CASE AUTH/3664/6/22

COMPLAINANT/DIRECTOR v ASTRAZENECA

Promotional email for Symbicort Turbohaler and alleged breach of undertaking

CASE SUMMARY

This case was in relation to an email with the subject line, 'AstraZeneca promotional email: Symbicort Turbohaler – Device matters when prescribing MART' and an alleged breach of the undertaking given in Case AUTH/1800/2/06.

The Panel ruled a breach of the following Clauses of the 2021 Code as the non-proprietary name was not present immediately adjacent to the brand name at its first appearance in the email and the Panel was concerned about the arrangements for the certification of the email in question:

Breach of Clause 5.1	**Failing to maintain high standards**
Breach of Clause 12.3	**For electronic advertisements, the non-proprietary name of the medicine must appear immediately adjacent to the brand name at its first appearance**

The Panel ruled no breach of the following Clauses of the 2021 Code in relation to the alleged breach of undertaking given in Case AUTH/1800/2/06 as the Panel considered that it was sufficiently different to this current case, including that it related to the actions of a representative:

No Breach of Clause 2	**Requirement that activities or material must not bring discredit upon, or reduce confidence in, the pharmaceutical industry**
No Breach of Clause 3.3	**Requirement to comply with an undertaking**
No Breach of Clause 5.1	**Requirement to maintain high standards**

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 a Symbicort Turbohaler (budesonide, formoterol fumarate) promotional email.

The complaint was also taken up in the name of the Director as the Authority was responsible for ensuring compliance with undertakings.

COMPLAINT

The complainant alleged that in the subject line of the promotional email, the brand name was mentioned without the generic name present, in breach of Clause 12.3.

The complainant alleged that this had previously occurred, almost identically, in Case AUTH/1800/2/06 where again the generic name was missed in the header of an email. The complainant alleged that this repeat would be in breach of Clause 3.3

The complainant asked the Authority to consider Clause 5.1.

When writing to AstraZeneca, the Authority asked it to consider the requirements of Clauses 3.3, 5.1 and 12.3 of the Code as cited by the complainant, and, in addition, Clause 2, in relation to the alleged breach of undertaking.

RESPONSE

AstraZeneca stated that the complainant's allegations could be broken down as follows:

1. In the subject line, the brand name was mentioned without non-proprietary name
2. Breach of undertaking (Case AUTH/1800/2/06)

AstraZeneca submitted that its response to these allegations would establish that:

- AstraZeneca regretted that the non-proprietary name was not included adjacent to the brand name in the subject line (at first mention) of the email.
- There had not been a breach of undertaking from Case AUTH/1800/2/06.

AstraZeneca would address each of the complainant's allegations below.

Background

AstraZeneca submitted that the email (GB-36390) was created by AstraZeneca UK in order to legitimately promote Symbicort Turbohaler to appropriate healthcare professionals (HCPs). AstraZeneca had contracted with a named media agency for them to deliver appropriate promotional content to HCP subscribers who had specifically consented to receiving promotional content from pharmaceutical companies. [Named media agency] sent the email on behalf of AstraZeneca only to those HCPs who had consented to being sent promotional emails, with AstraZeneca involvement being clear from the outset.

AstraZeneca materials generally underwent three review cycles:

1. Review
2. Pre-certification approval
3. Certification

AstraZeneca stated that the material subject to this complaint was certified by [named doctor] 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. The medical expertise of these individuals was confirmed annually by the GMC and they participated in a weekly signatory Code Clinic to understand challenging cases, acquire new knowledge and benefit from colleagues' perspectives. The [named agency's] signatories also attended a monthly Code Case Forum (providing an opportunity to share best practice), had daily access to colleagues and the Medical Director to sense check any grey areas of Code in direct relation to any job bags being worked on, and received regular guidance and feedback.

