

## **CASE AUTH/3630/4/22**

### **EX-EMPLOYEE v DAIICHI SANKYO**

#### **Mobile view of Daiichi Sankyo website promoting Lixiana**

#### **CASE SUMMARY**

This case was in relation to the homepage of Daiichi Sankyo's promotional Lixiana (edoxaban) mobile website which included the prescribing information and adverse event reporting statement within a collapsible menu bar.

The Panel ruled a breach of the following Clause(s) of the 2021 Code:

<b>Breach of Clause 12.1</b>	<b>Not meeting the requirement for prescribing information to be positioned for ease of reference</b>
<b>Breach of Clause 12.4</b>	<b>Failing to provide prescribing information by way of a clear, and prominent, direct, single click link</b>
<b>Breach of Clause 12.6</b>	<b>Failing to include a clear prominent statement as to where the prescribing information can be found</b>
<b>Breach of Clause 12.9</b>	<b>Failing to include the adverse event reporting statement in a prominent manner</b>
<b>Breach of Clause 5.1</b>	<b>Failing to maintain high standards</b>

The Panel ruled no breach of the following Clause(s) of the 2021 Code:

<b>No Breach of Clause 12.1</b>	<b>The requirement, amongst other things, for prescribing information to be provided in a clear and legible manner</b>
<b>No Breach of Clause 2</b>	<b>Requirement that activities or material must not bring discredit upon, or reduce confidence in, the pharmaceutical industry</b>

**This summary is not intended to be read in isolation.  
For full details, please see the full case report below.**

#### **FULL CASE REPORT**

An anonymous complainant who described him/herself as a former employee at Daiichi Sankyo complained about its promotional Lixiana (edoxaban) website <https://lixiana-hcp.co.uk/> (ref EDX/22/0052, date of preparation March 2022).

#### **COMPLAINT**

The complainant provided screenshots of the mobile phone view of this website (taken on a Chrome browser with the 'Desktop site' option activated on a modern Android phone) which allegedly did not contain any prescribing information or an adverse event reporting statement or

any visible link to these. Even when the 'Desktop site' option was deactivated in Chrome on an Android phone, there was still no prescribing information or an adverse event reporting statement or any visible link to these.

The complainant stated that while there was a non-prominent link to the summary of product characteristics (SPC) at the bottom of the page, this was not sufficient to meet the requirements for prescribing information which also required the legal classification and the cost to be stated.

The complainant alleged the following breaches:

Clause 12.1 - The prescribing information was not provided in a clear and legible manner or positioned for ease of reference.

Clause 12.4 - The prescribing information in this digital material was not provided either by inclusion in the material itself or by way of a clear, and prominent, direct single click link.

Clause 12.6 - This promotional material on the internet did not have a clear prominent statement as to where the prescribing information could be found.

Clause 12.9 - This promotional material did not include a prominent adverse event reporting statement.

Clause 5.1 - Due to the above failings, high standards had not been maintained.

In addition, the complainant alleged a breach of Clause 2 – Discredit had been brought on the pharmaceutical industry as the lack of easily accessible prescribing information and adverse event reporting statement meant patient safety had been prejudiced. Daiichi Sankyo had also had multiple and cumulative breaches of a similar and serious nature in the same therapeutic area within a short period of time (Case AUTH/3497/3/21 (a previous version of this Lixiana website), Case AUTH/3506/4/21 (a Lixiana journal advertisement), Case AUTH/3504/4/21 (a promotional website for a product also in the cardiology therapeutic area), Case AUTH/3507/5/21 and Case AUTH/3513/5/21 (Lixiana promotional videos), Case AUTH/3499/4/21 (promotion of drugs in the cardiology therapeutic area including Lixiana, on a public website), Case AUTH/3502/4/21 (promotion of drugs in the cardiology therapeutic area including Lixiana, on a public website)). This was on a background of already being under PMCPA audit following a public reprimand (Case AUTH/3285/12/19).

The complainant stated that given the repeated recent breaches of the Code, which he/she believed met the criteria for a Clause 2 breach, there were clearly concerns about Daiichi Sankyo's procedures.

When writing to Daiichi Sankyo, the Authority asked it to consider the requirements of Clauses 2, 5.1, 12.1, 12.4, 12.6 and 12.9 of the 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 breaches of Clauses 2, 5.1, 12.1, 12.4 and 12.9. Daiichi Sankyo did not dispute a breach of Clause 12.6.

This was Daiichi Sankyo's formal response to the alleged breaches.

Daiichi Sankyo stated that it had not responded to additional allegations by the complainant about previous Code breaches as in Daiichi Sankyo's view they were not relevant to this complaint and not within scope of its response.

