CASE AUTH/3637/4/22

COMPLAINANT v DAIICHI SANKYO

Alleged promotion of Nilemdo and Nustendi to the public

CASE SUMMARY

This case was in relation to Daiichi Sankyo's myldltreatment website for patients who had been prescribed Nilemdo (bempedoic acid) or Nustendi (bempedoic acid, ezetimibe).

The Panel ruled a breach of the following Clauses of the 2021 Code as patients visiting the website who were prescribed Nilemdo (bempedoic acid) would be made aware of ezetimibe's mechanism of action, as a selective cholesterol absorption inhibitor that prevents cholesterol from being absorbed in the gut, which would have likely encouraged patients prescribed Nilemdo to ask their health professional for Nustendi (bempedoic acid, ezetimibe). Furthermore, individuals on bempedoic acid and ezetimibe as separate tablets may have been encouraged to ask their health professional for the single tablet, Nustendi. Therefore, in the Panel's view, the webpage promoted Nustendi to individuals prescribed Nilemdo and likely encouraged such individuals to ask their health professional to prescribe Nustendi:

Breach of Clause 5.1	**Failing to maintain high standards**
Breach of Clause 26.1	**Promoting a prescription only medicine to the public**
Breach of Clause 26.2	**Encouraging members of the public to ask for a specific prescription only medicine**

The Panel ruled no breach of the following Clauses of the 2021 Code in relation to the alleged promotion of Nilemdo to individuals prescribed Nustendi, as the Panel noted that all patients visiting the webpage would have already been prescribed bempedoic acid. The Panel further ruled no breach as the complainant had not established that members of the public were exposed to product information due to a lack of disclaimer as alleged nor did the Panel consider that the matter was such that it brought discredit upon, or reduced confidence in, the industry:

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 26.1	**Requirement not to promote prescription only medicines to the public**
No Breach of Clause 26.2	**Requirement that information about prescription only medicines must not encourage the public to ask their health professional to prescribe a specific prescription only medicine.**

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 complained about Daiichi Sankyo's myldltreatment website.

Daiichi Sankyo manufactured Nilemdo (bempedoic acid) and Nustendi (bempedoic acid, ezetimibe).

COMPLAINT

The complainant alleged that the myldltreatment website, which was meant to be non-promotional but due to no segregation by product became promotional, was incorrectly allowed for members of the public to access. This website was in place from April 2021 and had recently been taken down by Daiichi Sankyo.

The website was meant to be for patients prescribed either Nilemdo or Nustendi (2 separate anti-cholesterol drugs manufactured by Daiichi Sankyo). The complainant alleged the website did not have different sections for the 2 products so members of the public (as there was no disclaimer) or patients taking only one of the products (Nilemdo and Nustendi could not be taken together, it was only ever one or the other) were exposed to product information they should not have seen. The complainant stated the website, which only consisted of the homepage, had information on both products including mentioning ezetimibe and other product information towards the bottom of the page when in fact the website should have been built as different areas depending on whether a patient was taking Nilemdo or Nustendi.

The complainant concluded the website had been taken down as Daiichi Sankyo realised it was promoting to members of the public.

When writing to Daiichi Sankyo, the Authority asked it to consider the requirements of Clauses 2, 5.1, 26.1 and 26.2 of the 2021 Code as cited by the complainant.

RESPONSE

Daiichi Sankyo welcomed the opportunity to provide further information as to the nature of the website in question and to also provide clarity in how patients, who have been prescribed Nilemdo or Nustendi, could access this website and the mitigation measures in place to ensure that the website was intended to be for the appropriate patients only and not by members of the public.

Daiichi Sankyo submitted, for background information, the website in question was a non-promotional website that was created specifically for patients who had been prescribed Nilemdo or Nustendi. It was intended for patients to understand more about managing their cholesterol as well as providing them with access to further information on either Nilemdo or Nustendi which they had been prescribed by their doctor. The homepage referred to general information on the disease area and was applicable to patients on both medicines. There were then links to each PIL (patient information leaflets) specifically so that patients could access the appropriate one for which they had been prescribed. All the information on these pages and subsequent screens applied to both products. Therefore, patients were not exposed to information they should not have seen.

The website in question (BEM/20/0243) was certified for use and went live in October 2020. The website was subsequently taken down in February 2022, after an internal decision to further evolve Daiichi Sankyo's patient offering with plans to add additional resources to the website and to update the disclaimer to align with the (health professional's) version under development.

