NO BREACH OF THE CODE

CASE AUTH/3776/6/23

COMPLAINANT v DAIICHI SANKYO

Allegations about a patient organisation education programme

CASE SUMMARY

This case was in relation to a guideline document associated with a cholesterol education programme on a patient organisation's website. The complainant alleged that this document was promotional and therefore should have been certified and should have included prescribing information. It contained images of a promotional document for Daiichi Sankyo medicines Nustendi (bempedoic acid-ezetimibe) and Nilemdo (bempedoic acid) and it was not made clear that both were contraindicated in patients on simvastatin doses greater than 40mg. The complainant further alleged that there was no declaration of involvement of Daiichi Sankyo on the guideline document or in the section of the patient organisation website that contained it.

The outcome under the 2021 Code was:

No Breach of Clause 2	**Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry**
No Breach of Clause 5.5	**Requirement to be sufficiently clear as to the company's role and involvement**
No Breach of Clause 6.1	**Requirement that information must be accurate, up-to-date and not misleading**
No Breach of Clause 6.2	**Requirement that claims/information/comparisons must be capable of substantiation**
No Breach of Clause 8.1	**Requirement to certify promotional material**
No Breach of Clause 12.1	**Requirement to include up-to-date prescribing information**

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

FULL CASE REPORT

A complaint was received from an anonymous, contactable complainant about Daiichi Sankyo.

COMPLAINT

The complaint wording is reproduced below with some typographical errors corrected:

> "[Named patient organisation] had been funded by Daiichi Sankyo for the set-up of a tackling cholesterol together education programme. As part of this funded programme, several documents were produced and available to HCPs. This included 'guidelines' which were hosted on [website link provided] The interactive lipid management pathway was one of these guidelines that had been funded. On page 8 of this lipid pathway management document, there was a clear picture of the daiichi sankyo funded promotional guidelines card snippet which referred to indications of Nilemdo and Nustendi. The indications specified on this guidelines card snippet discussed utilising nilemdo and nustendi in combination with statin therapy. However, both products were contraindicated with simvastatin therapy >40mg and this was not stated on the guidelines card snippet. Page 11 had another 2 images of the daiichi sankyo guidelines card, which again presented recommendations around usage of nilemdo and nustendi with statins with reference to the licensed indications but did not reference the requirement to be mindful of the contraindication of using nilmedo and nustendi with simvastatin >40mg. The need to refer to contraindications was actually a part of the SPC licensed indications section for Nilemdo and Nustendi but the information was missing on the guidelines card snippets. The HCP would not be aware of this contraindication if reading the images of the Daiichi Sankyo guidelines card presented in the interactive lipid management pathway document and was therefore a major risk to patient care considering the mass usage of simvastatin as treatment. There was also no prescribing information provided within this document. If Daiichi Sankyo had funded this interactive lipid management pathway document which also had inclusion of the guidelines card pictures for Daiichi Sankyo products, then this could only be a promotional item. The declaration of Daiichi Sankyo involvement was also missing at the beginning of this document for readers to be aware of the involvement. It was also important to note the home page of Tackling Cholesterol programme discussed Daiichi Sankyo funding so the standalone guidelines section should also have mentioned the involvement from the outset too. There was breaches of clauses 5.5, 6.1, 6.2, 12.1, 8.1 and 2."

When writing to Daiichi Sankyo, the PMCPA asked it to consider the requirements of Clauses 5.5, 6.1, 6.2, 12.1, 8.1 and 2 of the Code.

DAIICHI SANKYO'S RESPONSE

> As background, in 2021 the patient organisation [named patient organisation] developed a partnership with the NHS, the Academic Health Science Networks (AHSNs) and the Accelerated Access Collaborative to deliver the NHS's primary care education programme for health professionals to further the objectives of raising awareness of [named patient organisation] as a provider of education, and to provide learning opportunities on lipid management.
>
> [named patient organisation] approached DSUK for sponsorship of their primary care education programme in 2021 and 2022. Specifically, the sponsorship provided by DSUK in 2021 was to support the development of learning modules on the following topics:
>
> 1. Post-cardiovascular event management of cholesterol
> 2. Statins
> 3. Cholesterol results
> 4. Genetic conditions

5. Identifying and managing Familial Hypercholesterolaemia (FH) in Primary Care
6. Nutrition and Lipids
7. Cardiometabolic conditions
8. Dietetic support and lipid lowering therapies
9. Lipid management pathway
10. Update on lipid management prescribing

Please note that point 9. is not related to the guidance document that the complainant refers to in this case.