AstraZeneca Response

1. In the subject line, the brand name was mentioned without non-proprietary name

AstraZeneca submitted that at the first review round, the meta-data information sheet on Veeva described the promotional intentions, the audience, and the method of dissemination. At the top of the email, there was a disclaimer describing explicitly that:

- The email had been sent by PULSE but contained third party promotional information
- Intended audience was only for UK HCPs
- Clear instructions up front as to how to unsubscribe from any future mailings.

In the first review round, the email subject line stated, '**AstraZeneca promotional email: Webinar invitation - Asthma - How SMART is MART? Improving Asthma and Environmental outcomes'** and AstraZeneca believed that the content was code compliant. The subject line was amended to include the brand name following the review round, before the pre-certification approval stage. The pre-certification subject line stated: '**AstraZeneca promotional email: Symbicort Turbohaler – Device matters when prescribing MART'.**

AstraZeneca submitted that whilst it acknowledged the non-proprietary name was not included in the subject line, the brand name and non-proprietary name did appear most prominently at the top of the email. The subject line also included, 'AstraZeneca promotional email' so the intent of the email was clear. There was also a statement at the top of the email which provided the location of the prescribing information; single click links were provided for both Symbicort and Bricanyl products.

Omission of the non-proprietary name in the subject line, where a brand name was introduced, arose for several reasons:

i) The subject line of the email was altered at pre-certification round, whereby the materials had already undergone a thorough review and had been deemed code complaint (where no branding / drug appeared in the subject line). This was in line with the AstraZeneca Materials Management SOP (changes could be made prior to pre-certification approval), however AstraZeneca acknowledged that it was best practice that the material owner flags any changes with the reviewer / signatory team. Unfortunately, this did not happen in this instance, and had been raised with the brand teams following this complaint.

ii) The nominated signatory responsible for certifying the material was an experienced signatory and was not made aware of the change to the subject line following his/her approval at review round. At certification, he/she had checked the final version against the previously approved version and confirmed that no alterations had been made to the email content itself. He/she did not realise that the attachments had been amended, to

include the amended final form (ie email to be sent) with the new subject line. The subject line content had also been changed in the meta-data.

AstraZeneca stated that it acknowledged that in electronic advertisements, the non-proprietary name must appear immediately adjacent to the brand name at first appearance. AstraZeneca regretted that this was not the case in this email. AstraZeneca therefore accepted a breach of Clause 12.3.

AstraZeneca stated that it did not believe this email breached Clause 5.1, as permission was always sought prior to sending promotional emails and the promotional intent of the email was clear from the subject line. A statement at the top of the email clarified the email was intended for UK HCPs, not to be forwarded, and clarified why the recipient was receiving the email as they had opted-in to receive promotional information from pharmaceutical companies. This was followed with a statement on the location of the prescribing information within the email. Single click links were provided to the prescribing information for Symbicort and Bricanyl. Adverse event reporting information and an unsubscribe link were included at the bottom of the email. Given how explicit the email was in nature, with the reputable agencies involved, AstraZeneca did not concur that offence was caused by this omission. AstraZeneca therefore denied a breach of Clause 5.1.

2. Breach of undertaking (Case AUTH/1800/2/06)

With regards to Case AUTH/1800/2/06 ('the 2006 Case') which took place 16 years ago, an AstraZeneca sales representative sent an uncertified promotional email to an HCP. AstraZeneca submitted that this was a radically different set of facts to the ones present in this case and so it was clear from the outset that an allegation of a breach of undertaking was not relevant.

AstraZeneca submitted that in the 2006 Case, the complaint concerned an issue with the body of the email and not the subject line. The email in the 2006 Case did not include the non-proprietary name and prescribing information (PI). This oversight was due to both a significant IT upgrade occurring at the time and a lack of code knowledge of the sales representative. Since 2006, in compliance with the undertaking given, AstraZeneca had made significant efforts to ensure similar oversights would be avoided including: introducing new IT document management systems which did not allow sales representatives to access material before certification; mandatory training on the aforementioned IT systems for all users including sales representatives; and at least annual mandatory training on the Code for all appropriate staff including sales representatives.

