. It is obvious the focus is on enhancing 'MART' usage which fits in within the wide definition of

promotion. Astrazeneca had Symbicort Turbohaler 100/6 which had a licence for MART usage. As the product had an indication for MART, it was a clear indirect reference to drive Symbicort usage by mentions on the web pages. MART was a very specific indication and Symbicort Turbohaler 100/6 was long established for MART usage. There were breaches of the following clauses of ABPI code: 12.1, 12.9, 5.1, 2."

When writing to AstraZeneca, the Authority asked it to consider the requirements of Clauses 5.1, 12.1, 12.9 and 2 of the Code.

ASTRAZENECA'S RESPONSE

The response from AstraZeneca is reproduced below:

"**Complaint:**
The complainant alleged that there were multiple implied mentions of a product (by reference to Maintenance and Reliever therapy [MART] in the context of increasing MART prescribing) on the SENTINEL plus website, but prescribing information for relevant AstraZeneca medicines and adverse event reporting statement was not provided. The complainant noted that the website is supporting implementation of a guideline focusing on reducing short-acting beta agonist (SABA) usage in favour of MART for appropriate patients. They also alleged that as AstraZeneca's Symbicort Turbohaler 100/6 is long established for MART usage, and that this indirect reference to MART would drive an increase in Symbicort usage. The complainant alleged breaches of clauses 12.9, 12.1, 5.1 and 2.

AstraZeneca Response:
AstraZeneca can confirm that the presentation of information on the SENTINEL plus website, including information about Maintenance and Reliever Therapy (MART), is balanced and does not point towards one specific product. We consider the website to be non-promotional and prescribing information and adverse event reporting is therefore not required. **We, therefore, deny a breach of Clauses 12.1 and 12.9.**

SENTINEL Plus is a website for healthcare professionals (HCPs), predominantly primary care GPs, nurses, and pharmacists, hosting a variety of resources to support improving outcomes for asthma patients and implementation of evidence-based guidelines. It specifically aims to identify and address short-acting beta agonist (SABA) over-use, which has been associated with an increased risk of asthma attack (in rare cases death)(Nwaru B et al., 2020) , and is a significant contributor to carbon emissions. Reducing SABA over-use forms part of the NHS agenda as outlined by the NHS Longterm Plan, Life Sciences Vision and Greener NHS position. AstraZeneca provides this resource to HCPs as a donation. The website was published in January 2022.

MART is an established approach to managing asthma; there are currently 6 inhaler medicines licensed for MART Symbicort (budesonide/formoterol) Turbohaler 200/6 Inhalation powder; Fostair (beclometasone/formoterol) pMDI 100/6; Fobumix (budesonide/formoterol) Easyhaler 160/4; Luforbec (beclometasone/formoterol) pMDI 100/6; Wockair (budesonide/formoterol) inhalation powder 160/4; Duoresp (budesonide/formoterol) Spiromax 160/4.5 including both pressurised Metered Dose Inhalers (pMDIs) and Dry Powder Inhalers (DPIs).

One of the 6 licensed medicines is Symbicort, an AstraZeneca medicine. MART is a form of ICS and LABA treatment (as defined by NICE in 'Diagnosis, Monitoring and Chronic Asthma Management Guidelines'), and is recommended by NICE in its' treatment algorithm without linking to any specific medicine. Guidelines do not specify preference for Symbicort over other licensed medicines for MART.

SENTINEL Plus provides information in five key areas that align with current evidenced based guideline. One of those five areas includes the MART approach. All five interventions are presented in a balanced manner without favouring any specific medicine.

AstraZeneca regard referring to a class of medicines in this context is not encouraging prescription of a specific AstraZeneca product. We therefore deem the website to be non-promotional, and thus prescribing information and adverse event statement is not required. We believe Case AUTH/3172/3/19 aligns with this view where the panel ruled that mention of a class of medication – where there are multiple generics - does not point to one specific brand and as such was deemed non- promotional. We, therefore, deny a breach of Clauses 5.1, 12.1 and 12.9

Summary
We refute the alleged clause breaches in regard to this case. Referencing the MART approach in this instance does not direct to a specific product and does not therefore promote Symbicort. As the website is not promotional, prescribing information and the adverse reporting statement are not required. We believe that we have maintained high standards on this project.

