

COMPLAINANT v DAIICHI SANKYO

Alleged failure to certify the mobile version of a promotional website for Lixiana

An anonymous contactable complainant complained that Lixiana (edoxaban) promotional content on a website for health professionals and non-promotional content on a website for patients being used by Daiichi Sankyo had not been certified.

The complainant stated that on this homepage of the promotional website (lixiana-hcp.co.uk) (Date of preparation: March 2022 EDX/22/0052), there was a picture of patient heads at the top of the page and PINK writing to the side of the patient heads picture, which read, 'Your choice for ageing patients with NVAF [nonvalvular atrial fibrillation]'. This image and pink writing were on the desktop view. The mobile phone view had a different image of the patient heads (some of the heads were cropped on purpose) and the writing on the mobile view for 'Your choice for ageing patients with NVAF' was in white versus pink on the desktop view. Despite the clear and obvious differences in the promotional view for the desktop versus mobile version, the mobile version had not been approved separately. The codes and date of preparation on both desktop and mobile were the same but this was inappropriate due to the need to undertake separate approval on both desktop and mobile separately.

The complainant alleged that problems with the cropped image and the writing were also an issue on the three other pages. Therefore, in total, 4 pages of the promotional website were actually not certified for use on mobile phone due to the differences in the images of the patient heads and the colour of writing versus the desktop look.

The complainant stated that the patient website for Lixiana <https://myanticoagulant.co.uk/nvaf/> (Date of preparation: February 2022 – EDX/21/0963), had similar issues in that there were two pictures on this page of a fictional female patient on the desktop view. However, on mobile phone, these two pictures of the female patient were totally different to the ones used on the desktop. Therefore, there should have been two different approvals and certification for mobile and desktop views.

The complainant referred to <https://myanticoagulant.co.uk/vte/> (Date of preparation: February 2022 – EDX/21/0963) and stated that on this page, there were two images of a male fictional patient on the desktop. On mobile, the two images of the male fictional patient were totally different to the ones used on desktop. Therefore, there should have been two different certifications for the mobile and desktop but this had not been done.

The detailed response from Daiichi Sankyo is given below.

Health professional webpages

The Panel noted that the differences between the desktop and mobile versions highlighted by the complainant were in relation to the illustration of patient heads which appeared cropped in the mobile version and that the claim 'Your choice for ageing

patients with NVAF' was in pink on the desktop view and in white on the mobile view on four separate webpages on the lixiana-hcp.co.uk website.

Daiichi Sankyo 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, ie one for the desktop version and one for the mobile version and, if so, each would need to be 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 devices should be taken into consideration prior to certification to ensure that the content met the requirements of the Code when viewed on each different commonly used type of electronic device, eg desktop, laptop, tablet, smartphone etc.

The Panel noted Daiichi Sankyo's submission that the changes to the positioning of images on the mobile version at issue served to ease usability and readability on mobile devices and did not change the content, meaning or perception from that delivered by the desktop imagery.

The Panel considered, however, that whilst it appeared that in this instance the final form of the material as it would appear on mobile devices was reviewed by the Daiichi Sankyo signatory as part of the final check under the same job bag number in relation to all four webpages, the webpages were not identical on each platform; the colour used for the claim was different on each and therefore it considered that the final form differed for the mobile version compared to the desktop version and therefore each should have been certified separately which had not occurred. The Panel therefore ruled a breach of the Code.

The Panel did not consider that the particular circumstances of this case constituted a failure to maintain high standards or a breach of Clause 2 and no breaches were ruled in that regard.

Patient webpages

The Panel noted that the differences between the desktop and mobile versions highlighted by the complainant were in relation to the use of completely different illustrations of patients. The Panel noted that the desktop version had 2 images, each of an elderly woman and man looking straight ahead, one from a front angle and one from a side angle for each individual. The images appeared to be different to those used on the mobile website, which had two images each of the same elderly woman and man looking upwards from a front and side angle.

