CASE AUTH/3502/4/21

COMPLAINANT v DAIICHI-SANKYO

Promotion of Olmesartan, Prasugrel and Edoxaban on Daiichi-Sankyo website and breach of undertaking

An anonymous complainant, who could not be contacted using the contact details provided, alleged that Daiichi-Sankyo had promoted medicines to the public via its website in breach of its undertaking given in Case AUTH/3107/10/18.

The complainant submitted that following on from his/her recent complaints (Cases AUTH/3497/3/21 and AUTH/3499/4/21), he/she had been made aware of another major error on another website page.

The complainant noted that this particular page was accessible by anyone including health professionals, patients and members of the public. Providing product name, indications, descriptions, mechanisms of actions and superlatives in regard to three products was shocking and showed a lack of understanding of the Code. The complainant alleged that it was clear promotion to the public. The complainant stated that, in addition, it was also promotional to health professionals and therefore needed certification and mandatory promotional information. No prescribing information was provided and therefore it was in breach of multiple clauses of the Code. The complainant alleged that this was once again a breach of undertaking considering previous case rulings against Daiichi-Sankyo. The complainant further alleged that use of the word 'excellent' in describing olmesartan was inappropriate in breach of the Code. The complainant stated that the way Daiichi-Sankyo continued to operate, despite multiple compliance failings over a number of years, was a huge disrespect to the Code and the industry. Signatory knowledge was lacking and in view of the multiple compliance errors and continual poor practice, the PMCPA ought to consider temporary suspension from membership to protect patient safety.

The detailed response from Daiichi-Sankyo is given below.

The Panel noted Daiichi-Sankyo's submission that the draft content on the webpage at issue was created by Daiichi-Sankyo Europe (DSE) Corporate Communications team; it was stored in draft format only in the website wireframe and was never intended for external publication on the Daiichi-Sankyo UK website.

The Panel noted Daiichi-Sankyo's submission that as a result of a quality control error by Daiichi-Sankyo Europe, the status of the page was incorrectly set as live. The page was thus accessible through certain search terms on the Daiichi-Sankyo UK website, such as Daiichi-Sankyo product or brand names.

In the Panel's view, the webpage at issue promoted edoxaban, prasugrel and olmesartan and would potentially be seen by a broad audience including members of the public. The

Panel noted the statements on the webpage at issue and considered that they might encourage members of the public to ask their health professional to prescribe a specific prescription only medicine. The Panel therefore ruled breaches of the Code in relation to each medicine, as acknowledged by Daiichi-Sankyo.

The Panel noted its comments and rulings above. It appeared to the Panel that any user of the website could access the webpage in question if certain terms were searched for in the website's search function and the intended audience for the webpage had not been identified. The website contained promotional material which was not restricted to health professionals and other relevant decision makers as set out in the relevant supplementary information and a breach of the Code was ruled.

The Panel did not consider that the webpage was aimed at patients prescribed a Daiichi-Sankyo medicine and therefore the requirement to include information about reporting side effects was not relevant and no breach was ruled.

The Panel ruled a breach as Daiichi-Sankyo had failed to maintain high standards. The Panel did not consider that the particular circumstances in this case warranted a ruling of a breach of Clause 2 which was a sign of particular censure and reserved for such. No breach of Clause 2 was ruled.

The Panel noted Daiichi-Sankyo's submission that the corporate website was not promotional material and was not aimed at health professionals or other relevant decision makers. The Panel noted it comments above that, in its view, the webpage at issue was promotional and therefore the requirements of the Code in relation to promotional material would apply in that regard. The Panel noted Daiichi-Sankyo's submission that the webpage in question had not been approved for publication on the Daiichi-Sankyo UK website; it had not been reviewed by a signatory as required by the Code. The Panel therefore ruled a breach of the Code.

The Panel noted its comments above that in its view the webpage at issue was promotional and therefore prescribing information would be required for the health professional audience but had not been included. The Panel therefore ruled a breach of the Code in relation to Olmesartan, Prasugrel and Edoxaban.

