CASE AUTH/3919/6/24

COMPLAINANT v ASTRAZENECA

Allegations about a product website for members of the public

CASE SUMMARY

This case was in relation to a list of medicines on AstraZeneca's corporate website. The complainant alleged that the list contained errors related to the presence or absence of the black triangle symbol, and that one medicine was missing from the list.

The outcome under the 2021 Code was:

Breach of Clause 26.2	**Providing inaccurate information for the public**

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 at all times**
No Breach of Clause 9.1	**Requirement that all relevant personnel concerned with the preparation or approval of material or activities covered by the Code must be fully conversant with the Code and the relevant laws and regulations**
No Breach of Clause 26.2	**Requirement that information about prescription only medicines which is made available to the public must be factual, balanced, must not raise unfounded hopes of successful treatment or encourage the public to ask their health professional to prescribe a specific prescription only medicine**
No Breach of Clause 26.4	**Requirement to include the black triangle in material which relates to a medicine subject to additional monitoring and that is intended for patients taking that medicine**

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 about AstraZeneca UK Limited was received from an anonymous, contactable complainant who described themselves as a clinician.

COMPLAINT

The complaint wording is reproduced below with some typographical errors corrected:

> "I am reporting the risks to patient safety posed by a previous AstraZeneca product website containing reference information for patients. The website code number is GB-44613 & was launched in May 2023 and was updated to GB 39695 in November 2023.
>
> From the GB-44613 website, the attachments reveal a complete disregard to patient safety with sometimes missing, and at other times incorrect use of, the blank triangle.
>
> [Screenshot 1] shows the website is for patients and the public
> [Screenshot 2] shows when the website was launched ie May 2023
> [Screenshot 3] shows the disclaimer
> [Screenshot 4] shows how Calquence (an AZ medicine for CLL) is missing the very important black triangle. Clauses related to the black triangle, a failure to maintain high standards, and a clause 2 for compromising patient safety should be applied. This website was updated in Nov 2023 so until this time Calquence has had a missing black triangle. A complete risk to patient safety.
>
> Fasenra & Lokelma – two other AZ medicines have the black triangle on the GB-44613 website, incorrectly as the SPCs show that these should not be included.
>
> Most important of all for the GB44613 website is the fact that Imjudo (an AZ medicine) licensed for HCC and other cancers on the 6th June 2023 is completely missing from the GB44613 website which was live from May to November 2023. So for 6 months an AZ medicines reference information for the public was completely missing. This is highly concerning for a black triangle drug.
>
> Such major breaches of the Code compromise patient safety and erode trust in AZ and the pharmaceutical industry. For such a leading Oncology & Haematology company that claims to put patients first, this was not a great showing.
>
> As a clinician in my view the following clauses and context needs consideration and application
>
> 1. Two separate Clause 2 breaches for compromising patient safety in Haematology and GI cancers
> 2. Two separate audits of AZ procedures as to why patient safety is such an after thought
> 3. Two separate breaches for missing black triangles & for including black triangles elsewhere when not needed.
> 4. Two separate clauses for a failure to maintain any or high standards
> 5. Two reprimands, audits and undertaking for the undoubted risk to patient safety.
>
> A full audit of AZ SOPs and internal procedures is necessary as the extent of confusion with the other products where the black triangle still remains despite being no longer required e.g. with Fasenra and Lokelma.

Compliance training for [references to AstraZeneca roles] to instil a more compliant patient centric culture."

When writing to AstraZeneca, the PMCPA asked it to consider the requirements of Clauses 26.2, 26.4, 9.1, 5.1 and 2 of the 2021 Code.

ASTRAZENECA'S RESPONSE

The response from AstraZeneca is reproduced below:

"Thank you for your letter dated 10 June 2024, from a complainant who describes themselves as a clinician. The complaint is in relation to the astrazeneca.co.uk website live between May 2023 and November 2023, and specifically alleges the following:

1. Calquence is missing the black triangle
2. Fasenra and Lokelma have the black triangle included, although no longer required
3. Reference information for Imjudo was missing

The following clauses of the ABPI Code (the 'Code') have been alleged: 26.4, 26.2, 9.1, 5.1 and 2. AstraZeneca (AZ) will respond to each of the allegations below.