Daiichi Sankyo had not specifically commented on the use of different illustrations but 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, ie one for the desktop version and one for the mobile version and, if so, each would need to be separately certified.

The Panel considered that the images formed part of the content on the page and that these differed based on the platform it was viewed on. Whilst the Panel noted that the mobile website was reviewed as part of the same job bag, it considered that the final form differed for the mobile version compared to the desktop version and therefore each should have been certified separately which had not occurred. A breach of the Code was ruled.

The Panel did not consider that the particular circumstances of this case constituted a failure to maintain high standards or a breach of Clause 2 and no breaches were ruled in that regard.

An anonymous contactable complainant complained that Lixiana (edoxaban) promotional content on a website for health professionals and non-promotional content on a website for patients being used by Daiichi Sankyo had not been certified.

Lixiana was indicated for the prevention of stroke and systemic embolism in adult patients with nonvalvular atrial fibrillation (NVAf) with one or more risk factors, such as congestive heart failure, hypertension, age \geq 75 years, diabetes mellitus, prior stroke or transient ischaemic attack (TIA).

COMPLAINT

The complainant stated that on this homepage of the promotional website (lixiana-hcp.co.uk) (Date of preparation: March 2022 EDX/22/0052), there was a picture of patient heads at the top of the page and PINK writing to the side of the patient heads picture, which read, 'Your choice for ageing patients with NVAf [nonvalvular atrial fibrillation]'. This image and pink writing were on the desktop view. The mobile phone view had a different image of the patient heads (some of the heads were cropped on purpose) and the writing on the mobile view for 'Your choice for ageing patients with NVAf' was in white versus pink on the desktop view. Despite the clear and obvious differences in the promotional view for the desktop versus mobile version, the mobile version had not been approved separately. The codes and date of preparation on both desktop and mobile were the same but this was inappropriate due to the need to undertake separate approval on both desktop and mobile separately.

The complainant alleged that problems with the cropped image and the writing were also an issue on the following three pages: <https://lixiana-hcp.co.uk/engage-af-timi-48/> (Date of preparation: March 2022 EDX/22/0053), <https://lixiana-hcp.co.uk/etna-af-europe/> (Date of preparation: December 2020 EDX/20/1123), and <https://lixiana-hcp.co.uk/patient-material/> (March 2022 EDX/22/0054). Therefore, in total, 4 pages of the promotional website were actually not certified for use on mobile phone due to the differences in the images of the patient heads and the colour of writing versus the desktop look. The complainant alleged breaches of Clauses 8.1, 5.1 and 2 on all of these 4 pages.

The complainant stated that the patient website for Lixiana <https://myanticoagulant.co.uk/nvaf/> (Date of preparation: February 2022 – EDX/21/0963), had similar issues in that there were two pictures on this page of a fictional female patient on the desktop view. However, on mobile phone, these two pictures of the female patient were totally different to the ones used on the desktop. Therefore, there should have been two different approvals and certification for mobile and desktop views.

The complainant referred to <https://myanticoagulant.co.uk/vte/> (Date of preparation: February 2022 – EDX/21/0963) and stated that on this page, there were two images of a male fictional patient on the desktop. On mobile, the two images of the male fictional patient were totally different to the ones used on desktop. Therefore, there should have been two different certifications for the mobile and desktop but this had not been done.

The complainant alleged breaches of Clauses 8.3, 9.1 (which the case preparation manager took to be a reference to Clause 5.1 in the 2021 Code) and 2 with regard to the patient website. These basic errors undermined certification and the process of self-regulation.

When writing to Daiichi Sankyo, the Authority asked it to consider the requirements of Clauses 2, 5.1, 8.1 and 8.3 of the 2021 Code.

RESPONSE

Daiichi Sankyo stated that it took its obligations under the Code seriously, strove to maintain high standards and behaved responsibly and ethically at all times. Daiichi Sankyo denied all alleged breaches.