### **Allegation 1**

Daiichi Sankyo submitted that the prescribing information was provided in a clear and legible manner on the desktop version of the site. The prescribing information was also provided in a clear and legible manner on the mobile version of the site, within a collapsible and easily accessible menu bar.

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

Therefore, Daiichi Sankyo disputed that there had been a breach of Clause 12.1.

### **Allegation 2**

Daiichi Sankyo submitted that the prescribing information was clearly provided in this digital material through a prominent single click link on the desktop website. The mobile version of the same website included a compressed menu bar list that required a drop down on mobile or tablet to expand it, which contained a prominent and direct single click link to the prescribing information which was in line with Clause 12.4 guidance.

Therefore, Daiichi Sankyo disputed that there had been a breach of Clause 12.4.

### **Allegation 3**

Daiichi Sankyo submitted that the prescribing information was clearly provided in this digital material, though Daiichi Sankyo accepted that the menu bar on the mobile version must be expanded before the prescribing information was displayed, where it was in a prominent position.

Therefore, Daiichi Sankyo did not dispute a breach of Clause 12.6.

### **Allegation 4**

Daiichi Sankyo submitted that the adverse event reporting statement was provided in a clear and legible manner on the splash page when first accessing the website. This was visible to all visitors of the website on both desktop and mobile versions. The adverse event reporting statement was therefore clearly visible in this promotional material.

The adverse event reporting statement was also provided in a clear and legible manner at the top of the page on the desktop version of the website. The adverse event reporting statement

was also provided in a clear and legible manner on the mobile version of the website within the easily accessible menu bar. In addition, the adverse event reporting statement formed part of the displayed prescribing information.

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

Therefore, Daiichi Sankyo disputed that there had been a breach of Clause 12.9.

### **Allegation 5**

Daiichi Sankyo agreed that a compressed menu bar on the mobile version of this website required a health professional to expand the menu bar, but the prescribing information and the adverse event reporting statement were clearly accessible and prominent in this location and available in a direct, single click link. Additionally, the prescribing information and adverse event reporting statements were accessible via a direct, single click link on the top of the page in the desktop version of the website.

Therefore, Daiichi Sankyo disputed that there had been a breach of Clause 5.1.

### **Allegation 6**

Daiichi Sankyo stated that the prescribing information and adverse event reporting statements were clearly provided in this digital material, though Daiichi Sankyo accepted that the menu bar on the mobile version must be expanded before the prescribing information and adverse event reporting statement were displayed. Furthermore, the adverse event reporting statement was provided in a clear and legible manner on the initial page when first accessing the HCP website. As these links were available on the website, there was no prejudice to patient safety.

Therefore, Daiichi Sankyo disputed that there had been a breach of Clause 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 webpage at issue referred to by the complainant was the homepage of a Lixiana (edoxaban) promotional website for health professionals. The complainant had provided screenshots of the mobile phone view of the website, taken with the desktop site option activated on an android phone, and alleged that it did not contain prescribing information nor an adverse event reporting statement nor any visible link to these; the complainant alleged that the same was true with the desktop site option deactivated on his/her android phone.

The Panel noted that Daiichi Sankyo responded in relation to both its desktop and mobile versions of the site. In the Panel's view, the complainant's allegations were in relation to viewing the website from a mobile phone, with and without the 'Desktop site' option activated on an android phone. The Panel thus made its rulings in relation to viewing the website from a

mobile phone and considered Daiichi Sankyo's submission with regard to the mobile phone website.

Clause 12.1 stated, *inter alia*, that the prescribing information listed in Clause 12.2 must be provided in a clear and legible manner and must be positioned for ease of reference.

With regard to the complainant's allegation that the prescribing information was not provided in a clear and legible manner, the Panel noted that neither the complainant nor Daiichi Sankyo provided a copy of the prescribing information; Daiichi Sankyo submitted that it was clear and legible. The complainant had the burden of proof and in that regard, the Panel considered the complainant had not established that the prescribing information was not clear and legible and therefore no breach of Clause 12.1 was ruled in that regard.

In relation to the complainant's allegation that the prescribing information was not positioned for ease of reference, the Panel noted Daiichi Sankyo's submission that the prescribing information was provided on the mobile version of the website within a collapsible menu bar. The Panel did not consider that the provision of prescribing information within a menu that required expansion to see the link to it, without any signposting, could be considered as positioned for ease of reference and thus the Panel ruled a breach of Clause 12.1 in that regard.

The Panel noted Daiichi Sankyo's submission that the compressed menu bar, when expanded, contained a prominent and direct single click link to the prescribing information. In the Panel's view, however, the reader would be required to click twice from the homepage to reach the prescribing information page; one click to expand the menu bar to see the option and another click to the prescribing information. In the Panel's view, this did not meet the requirements of Clause 12.4 which required a clear, and prominent, direct, single click link and the Panel ruled a breach of Clause 12.4 accordingly.

