

CASE AUTH/3587/12/21

COMPLAINANT v ASTRAZENECA

Promotion of Symbicort and alleged breach of undertaking

An anonymous complainant who described him/herself as a health professional complained about the promotion of Symbicort (budesonide formoterol fumarate dihydrate) by AstraZeneca. The material at issue was a webpage.

The complainant was concerned that AstraZeneca had not provided prescribing information or the generic name adjacent to brand mention for Symbicort. The complainant also alleged that the spirit of the Code was also not met by a breach of undertaking.

The complainant provided a link to a promotional page with cost claims about Symbicort Turbohaler and although price and brand name were mentioned with great frequency, no generic name was provided next to any of the 3 mentions of Symbicort and no prescribing information was available. The complainant alleged breaches of the Code including Clause 2. If a disclaimer was clicked on to say read and accepted, this then moved onto showing a graph with Symbicort prices (GB-25816: February 2021) with % discount quarter.

The complainant stated however, no generic name or prescribing information was available for this promotional graph. This was also alleged to be in breach of the Code including Clause 2. The Panel had already found AstraZeneca in breach for not providing prescribing information for Symbicort in a different case (Case AUTH/3488/3/21). The complainant alleged a breach of the undertaking provided from the previous case as the prescribing information for Symbicort was again not provided, alongside an alleged breach of Clause 2 for not obeying the undertaking.

The detailed response from AstraZeneca is given below.

The Panel noted that the complainant had provided a link to the material at issue but provided no information as to how he/she had accessed the material. The case preparation manager downloaded the material from the link and provided it to AstraZeneca when notifying the company of the complaint.

The Panel noted the complainant's allegation that the webpage at issue, a Symbicort cost calculator on the medicines.astrazenca.co.uk website, omitted the non-proprietary name for Symbicort and lacked prescribing information in breach of the undertaking given in Case AUTH/3488/3/21.

The Panel noted AstraZeneca's submission that the webpage at issue was still undergoing approval and had not yet been certified or issued. According to AstraZeneca, the webpage could only be accessed using a specific URL link, it could not

be navigated to via the AZ Medicines website and was not indexed or optimised for search engines.

The Panel noted that the webpage was not restricted in any way and that it could access it without any indication that the webpage was in draft form or was undergoing approval. The Panel noted AstraZeneca's submission that the specific test link was used only by the approval team, was not shared outside the approval system and the webpage could not be accessed by a visitor using search engine terms or through browsing the AstraZeneca website. The Panel further noted AstraZeneca's submission that the link sent to the PMCPA had only ever been accessed by internal AstraZeneca staff members prior to the date of the complaint.

Taking all the factors into account, and on the evidence available before it, the Panel did not consider that the lack of obligatory information on what appeared to be internal material on a staging/test link for draft content amounted to breaches of the Code as alleged. It therefore ruled no breaches of the 2021 Code. The undertaking signed in Case AUTH/3488/3/21 had therefore not been breached, and the Panel ruled no breach of the 2021 Code.

In the Panel's view, companies should ensure that draft promotional material which was only meant for internal use was inaccessible by people outside of the company. Given its rulings and the specific circumstances of this case, the Panel did not consider that there was evidence to show that the company had failed to maintain high standards and no breach of the 2021 Code was ruled. The Panel did not consider the circumstances warranted a ruling of a breach of Clause 2 which was reserved as a sign of particular censure. No breach of the Code was ruled.

Upon appeal by the complainant, the Appeal Board noted that the complainant had the burden of proving his/her complaint on the balance of probabilities. AstraZeneca stated that there had been no evidence of a technical failure and it had checked that the cost calculator could not be accessed directly from its medicine's website nor was it discoverable by searching on Google. The cost calculator was only accessible via a complex link. The Appeal Board noted AstraZeneca's submission that only its review team had access to the cost calculator via the item's job bag; investigations by the company's digital team found that the only recorded external single access to the webpage in question appeared to be consistent with the PMCPA case preparation manager accessing the page via the link in the complaint.

The Appeal Board considered that the complainant had not provided any evidence to show that the cost calculator, that was still undergoing the internal approval process, could be accessed from the AstraZeneca medicines website as alleged. The Appeal Board agreed with the Panel's comments above and upheld its rulings of no breaches of the 2021 Code including Clause 2. The appeal was unsuccessful.