Daiichi Sankyo submitted this website was intended as a post-prescription website for patients only and the main routes of access to this resource were:

- Via the direct URL from the patient brochures intended to be distributed by health professionals once a patient had been prescribed Nilemdo/Nustendi;
- by scanning of the QR codes on the patient brochures intended to be distributed by health professionals once a patient had been prescribed Nilemdo or Nustendi;

or alternatively, if a patient arrived at the health professional website landing page whilst searching for information on Nilemdo or Nustendi, there was an option for the patient to self-certify as a patient which would then re-direct the patient to the www.myldltreatment.co.uk website. The health professional landing page also had an option for 'member of the public' which would re-direct the member of the public to the Daiichi Sankyo UK corporate website.

When the patient accessed the patient website, contrary to the complainant's allegation that 'there was no disclaimer', there was, according to Daiichi Sankyo, in fact a clear disclaimer stating that the website was intended for UK patients prescribed Nilemdo or Nustendi; and there was the option if the site visitor was not a patient to click, which in the event that a visitor, who is not a patient were to access, this would bring the user back to the health professional landing page where they could confirm if they are a health professional, patient, or member of the public and redirect accordingly.

Daiichi Sankyo submitted, as evident from above, accessibility was limited to, and intended for, use by patients who had been prescribed Nilemdo or Nustendi only as the URL and QR codes were only available on the individual patient brochures which were offered by health professionals post prescription. Owing to the limitations on accessibility to this resource as well as the requirement to self-certify as a patient or member of the public if accessed via an alternative route, Daiichi Sankyo refuted the allegation that this website 'incorrectly allowed for members of the public to access'.

The only information that was available to patients on this website, according to Daiichi Sankyo, was the PIL and patient brochures for each of the respective medicines. Daiichi Sankyo submitted a screenshot to show the point at which the patient could access the PIL for Nilemdo or Nustendi, both of which were accessible to the general public and available via the eMC website and had been provided on this platform for ease of access to the Nilemdo and Nustendi patients on this website.

Daiichi Sankyo submitted a further screenshot to outline the location further down the page on the website where the patient brochures for Nilemdo and Nustendi were available to access. Prior to downloading the brochures, there was an explicit statement and instruction to the patients to 'Download the patient brochure for the medicine your doctor has prescribed'. The patient brochures available on this platform were an electronic version of the materials that the patients would have received from their health professional post prescription.

In addition, to ensure that information was only accessed by the relevant patients, the front page of the versions of the patient brochures that were available to download stated clearly that this is intended for patients who have been prescribed Nilemdo or Nustendi respectively.

Daiichi Sankyo stated the landing page required the user to confirm that they were a patient before entering the website. The patient homepage had a clear disclaimer to state who the intended audience was, Daiichi Sankyo had only provided reference information in the form of the PIL for both medications (publicly available) and provided patients with the option to access and download a patient brochure for the medicine prescribed by the patient's doctor, with subsequent upfront disclaimers on the front of those document pages to state that the material was intended for patients prescribed Nilemdo or Nustendi. For example, 'This guide is intended for patients who have been prescribed NILEMDO®'. Daiichi Sankyo submitted that no information on specific products were displayed on the website.

Daiichi Sankyo disagreed with the complainant's allegation that members of the public or patients 'were exposed to product information they should not have seen'. Daiichi Sankyo submitted, as outlined above, that access to the website had been restricted to, and communicated as, a resource for patients who had been prescribed either Nilemdo or Nustendi only. Daiichi Sankyo believed that appropriate measures had been put in place as demonstrated above, to facilitate the intended audience only accessing the contents of the myldltreatment website. Daiichi Sankyo stated prescription-only medicines had not been advertised to the public and denied a breach of Clause 26.1; consequently, Daiichi Sankyo submitted there was no evidence to suggest a breach of Clause 26.2.

Daiichi Sankyo stated it had demonstrated that high standards had been maintained meaning that there was no breach of Clause 5.1 and subsequently no breach of Clause 2.

PANEL RULING

The Panel noted Daiichi Sankyo's submission that the myldltreatment website was a non-promotional website intended for patients prescribed Nilemdo or Nustendi; the website, certified in October 2020, was taken down in February 2022.

The website at issue had a black banner at the very top, with the disclaimer that information on the website was intended for UK patients prescribed Nilemdo or Nustendi, along with a hyperlink to re-direct those who were not a patient. The webpage started with the large heading 'NILEMDO (bempedoic acid) and NUSTENDI (bempedoic acid and ezetimibe) patient information' beneath which were buttons that appeared to link to the respective patient information leaflets; to the right of this was the side-effect reporting statement for patients and the statement that the medicines were subject to additional monitoring. The webpage thereafter appeared to have five further sections, to which the header also appeared to link to, including 'Understanding Cholesterol', 'Cholesterol levels', 'Managing your high cholesterol', 'Medicines' and 'Contact Us'.