The Panel noted its comments and rulings above and considered that Daiichi-Sankyo had failed to maintain high standards in this regard and a breach of Clause 9.1 was ruled. The Panel noted that Clause 2 was a sign of particular censure and reserved for such use. The Panel did not consider that the particular circumstances of this case warranted a ruling of a breach of Clause 2 and ruled no breach accordingly.

With regard to the claim 'Olmesartan is an angiotensin receptor blocker (ARB) with excellent blood pressure lowering efficacy', the Panel noted Daiichi-Sankyo's submission that the use of the superlative, excellent, was inappropriate and a breach of the Code was ruled as acknowledged by Daiichi- Sankyo. The company had failed to maintain high standards and a breach of the Code was ruled.

The Panel noted that in Case AUTH/3107/10/18, Daiichi-Sankyo was ruled in breach of the Code as a webpage on the corporate website advertised prescription only medicines to the public and access to that webpage had not been restricted to health professionals

and other relevant decision makers and its undertaking, accepting the Panel's decision, was dated 22 February 2019. Turning to the present case, Case AUTH/3502/4/21, the Panel ruled breaches of the Code because the webpage in question on the corporate website promoted prescription only medicines to the public and access to the webpage had not been restricted to health professionals. There had thus been a failure to comply with the undertaking given in Case AUTH/3107/10/18 and a breach of the Code was ruled. The Panel considered that high standards had not been maintained and a breach of the Code was ruled.

The Panel noted Daiichi-Sankyo's submission that it took all the necessary steps to ensure that the material in question with regards to Case AUTH/3107/10/18 was discontinued, removed and no longer in use. The Panel further noted Daiichi-Sankyo's submission that the corporate website page at issue was never intended to be externally facing and was visible only as a result of an undetected backend error when it was mistakenly enabled as a result of a quality control error by Daiichi-Sankyo Europe.

The Panel noted that inadequate action leading to a breach of undertaking was an example of an activity likely to be in breach of Clause 2. Whilst the Panel was concerned that Daiichi-Sankyo had only became aware of the availability of the webpage at issue on receipt of this complaint, noting its comments and rulings above, it did not consider that the particular circumstances of this case warranted a ruling of a breach of Clause 2 which was a sign of particular censure and was reserved for such use. On balance, no breach of the Code was ruled.

An anonymous complainant, who could not be contacted using the contact details provided, alleged that Daiichi-Sankyo had promoted medicines to the public via its website in breach of its undertaking given in Case AUTH/3107/10/18.

COMPLAINT

The complainant submitted that following on from his/her recent complaints (Cases AUTH/3497/3/21 and AUTH/3499/4/21), he/she had been made aware of another major error on the following UK website page: https://www.daiichi-sankyo.co.uk/boxes-for-footer-content Last Update: 09.11.2020. The complainant stated that on this page as could be seen by the hyperlink provided, the following products and descriptions were mentioned:

> 'Olmesartan High blood pressure is one of the most common causes of cardiovascular diseases in the world. Olmesartan is an angiotensin receptor blocker (ARB) with excellent blood pressure lowering efficacy. Prasugrel Our oral antiplatelet agent prasugrel helps to keep blood platelets from clotting together and developing a blockage in arteries in patients who had an acute coronary syndrome (ACS) and underwent a percutaneous coronary intervention (PCI). Edoxaban Edoxaban is a once-daily, non-vitamin K antagonist (non-VKA) oral anticoagulant (NOAC) that specifically, reversibly and directly inhibits factor Xa, an important factor in the coagulation system that leads to blood clotting.'