Background

Astrazeneca.co.uk is a corporate website for the AstraZeneca UK Marketing Company. It is intended for members of the public. The website address is included in corporate materials.

The astrazeneca.co.uk website has corporate information about the UK Marketing Company, including ongoing partnerships with organisations, information about our therapy areas, list of medicines, sustainability agenda, available donations and career opportunities. There is also a section intended for media where relevant articles and the latest UK press releases are hosted.

The medicines webpage section is the subject to this complaint. Each webpage on the website has a unique job code. The job number provided by the complainant is for the website landing page (GB-44613). The medicines webpage provided by the complainant was approved in July 2023 (GB-47059).

July 2023 – November 2023

The medicines webpage (GB-47059) included a list of AZ medicines, with an adjacent link to the relevant Summary of Product Characteristics (SPC) hosted on the electronic medicines compendium (EMC). Prior to November 2023, changes to the medicines page were requested by the AZ regulatory team, implemented by the Communications team, and approved by the Nominated Signatory before being made live. The Nominated Signatory who approved the material in July 2023 is a GPhC registered pharmacist.

There is a clear disclaimer at the top of the medicines webpage, stating that the information is intended for members of the public.

From November 2023
In 2023, as part of our regular review, AZ recognised the potential risk associated with the medicines webpage being kept up to date. As a result, the list of medicines was removed and a link to the AZ medicines list on EMC was included instead. The information related to medicines is automatically updated on EMC following a regulatory update.

This change was made and the new medicines webpage certified in November 2023 (GB-39695). Any regulatory changes to the information associated with medicines, including presence/removal of black triangles, are now automatically updated on EMC.

AstraZeneca's response to allegations against astrazeneca.co.uk

The Code states that when required by the licensing authority, promotional material and materials for patients include an inverted black triangle to denote that additional monitoring is required in relation to adverse reactions. This black triangle should appear once and located adjacent to the most prominent display of the name of the product. As outlined above, astrazeneca.co.uk is a corporate website for the UK Marketing Company, intended for members of the public. The intended audience is made clear via disclaimer at the top of the medicines webpage. As a non-promotional website intended for public audience, the black triangle requirements of the Code do not apply. **AZ therefore denies breach of clause 26.4.**

We acknowledge that inclusion of the black triangle may be considered good practice, even if it is not a Code requirement in materials for general public. In this instance, we accept it was missing from Calquence and incorrectly included for Fasenra and Lokelma, however once the reader clicked through to the SPC (via a direct, single click link adjacent to the medicine name), the black triangle (or lack of) was clearly visible. Despite this, we understand that information provided on our websites (including inclusion of black triangles) should be accurate and up to date. This potential risk was recognised in 2023, and addressed as outlined above. From November 2023, information about our medicines (with inclusion of the black triangle) is always completely up to date. We believe that the actions taken in November 2023 to improve the governance of this webpage demonstrates that **AZ have upheld high standards** and is within the spirit of self-regulation.

The medicines webpage subject to complaint listed AZ medicine names and linked directly to reference information (SPC hosted on EMC) as permitted by clause 26.2 of the Code. There was no additional information about that medicine on the webpage, and therefore the information is entirely non-promotional and suitable for public viewing. **AstraZeneca therefore refute breach of clause 26.2**.

Imjudo gained marketing authorisation on 6th June 2023. It was not added to the medicines webpage list in the July 2023 update. The Code does not mandate that the company website hosts reference information for all of their medicines on the company website (26.2 SI 'When companies decide to make reference information available….'). The medicines webpage does not state that all AZ medicines are listed. As previously

mentioned, the website now links directly to the AZ medicine list on EMC, so we have eliminated the potential of this being missed in the future. **AZ strongly deny that this culminates in any breach of the Code**.

