CASE AUTH/3661/6/22

ANONYMOUS HEALTH PROFESSIONAL/DIRECTOR v ASTRAZENECA

Concerns about certification of the Forxiga website and an alleged breach of undertaking

CASE SUMMARY

This case was in relation to the alleged failure to separately certify mobile phone and desktop versions of the Forxiga website and an alleged breach of undertaking.

The Panel ruled a breach of the following Clause of the 2021 Code on the basis that the final form differed between the desktop and mobile versions of the website due to the inclusion of a prominent statement about the intended audience at the top of the desktop webpage but not at the top of the mobile version:

Breach of Clause 8.1	**Failure to meet the requirements for certifying material**

The Panel ruled no breach of the following Clauses of the 2021 Code in relation to high standards and the failure to separately certify the desktop and mobile webpage and in relation to an alleged breach of undertaking.

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 someone who described themselves as an anonymous, contactable health professional about AstraZeneca UK Limited. The complaint concerned certification of the Forxiga website and an alleged breach of undertaking. The alleged breach of undertaking proceeded in the name of the Director as it is the Authority's responsibility to ensure compliance with undertakings.

COMPLAINT

The complainant alleged that promotional material on the Forxiga Diabetes website was not certified for mobile phone usage (GB-28401 | DOP: July 2021).

The complainant stated the desktop version of this website had the disclaimer 'This website is intended for Health Care Professionals in Great Britain. For other UK residents and Northern Ireland Health Care Professionals please visit astrazeneca.co.uk' in prominence right at the top in white with a grey background. This same message was repeated right at the bottom of the desktop page. However, the complainant stated, on the mobile phone version, the writing at the top, which stated, 'This website is intended for Health Care Professionals in Great Britain. For other UK residents and Northern Ireland Health Care Professionals please visit astrazeneca.co.uk', was missing.

The complainant further stated that on the desktop version for this website, underneath the picture of the fictional patient, it said 'HOME > FORXIGA IN TYPE 2 DIABETES' (in blue colour text). This message was not present on the mobile phone version.

The complainant alleged that as a result of these major differences between the desktop version and mobile phone version, the content should have been certified separately for usage on a mobile. However, this had not been the case as the unique code and date of creation of the page were the same for mobile and desktop.

The complainant stated, more concerningly, this was a breach of undertaking as AstraZeneca had been found in breach for lack of certification on mobile devices previously in Case AUTH/3488/3/21 where a breach of Clause 14.1 was given. Uncertified content was being used for promotion and the undertaking had been broken.

It was concerning that the signatories were not being assessed for understanding and applicability of the Code leading to breaches; the complainant stated AstraZeneca did not take the standards or parameters of the Code seriously. Clauses 3.3, 8.1, 5.1 and 2 had allegedly been breached.
When writing to AstraZeneca, the Authority asked it to consider the requirements of Clauses 2, 3.3, 5.1 and 8.1 of the 2021 Code.

RESPONSE

AstraZeneca submitted that it took compliance with the ABPI Code extremely seriously and was committed to maintaining high standards in relation to all information it provided about its products and in all related activities.

The Complaint

AstraZeneca stated the complainant made several allegations which were summarised by AstraZeneca as follows:

1 The mobile version of the Forxiga Diabetes Website was not certified

The complainant alleged that the Forxiga website content was different on desktop and mobile devices but had the same unique job code and date of preparation. As the content was different on the two devices, they should have been certified separately. The complainant alleged, therefore, that the website had not been certified for use on mobile devices.

2 Breach of previous undertaking

The complainant alleged that lack of certification of the website on a mobile device constituted a breach of undertaking of Case AUTH/3488/3/21, where AstraZeneca had been found in breach of Clause 14.1 of the 2019 ABPI Code for lack of certification of an AstraZeneca website on mobile devices.

3 General allegation

The complainant questioned the working environment and signatories of AstraZeneca.

AstraZeneca had been asked to consider Clauses 2, 5.1, 3.3 and 8.1 of the 2021 ABPI Code when responding to these allegations.

AstraZeneca submitted, in its response to these allegations, it will establish that:

- The website for use on both desktop and mobile device was certified in final form by a nominated medical signatory who had completed all necessary training. Due to formatting differences of desktop and mobile views, there were small content differences between the content on each platform (albeit no difference in promotional content). The certification of desktop and mobile content was completed in one job bag in Veeva Vault PromoMats (VVPM), in line with AstraZeneca website approval guidance. The content on each platform was in line with the Code.

- AstraZeneca took previous undertakings and compliance with the Code very seriously and corrective and preventative steps were taken following Case AUTH/3488/3/21. AstraZeneca did not breach it's undertaking in this case, as the mobile version of the website was certified by a nominated medical signatory.

AstraZeneca addressed each of the complainant's allegations according to the relevant clauses of the Code.