The sponsorship provided by DSUK in 2022 was for the following activities:

- To build on the educational programme launched in 2021 and offer new learning e-modules, maintain the current six e-learning modules available and ensure a greater level of awareness and completion of the programme.
- To develop case studies for the Lipid Pathway, in addition to providing updated versions to include new medicines and case studies for the Statin Intolerance Pathway.
- To develop a shared decision-making e-learning module, 2x nutrition e-modules, a post CVD event management e-learning module and FH and other genetic conditions

Appendix I in the agreements for both the 2021 and 2022 programmes clearly state that [named patient organisation] retains full editorial control over all materials published as a result of the agreement and the medical accuracy, balance and ethical integrity of all activities*.

*Please note that the 2021 and 2022 agreements have similar issues to those identified in Cases AUTH/3594/12/21 and AUTH/3629/4/22 in that they refer to a 'service' being provided by [named patient organisation], and this is being addressed as part of the corrective actions associated with these cases.

The material on the [named patient organisation] website that was developed as a result of the most recent (2022) support can be found in the section 'Tackling Cholesterol Together'.

On entering this section there is a very clear declaration of the involvement of DSUK as well as a number of other pharmaceutical companies.

'Tackling Cholesterol Together' page. Image showing the following text 'The Tackling Cholesterol Together Education Programme is intended for UK healthcare professionals only. This programme has been funded by the pharmaceutical companies below and these companies have had no input into the content or development of this programme. [named patient organisation], the AHSN Network and the NHS retain full control over all Tackling Cholesterol Together published materials and the medical accuracy, balance and ethical integrity of all activities undertaken."' The name and logos of four pharmaceutical companies, including Daiichi Sankyo, appear underneath.

This declaration reflects the statement in the agreement that DSUK supported these materials at arms-length.

Below this are a number of tiles relating to certain material developed as part of the 'Tackling Cholesterol Together' programme.

When the reader clicks on the tile for 'Webinars', 'e-Learning', 'Podcasts' or 'Clinics' the same declaration as noted above appears prominently at the top of the page. Thus, the involvement of DSUK in the development of these materials is clear. When the tile for 'Videos' is clicked, it is clear that a company other than DSUK has supported the development of these, and clicking on the tile for 'Guidelines' reveals a clear statement that the guidelines in this section were developed with no input from any pharmaceutical company, as noted below:

'Guidelines' page. Image showing the following text: 'The guidelines detailed below are documents provided by the AHSN Network and are independent to any Pharmaceutical funding received. This area provides pathway resources such as Statin intolerance and Lipid management. Check out our interactive Lipid management pathway; which is an interactive version of the AAC, NICE-endorsed Summary of National Guidance for Lipid Management for Primary and Secondary Prevention of CVD'

It is in this latter section that the guidelines at issue (interactive lipid management pathway) could be found.

DSUK therefore refutes the allegation that we funded the interactive lipid management pathway document; DSUK had no involvement whatsoever in its development, as clearly indicated in a declaration at the top of the relevant web page and in the relevant agreements with [named patient organisation] (as detailed above).

It therefore follows that DSUK had no responsibility for the content of the guidelines (including the inclusion or otherwise of any contraindications for our medicines), the guidelines would not be considered promotional for DSUK medicines and prescribing information would not be required. Given that the material would not be considered promotional they would not require certification by DSUK.

With all the above in mind we deny any breach of Clauses 5.5, 6.1, 6.2, 8.1, 12.1 and 2.

In terms of the inclusion of a screen shot of DSUK promotional material in the guidelines, we are not aware of how these came into the possession of [named patient organisation]. The NICE TAG summary card (BEM/21/0086) was certified for promotional use with health professionals, payers and policy makers and was provided to DSUK representatives to distribute via email. The intended audience did not include patient organisations such as [named patient organisation].

An electronic copy of the document was also placed on the independent MGP Guidelines website and was available for health professionals to download. Whilst patient organisations were not the target audience for the document, it is entirely possible that health professionals in the NHS and/or AHSN accessed it and provided to [named patient organisation] as part of the collaboration noted above. Neither AHSN or [named patient organisation] sought permission from DSUK to use its material and DSUK were unaware that it was on the [named patient organisation] website until receipt of this complaint; the

interactive lipid management pathway document has been removed from the [named patient organisation] website.

