**CASE AUTH/3396/10/20**

# COMPLAINANT v DAIICHI-SANKYO

## Out-of-date material

**An anonymous Sanofi employee complained that material used by Daiichi-Sankyo to promote Nilemdo (bempedoic acid) was out-of-date with regard to the information given about Sanofi's medicine Praluent (alirocumab). Nilemdo and Praluent were both indicated in certain adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet.**

**The complainant stated that he/she had complained in a personal capacity, although his/her knowledge of the material at issue was due to his/her job at Sanofi. The complainant stated that he/she was not representing Sanofi in this complaint and Sanofi was not aware of it at all.**

**It has previously been decided, following consideration by the then Code of Practice Committee and the ABPI Board of Management, that private complaints from pharmaceutical company employees had to be accepted. To avoid this becoming a means of circumventing the normal procedures for inter-company complaints, the employing company would be named in the report. The complainant was advised that if he/she wished to proceed with the complaint in his/her private capacity, Sanofi would be named in the report and Daiichi-Sankyo would be informed of his/her employment status. The complainant was given an opportunity to withdraw the complaint but agreed to go ahead on the above basis.**

**The complainant stated that Praluent used to have a black triangle, but as of 16 September 2020, the Electronic Medicines Compendium (eMC) website was updated to remove it.**

**The complainant stated that due to his/her role he/she was in contact with hospital staff who would be regarded as 'decision makers' under the Code and in September 2020 had informed one of those decision makers when the black triangle for Praluent was removed. The decision maker contacted the complainant on 1 October 2020 to tell him/her that in a virtual meeting in the last week with Daiichi-Sankyo, a document used at that meeting showed a black triangle next to alirocumab (Praluent). The decision maker took a photograph of the screen and forwarded it to the complainant (copy provided). The decision maker did not state the specific date of the meeting with Daiichi-Sankyo or the name of the representative, but stated it was in the last week and therefore it must have been after 16 September 2020 when the eMC website was publicly updated.**

**The complainant stated that there could well be a deliberate motivation by Daiichi-Sankyo to sow doubt about the safety profile of Praluent, so it could displace Praluent with its new product which it was offering for free. Daiichi-Sankyo would surely have been aware that the black triangle had been removed from one of its main competitor**

**products, so the complainant could only think this was a deliberate act to keep using materials showing Praluent with a black triangle.**

**The complainant alleged breaches of the Code because the material used in the meeting was not accurate and disparaged Praluent by giving the impression of a safety concern which was unwarranted. Therefore, this also breached the Code including Clause 2 because high standards had not been maintained and discredit had been brought to the industry.**

**The detailed response from Daiichi-Sankyo is given below.**

**The Panel noted that the screenshot provided by the complainant appeared to be the same as the first page from a Free of Charge Scheme Communications Document provided by Daiichi-Sankyo titled NILEMDO▼ (bempedoic acid) Free of charge (FOC) scheme. Under the subtitle Executive Summary, it stated 'A Free of Charge (FOC) scheme is available for NILEMDO when used in adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia who are considered high/very-high risk and who are statin intolerant or for whom a statin is contraindicated and who are not at goal with ezetimibe but are not eligible for alirocumab▼ or evolocumab'. The Panel noted that according to its certificate, the material was certified on 3 September 2020.**

**The Panel noted that whilst the black triangle had been removed from the Praluent SPC on the eMC website on 16 September 2020, Daiichi-Sankyo stated that it did not become aware of it until 22 September 2020. The Panel noted Daiichi-Sankyo's submission that it had no evidence that the material at issue had been used at any meetings between 22 September and 5 October 2020 as the material used at meetings with health professionals was not recorded in its system. The Panel noted, however, that the sales force was only instructed to stop using the material at issue on 5 October 2020 when new material without the Praluent black triangle was issued. The Panel considered therefore that, on the balance of probabilities, material which associated Praluent with a black triangle would have likely been in use between 16 September and 5 October 2020 and the material was not up-to-date at that time and this was disparaging. The Panel therefore ruled breaches of the Code.**