An anonymous complainant who described him/herself as a health professional complained about the promotion of Symbicort (budesonide formoterol fumarate dihydrate) by AstraZeneca. The material at issue was a page on a website.

COMPLAINT

The complainant stated that he/she was concerned that AstraZeneca was not acting in the dignified spirit of the Code in needing to provide prescribing information and providing the generic name adjacent to brand mention for Symbicort. The complainant also alleged that the spirit was also not met by a breach of undertaking.

The complainant referred to a promotional information page with cost claims about Symbicort Turbohaler and a link was provided. The complainant explained that the following disclaimer came up on first access after confirmation as a health professional.

'This is not an inducement to prescribe, supply, administer, recommend, buy or sell medicines by the, gift, offer or promise of any benefit or bonus, whether in money or in kind.

- Please note: VAT IS NOT INCLUDED WITHIN THIS CALCULATOR: VAT will be applied according to the HMRC and the Dept of Health rules
- Please note: THE DISPENSING FEE IS NOT INCLUDED WITHIN THIS CALCULATOR
- Please Note: All Comparisons are for 28 Days treatment at recommended maintenance dose, with prices pro-rated where appropriate.
- Please refer to the individual drug SPC for all dosing guidance.
- Please Note: Volume restrictions are in place based on local need and are limited to the capacity of each individual dispensing practice.
- *Gross Return per Pack per quarter = (List Price - Clawback)-(List Price – Manufactures Dispensing Scheme), Clawback set at [X]%
- Date of Preparation: October 2021, Document Number: GB-31361

Product	List price	Source
Symbicort® Turbohaler 100/6	£28.00	MIMS Oct 2021
Symbicort® Turbohaler 200/6 or 400/12	£28.00	MIMS Oct 2021
Symbicort® Pmdi 200/6	£28.00	MIMS Oct 2021.'

The complainant stated that although price and brand name were mentioned with great frequency, no generic name was provided next to any of the 3 mentions of Symbicort and no prescribing information was available. This seemed a breach of Clauses 12.1, 12.3, 12.4, 12.6, 5.1 and 2. If the disclaimer was clicked on to say read and accepted, this then moved onto showing a graph with Symbicort prices (GB-25816: February 2021) with % discount quarter.

The complainant stated however, no generic name or prescribing information was available for this promotional graph. This seemed a breach of Clauses 12,1,12.3, 12.4, 12.6, 5.1 and 2. The Panel had already found AstraZeneca in breach for not providing prescribing information for Symbicort in a different Case (AUTH/3488/3/21). Directly as a result, this was a breach of a signed undertaking declaration provided from the previous case as the prescribing information for Symbicort was again not provided. The complainant was not sure what clause was for the alleged breach of undertaking and asked that it be considered this alongside an alleged breach of Clause 2 for not obeying the undertaking.

When writing to AstraZeneca, the Authority asked it to consider the requirements of Clauses 2, 3.3, 5.1, 12.1, 12.3, 12.4 and 12.6 of the Code.

RESPONSE

AstraZeneca stated that it took this complaint very seriously and had carried out a thorough internal investigation.

Background

AstraZeneca stated that the item in question was a Symbicort Cost Calculator, intended to represent purchased volumes of Symbicort per quarter and the corresponding average discount and gross profit per pack achieved. This webpage was to be accessed using a specific link in an email to be sent by AstraZeneca staff to external health professionals. The webpage was not indexed or optimised for search engine optimisation and would not return a listing in a search engine results page if general search terms were used.

It was important to note that the job bag for this item, GB-31361 (copy provided), had not yet been approved and the item was not in use.

The job bag comprised:

- **a Veeva Approved Email**, intended to be sent by AstraZeneca dispensing account specialist sales teams to dispensing managers and dispensing doctors. This email contained a link with a specific URL to a webpage containing the cost calculator, which could not be accessed in any other way. (The email containing the specific link would take the reader to the <https://medicines.astrazeneca.co.uk/> website. The wireframe for this website was approved under job bag GB-25816 (copy provided))
- **a disclaimer**, which required the reader to 'accept and understand'. This pop-up disclaimer would always appear before a reader could fully access the linked webpage.
- **a webpage**, containing the cost calculator graph representing purchased volumes of Symbicort per quarter year and the corresponding average discount and gross profit per pack achieved. This could only be reached after using the specific link and accepting the disclaimer - it could not be navigated to via the AZ Medicines website or through search engine terms.