Background Information and response to individual breach allegations

Daiichi Sankyo had attempted to respond to the complaint as thoroughly as possible; however, as there was no evidence provided by the complainant of the images in question for any of the allegations, Daiichi Sankyo had had to make assumptions on which images were being referred to.

Health professional website

With regard to the alleged failure to certify separately the desktop and mobile versions of the homepage of the promotional website (Date of preparation: March 2022 EDX/22/0052), (allegation 1), Daiichi Sankyo submitted that the Code stated that the final form of the material must be certified and laid down no requirement to have separate job bags for mobile versions of webpages. The final form of the website on a standard desktop screen and mobile device was checked as part of the final form check, under the same job bag number, by the medical signatory and this fulfilled the requirements for Clause 8.1. This was further supported by the Panel ruling of no breach of the Code in Case AUTH/3504/4/21 where the same process was followed.

Daiichi Sankyo referred to the following guidance on the PMCPA website:

‘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.’

Daiichi Sankyo confirmed that the changes to the positioning of images on the mobile version at issue served to ease usability and readability on mobile devices and did not change the content, meaning or perception from that delivered by the desktop imagery.

Therefore, Daiichi Sankyo disputed that there had been a breach of Clause 8.1 and by extension, Clauses 5.1 and 2.

Daiichi Sankyo submitted similar comments in relation to the other three pages referred to by the complainant, ie that bearing in mind guidance on the PMCPA website, changes to the positioning of images on the mobile version served to ease usability and readability on mobile devices and did not change the content, meaning or perception from that delivered by the desktop imagery. Therefore, Daiichi Sankyo disputed that there had been a breach of Clause 8.1 and by extension, Clauses 5.1 and 2.

Patient website

With regard to the alleged failure to certify separately the desktop and mobile versions of the patient website, Daiichi Sankyo submitted that the Code stated that the final form of the material must be certified and laid down no requirement to have separate job bags for mobile versions of webpages. The final form of the website on a standard desktop screen and mobile device was checked as part of the final form check, under the same job bag number, by the medical signatory and this fulfilled the requirements for Clause 8.1. This was further supported by the Panel ruling of no breach of the Code in Case AUTH/3504/4/21 where the same process was followed.

Daiichi Sankyo referred, again, to the guidance on the PMCPA website, changes to the positioning of the figures in the images on the mobile version served to maintain focus on the text (as per the desktop imagery) and ensured readability on mobile devices. This did not change the content, meaning or perception from that delivered by the desktop imagery. Therefore, Daiichi Sankyo disputed that there had been a breach of Clauses 8.3, 9.1 and 2.

Conclusion

Daiichi Sankyo stated that it had acted in line with the requirements of the Code, maintained high standards and had not brought discredit upon, or reduced confidence in, the industry.

PANEL RULING

The Panel noted that the complaint concerned differences between the desktop and mobile versions of pages on two websites. Similar allegations were made about pages on the health professional website (lixianahcp.co.uk) and the patient website (myanticoagulant.co.uk).

The Panel noted Daiichi Sankyo's submission that as there was no evidence provided by the complainant of the images in question for any of the allegations, the company had had to make assumptions as to which images were being referred to. The Panel noted that the complainant had provided links to the job codes and the date of preparation of the webpages at issue. The Panel noted, however, that whilst the case preparation manager downloaded and saved pdfs of the websites from the links provided by the complainant and sent these to Daiichi Sankyo, screenshots of the links were not downloaded, saved and provided to the company. This meant that the pdf copies included the text but not the photographs or the format as seen by readers of

the websites. Daiichi Sankyo had provided copies of the patient website (Date of preparation: February 2022 – EDX/21/0963) and only the health professional website page <https://lixiana-hcp.co.uk/etna-af-europe/> (Date of preparation: December 2020 EDX/20/1123)) and not the remaining three health professional pages referred to by the complainant (EDX22/0052, EDX22/0053 and EDX22/0054, all with a date of preparation of March 2022). The Panel noted that the complainant had described the image and claim at issue and stated that they were the same on all four of the health professional website pages cited. This was not disputed by Daiichi Sankyo and so the Panel made its rulings on this basis.