The Forxiga Website

AstraZeneca submitted that the Forxiga website was owned by AstraZeneca and provided information about Forxiga (dapagliflozin) to health professionals in Great Britain (GB). Forxiga was a prescription only medicine indicated for Type 2 diabetes mellitus in adults and children aged 10 years and above for the treatment of insufficiently controlled type 2 diabetes as an adjunct to diet and exercise; - as monotherapy when metformin was considered inappropriate due to intolerance,- in addition to other medicinal products for the treatment of type 2 diabetes. Forxiga also had two additional indications in Heart Failure and Chronic Kidney Disease (a copy of the summary of product characteristics (SPC) was provided. The website included content for all of the three licensed indications for Forxiga; illustrating the trial evidence, safety information and dosing considerations for each indication.

AstraZeneca submitted the content of the desktop and mobile versions for the Diabetes page were both included and certified in VVPM under unique job code GB-24801. The website home and mandatory sections pages for both desktop and mobile versions were certified under unique job code GB-37284.

According to AstraZeneca, a 'Healthcare Professional declaration' pop-up was displayed when the user tried to access the website. In order for the user to access promotional information on

the website, they must have first confirmed that they were a 'GB Healthcare Professional'. If they were not a Healthcare Professional, or were a Healthcare Professional based in Northern Ireland (NI), they were automatically re-directed to the AstraZeneca UK website intended for a public audience. AstraZeneca submitted both the desktop and mobile website versions had this 'Healthcare professional declaration' pop-up before the user can access the Forxiga website.

AstraZeneca's response to the complaint

Allegation 1

The complainant alleged that the Forxiga website content was different on desktop and mobile devices but had the same unique job code and date of preparation. As the content was different on the two devices, they should have been certified separately. The complainant alleged, therefore, that the website had not been certified for use on mobile devices.

AstraZeneca response

AstraZeneca submitted the mobile version was different to the desktop version in two ways:

1 Omittance of the wording '*This website is intended for Health Care Professionals in Great Britain. For other UK residents and Northern Ireland Health Care Professionals please visit astrazeneca.co.uk*' at the top of the page of the mobile version.

2 Underneath the page title, on the desktop version of the website, there was '*Home > Forxiga in Type 2 Diabetes'* (in blue colour text). Due to different navigation functionality, this was not present on the mobile version of the website.

AstraZeneca submitted the website was clearly signposted as for Healthcare Professionals in GB by the presence of an 'Healthcare Professional declaration' pop-up, which required all users to confirm that they were Healthcare Professionals based in GB before they accessed any content. In addition to this, there was a disclaimer in the footer of each page on the site, which stated:

> *'This website is intended for Healthcare Professionals in Great Britain. For other UK residents and Northern Ireland Healthcare Professionals please visit astrazeneca.co.uk.*'

The pop-up and the disclaimer in the footer appeared on the desktop and mobile versions of the website.

AstraZeneca believed this made it sufficiently clear that the website was intended for healthcare professionals based in GB only. As there was more space at the top of the screen on the desktop version of the website, a third disclaimer was also included here when accessed via the desktop. This was not required by the Code given other safeguards in place. As there was less space available when viewing on a mobile device, it was not included at the top of the screen when viewing in this format.

AstraZeneca submitted that for websites to be approved in VVPM, the website owner must take screenshots of every part of the site. Once combined, the PDFs of all screenshots were uploaded in the job bag. If the website was also accessible on a mobile device and there were

some differences in content, the website owner was required to include screenshots of the desktop and mobile versions in one PDF for approval in VVPM. This was outlined in the AstraZeneca Website Approval Guidance Document. The Nominated Medical Signatory would also check the final form of the website on all applicable devices before certification.

The metadata in VVPM for GB-24801 stated that the website was to be accessed on desktop and mobile devices, and screenshots of the desktop and mobile website versions were included in the job bag. Links to the staging site were also included in the meta data to allow review of content in final form on all devices prior to certification.

AstraZeneca refuted breaches of Clauses 5.1 and 8.1 of the 2021 ABPI Code because the website was certified in its final form, by a nominated medical signatory, on both desktop and mobile devices.

Allegation 2

The complainant alleged that the above breach of the Code also constituted a breach of undertaking of Case AUTH/3488/3/21.

AstraZeneca's response

As described above, the website was certified for use on both desktop and mobile devices by a nominated medical signatory, therefore there was no breach of undertaking of Case AUTH/3488/3/21 according to AstraZeneca.

AstraZeneca therefore refuted breaches of Clauses 3.3, 5.1 and 2 of the 2021 ABPI Code.

General summary allegation

The complainant concluded by questioning the working environment and signatories.

AstraZeneca's response

AstraZeneca stated it took the competency of its nominated signatories very seriously. AstraZeneca submitted it had dedicated training processes to ensure that its signatories had good working knowledge of the ABPI Code and its nominated signatories were revalidated annually by the Medical Ethics team, offered Code trainings throughout the year (including quarterly Code Case reviews and bespoke training sessions in response to identified training needs), participated in fortnightly Nominated Signatory Forum meetings (providing an opportunity to share best practice and discuss and align on 'grey areas' of the Code), had frequent manager meetings to ask Code-related questions and they received a monthly summary of recently published PMCPA cases for self-learning.

The nominated medical signatory who certified this content had been a registered nominated signatory for AstraZeneca since 2018.