The Panel noted Daiichi Sankyo's submission that the main routes of access to the webpage at issue were via the direct URL or QR Code available in patient brochures distributed by health professionals once a patient had been prescribed Nilemdo or Nustendi; alternatively, if a patient/member of the public arrived at the health professional website landing page following a general internet search, there was an option to self-certify as either a patient or member of the public, which would re-direct the visitor to the myldltreatment website or the UK corporate

website, respectively. The myldltreatment website had a black banner at the very top of the webpage, with the disclaimer that information on the website was intended for UK patients prescribed Nilemdo or Nustendi, and a hyperlink to re-direct those who were not a patient back to the 'HCP landing page' where they could select if they were a health professional, patient, or member of the public, and be redirected accordingly.

The Panel noted that the supplementary information to Clause 26.2 stated, amongst other things, that a pharmaceutical company website providing information for the public as well as promotion to health professionals must have the sections for each target audience clearly separated and the intended audience identified. This is to avoid the public needing to access material for health professionals unless they choose to.

In relation to the allegation that members of the public were exposed to product information as there was 'no disclaimer', the Panel considered the routes of access to the webpage at issue and the banner at the top of this webpage, which was labelled '…for UK patients who have been prescribed Nilemdo or Nustendi', and the redirect option for those who were not such a patient to the UK corporate site, and considered that the complainant had not established that members of the public were exposed to product information due to a lack of disclaimer, as alleged, and **no breach of Clauses 26.1 and 26.2** were ruled based on the narrow allegation.

However, the Panel noted the allegation that although the website was meant to be non-promotional, it had become promotional due to the lack of segregation and separate areas for patients prescribed either Nilemdo or Nustendi, which meant that the webpage promoted one of these prescription only medicines to individuals who had been prescribed the other.

The Panel noted the content of the webpage at issue.

The sections entitled 'Understanding Cholesterol' and 'A quick guide to cholesterol levels' provided information on the disease area. The section 'Managing your high cholesterol' provided lifestyle advice and included buttons to Nilemdo and Nustendi patient brochures with the accompanying text 'download the patient brochure for the medicine your doctor has prescribed'.

The 'Medicines to lower your cholesterol' section described in layman terms how several types of medication classes work, including adenosine triphosphate citrate lyase (ACL) inhibitors, PCSK9 inhibitors, Resins, Selective cholesterol absorption inhibitors, and statins; however, unlike for the other classes, bempedoic acid and ezetimibe were given as named examples for ACL inhibitors and selective cholesterol absorption inhibitors, respectively.

The Panel considered that the information on the disease area and lifestyle advice was relevant for patients regardless of which medicine they had been prescribed. However, the webpage also prominently included the brand names, active ingredients, therapeutic use and mechanism of action for Nilemdo and Nustendi and this was visible to all visitors of the webpage, including individuals who would not have been prescribed one of these medicines (Nilemdo and Nustendi could not be taken together).

Whilst there were clearly labelled tabs to access specific Nilemdo or Nustendi information within the webpage at issue, the 'Medicines to lower your cholesterol' section only provided named examples of an ACL inhibitor (bempedoic acid) and a selective cholesterol absorption inhibitor (ezetimibe), which, in the Panel's view, brought undue emphasis to the mechanisms of action of

these medicines. The Panel considered that patients visiting the website, who were prescribed bempedoic acid only (Nilemdo), would also have ezetimibe's mechanism of action brought to their attention, as a selective cholesterol absorption inhibitor that prevents cholesterol from being absorbed in the gut. The Panel considered that this would likely encourage patients prescribed Nilemdo to ask their health professional for Nustendi (bempedoic acid, ezetimibe). Furthermore, individuals on bempedoic acid and ezetimibe as separate tablets may have been encouraged to ask their health professional for the single tablet, Nustendi. Therefore, in the Panel's view, the webpage promoted Nustendi to individuals prescribed Nilemdo and likely encouraged such individuals to ask their health professional to prescribe Nustendi. **A breach of Clause 26.1 and 26.2** was ruled.

However, given all patients visiting the webpage would already be taking bempedoic acid as either Nilemdo or as part of Nustendi, the Panel considered that the webpage did not promote bempedoic acid and would not encourage patients on Nustendi to ask their health professional to prescribe them Nilemdo. Accordingly, the Panel ruled **no breach of Clauses 26.1 and 26.2** in that regard.

The Panel, noting its comments and rulings above, considered that high standards had not been maintained and **a breach of Clause 5.1** was ruled.

Clause 2 was a sign of particular censure and was reserved for such use. The Panel considered that the matter was adequately covered by its rulings above and was not such that it brought discredit upon, or reduced confidence in, the industry and **no breach of Clause 2 was ruled**.

Complaint received **23 April 2022**

Case completed **24 May 2023**