AstraZeneca has a robust training program for employees to ensure that relevant personnel are conversant with the Code and relevant regulations. This includes quarterly PMCPA Code Case reviews, mandatory compliance training for Marketing, Medical (including nominated signatories), Compliance, Legal, Market Access, Corporate and Government affairs and Digital teams, to attend. There are also fortnightly 'code condensed' posts on our internal communication platform workplace, summarising recent code cases of interest. This training includes AZ Medical Leaders, Heads of Commercial and MSLs mentioned in the complainant's letter, and therefore we strongly disagree with complainant's comments on AZ's compliance culture. We ascertain that sufficient training is available to the relevant members of staff, and therefore **deny breach of 9.1**.

In summary, AstraZeneca takes its obligations under the ABPI Code of Practice very seriously and has internal processes in place to ensure that we uphold high ethical standards and in line with the ABPI code.

AstraZeneca has not posed any risk to patient safety, and has maintained high standards throughout as set out above. In addition, the material subject to complaint is no longer accessible by members of the public (since November 2023). **We therefore strongly refute breach of clauses 5.1 and 2**.

Summary

In response to the allegations relating to the astrazeneca.co.uk medicines webpage:

1. Calquence was missing a black triangle: The Code requirements for inclusion of the black triangle are not applicable for non-promotional public facing materials.
2. Fasenra and Lokelma have the black triangle included, although no longer required: The Code requirements for inclusion of the black triangle are not applicable for non-promotional public facing materials. In addition, additional monitoring with black triangle would not have resulted in any patient safety issues.
3. Reference information for Imjudo was missing: It is not mandatory to include reference information for company medicines on the company website.

The work undertaken by AZ to update the website, after recognising the potential risk of the medicines page requiring frequent updating as detailed in our response, is a demonstration of AZ's commitment to ensuring the highest standards possible for those who access our corporate webpages.

In conclusion, **AstraZeneca strongly refutes all alleged breaches of the Code**.

We would like to highlight that the version of the medicines webpage subject to complaint has not been publicly accessible since November 2023, indicating that the complainant waited for at least 8 months before submitting this complaint. This is

surprising given that patient safety is highlighted by the complainant as the key concern. We believe that it is clear that this complaint is vexatious in nature and has not been made in good faith – it is not in the spirit of the Code."

PANEL RULING

This complaint was in relation to AstraZeneca's corporate website. The complainant provided screenshots that appeared to be from the landing and medicines pages of the corporate website and several search results from the electronic medicines compendium ("emc") website. However, the Panel interpreted the allegations to be solely about the medicines webpage that included a list of medicines marketed by AstraZeneca, with links to the relevant summaries of product characteristics on the emc website. The Panel restricted its rulings to this webpage only.

The complainant alleged that, between May 2023 and November 2023, the webpage contained the following errors:

1. Calquence (acalabrutinib) was listed without the required black triangle symbol.
2. Fasenra (benralizumab) and Lokelma (sodium zirconium cyclosilicate) were both listed with a black triangle when neither required it.
3. Imjudo (tremelimumab), a black triangle product, was missing from the webpage.

Clause 26.4

The Panel noted that Clause 26.4 has two limbs to it. The first is that "*Any material which relates to a medicine and which is intended for patients taking that medicine*" (Panel's emphasis) must include a statement about reporting side effects. The second limb of this clause begins "*When the material relates to a medicine which is subject to additional monitoring, an inverted black equilateral triangle must be included together with the statement below…"*.

The second limb's reference to "*the material*" relates back to the first limb wording: "*Any material … intended for patients taking that medicine*". In other words, the black triangle requirement of Clause 26.4 applies to material intended for patients taking that medicine.

The Panel concluded that, as the webpage in question was not specifically intended for patients taking the medicine, Clause 26.4 did not apply and there was therefore no requirement for a black triangle to be included. On that basis, the Panel ruled **no breach of Clause 26.4**.

Clause 26.2

The Panel considered the relevant requirement of this clause, for the purpose of this case, to be "*Information about prescription only medicines which is made available to the public … must be factual … It must not … be misleading with respect to the safety of the product*."

AstraZeneca acknowledged that the black triangle was missing from Calquence, and incorrectly included for Fasenra and Lokelma.