AstraZeneca therefore refuted breaches of Clauses 5.1 and 2 of the 2021 ABPI Code.

Summary of AstraZeneca's position

In conclusion, AstraZeneca reiterated that it took compliance with the Code extremely seriously and was committed to maintaining high standards in relation to all information it provided about its products and in complying with the Code. AstraZeneca was confident that the content of the website was compliant with the Code and the certification process for digital materials was followed correctly. For the reasons provided above, AstraZeneca refuted all allegations by the complainant and denied breaches of Clauses 2, 5.1, 3.3 and 8.1 of the Code.

PANEL RULING

The Panel noted the complaint concerned the diabetes webpage of the www.forxiga.co.uk website which had been certified with one job code for mobile and desktop versions but which allegedly required separate certification due to two key differences in the content.

The Panel noted guidance issued by the PMCPA about whether material had to be certified for each platform it appeared on stated:

> 'Does material have to be certified for each platform it appears on, eg computer, tablet and mobile?
>
> Clause 8.1
>
> Companies must ensure that the final form viewed is not distorted and the requirements of the Code are complied with eg the legibility of the prescribing information.
> If companies have the technology to ensure that that which is viewed irrespective of the platform will be appropriately formatted and are confident that the final form will be identical on each platform then these do not require separate certification.'

The Panel noted that the first difference was in relation to the following prominent statement about the intended audience visible on the top of the desktop webpage but not on the mobile webpage: 'This website is intended for Health Care Professionals in Great Britain. For other UK residents and Northern Ireland Health Care Professionals please visit astrazeneca.co.uk'. The second difference was that the webpage navigation reference, 'Home > FORXIGA IN TYPE 2 DIABETES', which appeared beneath a promotional banner towards the top of the desktop webpage was missing on the mobile website.

The Panel noted AstraZeneca's submission that due to formatting differences of desktop and mobile views, there were small content differences between the content on each platform (albeit no difference in promotional content); the certification of desktop and mobile content were completed in one job bag in line with AstraZeneca's website approval guidance.

The Panel noted AstraZeneca's submission that its guidance required the website owner to take screenshots of every part of the site, which once combined would be uploaded in the job bag. If the website was also accessible on a mobile device and there were some differences in content, the website owner must include screenshots of the desktop and mobile versions in one PDF for approval.

The Panel noted AstraZeneca had not disputed that there were differences in this regard. The question for the Panel was whether the differences meant that there were two final forms of the website, ie one for the desktop version and one for the mobile version and, if so, whether each had been separately certified.

In the Panel's view, the Code did not necessarily require a website to be certified multiple times for each different device it might be viewed upon, however, it considered that the appearance of the material on different commonly used devices should be taken into consideration prior to certification to ensure that if the final forms differed they were subject to separate certification.

Whilst the Panel noted the navigation reference 'Home > FORXIGA IN TYPE 2 DIABETES' appeared on the desktop version and not the mobile version, the Panel did not consider this necessarily required separate certification; in the Panel's view, this would be considered to be, on balance, a technical matter of webpage functionality and navigation as opposed to part of the substantive content of the webpage itself. In any event, the webpage location was made clear by the highlighted menu tab at the top of the webpage. On the other hand, the Panel considered that AstraZeneca had chosen to include a prominent highlighted banner statement about the intended audience of the webpage, GB health professionals, at the top of the page on the desktop version but not at the top of the mobile version as there was less space.

Whilst the Panel had no evidence before it to show whether the pop-up box appeared for all mobile and desktop users when accessing the page in question, it did not consider that this would alter its consideration as the issue was not whether the intended audience was clear.

The Panel considered the issue before it was in relation to whether the omission of the prominent banner on the mobile webpage meant that the differences between the mobile and desktop webpages were such that they were two final forms requiring separate certification with regard to Clause 8.1. In the Panel's view, the final form, on balance, was different on the desktop and mobile versions. The Panel considered that the two versions should have been certified separately and a **breach of Clause 8.1** was ruled.

The Panel, noting that AstraZeneca had nonetheless reviewed the mobile website for certification, considered that the particular circumstances of this case did not mean that AstraZeneca had failed to maintain high standards and **no breach of Clause 5.1** was ruled.

With regard to the alleged breach of undertaking, the Panel noted that in the previous case, Case AUTH/3488/3/21, AstraZeneca had acknowledged a breach of Clause 14.1 of the 2019 Code (Clause 8.1 of the 2021 Code) as the signatory had failed to review the Trixeo website on a mobile device for certification purposes, contrary to its training processes. However, in the current case, Case AUTH/3661/6/22, the Panel noted the signatory had reviewed the mobile website for certification, albeit with some differences in content and contrary to Clause 8.1. In the Panel's view, the current case was sufficiently different from Case AUTH/3488/3/21 such that there had been no breach of the undertaking given in that case. **No breach of Clause 3.3** was ruled.

The Panel noted its comments and rulings above in relation to the alleged breach of undertaking and ruled **no breach of Clauses 5.1 and 2**.

Complaint received **17 June 2022**

Case completed **2 June 2023**