**The Panel noted that the Code required that materials were up-to-date and queried why Daiichi-Sankyo was not aware that the SPC for Praluent had been updated on the eMC website to remove the black triangle until six days after it had occurred, and why it had not withdrawn the out-of-date material in question as soon as it became aware of the change. The Panel considered that high standards had not been maintained in that regard and a breach of the Code was ruled.**

**The Panel did not consider that the particular circumstances of this case warranted a ruling of a breach of Clause 2 which was used as a sign of particular censure and reserved for such use. No breach of the Code was ruled which was upheld on appeal by the complainant.**

An anonymous Sanofi employee complained that material used by Daiichi-Sankyo to promote Nilemdo (bempedoic acid) was out-of-date with regard to the information given about Sanofi's medicine Praluent (alirocumab). Nilemdo and Praluent were both indicated in certain adults

with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet.

The complainant stated that he/she had complained in a personal capacity, although for full disclosure, his/her knowledge of the material at issue was due to his/her job at Sanofi. The complainant stated that he/she was not representing Sanofi in this complaint and Sanofi was not aware of it at all.

It has previously been decided, following consideration by the then Code of Practice Committee and the ABPI Board of Management, that private complaints from pharmaceutical company employees had to be accepted. To avoid this becoming a means of circumventing the normal procedures for inter-company complaints, the employing company would be named in the report. The complainant was advised that if he/she wished to proceed with the complaint in his/her private capacity, Sanofi would be named in the report and Daiichi-Sankyo would be informed of his/her employment status. The complainant was given an opportunity to withdraw the complaint but agreed to go ahead on the above basis.

**COMPLAINT**

The complainant stated that Praluent used to have a black triangle, but as of 16 September 2020, the Electronic Medicines Compendium (eMC) website was updated to remove it. The complainant attached a screenshot from eMC to show that the black triangle was removed on that date from the summary of product characteristic (SPC).

The complainant stated that due to his/her role he/she was in contact with hospital staff who would be regarded as 'decision makers' under the Code and on 16 September 2020 he/she had informed one of those decision makers when the black triangle for Praluent was removed. The decision maker contacted the complainant on 1 October 2020 to tell him/her that in a virtual meeting in the last week with Daiichi-Sankyo to talk about a 'free of charge' scheme for Nilemdo, which was also indicated for dyslipidemia, a document used at that meeting showed a black triangle next to alirocumab (Praluent). The decision maker was surprised to see the black triangle as he/she was aware that it was no longer valid; he/she took a photograph of the screen and forwarded it to the complainant (copy provided). The decision maker did not state the specific date of the meeting with Daiichi-Sankyo or the name of the representative, but stated it was in the last week and therefore it must have been after 16 September 2020 when the eMC website was publicly updated.

The complainant stated that he/she did not have any more details from the decision maker.

The complainant stated that there could well be a deliberate motivation by Daiichi-Sankyo to sow doubt about the safety profile of Praluent, so it could displace Praluent with its new product which it was offering for free. Daiichi-Sankyo would surely have been aware that the black triangle had been removed from one of its main competitor products, so the complainant could only think this was a deliberate act to keep using materials showing Praluent with a black triangle.

The complainant alleged a breach of Clause 7.2 because the material used in the meeting was not accurate by showing a black triangle which should not have been there. The complainant also alleged a breach of Clause 8.1 because it disparaged Praluent by giving the impression of a safety concern which was unwarranted. Therefore, this also breached Clauses 9.1 and 2

because high standards had not been maintained and discredit had been brought to the industry.

When writing to Daiichi-Sankyo, the Authority asked it to consider the requirements of Clauses 7.2, 8.1, 9.1 and 2 of the Code.

**RESPONSE**

Daiichi-Sankyo stated that, in full consideration of the information presented by the complainant, it denied all breaches. The complainant had the burden of proving his/her complaint on the balance of probabilities. The complainant had not established clear evidence that an alleged meeting took place between Daiichi-Sankyo and a 'decision-maker' as the screenshot provided by the complainant did not reference a date.

