

CASE AUTH/3769/5/23

COMPLAINANT/DIRECTOR v ASTRAZENECA

Alleged breach of undertaking

CASE SUMMARY

A complaint was received following the publication of Case AUTH/3585/11/21, in which AstraZeneca was found, among other things, to have breached Clause 12.1 of the Code by not providing Symbicort prescribing information on certain pages of the Trixeo website, including the homepage, where Symbicort was mentioned by its non-proprietary name. The complainant alleged that this was a breach of undertaking because AstraZeneca had previously (Case AUTH/3488/3/21) been found in breach of Clause 4.1 of the 2019 Code for lack of Symbicort prescribing information on the same Trixeo website.

The outcome under the 2021 Code was:

Breach of Clause 2	Bringing discredit upon, and reducing confidence in, the pharmaceutical industry
Breach of Clause 3.3	Failing to comply with an undertaking
Breach of Clause 5.1	Failing 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 about AstraZeneca. The complaint concerned an alleged breach of undertaking. As the PMCPA was responsible for ensuring compliance with undertakings, the complaint was also taken up in the name of the Director.

COMPLAINT

The complaint wording is reproduced below.

'There had been a major breach of undertaking in respect to the Trixeo product Website, which mentioned Symbicort by generic name on the home page but did not provide the prescribing information for Symbicort. In case AUTH/3488/3/21, Symbicort was mentioned on the Trixeo website homepage by generic name and no prescribing information was provided for Symbicort. The panel ruled a breach of clause 4.1 as a result in AUTH/3488/3/21. The exact same website was then put back up live in a short time span with the same compliance breach, whereby Symbicort was again mentioned by the generic name on the Trixeo website homepage, but prescribing information was not provided. A breach of clause 12.1

was ruled again in AUTH/3585/11/21. In the initial case, AUTH/3488/3/21, AZ [AstraZeneca] had incorrectly argued that Symbicort mention by generic name only did not require prescribing information. However, it was very concerning that despite the panel ruling a breach and then AZ signing an undertaking, the exact compliance breach then took place in case AUTH/3585/11/21 in regards to the Trixeo website aspect of this case. In case AUTH/3585/11/21, AZ argued yet again that symbicort mention by generic name on the Trixeo homepage website did not need prescribing information which was concerning, considering an undertaking was in place not so long before around the exact same breach took place as per Case AUTH/3488/3/21. Self-regulation relied heavily on undertakings and this was a clear example where the panel rulings, case precedent and the spirit of the code had been totally ignored. As there had been inadequate action to prevent a breach of undertaking and the lack of symbicort prescribing information had happened in quick succession after a breach on the exact same website, clauses 3.3, 5.1 and 2 had been breached. How could the same compliance breach have [happened] a second time if the undertaking had been communicated to reviewers? How could the same breach have happened so quickly despite the panel ruling in the initial case?’

When writing to AstraZeneca, the PMCPA asked it to consider the requirements of Clauses 3.3, 5.1 and 2 of the Code.

ASTRAZENECA’S RESPONSE

The response from AstraZeneca is reproduced below.

‘The complainant refers to two previous cases which had been carefully considered by the PMCPA and closed, AUTH/3488/3/21 and AUTH/3585/11/21, in chronological order.

In both cases, AstraZeneca accepted Panel rulings and related breaches, and took actions to avoid similar breaches in the future including mandatory training of all relevant staff (details included in appendix). In case AUTH/3585/11/21, AstraZeneca acknowledged the oversight in not including the Symbicort prescribing information, and voluntarily accepted breaches of Clauses 12.1 and 12.4 in its initial response to the PMCPA ahead of Panel rulings.

It is AstraZeneca’s understanding that the complainant has not introduced any new information or evidence which would change the outcome of these historical cases. In addition, the current website which was live at the time of this complaint is fully compliant with the Code and specifically includes the Symbicort prescribing information where required. The website can be accessed at [website URL provided]

AstraZeneca therefore refutes breaches of Clauses 3.3, 5.1, and 2 of the Code.

Summary

In summary, AstraZeneca co-operated fully with the PMCPA on cases AUTH/3488/3/21 and AUTH/3585/11/21, accepted Panel rulings and breaches, and took actions to avoid similar breaches. AstraZeneca does not have, nor has the complainant provided, any additional information which the PMCPA did not consider

when reviewing the above cases. AstraZeneca therefore refutes breaches of Clauses 3.3, 5.1, and 2 of the Code.