The Panel decided to treat the three medicines that were incorrect as regards their black triangle status as one matter/allegation in this case. In doing so, the Panel had regard to the overriding objective in the PMCPA Constitution and Procedure, which requires cases to be dealt

with fairly and justly. In particular, the Panel relied upon the requirement to deal with cases "*in ways which are proportionate to the importance of the case and the complexity of the issues*".

In the Panel's view, irrespective of the fact that black triangle information was not a requirement on the webpage at issue, once AstraZeneca had decided to include this information, Clause 26.2 required that the information provided to the public was accurate and not misleading about the safety of products. The Panel considered that not including the black triangle symbol for Calquence (when it had been included for other medicines on the webpage) implied that Calquence was not subject to additional monitoring, which was not the case. The Panel considered that erroneously including the black triangle symbol for Fasenra and Lokelma could also potentially cause confusion.

The Panel therefore ruled a **breach of Clause 26.2** in relation to Calquence, Fasenra and Lokelma.

Regarding the complainant's allegation about Imjudo not being included in the list of medicines on the webpage, the Panel considered that there was no Code requirement for companies to provide such reference information. The Panel noted that this was a corporate website intended for the public, with corporate information relating to the UK marketing company. It also included information about ongoing partnerships with organisations, therapy areas, a list of medicines, sustainability agenda, available donations, career opportunities and a media section. The supplementary information to Clause 26.2 (under the heading "Information to the Public"), stated that pharmaceutical companies were not obliged to provide reference information, although it may be good practice to do so in certain situations. The Panel also acknowledged that there was nothing on the webpage that stated that the list of medicines was a complete list of every AstraZeneca medicine. The Panel therefore ruled **no breach of Clause 26.2** in relation to Imjudo.

Clause 9.1

Clause 9.1 required that "*All relevant personnel … concerned in any way with the preparation or approval of material or activities covered by the Code must be fully conversant with the Code and the relevant laws and regulations*".

The complainant had the burden of proving their complaint on the balance of probabilities. All complaints were judged on the evidence provided by the parties. In this case, the Panel did not consider that the complainant had made out a clear allegation, nor had they provided any evidence, to substantiate their allegation of a breach of this clause. Although there had been errors on the webpages (that led to the breach of Clause 26.2 above), that did not automatically mean that there must be personnel that were not conversant with the Code. It was not for the Panel to make out a complainant's case for them.

In its response to this complaint, AstraZeneca provided details of its training and compliance programme. AstraZeneca submitted that the job roles listed in the complainant's comment about compliance training *were* included in AstraZeneca's training programme.

The Panel concluded that the complainant had failed to satisfy their burden of proof in relation to this clause and the Panel ruled **no breach of Clause 9.1**.

Clauses 5.1 and 2

In relation to the allegation that AstraZeneca had failed to maintain high standards and/or had brought discredit upon, or reduced confidence in, the pharmaceutical industry, the Panel considered and accepted the following factors:

1. The webpage was part of a corporate, non-promotional website intended for members of the public. It was not aimed at patients taking the medicines, nor prescribers. It was merely a list of AstraZeneca's medicines.
2. AstraZeneca had itself recognised (before receiving this complaint) that such a list of medicines was difficult to keep up-to-date and it had proactively addressed this issue by replacing the list with a link to the live list of AstraZeneca's medicines in Great Britain and Northern Ireland on the emc website.
3. There was no Code requirement for the black triangle symbol to be included in this type of material, and the Panel had ruled no breach of Clause 26.4 above.
4. There was no Code requirement for companies to provide reference information about their medicines, and the Panel had ruled no breach of Clause 26.2 above in relation to Imjudo.
5. Although three medicines on the webpage were presented incorrectly with regard to the black triangle symbol, there was a link to the summary of product characteristics on the emc website for each medicine, which would have had the correct information.
6. Given the Panel considered this matter was not likely to result in a patient being harmed, the Panel concluded that a breach of Clause 26.2 was sufficient in relation to this case.

In light of these considerations, the Panel ruled **no breaches of Clause 5.1 and Clause 2**.

Complaint received **5 June 2024**

Case completed **30 June 2025**