The complainant noted that this particular page was accessible by anyone including health professionals, patients and members of the public. Providing product name, indications, descriptions, mechanisms of actions and superlatives in regard to three products was shocking and showed a lack of understanding of the Code. The complainant alleged that it was clear

promotion to the public which was in breach of the following clauses several times for each of the three products – 26.1 (x3), 26.2 (x3), 26.3 (x3), 28.1, 28.3, 9.1(x3) and Clause 2 (x3). The complainant stated that, in addition, it was also promotional to health professionals and therefore needed certification and mandatory promotional information. No prescribing information was provided and therefore it was in breach of Clauses 4.1 (x3 times), 14.1, 9.1 and 2 (3 times). The complainant alleged that this was once again a breach of undertaking considering previous case rulings against Daiichi-Sankyo; a breach of Clauses 29, 9.1 and 2 was alleged. The complainant further alleged that use of the word 'excellent' in describing olmesartan was inappropriate in breach of Clauses 7.10 and 9.1. The complainant stated that the way Daiichi-Sankyo continued to operate, despite multiple compliance failings over a number of years, was a huge disrespect to the Code and the industry. Signatory knowledge was lacking and in view of the multiple compliance errors and continual poor practice, the PMCPA ought to consider temporary suspension from membership to protect patient safety.

When writing to Daiichi-Sankyo, the Authority asked it to consider the requirements of Clauses 2, 4.1, 7.10, 9.1, 14.1, 26.1, 26.2, 26.3, 28.1, 28.3 and 29 of the Code as cited by the complainant.

RESPONSE

Daiichi-Sankyo UK submitted that it took its obligations under the ABPI Code of Practice seriously, strove to maintain high standards and behaved responsibly and ethically at all times.

Daiichi-Sankyo https://www.daiichi-sankyo.co.uk/boxes-for-footer-content.

1 Daiichi-Sankyo UK submitted that it would like to make clear at the outset that this page was from the corporate website; the existence of this page, both in draft or published form, was unknown to Daiichi-Sankyo UK until notified via the complaint. The reference, 'Last Update: 09.11.2020' related to the date the corporate website was last updated, and not related to the specific content at issue. The particular page at issue was never seen or approved by Daiichi-Sankyo UK.

2 The draft content on this page was created by Daiichi-Sankyo Europe (DSE) Corporate Communications team. The footers were associated to both enabled and non-live/disabled pages across all Daiichi-Sankyo group sites. Daiichi-Sankyo Europe and Daiichi-Sankyo UK were not aware that these 'behind the scene' footers were live and searchable via the Daiichi-Sankyo UK website search function.

3 The page was not immediately visible on the Daiichi-Sankyo UK website and unbeknown to both Daiichi-Sankyo UK and Daiichi-Sankyo Europe, they were searchable and in the public domain. In addition, you could not find this page through the normal navigation unless you searched for certain terms.

4 The content on the page was not, and had not ever, been approved for publication on the Daiichi-Sankyo UK website at any point. It had not been reviewed through Veeva PromoMats by an appropriately qualified person or medical signatory. The page was never intended for publication, not aimed at any UK audience and was stored in draft format only in the wireframe of the website.

5 As a result of a quality control error by Daiichi-Sankyo Europe, the status of this page was incorrectly set as live. The pages were thus accessible through certain search terms on the Daiichi-Sankyo UK website, such as Daiichi-Sankyo product or brand names.

6 The page subject to complaint was draft, non-approved content which was never intended for external publication on the Daiichi-Sankyo UK website. The appearance and accessibility was the result of human error and quality control issues. Remedial actions to disable all draft or non-live content have been taken immediately and the page has now been deleted. Product queries via the search function will now direct the user only to the Daiichi-Sankyo UK approved pages.

7 Instructions have now been given by Daiichi-Sankyo Europe to all affiliates to disable and/or delete pages, footers or side boxes that are not live or approved to prevent similar issues occurring in the future. Processes for website management and approval and publication of content have also been updated with the view to avoiding quality technical control errors moving forward.

Response to breach allegations

1 Daiichi-Sankyo UK acknowledged that because the page at issue was accessible externally at the time of the complaint, certain Code breaches might have occurred. Daiichi-Sankyo reiterated that this was a genuine technical mistake with no intention to promote the three prescription-only medicines to health professionals, other relevant decision makers, members of the public, and the like through this corporate platform.