Daiichi-Sankyo recognised the material at issue. However, the inability to clearly evidence a date of the alleged meeting was fundamental, and until that was established, Daiichi-Sankyo could not provide detailed comment on the specific breach allegations. Daiichi-Sankyo noted that the complainant was anonymous but contactable. If the complainant could provide clear evidence of the meeting date that would help Daiichi-Sankyo to investigate fully and provide further clarity.

Daiichi-Sankyo submitted that on 22 September 2020 it found out that Praluent had had the black triangle removed. On that date, the owners of all approved Nilemdo materials were asked to identify and withdraw any materials that might refer to Praluent with a black triangle and get it reapproved without the black triangle. Daiichi-Sankyo fully recognised this change was not a patient safety issue, however, managed the change on a timely basis. The sales force was instructed to stop using the material at issue on 5 October 2020 and new material without the Praluent black triangle was issued to the sales force to use instead.

Daiichi-Sankyo stated that based on the information above and that provided by the complainant, it denied any breaches of Clause 7.2.

With regard to Clause 8.1, Daiichi-Sankyo stated that there was no intent to disparage, and Daiichi-Sankyo's material did not disparage any medicine or product. Based on the information above, Daiichi-Sankyo denied any breach of Clause 8.1.

Daiichi-Sankyo submitted that in the response provided above, it had shown robust processes and had maintained high standards. The company denied a breach of Clause 9.1. The company also denied a breach of Clause 2.

In response to a request for further information, Daiichi-Sankyo provided a certificate for the material at issue (ref BEM/20/0202, September 2020) which showed that it had been certified on 3 September 2020. Daiichi-Sankyo submitted that it did not have the information to support the view that the material at issue was used by Daiichi-Sankyo between 16 September and 5 October 2020, including at any meetings with health professionals and/or other relevant decision makers. The company's customer relationship management (CRM) system would record that a health professional was detailed with a specific product(s) – time, day and discussion, but not the material used.

**PANEL RULING**

With respect to the allegation that a document which associated Praluent with a black triangle was used at a meeting between Daiichi-Sankyo and a 'decision-maker' after 16 September 2020 when the Praluent SPC on the eMC website had been updated to remove the black triangle, the Panel noted Daiichi-Sankyo's submission that the complainant had not provided evidence that such a meeting had taken place as the screenshot provided by the complainant did not reference a date. The Panel noted that according to the complainant, the decision maker contacted him/her on 1 October 2020 regarding a virtual meeting held in the last week.

The Panel noted that the screenshot provided by the complainant appeared to be the same as the first page from a Free of Charge Scheme Communications Document (ref BEM/20/0202, September 2020) provided by Daiichi-Sankyo titled NILEMDO▼ (bempedoic acid) Free of charge (FOC) scheme. Under the subtitle Executive Summary, it stated 'A Free of Charge (FOC) scheme is available for NILEMDO when used in adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia who are considered high/very-high risk and who are statin intolerant or for whom a statin is contraindicated and who are not at goal with ezetimibe but are not eligible for alirocumab▼ or evolocumab'. The Panel noted that according to its certificate, the material was certified on 3 September 2020.

The Panel noted that whilst the black triangle had been removed from the Praluent SPC on the eMC website on 16 September 2020, Daiichi-Sankyo stated that it did not become aware of it until 22 September 2020. The Panel noted Daiichi-Sankyo's submission that it had no evidence that the material at issue had been used at any meetings between 22 September and 5 October 2020 as the material used at meetings with health professionals was not recorded in its CRM system. The Panel noted, however, that the sales force was only instructed to stop using the material at issue on 5 October 2020 when new material without the Praluent black triangle was issued for use. The Panel considered therefore that, on the balance of probabilities, material which associated Praluent with a black triangle would have likely been in use between 16 September and 5 October 2020 and the material was not up-to-date at that time. The Panel therefore ruled a breach of Clause 7.2. In the Panel's view, by associating Praluent with a black triangle denoting that additional monitoring was required in relation to adverse reactions when it was no longer required, disparaged Praluent and a breach of Clause 8.1 was ruled.