Clause 12.6 stated that promotional material provided on the internet must include a clear prominent statement as to where the prescribing information can be found.

The Panel noted that the screenshot of the mobile version of the website provided by Daiichi Sankyo listed 'Prescribing Information', which the company explained would only be seen after expanding the menu bar.

The Panel considered that the presentation of a prescribing information link within a menu bar, that required expansion in order for it to be seen, did not meet the Code's requirement for a clear prominent statement and a breach of Clause 12.6 was ruled as acknowledged by Daiichi Sankyo.

In relation to the complainant's allegation that the material did not include a prominent adverse event reporting statement, the Panel noted Daiichi Sankyo's submission that the adverse event reporting statement was given on the 'splash' page which was visible when first accessing the website. The Panel noted that the splash page stated the website was for UK Healthcare Professionals and gave visitors the option to confirm if they were a health professional or not. It appeared to the Panel that if the visitor confirmed they were a health professional, they would proceed to the Lixiana promotional website; if 'No I am not an HCP' was selected, it appeared visitors would be redirected elsewhere.

Clause 12.9 required that all promotional material include the prominent adverse event reporting statement as referred to in the Code. In the Panel's view, given the splash page appeared to act as a gateway that might be visible to both health professionals and non-health professionals, the splash page could not be considered as part of the promotional website.

The Panel further queried if the adverse event reporting statement on the splash page would meet the requirements of Clause 12.9, particularly given that once the individual confirmed that they were a health professional, it would likely be difficult to navigate back to the splash page. The adverse event reporting statement concerns the safety of medicines, and it is important that readers of materials can access information about reporting adverse events as easily as possible.

The Panel noted Daiichi Sankyo's submission that the adverse event reporting statement had been provided on the mobile version of the website within the collapsible menu bar. Further, according to Daiichi Sankyo, the adverse event reporting statement was displayed within the prescribing information, which the Panel did not have before it.

The Panel, noting the use of the term 'prominent' in the complainant's citation of Clause 12.9, did not consider that the provision of the adverse event reporting statement within a menu bar that required expansion, or within the prescribing information which was positioned in the same collapsible menu, was sufficiently prominent. Furthermore, a link to the adverse event reporting statement did not meet the requirements of Clause 12.9; the adverse event reporting statement should appear as an integral part of the promotional website. The Panel considered that the requirements of Clause 12.9 had not been met and ruled a breach of Clause 12.9.

The Panel considered that it was important that health professionals could access prescribing information and other obligatory information in promotional material as easily as possible. The Panel considered that failure to meet the Code's requirements in this regard, when promotional material was viewed on a mobile phone, meant that Daiichi Sankyo had failed to maintain high standards. A breach of Clause 5.1 was ruled.

Clause 2 was a sign of particular censure and was reserved for such use. The supplementary information to this clause listed cumulative breaches of a similar and serious nature in the same therapeutic area within a short period of time as an example of an activity likely to be in breach of Clause 2. The Panel noted the complainant cited numerous completed Daiichi Sankyo cases in this regard.

The Panel noted that breaches of the Code ruled in Case AUTH/3497/3/21, which the complainant referred to as a previous version of this Lixiana website, was in relation to a misleading claim about lactose and that Daiichi Sankyo had omitted information that Lixiana was not recommended in patients with end stage renal disease or on dialysis.

The Panel noted in Case AUTH/3506/4/21 that a statement that prescribing information would be found overleaf was missing from a journal advertisement.

The breaches ruled in Case AUTH/3504/4/21 were in relation to promotional claims for Nilemdo and Nustendi and the non-proprietary name not being readily readable.

With regard to Case AUTH/3507/5/21 and Case AUTH/3513/5/21, the Panel noted that it had ruled breaches in relation to a promotional video being viewable by members of the public due to it not having the correct privacy settings.

In Case AUTH/3499/4/21 and Case AUTH/3502/4/21, promotional webpages were incorrectly set as live on the Daiichi Sankyo corporate website; breaches of the Code were ruled, including for omitting prescribing information in each case.

In the Panel's view, the case in question (Case AUTH/3630/4/22), where the prescribing information and adverse event reporting statement on the mobile version of a website were only accessible once the menu button was expanded, was not sufficiently similar to the cases cited by the complainant such that, in the Panel's view, it did not represent cumulative breaches of a similar and serious nature in the same therapeutic area within a short period of time as referred to in the supplementary information of Clause 2. Furthermore, noting that the prescribing information and adverse event reporting statement were available when material was viewed on a mobile device, albeit within a collapsible menu bar, the Panel did not consider that the particular circumstances of this case warranted a ruling of a breach of Clause 2. It followed that no breach of Clause 2 was ruled.

**Complaint received**      **11 April 2022**

**Case completed**        **15 March 2023**