AstraZeneca's Response

AstraZeneca submitted that as the job bag GB-31361 was still undergoing approval, the final certified version, certificate and signatory details could not be provided to the Panel.

AstraZeneca stated that its investigation had confirmed that the webpage with the disclaimer and cost calculator was not discoverable using general search terms on Google such as 'Symbicort Dispensing Calculator', 'Symbicort Cost Calculator' and 'Symbicort Dispensing'. The only way to access the disclaimer and cost calculator was by using a specific and complex test link that was only available from the attachments of the draft Veeva job bag GB-31361.

Whilst the case preparation manager could access the link provided by the complainant, that test link was used only by the approval team to access the cost calculator graph. This specific URL was not shared outside the approval system and the webpage could not be accessed by a visitor using search engine terms or through browsing the AstraZeneca website.

AstraZeneca stated that furthermore, its investigation showed that the link sent to the PMCPA had only ever been accessed by internal AstraZeneca staff members prior to the date of the complaint.

As per the standard procedure within pharmaceutical companies, staging/test links for draft content were the only way approval teams could check functionality complied with the Code. In this case, as this was internal material not shared externally and still undergoing approval, there had been no breach of the Code.

Previous Relevant Ruling

AstraZeneca stated that in Case AUTH/3369/8/20, two promotional leavepieces could no longer be viewed or downloaded directly from the PfizerPro website, but the URLs could still be accessed via a Google search. Additionally, the health professional self-validation disclaimer was not activated as Pfizer did not know these leavepieces could still be accessed. As these leavepieces could not be accessed via the PfizerPro platform, the Panel ruled no breaches of the Code as they noted 'it seemed reasonable in this case to consider the leavepieces as material on an internal company site'.

In Case AUTH/2918/12/16 involving GlaxoSmithKline, a Relvar cost calculator which was hosted on an internal GlaxoSmithKline server was accessed via a search engine. GlaxoSmithKline submitted that if the cost calculator was accessed in a way that it was intended (instead of via a search engine), the obligatory information would have been provided. The Panel ruled that although material that 'did not appear to meet the requirements of the Code could be accessed, it seemed reasonable in this case to consider it as material on an internal company hosting server rather than that which was intended for UK health professionals.' Again, the Panel ruled no breaches of the Code.

Given the vast number of similarities between this complaint and these other Panel rulings, AstraZeneca would urge the Panel in this case to rule consistently. Indeed, the fact that the AstraZeneca job bag in question was still undergoing approval, should reinforce the dismissal of all allegations.

Should the Panel have felt that AstraZeneca's actions in relation to the undertaking for Case AUTH/3488/3/21 was still relevant to their decision in this case, then AstraZeneca could provide further information upon request.

AstraZeneca stated that as Clauses 12.1, 12.3, 12.4 and 12.6 were not applicable, the undertaking signed in Case AUTH/3488/3/21 had not been breached, and therefore AstraZeneca denied breaches of Clauses 3.3, 5.1 and 2.

Summary

AstraZeneca submitted that as with all materials subject to certification, during the approval process full compliance checks (Code and standard operating procedures (SOPs)) would have been made and changes implemented before this item was fully approved in its final form and disseminated for use. The material in question was still undergoing approval at the time the complaint was made and was not used nor accessed outside AstraZeneca. The content that was in the process of development could only be accessed with the specific test link provided in the Veeva job bag. Previous case precedent had demonstrated that content on an internal company hosting server, such as this, was not intended for health professionals and, therefore,

could not breach the Code as alleged. On this basis AstraZeneca denied that any breach of the Code had occurred.

AstraZeneca took all complaints seriously and strove to maintain high standards and so it was disappointing for AstraZeneca to receive a complaint in these circumstances. AstraZeneca had taken steps internally to raise awareness of its whistle-blowing policy so that issues and concerns could be dealt with internally rather than taking up the Panel's limited time and resources

PANEL RULING

The Panel noted that the complainant had provided a link to the material at issue. The complainant provided no information as to how he/she had accessed the material. The case preparation manager accessed and downloaded the material from the link and provided it to AstraZeneca when notifying the company of the complaint.

The Panel noted the complainant's allegation that the webpage at issue, a Symbicort cost calculator on the medicines.astrazenca.co.uk website, did not comply with the requirements in the Code due to the omission of the non-proprietary name for Symbicort along with the lack of prescribing information in breach of the undertaking given in Case AUTH/3488/3/21.