The NICE TAG summary card (BEM/21/0086) was available to download by health care professionals via the MGP Guidelines website from 4th June 2021 to 4th December 2021. For completeness, below are the dates that the above item, BEM/21/0086 was approved and subsequently withdrawn from the DSUK sales force

- Approved for use on May 19th, 2021, then reapproved on November 30th, 2021
- Items were withdrawn from the DSUK sales force on November 16th, 2022
- Withdrawn from Veeva on December 2nd, 2022

I trust that the above and enclosed provide sufficient information for the Panel to consider this matter. However, should you have any further questions, please do not hesitate to contact me."

PANEL RULING

An anonymous, contactable complainant made allegations about a guideline document associated with the "Tackling cholesterol Together" education programme on a patient organisation's website. The complainant alleged that this document was promotional and therefore should have been certified and should have included prescribing information. It contained images of a promotional document for Daiichi Sankyo medicines Nustendi (bempedoic acid-ezetimibe) and Nilemdo (bempedoic acid) and it was not made clear that both were contraindicated in patients on simvastatin doses greater than 40mg. The complainant further alleged that there was no declaration of involvement of Daiichi Sankyo on the guideline document or in the section of the patient organisation website that contained it.

The Panel did not have the entire website before it, but the Panel took account of screenshots taken from the links provided by the complainant. The Panel noted the "Tackling Cholesterol Together" education programme was for UK health professionals only and was in a section of the patient organisation's website for health professionals. At the top of the page, in a box, was the declaration:

> "The Tackling Cholesterol Together Education Programme is intended for UK healthcare professionals only. This programme has been funded by the pharmaceutical companies detailed below and these companies have had no input into the content or development of this programme. [Named patient organisation], the [Academic Health Science Networks] AHSN Network and the NHS retain full control over all Tackling Cholesterol Together published materials and the medical accuracy, balance and ethical integrity of all activities undertaken."

Below this were the names and logos of four pharmaceutical companies, including Daiichi Sankyo. Below the declaration was the title "Tackling Cholesterol Together" and six tiles labelled "Webinars", "e-learning", "Podcasts", "Clinics", "Videos" and "Guidelines". Selecting the "Guidelines" tile opened a new page. At the top of the "Guidelines" page was the statement:

> "This area provides pathway resources such as Statin intolerance and Lipid management. Check out our interactive Lipid management pathway, which is an interactive version of

> the [Accelerated Access Collaborative] AAC, [National Institute for Health and Care Excellence] NICE-endorsed Summary of National Guidance for Lipid Management for Primary and Secondary Prevention of [cardiovascular disease] CVD."

The Panel noted that the statement at the top of the "Guidelines" page in the link provided by the complainant differed from the screenshot provided by Daiichi Sankyo. The screenshot provided by Daiichi Sankyo included the additional statement:

> "The guidelines detailed below are documents provided by the AHSN Network and are independent to any Pharmaceutical funding received."

It appeared to the Panel that this additional statement was added to the webpage after the date the complaint was made, so the Panel has made its ruling on the basis of the screenshot provided by the complainant.

The Panel noted the material at issue was accessed via the "Interactive Lipid Management Pathway" tab. It had the "Tackling Cholesterol Together" logo at the top and was titled "One-stop interactive National Guidance for Lipid Management for Primary and Secondary Prevention of CVD." Page 8 was titled "Lipid optimisation in secondary prevention when lipid targets are not achieved". There was an algorithm describing various treatment options available for patients who had uncontrolled cholesterol despite being on statin treatment for three months. Next to the algorithm was a partially obscured image of page one of the Daiichi Sankyo NICE technology appraisal guidance TA694 guidelines card for Nilemdo and Nustendi. Only part of the recommendations and marketing authorisation indication sections could be read.

Page 11 was titled "Bempedoic acid and ezetimibe guidelines" and included two screenshots of the Daiichi Sankyo NICE technology appraisal guidance TA694 guidelines card. The screenshots clearly showed the NICE recommendations as well as the indications for Nilemdo and Nustendi.

The Panel noted that Daiichi-Sankyo accepted that the material on page 8 and page 11 was company promotional material.

The Panel noted that whilst the declaration of pharmaceutical company sponsorship on the "Tackling Cholesterol Together" webpage did not identify which materials had been sponsored, it was nonetheless clear that, other than the provision of funding, the companies had no input into the content or development of the programme. This lack of input also applied to the medical accuracy, balance and ethical integrity of all activities carried out by the patient organisation.