2 Confirmation of the product narrative at issue:

a) **Olmesartan –** High blood pressure is one of the most common causes of cardiovascular diseases in the world. Olmesartan is an angiotensin receptor blocker (ARB) with excellent blood pressure lowering efficacy.
b) **Prasugrel –** The oral antiplatelet agent Prasugrel helps to keep blood platelets from clotting together and developing a blockage in arteries in patients who had an acute coronary syndrome (ACS) and underwent a percutaneous coronary intervention (PCI).
c) **Edoxaban –** Edoxaban is a once-daily, non-vitamin K antagonist (non-VKA) oral anticoagulant (NOAC) that specifically, reversibly and directly inhibits factor Xa, an important factor in the coagulation system that leads to blood clotting.

3 Admission of Code of Practice breaches.

In the case of the narrative at issue for all three prescription-only medicines quoted in Part 2, Daiichi-Sankyo UK acknowledged the following breaches of Clauses 26.1 and 26.2.

In respect of the Olmesartan narrative in Section 2a, Daiichi-Sankyo acknowledged that the use of the superlative (excellent) was inappropriate and breached Clause 7.10. Daiichi-Sankyo UK further acknowledged that the breaches cited in Section 3 meant that it failed to maintain high standards, notwithstanding that this was a genuine technical mistake with no intention to promote the three prescription-only medicines to health professionals, other relevant decision makers, members of the public, and the like. For clarity, Daiichi-Sankyo UK acknowledged that it might have breached Clause 9.1 of the Code.

4 Denial of Clause breaches:

a) Clause 4.1 – Daiichi-Sankyo submitted that the corporate website was not promotional material and was not aimed at health professionals or other relevant decision makers. Therefore, the availability of the prescribing information was not relevant in this case. For this reason, Daiichi-Sankyo UK refuted a breach of Clause 4.1.

b) Clause 14.1 – Daiichi-Sankyo submitted that the page on the corporate website page was not promotional material and was never intended for publication and was never aimed at healthcare professionals. Therefore, the page was not approved for use by a Daiichi-Sankyo UK Signatory. For this reason, Daiichi-Sankyo UK denied a breach of Clause 14.1

c) Clause 26.3 – Daiichi-Sankyo submitted that the corporate website page was never aimed at patients prescribed prescription only medicines. Daiichi-Sankyo UK would have included this information for patients about how to report adverse events if the website page was approved for such use. Daiichi-Sankyo UK website section under its UK products clearly had signposted under '*Adverse Event Reporting*', information on how to report adverse events. For this reason, Daiichi-Sankyo UK denied a breach of Clause 26.3.

d) Clause 28.1 – Daiichi-Sankyo submitted that the corporate website page was not directed or aimed at a UK audience or members of the public. This page was not openly accessible to members of the public and set live in error at the back end of the wireframe. For this reason, Daiichi-Sankyo UK denied a breach of Clause 28.1.

e) Clause 28.3 – Daiichi-Sankyo submitted that the corporate website page was not intended for members of the public and was never aimed at any specific UK audience. This box footer page was not openly accessible to members of the public and was set live in error at the back end of the wireframe. For this reason, Daiichi-Sankyo UK denied a breach of Clause 28.3.

Clause 2 relating to the webpage at issue:

Contrary to the argument put forward by the complainant, Daiichi-Sankyo UK believed that there was no credible evidence that patient safety and/or public health had been jeopardised. This corporate website page was not directed at any UK audience as stated above. Daiichi-Sankyo UK took compliance very seriously: it immediately carried out an investigation and implemented the remediation quickly and effectively. For this reason, Daiichi-Sankyo denied a breach of Clause 2.

Clause 2 and Clause 29 relating to breach of undertaking:

Contrary to the argument put forward by the complainant, Daiichi-Sankyo UK denied a breach of undertaking. Daiichi-Sankyo UK took the breach of an undertaking very seriously: it took all the necessary steps to ensure that the material in question with regard to Case AUTH/3107/10/18 was discontinued, removed and no longer in use.