In this case the email was certified, and both non-proprietary names and PI were included in the body of the email. AstraZeneca did not agree that there had been a breach of the undertaking given in the 2006 Case. Therefore, AstraZeneca refuted the allegation of breaches of Clauses 2 and 3.3.

Summary of AstraZeneca's position

It was AstraZeneca's position that there had been an unfortunate, human error made in this instance which had resulted in the exclusion of the non-proprietary name immediately adjacent to the brand name at first appearance. Therefore, AstraZeneca accepted a breach of Clause 12.3. In AstraZeneca s extensive internal investigation, the company found no evidence that

similar errors had occurred in five other emails created and distributed with PULSE in 2022. In addition, AstraZeneca maintained that the oversights which occurred in the 2006 case did not occur in this case and that the 2006 case related to a radically different set of circumstances: AstraZeneca refuted a breach of undertaking and the related allegations of breaches of Clauses 2 and 3.3.

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

PANEL RULING

The Panel noted that the subject line of the email in question stated: 'AstraZeneca promotional email: Symbicort Turbohaler – Device matters when prescribing MART'. Near the top of the body of the email was the Symbicort Turbohaler logo, which stated the non-proprietary name (budesonide/formoterol).

Clause 12.3 of the Code stated, amongst other things, that for electronic advertisements, 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 in a size such that the information is easily readable.

The Panel noted that the subject line of the email was the first appearance of the brand name for the promotional material in question; it might also be the only part of the material read by recipients. The Panel considered that the non-proprietary name was not present immediately adjacent to the brand name at its first appearance in the email in question and **a breach of Clause 12.3** was ruled as acknowledged by AstraZeneca.

The Panel was concerned that the document certified did not include the subject line of the email as a part of the final form of the material uploaded for certification. Given that the subject line was the first, and might be the only, information read by the recipient, the Panel considered that it was a fundamental part of the promotional material and queried why a signatory would need to open a separate attachment in the electronic approval system to view and approve it; in the Panel's view, the email subject line should be an integral part of the final form of the material uploaded to the approval system for certification by the signatory and should not just be referenced in the meta-data or attached as an associated document. The Panel considered that the arrangements were such that AstraZeneca had failed to maintain high standards and **a breach of Clause 5.1** was ruled.

With regard to the alleged breach of undertaking given in Case AUTH/1800/2/06, the Panel noted that that case related to an uncertified invitation to a gastroenterology meeting, emailed by a representative, which referred to Nexium. In that case, Nexium was mentioned within the email and its attachment (an agenda), with no mention of the generic name (esomeprazole), and no prescribing information; AstraZeneca was found in breach of Clauses 4.1 and 4.3 of the 2003 Code.

Turning to the current case, Case AUTH/3664/6/22, the Panel noted the material had been certified, distributed by a third party provider and contained prescribing information.

That a similar clause had been ruled in breach of the Code across both cases for the omission of the non-proprietary name immediately adjacent to the brand name at its first appearance did

not necessarily mean that the current case was automatically in breach of an undertaking. Whether a case was in breach of an undertaking depended on a consideration of all the circumstances and each case should be looked at on its individual merits. The nature of the materials/activities in question and the steps taken to avoid similar breaches in the future would be relevant.

The Panel noted the steps taken by AstraZeneca following Case AUTH/1800/2/06 to comply with its undertaking which included:

- introducing new IT document management systems which did not allow sales representatives to access material before certification;
- mandatory training on the aforementioned IT systems for all users including sales representatives;
- and at least annual mandatory training on the Code for all appropriate staff including sales representatives.

Noting its comments above about the two cases, and the steps taken by AstraZeneca to comply with its undertaking given in Case AUTH/1800/2/06, the Panel, particularly noting that the actions in Case AUTH/1800/2/06 related to those of a representative, considered that the cases were sufficiently different such that AstraZeneca was not in breach of the undertaking given in Case AUTH/1800/2/06, and thus **no breach of Clause 3.3** was ruled. The Panel consequently ruled **no breach of Clause 5.1 and Clause 2 in this regard**.

Complaint received **21 June 2022**

Case completed **8 June 2023**