AstraZeneca takes its compliance with the Code and responsibility to uphold confidence in the industry extremely seriously. We refute bringing the pharmaceutical industry into disrepute, not maintaining high standards and therefore deny being in breach of Clauses 2 and 5.1."

PANEL RULING

This case related to allegations regarding AstraZeneca's SENTINEL Plus website which included information about Maintenance and Reliever Therapy (MART). The complainant was concerned that there were multiple implied mentions of AstraZeneca's product Symbicort (by use of the word MART in the context of increasing MART prescribing) on the SENTINEL Plus website but prescribing information and adverse event reporting was not provided.

The Panel noted AstraZeneca submitted that the SENTINEL Plus website was for healthcare professionals, predominantly primary care GPs, nurses, and pharmacists that specifically aimed "to identify and address short-acting beta agonist (SABA) over-use, which has been associated with an increased risk of asthma attack (in rare cases death), and is a significant contributor to carbon emissions".

The homepage of the website described SENTINEL Plus as "a quality improvement package based on the SENTINEL project and developed with the aim of improving outcomes for adult asthma patients through identifying SABA over reliance". It went on to state the project included a package of resources including health professional education, implementation of SENTINEL Plus 'Gold Standard' prescribing practice, targeted asthma reviews, patient support and education, and real-time data monitoring and reporting of asthma care metrics. "The SENTINEL

project" webpage described the project as "a quality improvement initiative undertaken in [named region], supported through a Joint Working Agreement between [named NHS Hospital] and AstraZeneca UK" and included that the SENTINEL project "developed an intervention to implement the local asthma guideline which has a focus on reducing SABA over-reliance and using Maintenance and Reliever Therapy (MART) for appropriate patients".

The Panel noted the broad definition of promotion as set out in Clause 1.17 and further noted that it was possible for material to be promotional without mentioning a specific product. The Panel noted that MART was an asthma treatment plan where one combination inhaler (either dry powder inhalers or metered dose inhalers with an inhaled steroid and formoterol) was used instead of two separate preventer and reliever inhalers. The Panel noted AstraZeneca's submission that MART was an established approach to managing asthma; there were, at the time, six inhaler medicines licensed for MART, one of which was Symbicort. MART was recommended by NICE in its treatment algorithm without linking to any specific medicine and that guidelines did not specify preference for Symbicort.

The Panel noted that the SENTINEL Plus website was described on the home page as 'Funded by AstraZeneca' and co-developed with a named medical school and named NHS trust. The relationship between the parties was not entirely obvious; although it was clear that they were closely aligned. The website stated the relationship to be a joint working agreement and AstraZeneca submitted it provided the website resource to HCPs as a donation.

The Panel did not have the entire website before it but noted that on the webpages provided the role of AstraZeneca was stated. AstraZeneca submitted that the website was non promotional and thus did not require prescribing information or the adverse event reporting statement.

The Panel considered that reference to MART was in effect a reference to a treatment plan using certain combination inhalers. AstraZeneca's Symbicort was one of six combination therapies available. Neither the published clinical guidance nor the webpages provided referred to specific medicines. The Panel did not have a copy of the local asthma guideline which the joint working project was designed to implement. The Panel noted that implementation of a MART treatment plan might increase the prescribing of certain combination therapies including Symbicort. The Panel did not know how health professionals were directed to the website and queried how those health professionals based within the region the SENTINEL initiative was undertaken in might be aware of it.

The Panel noted that the complainant bore the burden of proof. On balance and based on the limited material and information before it, the Panel did not consider that the webpages at issue on the SENTINEL Plus website were promotional; as such, prescribing information and the adverse event reporting statement were not required as alleged. **No breach of Clauses 2, 5.1, 12.1 and 12.9** were ruled.

Complaint received **29 August 2023**

Case completed **8 November 2024**