The Panel noted that the Code required that materials were up-to-date and queried why Daiichi-Sankyo was not aware that the SPC for Praluent had been updated on the eMC website to remove the black triangle until six days after it had occurred, and why it had not withdrawn the out-of-date material in question as soon as it became aware of the change. The Panel considered that high standards had not been maintained in that regard and a breach of Clause 9.1 was ruled.

The Panel did not consider that the particular circumstances of this case warranted a ruling of a breach of Clause 2 which was used as a sign of particular censure and reserved for such use. No breach of Clause 2 was ruled.

**APPEAL BY THE COMPLAINANT**

The complainant appealed the Panel's ruling of no breach of Clause 2.

The complainant stated that the reason for his/her appeal was that in response to a request for more information, the company admitted that it did not keep a record in its CRM system of materials used in its meetings with health professionals and other relevant decision makers. The complainant stated that he/she found this astonishing. The complainant queried how the company could be sure its representatives were using approved, unexpired materials if it kept no record of what they used in calls? The complainant alleged that this lack of record keeping had meant Daiichi-Sankyo had been unable to submit full information to the Panel regarding the use of the material in question in this case. This poor CRM system management brought discredit to the industry in his/her mind.

The complainant noted from another case, Case AUTH/3285/12/19 that the company was under audit by the PMCPA. The complainant stated that he/she found it even more astonishing that even under a period of increased scrutiny, Daiichi-Sankyo did not know what materials its representatives were using in calls.

The complainant noted that Daiichi-Sankyo had also admitted not even knowing about the black triangle update for some days and then delaying withdrawing its material. The complainant alleged that not keeping timely track of the status of a competitor's SPC updates including black triangle information was a serious deficiency in Daiichi-Sankyo's processes, and furthermore deliberately carrying on using the outdated material brought discredit to the industry and was worthy of a Clause 2 breach.

**RESPONSE FROM DAIICHI-SANKYO**

Daiichi-Sankyo submitted that the Panel had made the correct rulings, including its decision that the circumstances of this case did not warrant a ruling of a breach of Clause 2 which was a sign of particular censure and reserved for such use. The supplementary information listed examples of activities that were likely to be in breach of Clause 2 such as prejudicing patient safety and/or public health, excessive hospitality, inducements to prescribe, unacceptable payments, inadequate action leading to a breach of undertaking, promotion prior to the grant of a marketing authorization, conduct of company employees/agents that fell short of competent care and multiple/cumulative breaches of a similar and serious nature in the same therapeutic area within a short period of time. This case did not fall under the circumstances that warranted a Clause 2 ruling.

**FINAL COMMENTS FROM THE COMPLAINANT**

The complainant had no final comments.

**APPEAL BOARD RULING**

The Appeal Board noted that the Panel had ruled breaches of the Code (Clauses 7.2 and 8.1) as well as a breach of Clause 9.1, for failing to maintain high standards, as Daiichi-Sankyo had continued to use material that associated Sanofi's medicine Praluent with a black triangle after the black triangle had been removed from the SPC. These rulings were not appealed.

The Appeal Board noted that the complainant's concerns about the CRM system were not part of the original allegations. Further there was no requirement in the Code for companies to record what materials were used with a particular health professional.

The Appeal Board noted that Clause 2 was a sign of particular censure and reserved for such use. The Appeal Board did not consider that in the particular circumstances of this case a breach of Clause 2 was warranted. In the Appeal Board's view, the complainant's concerns regarding the continued use of material that associated Praluent with a black triangle were adequately covered by the Panel's ruling of a breach of Clause 9.1. The Appeal Board upheld the Panel's ruling of no breach of Clause 2. The complainant's appeal was unsuccessful.

**Complaint received** **5 October 2020**

**Case completed** **27 May 2021**