AstraZeneca takes all allegations of non-compliance seriously and always strive to learn from any mistakes made, and implement the knowledge learnt into future practices.'

PANEL RULING

The Panel noted AstraZeneca's submission that the Triexo website live at the time this complaint (Case AUTH/3769/5/23) was made in May 2023 included Symbicort prescribing information. The Panel considered that there were no allegations in relation to the website that was live on the date this complaint was made and therefore made no ruling in this regard.

This complaint was received following the publication of the case report for Case AUTH/3585/11/21, in which AstraZeneca was found, among other things, to have breached Clause 12.1 of the Code by not providing Symbicort prescribing information on certain pages of the Triexo website, including the homepage, where Symbicort was mentioned by its non-proprietary name. The complainant alleged that this was a breach of undertaking because AstraZeneca had previously been found in breach of Clause 4.1 of the 2019 Code in Case AUTH/3488/3/21 for lack of Symbicort prescribing information on the same Triexo website.

The Panel noted AstraZeneca's submission that no new information or evidence had been provided that would change the outcome of the completed cases. The Panel noted that the complainant in Case AUTH/3585/11/21 had not alleged a breach of undertaking. The Constitution and Procedure did not allow the Panel to rule upon matters which were not the subject of a complaint and so the Panel could not rule upon a potential breach of undertaking in Case AUTH/3585/11/21. A breach of undertaking had been alleged in this case (Case AUTH/3769/5/23) and therefore the Panel was able to consider and rule on the matter.

The Panel noted that the two cases referred to by the complainant were in relation to the Triexo promotional website. In Case AUTH/3488/3/21, the Panel ruled, among other things, that AstraZeneca had breached Clause 4.1 of the 2019 Code by not including prescribing information for Symbicort, which was mentioned on the website homepage by its non-proprietary name. AstraZeneca signed an undertaking in September 2021 that gave an assurance that it would take all possible steps to avoid similar breaches of the Code occurring in the future. The complaint in Case AUTH/3585/11/21 was received two months later, in November 2021. In Case AUTH/3585/11/21, the Panel ruled, among other things, a breach of Clause 12.1 of the 2021 Code in relation to not including the Symbicort prescribing information on certain pages of the Triexo website, including the homepage, where it had been referred to by its non-proprietary name.

The Panel considered that not including Symbicort prescribing information on the Triexo website homepage that was live at the time of the complaint in November 2021 (Case AUTH/3585/11/21), where Symbicort was referred to by its non-proprietary name, breached the undertaking given in September 2021 for Case AUTH/3488/3/21; the Panel therefore ruled a **breach of Clause 3.3**.

The Panel considered that an undertaking was an important document and by failing to comply with it, AstraZeneca had failed to maintain high standards. The Panel ruled **a breach of Clause 5.1**.

The supplementary information to Clause 2 included inadequate action leading to a breach of undertaking as an example of an activity likely to be in breach of Clause 2. AstraZeneca submitted that it had taken action following Cases AUTH/3488/3/21 and AUTH/3585/11/21 to avoid similar breaches in the future and provided a report showing that certain staff had completed mandatory training on Case AUTH/3488/3/21 in mid-December 2021. The Panel noted that AstraZeneca signed the undertaking relating to Case AUTH/3488/3/21 in September 2021 and the complaint for Case AUTH/3585/11/21 was received in November 2021; therefore, the mandatory staff training on Case AUTH/3488/3/21 in December 2021 did not take place until after receipt of the complaint for Case AUTH/3585/11/21. The Panel considered that it had no evidence before it that AstraZeneca had taken all possible steps following Case AUTH/3488/3/21 to avoid similar breaches of the Code in the future, as required by the undertaking signed in September 2021. The Panel noted that a form of undertaking and assurance was an important document that underpinned self-regulation. Companies had to give an undertaking that all possible steps would be taken to avoid similar breaches of the Code in future (Paragraph 7.1 of the Constitution and Procedure). It was very important for the reputation of the industry that companies complied with undertakings. The Panel considered that AstraZeneca's failure to comply with the undertaking and assurance given in Case AUTH/3488/3/21 had brought discredit upon and reduced confidence in the pharmaceutical industry. The Panel ruled **a breach of Clause 2**.

Complaint received **22 May 2023**

Case completed **15 April 2024**