As a result of Case AUTH/3107/10/18, Daiichi-Sankyo had implemented the steps and processes below to:

i) remove the product content that was subject to the original complaint
ii) update the product content to contain product name, SPC and PIL – review and certify https://www.daiichi-sankyo.co.uk/ website content on a regular and frequent basis to ensure there was no promotional content
iii) create clear policies and protocols for corporate website management, including clear lines of accountability and ownership amongst Daiichi-Sankyo UK employees
iv) ensure all relevant staff and teams responsible for non-promotional external communications and website content undertook regular internal and externally provisioned training on the Code.

The corporate website page at issue was never intended to be externally facing and was visible only as a result of an undetected back-end error. The page was never certified for use. With regard to Case AUTH/3107/10/18, Daiichi-Sankyo UK took all possible steps to comply with the breach of undertaking regarding as described above. For these reasons, Daiichi-Sankyo UK denied a breach of Clause 2 and Clause 29.

In conclusion Daiichi-Sankyo submitted that it was with regret that the errors occurred, however it trusted that the immediate actions taken with urgency to investigate and remediate this matter demonstrated to the PMCPA that it had taken this matter seriously, and had not brought discredit on, nor reduced confidence in, the pharmaceutical industry.

PANEL RULING

The Panel noted Daiichi-Sankyo's submission that the draft content on the webpage at issue was created by Daiichi-Sankyo Europe (DSE) Corporate Communications team; it was stored in draft format only in the wireframe of the website and was never intended for external publication on the Daiichi-Sankyo UK website.

The Panel noted Daiichi-Sankyo's submission that as a result of a quality control error by Daiichi-Sankyo Europe, the status of the page was incorrectly set as live. The page was thus accessible through certain search terms on the Daiichi-Sankyo UK website, such as Daiichi-Sankyo product or brand names.

In the Panel's view, the webpage at issue promoted edoxaban, prasugrel and olmesartan and would potentially be seen by a broad audience including members of the public. The Panel noted the statements on the webpage at issue and considered that they might encourage members of the public to ask their health professional to prescribe a specific prescription only medicine. The Panel therefore ruled a breach of Clause 26.1 and Clause 26.2 in relation to each medicine, as acknowledged by Daiichi-Sankyo.

The Panel noted that the supplementary information to Clause 28.1 stated that unless access to promotional material about prescription only medicines was limited to health professionals and other relevant decision makers, a pharmaceutical company website or a company sponsored website must provide information for the public as well as promotion to health professionals with the sections for each target audience clearly separated and the intended audience identified. This was to avoid the public needing to access material for health professionals unless they chose to. The Panel noted its comments and rulings above. It appeared to the Panel that any

user of the website could access the webpage in question if certain terms were searched for in the website's search function and the intended audience for the webpage had not been identified. The website contained promotional material which was not restricted to health professionals and other relevant decision makers as set out in the relevant supplementary information to Clause 28.1 and a breach of Clause 28.1 was ruled.

Clause 28.3 required that information about medicines covered by Clauses 28.1 and 28.2 which was provided on the internet and which was intended for members of the public must comply with Clause 26.2. The Panel noted its rulings of breaches of the Code in relation to material for the public as set out above and therefore ruled a breach of Clause 28.3.

The Panel noted that Clause 26.3 required that any material which related to a medicine and which is intended for patients taking that medicine must include the statement below or a similar one: 'Reporting of side effects: If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the Yellow Card Scheme at [a web address which links directly to the MHRA Yellow Card site]. By reporting side effects you can help provide more information on the safety of this medicine'. The Panel did not consider that the webpage was aimed at patients prescribed a Daiichi-Sankyo medicine and therefore the requirement of Clause 26.3 was not relevant and no breach was ruled in relation to the webpage.

The Panel noted its comments and rulings above and considered that Daiichi-Sankyo had failed to maintain high standards in this regard and a breach of Clause 9.1 was ruled. The Panel did not consider that the particular circumstances in this case warranted a ruling of a breach of Clause 2 which was a sign of particular censure and reserved for such. No breach of Clause 2 was ruled.