The Panel noted that Daiichi Sankyo's response quoted part of the guidance issued by the PMCPA about whether material had to be certified for each platform it appeared on. The complete answer was as follows (**emphasis added**):

'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 Case AUTH/3504/4/21, cited by Daiichi Sankyo relating to certification of a mobile version of a website, concerned the provision of prescribing information. In Case AUTH/3504/4/21, the Panel noted that from the certified job bag material provided by Daiichi Sankyo, that the website had a number of links to the relevant prescribing information. The Panel did not have before it a copy of what was visible when each of these links was accessed. The Panel noted Daiichi Sankyo's submission that prescribing information was provided as a single click link on the mobile version of the website; the final form of the website on a standard desktop screen and mobile device was checked as part of the final form check by the medical signatory. The Panel noted that the complainant bore the burden of proof and did not consider that he/she had established that prescribing information was not provided as a single click link on the mobile version of the website or that the website had not been certified as required by the Code and no breach of Clause 14.1 was ruled. The Panel consequently ruled no breach of Clauses 9.1 and 2 of the 2019 Code.

Turning to the case now before it, Case AUTH/3615/3/22, the Panel considered that there was a difference to the previous case (Case AUTH/3504/4/21). The current case referred to differences between the versions of the material and not to the provision of the prescribing information.

Health professional webpages

The Panel noted that the differences between the desktop and mobile versions highlighted by the complainant were in relation to the illustration of patient heads which appeared cropped in the mobile version and that the claim 'Your choice for ageing patients with NVAF' was in pink on

the desktop view and in white on the mobile view on four separate webpages on the lixiana-hcp.co.uk website.

Daiichi Sankyo 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, ie one for the desktop version and one for the mobile version and, if so, each would need to be 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 devices should be taken into consideration prior to certification to ensure that the content met the requirements of the Code when viewed on each different commonly used type of electronic device, eg desktop, laptop, tablet, smartphone etc.

The Panel noted Daiichi Sankyo's submission that the changes to the positioning of images on the mobile version at issue served to ease usability and readability on mobile devices and did not change the content, meaning or perception from that delivered by the desktop imagery.

The Panel considered, however, that whilst it appeared that in this instance the final form of the material as it would appear on mobile devices was reviewed by the signatory as part of the final check under the same job bag number in relation to all four webpages, the webpages were not identical on each platform; the colour used for the claim was different on each and therefore it considered that the final form differed for the mobile version compared to the desktop version and therefore each should have been certified separately which had not occurred. The Panel therefore ruled a breach of Clause 8.1.

The Panel did not consider that the particular circumstances of this case constituted a breach of Clauses 5.1 and 2 and no breaches were ruled in that regard.

Patient webpages

The Panel noted that the differences between the desktop and mobile versions highlighted by the complainant were in relation to the use of completely different illustrations of patients. The Panel noted that the desktop version had 2 images, each of an elderly woman and man looking straight ahead, one from a front angle and one from a side angle for each individual. The images appeared to be different to those used on the mobile website, which had two images each of the same elderly woman and man looking upwards from a front and side angle.

Daiichi Sankyo had not specifically commented on the use of different illustrations but 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, ie one for the desktop version and one for the mobile version and, if so, each would need to be separately certified.

The Panel considered that the images formed part of the content on the page and that these differed based on the platform it was viewed on. Whilst the Panel noted that the mobile website was reviewed as part of the same job bag, it considered that the final form differed for the mobile version compared to the desktop version and therefore each should have been certified separately which had not occurred. A breach of Clause 8.3 was ruled.

The Panel did not consider that the particular circumstances of this case constituted a breach of Clauses 5.1 and 2 and no breaches were ruled in that regard.

Complaint received	10 March 2022
Case completed	2 December 2022