CASE AUTH/3107/10/18

COMPLAINANT v DAIICHI-SANKYO

Alleged promotion to the public

A complainant who described him/herself as a concerned UK health professional alleged that certain pages of the Daiichi-Sankyo website promoted products to the public.

The complainant provided a link and noted that the Daiichi-Sankyo website did not have separate areas for patients and health professionals. The complainant alleged that there was information on the pages leading from the link in question that promoted to the public since the information provided included the generic name, the brand name and the indication.

The detailed response from Daiichi-Sankyo is given below.

The Panel noted Daiichi-Sankyo's submission that it was not necessary for the website to have separate areas for health professionals and members of the public as the entire website was non-promotional and contained only reference information.

The Panel noted that the page which appeared when you clicked on the link provided by the complainant was headed 'Daiichi-Sankyo UK Ltd', followed by 'Products > UK Products'. The opening paragraph read 'Daiichi Sankyo's products treat and prevent serious illnesses as well as help people to live longer and have healthier lives. While maintaining its portfolio of marketed pharmaceuticals for acute coronary syndromes and atrial fibrillation, Daiichi-Sankyo is engaged in the development of treatments focussed on the discovery of novel oncology therapies'.

Medical professionals were advised that they could obtain more detailed information on Daiichi-Sankyo's products by contacting its medical services department on the email address or contact number provided.

The page then listed the brand names of Daiichi-Sankyo UK's eight 'key products' and included the non-proprietary name and indication in tabular format. The webpage stated that the products were listed in alphabetical order however this was not so; Efient (Prasugrel) and Lixiana (Edoxaban) were listed first and Evista (Raloxifene) and Motifene (Diclefenac sodium) last.

Below the table was information directed at patients including how to report adverse events and instructions to contact their health professional for queries about their medicine and/or health.

The Panel noted that there did not appear to be any further information available for the public regarding the majority of the prescription only medicines listed. Following the information about reporting adverse events further information on Edoxaban (Lixiana) and Prasugrel (Efient) was provided which included a more detailed description of each medicine's indication and information on the condition(s) each was used to treat.

Beneath the heading Edoxaban it was explained that atrial fibrillation (AF) was the most common heart rhythm disturbance encountered by doctors and that the most worrying consequence of AF was stroke. The last paragraph stated that Edoxaban was a blood thinner that could be used in patients with atrial fibrillation to prevent strokes. In the Panel's view, this was a claim for Edoxaban.

Below the information regarding Edoxaban were two links directing the reader to further information: the first link went to a third party site and the second link appeared to no longer be active.

There were no links to the SPC or PIL for any of the eight medicines listed. The material did not appear to be a fair reflection of the medicines' risk/benefit profiles. In the Panel's view, the material was limited and did not qualify as reference information as referred to in the Code.

The Panel noted that the Code prohibited the promotion of prescription only medicines to the public. The Panel noted the opening paragraph on the webpage in question set out above, which stated that Daiichi-Sankyo's products treat and prevent serious illnesses as well as help people to live longer and have healthier lives which preceded the list of medicines and was therefore, in the Panel's view, a claim for those medicines. The Panel further noted that the webpage in question included the medicines' brand names, non-proprietary names and indications listed in one single table and included additional information on Edoxaban and Prasugrel. In addition, the Panel noted that members of the public looking for information on one particular medicine would automatically be faced with the brand name, non-proprietary name and indication of all of Daiichi-Sankyo's medicines. In the Panel's view, noting its comments above, the webpage in question advertised prescription only medicines to the public and a breach of the Code was ruled.

The Panel noted that the Code required that promotional material about prescription only medicines directed to a UK audience which was provided on the internet must comply with all relevant requirements of the Code. The supplementary information 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 MHRA Blue Guide stated that the public should not be encouraged to access material which was not intended for them. The Panel noted its comments and ruling above. The Panel noted that Daiichi-Sankyo considered that the webpage in question was reference information directed at members of the public. In the Panel's view, the webpage at issue promoted prescription only medicines and therefore access should have been restricted to health professionals and other relevant decision makers because information had not been provided for the public as required by the relevant supplementary information. The Panel noted that access to the webpage had not been so restricted and therefore a breach of the Code was ruled.

The Panel noted its comments and rulings above and considered that Daiichi-Sankyo had failed to maintain high standards and a breach of the Code 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.

A complainant who described him/herself as a concerned UK health professional alleged that certain pages of the Daiichi-Sankyo website promoted products to the public.

COMPLAINT

The complainant provided a link (https://www.daiichi-sankyo.co.uk/products/european-products/) and noted that the Daiichi-Sankyo website did not have separate areas for patients and health professionals. The complainant alleged that there was information on the pages leading from the link in question that promoted to the public since the information provided included the generic name, the brand name and the indication.

When writing to Daiichi-Sankyo, the Authority asked it to consider the requirements of Clauses 2, 9.1, 26.1 and 28.1.

RESPONSE

Daiichi-Sankyo noted that it had not been asked to consider the requirements of Clause 26.2 and its supplementary information. In the company's view this was a mistake on the part of the case preparation manager as Clause 26.2 was relevant to the complaint. Daiichi-Sankyo referred to the supplementary information to Clause 26.2 in relation to reference information.

Daiichi-Sankyo submitted that the information provided on the webpage at issue fitted the definition of reference information; the product trademark, substance and indication information provided were non-promotional, factual, balanced and appropriate for the public. The information provided did not raise unfounded hopes of successful treatment, it did not mislead with respect to the safety of any of the products referred to and there were no statements that might encourage members of the public to ask their health professional to prescribe a specific prescription only medicine.