The Panel noted Daiichi-Sankyo's submission that the corporate website was not promotional material and was not aimed at health professionals or other relevant decision makers. The Panel noted it comments above that, in its view, the webpage at issue was promotional and therefore the requirements of the Code in relation to promotional material would apply in that regard. The Panel noted Daiichi-Sankyo's submission that the webpage in question had not been approved for publication on the Daiichi-Sankyo UK website; it had not been reviewed by a signatory as required by the Code. The Panel therefore ruled a breach of Clause 14.1.

The Panel noted its comments above that in its view the webpage at issue was promotional and therefore prescribing information would be required for the health professional audience but had not been included. The Panel therefore ruled a breach of Clause 4.1 in relation to Olmesartan, Prasugrel and Edoxaban.

The Panel noted its comments and rulings above and considered that Daiichi-Sankyo had failed to maintain high standards in this regard and a breach of Clause 9.1 was ruled. The Panel noted that Clause 2 was a sign of particular censure and reserved for such use. The Panel did not consider that the particular circumstances of this case warranted a ruling of a breach of Clause 2 and ruled no breach accordingly.

Clause 7.10 stated, *inter alia*, that exaggerated or all-embracing claims must not be made and superlatives must not be used except for those limited circumstances where they relate to a clear fact about a medicine. Claims should not imply that a medicine or an active ingredient has some special merit, quality or property unless this can be substantiated.

With regard to the claim 'Olmesartan is an angiotensin receptor blocker (ARB) with excellent blood pressure lowering efficacy', the Panel noted Daiichi-Sankyo's submission that the use of the superlative, excellent, was inappropriate and a breach of Clause 7.10 was ruled as acknowledged by Daiichi- Sankyo. The Panel considered that in using the claim, Daiichi-Sankyo had failed to maintain high standards and a breach of Clause 9.1 was ruled.

The Panel noted that a form of undertaking and assurance was an important document. Companies had to give an undertaking that the material in question and any similar material, if not already discontinued or no longer in use would cease forthwith and give an assurance that all possible steps would be taken to avoid similar breaches of the Code in future (Paragraph 7.1 of the Constitution and Procedure). It was very important for the reputation of the industry that companies complied with undertakings.

The Panel noted that in Case AUTH/3107/10/18, Daiichi-Sankyo was ruled in breach of the Code as a webpage on the corporate website advertised prescription only medicines to the public and access to that webpage had not been restricted to health professionals and other relevant decision makers and its undertaking, accepting the Panel's decision, was dated 22 February 2019. Turning to the present case, Case AUTH/3502/4/21, the Panel ruled breaches of the Code because the webpage in question on the corporate website promoted prescription only medicines to the public and access to the webpage had not been restricted to health professionals. There had thus been a failure to comply with the undertaking given in Case AUTH/3107/10/18 and a breach of Clause 29 was ruled. The Panel considered that high standards had not been maintained and a breach of Clause 9.1 was ruled.

The Panel noted Daiichi-Sankyo's submission that it took all the necessary steps to ensure that the material in question with regards to Case AUTH/3107/10/18 was discontinued, removed and no longer in use. The Panel noted Daiichi-Sankyo's submission that it had updated the product content to contain product name, SPC and PIL and reviewed and certified the website content on a regular and frequent basis to ensure there was no promotional content; it had created policies and protocols for corporate website management, including lines of accountability and ownership amongst Daiichi-Sankyo UK employees, and ensured that all relevant staff and teams responsible for non-promotional external communications and website content undertook regular internal and externally provisioned training on the Code.

The Panel further noted Daiichi-Sankyo's submission that the corporate website page at issue was never intended to be externally facing and was visible only as a result of an undetected backend error when it was mistakenly enabled as a result of a quality control error by Daiichi-Sankyo Europe.

The Panel noted that inadequate action leading to a breach of undertaking was an example of an activity likely to be in breach of Clause 2. Whilst the Panel was concerned that Daiichi-Sankyo had only became aware that the webpage at issue was available on its website on receipt of this complaint, noting its comments and rulings above, it did not consider that the particular circumstances of this case warranted a ruling of a breach of Clause 2 which was a sign of particular censure and was reserved for such use. On balance, no breach of Clause 2 was ruled.

Complaint received 10 April 2021

Case completed **6 December 2021**