The Panel noted AstraZeneca's submission that the webpage at issue was still undergoing approval and had not yet been certified or issued. According to AstraZeneca, the webpage could only be accessed using a specific URL link, it could not be navigated to via the AZ Medicines website and was not indexed or optimised for search engines; it would not return a listing in a search engine results page if general search terms were used.

The Panel noted that that the webpage was not restricted in any way and that it could access it without any indication that the webpage was in draft form or was undergoing approval. The Panel noted AstraZeneca's submission that whilst the case preparation manager could access the link provided by the complainant, that test link was used only by the approval team to access the cost calculator graph. This specific URL was not shared outside the approval system and the webpage could not be accessed by a visitor using search engine terms or through browsing the AstraZeneca website. The Panel further noted AstraZeneca's submission that its investigation showed that the link sent to the PMCPA had only ever been accessed by internal AstraZeneca staff members prior to the date of the complaint.

Taking all the factors into account, and on the evidence available before it, the Panel did not consider that the lack of obligatory information on what appeared to be internal material on a staging/test link for draft content amounted to breaches of the Code as alleged. It therefore ruled no breach of Clauses 12.1, 12.3, 12.4 and 12.6 of the 2021 Code. The undertaking signed in Case AUTH/3488/3/21 had therefore not been breached, and the Panel ruled no breach of Clause 3.3 of the 2021 Code.

In the Panel's view, companies should ensure that draft promotional material which was only meant for internal use was inaccessible by people outside of the company. Given its rulings and the specific circumstances of this case, the Panel did not consider that there was evidence to show that the company had failed to maintain high standards and no breach of Clause 5.1 of the 2021 Code was ruled. The Panel did not consider the circumstances warranted a ruling of a breach of Clause 2 which was reserved as a sign of particular censure. No breach of Clause 2 was ruled.

APPEAL BY THE COMPLAINANT

The complainant noted that no breaches were found on the basis that the calculator was hosted on an internal platform which was apparently undergoing approval and no one could access this. The complainant appealed the Panel's rulings of no breaches of Clauses 2, 3.3, 5.1, 12.1, 12.3, 12.4 and 12.6 of the 2021 Code.

The complainant alleged that the cost calculator was available on the main website as provided by the link sent across to case preparation manager at the time. There was no need to search for any search terms and as a health professional, the page and the cost calculator was visible at time of complaint automatically. If indeed this were a test platform or some internal test server, the content would not have appeared on the main website. The page could be navigated by the AstraZeneca website as it had clearly been made live. It was clear the internal testing or whatever platform AstraZeneca used for testing had possibly malfunctioned and the page had gone live on the actual website. The complainant stated that AstraZeneca clearly had issues with technical restrictions as proven in the published Case AUTH/3488/3/21 concerning a Trixeo Website. Even during this previous case, there had been a malfunction which then had to be fixed as the health professional disclaimer had broken. Essentially the draft form of the webpage (Symbicort cost calculator) in this case had gone live and therefore there was clear exposure without mandatory promotional requirements. This was very different to the Pfizer pro website case so the rulings for that case could not be applied to this case. There was no search engine search for the webpage in question within this case, the page appeared when browsing the AstraZeneca promotional website and the link was subsequently submitted to case preparation manager. If the page was still in approval, AstraZeneca should have taken steps for it not to appear on the live website.

Therefore, the complainant alleged that all no breach clauses previously cited were actually in breach, including breach of undertaking. The complainant requested the Appeal Board look at this case in more detail considering this was obviously an agency error in making the page go live.

RESPONSE FROM ASTRAZENECA

AstraZeneca noted the following concerns raised by the complainant in his/her appeal:

- The cost calculator was available on the live AstraZeneca medicines website, not an internal test server, and was accessible via the AstraZeneca medicines website.
- AstraZeneca suffered technical malfunctions which led to the cost calculator page going live on the Astra medicines website.

AstraZeneca submitted that it re-iterated the position laid out in its original response, to address each of the complainant's concerns.

The cost calculator was available on the live AstraZeneca medicines website, not an internal test server, and was accessible via the AstraZeneca medicines website

AstraZeneca submitted that as detailed in its initial response, the webpage with the disclaimer and cost calculator had not been discoverable using general search terms on Google (such as

'Symbicort Dispensing Calculator', 'Symbicort Cost Calculator' and 'Symbicort Dispensing'). The only way to access the disclaimer and cost calculator was by using a specific and complex test link that was only available from the draft Veeva job bag GB-31361 hosted on its internal systems only.