The company thus did not consider that the webpage in question was in breach of either Clause 26.1 or 26.2.

With regard to Clause 28.1, Daiichi-Sankyo stated that as that clause referred to promotional material on websites, and its separation from non-promotional material on the same website, it was not relevant. The complainant stated that the website did not have separate areas for patients and health professionals. Daiichi-Sankyo submitted that it was not necessary to have these separate areas as the entire website was non-promotional and thus, there had been no breach of Clause 28.1.

Given that the webpage in question was entirely in line with the requirements of Clauses 26.1 and 26.2, and that Clause 28.1 was not relevant, Daiichi-Sankyo did not consider that there had been a breach of either Clauses 9.1 or Clause 2.

Daiichi-Sankyo submitted that as the website was not promotional and contained only reference information there was no certificate approving the webpage in question.

PANEL RULING

The Panel noted Daiichi-Sankyo's submission that it was not necessary for the website to have separate areas for health professionals and members of the public as the entire website was non-promotional and contained only reference information.

The Panel noted Daiichi-Sankyo's comments about, and response to, the requirements of Clause 26.2 which was not raised by the case preparation manager. The Panel noted that the complaint concerned the promotion of prescription only medicines to the public which fell within the remit of Clause 26.1. In the Panel's view, the complainant's allegation did not raise a Clause 26.2 matter and hence that Clause had not been raised by the Case Preparation Manager and whilst the company had responded in relation to the requirements of Clause 26.2 the Panel could make no ruling under that Clause.

The Panel noted that the page which appeared when you clicked on the link provided by the complainant was headed 'Daiichi-Sankyo UK Ltd', followed by 'Products > UK Products'. The opening paragraph read 'Daiichi-Sankyo's products treat and prevent serious illnesses as well as help people to live longer and have healthier lives. While maintaining its portfolio of marketed pharmaceuticals for acute coronary syndromes and atrial fibrillation, Daiichi-Sankyo is engaged in the development of treatments

focussed on the discovery of novel oncology therapies'.

Medical professionals were advised that they could obtain more detailed information on Daiichi-Sankyo's products by contacting its medical services department on the email address or contact number provided.

The page then listed the brand names of Daiichi-Sankyo UK's eight 'key products' and included the non-proprietary name and indication in tabular format. The webpage stated that the products were listed in alphabetical order however this was not so; Efient (Prasugrel) and Lixiana (Edoxaban) were listed first and Evista (Raloxifene) and Motifene (Diclefenac sodium) last.

Below the table was information directed at patients including how to report adverse events and instructions to contact their health professional for queries about their medicine and/or health.

The Panel noted that there did not appear to be any further information available for the public regarding the majority of the prescription only medicines listed. Following the information about reporting adverse events further information on Edoxaban (Lixiana) and Prasugrel (Efient) was provided which included a more detailed description of each medicine's indication and information on the condition(s) each was used to treat.

Beneath the heading Edoxaban it was explained that atrial fibrillation (AF) was the most common heart rhythm disturbance encountered by doctors and that the most worrying consequence of AF was stroke. The last paragraph stated that Edoxaban was a blood thinner that could be used in patients with atrial fibrillation to prevent strokes. In the Panel's view, this was a claim for Edoxaban.

Below the information regarding Edoxaban were two links directing the reader to further information: the first link, http://www.anticoagulation.org.uk, went to a third party site and the second link, http://www.anticoagulationeurope.org, appeared to no longer be active.

There were no links to the SPC or PIL for any of the eight medicines listed. The material did not appear to be a fair reflection of the medicines' risk/benefit profiles. In the Panel's view, the material was limited and did not qualify as reference information as referred to in the supplementary information to Clause 26.2 of the Code.

The Panel noted that Clause 26.1 prohibited the promotion of prescription only medicines to the public. The Panel noted the opening paragraph on the webpage in question set out above, which stated that Daiichi-Sankyo's products treat and prevent serious illnesses as well as help people to live longer and have healthier lives which preceded the list of medicines and was therefore, in the Panel's view, a claim for those medicines. The Panel further noted that the webpage in question included the medicines' brand names, non-proprietary names and indications listed in one single table and included additional information on Edoxaban and Prasugrel. In addition, the Panel noted that members of the public looking for information on one particular medicine would automatically be faced with the brand name, non-proprietary name and indication of all of Daiichi-Sankyo's medicines. In the Panel's view, noting its comments above, the webpage in question advertised prescription only medicines to the public and a breach of Clause 26.1 was ruled.

The Panel noted that Clause 28.1 required that promotional material about prescription only medicines directed to a UK audience which was provided on the internet must comply with all relevant requirements of the Code. The supplementary information 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 MHRA Blue Guide stated that the public should not be encouraged to access material which was not intended for them. The Panel noted its comments and ruling above. The Panel noted that Daiichi-Sankyo considered that the webpage in question was reference information directed at members of the public. In the Panel's view, the webpage at issue promoted prescription only medicines and therefore access should have been restricted to health professionals and other relevant decision makers because information had not been provided for the public as required by the relevant supplementary information. The Panel noted that access to the webpage had not been so restricted and therefore a breach of Clause 28.1 was ruled.

The Panel noted its comments and rulings above and considered that Daiichi-Sankyo had failed to maintain high standards 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.

Complaint received **29 October 2018**

Case completed **22 February 2019**