AstraZeneca submitted that whilst the PMCPA case preparation manager could access the link provided by the complainant, that test link was only used by the approval team to access the cost calculator graph. AstraZeneca submitted that its investigations confirmed that the link was not shared outside the approval system and the webpage could not be accessed by a visitor using search engine terms, or through browsing the AstraZeneca website.

AstraZeneca stated that its investigations showed that the link sent to the case preparation manager had only ever been accessed by internal AstraZeneca staff members prior to the date of the original complaint. AstraZeneca had reviewed the access list to the webpage following the original complaint and confirmed that there was one external user who accessed the webpage directly, either by entering the specific URL into the browser, or by clicking on a direct link to the webpage. This was consistent with someone from the PMCPA accessing the webpage as part of the investigation. This further demonstrated that the webpage could not and was not accessed inappropriately by external users. In addition, during AstraZeneca's investigation, the company thoroughly searched the AstraZeneca's medicines website and could not reach the webpage in question. The complainant alleged that he/she was able to navigate to this page via browsing the AstraZeneca medicines website, however, AstraZeneca had not been provided with evidence that substantiated this claim.

AstraZeneca suffered technical malfunctions which led to the cost calculator page going live on the AstraZeneca medicine website

AstraZeneca submitted that this was a new allegation made by the complainant in this case, and this was not included in the original list of allegations in the complaint letter. However, for completeness, AstraZeneca's response to this was below:

As previously mentioned, the cost calculator page was still undergoing approval and had not been made available or shared externally. It was not discoverable by searching on Google and was only accessible via a complex link. The webpage was subject to an extensive approval process with full compliance checks (ABPI and AstraZeneca SOPs). Such checks ensured that changes were made and implemented before the item was fully approved in its final form and disseminated for use. AstraZeneca had found no evidence to suggest that the cost calculator webpage suffered a malfunction and was discoverable externally, without the specific link. Further to this, the complainant had been unable to substantiate their claims that AstraZeneca suffered technical malfunctions resulting in a breach of the Code.

Summary

AstraZeneca submitted that its investigations confirmed that:

- 1 The webpage in question could not be discovered using general search terms.
- 2 The material in question was still undergoing approval at the time the complaint was made and was not used nor accessed outside AstraZeneca.

- 3 The complex link used to access this webpage had only been used by the internal AstraZeneca approval team; and,
- 4 As with all materials subject to certification, during the approval process, full compliance checks would have been made and changes implemented before this item was fully approved in its final form and disseminated for use.
- 5 The complainant had been unable to provide evidence that they could access the webpage via the live AstraZeneca medicines website. Moreover, the complainant had not substantiated his/her claim that a technical malfunction had resulted in the webpage being made live to the public.

AstraZeneca therefore submitted that no breach of the Code had occurred and it agreed with the Panel's rulings.

AstraZeneca submitted that it subscribed fully to the high ethical and moral spirit of the Code and took its responsibilities under the Code very seriously. AstraZeneca considered the ruling of the Panel to be fair, balanced and in line with previous case precedent.

FINAL COMMENTS FROM THE COMPLAINANT

The complainant provided no final comments.

APPEAL BOARD RULING

The Appeal Board noted that the complainant had the burden of proving his/her complaint on the balance of probabilities. The representatives from AstraZeneca stated that there had been no evidence of a technical failure that would have allowed the cost calculator to be viewed on the live AstraZeneca medicines website as alleged by the complainant. AstraZeneca had checked and confirmed that the cost calculator could not be accessed directly from its medicine's website nor was it discoverable by searching on Google. The cost calculator was only accessible via a complex link. The Appeal Board noted AstraZeneca's submission that only members of the AstraZeneca review team had access to the cost calculator via the item's job bag; investigations by the company's digital team found that the only external single access to the webpage in question, recorded by AstraZeneca, was after the complaint and appeared to be consistent with the PMCPA case preparation manager accessing the page via the link provided in the complaint.

The Appeal Board considered that the complainant had not provided any evidence to show that the cost calculator, that was still undergoing the internal approval process, could be accessed from the AstraZeneca medicines website as alleged. The Appeal Board agreed with the Panel's comments above and upheld its rulings of no breach of Clauses 2, 3.3, 5.1, 12.1, 12.3, 12.4 and 12.6 of the 2021 Code. The appeal was unsuccessful.

Complaint received 2 December 2021

Case completed 16 June 2022