Although there was no clarifying statement in relation to the "Guidelines" page specifically, the Panel considered that it was not unreasonable to assume that the declaration of involvement on the "Tackling Cholesterol Together" home page also applied to the guidelines section, including the "Interactive Lipid Management Pathway" document at issue.

The Panel noted that a pharmaceutical company could be involved in sponsoring a patient organisation's activity, providing that activity complied with the Code e.g.:

- it did not promote or request promotion of a particular medicine
- it did not advertise prescription only medicines to the public
- the involvement of the company was made clear
- there was a declaration accurately reflecting the nature of the company's involvement.

Whether a pharmaceutical company was responsible for the activity and materials as a result of a sponsorship would depend on the sponsorship arrangements.

The Panel considered the patient organisation proposals from 2021 and 2022 and noted that the activity had not been initiated by Daiichi Sankyo. The Panel further noted Daiichi-Sankyo's submission that the sponsorship was an arms' length arrangement and noted that this was consistent with the declaration of involvement on the "Tackling Cholesterol Together'' webpage. The Panel noted that parts of the 2021 and 2022 agreements (e.g. the references to a "service" being provided by the patient organisation) appeared to be inconsistent with Daiichi-Sankyo's submission that this was an arms' length arrangement. However, the Panel noted that this point had already been accepted by Daiichi-Sankyo in previous PMCPA cases and forms part of their corrective action relating to those cases.

The Panel noted that the first point it had to consider was whether the material at issue was covered by either agreement.

Appendix 1 of the 2021 agreement referred to the activity as "Primary Care Education Programme 2021". The contributions of the patient organisation were stated to include:

> "In line with recent guidance and focus on areas to help diagnose people with high cholesterol [NHS Long Term Plan/CVD Prevent/ABC of CVD/RPS CVD Report], [named patient organisation], will provide educational opportunities and support for GPs to understand more about the diagnosis, treatment and management of cholesterol. This learning programme, while primarily aimed at GPs, is also available for other healthcare professionals working in primary care such as community pharmacist and practice nurses.
>
> The learning modules/topics will include:
> 1. Post-cardiovascular event management of cholesterol
> 2. Statins
> 3. Cholesterol results
> 4. Genetic conditions
> 5. Identifying and managing FH in Primary Care
> 6. Nutrition and lipids
> 7. Cardiometabolic conditions
> 8. Dietetic support and lipid lowering therapies
> 9. Lipid management pathway
> 10. Update on lipid management prescribing
>
> The education programme will be available in the HCP area of the [named patient organisation] website. Only HCP can access this site."

It was also stated that Daiichi Sankyo would be acknowledged on all documentation, whereby [named patient organisation] retained full editorial control over all published materials and the medical accuracy, balance and ethical integrity of all activities. Additionally, Daiichi Sankyo would have its logo included in the HCP education area of the [named patient organisation] website. [Named patient organisation] would include on each supported module the appropriate wording and positioning of any statement associated with financial support.

The agreement further stated that Daiichi Sankyo would have no input into the educational content of the programme and would provide funding for the e-modules only. Daiichi Sankyo

would not have access to any individual identifiable data but would receive quarterly update reports on progress and development of the programme.

The 2022 agreement was titled "Patient organisation agreement" but was otherwise very similar in content to the 2021 agreement. The 2022 agreement also went on to state that:

> "In 2022 [named patient organisation] is seeking support to develop case studies for the Lipid Pathway, in addition to providing updated versions to include new medicines and case studies for the Statin Intolerance Pathway. Also looking to develop a shared decision-making e-learning module, 2x nutrition e-modules, a post CVD event management e-learning module and FH and other genetic conditions."

Daiichi Sankyo would receive quarterly update reports on progress and development of the programme, including data analytics.

As with the 2021 agreement, the 2022 agreement stated that Daiichi Sankyo would have no educational input to the programme and would provide funding for the e-modules only.

The Panel noted the clarification email from the patient organisation; it stated that the "Lipid management pathway" e-module referred to in the 2021 agreement included information about the lipid management pathway and how to navigate it. However, it did not refer to the AHSN latterly produced "Interactive Lipid Management Pathway" guideline document, which was separate. The sponsorship funding provided by Daiichi Sankyo and other pharmaceutical companies was for the e-module only. The 2022 agreement stated that funding was provided for the further development of the existing e-modules as well as development of new e-modules.

The Panel concluded that Daiichi Sankyo did not directly or indirectly sponsor the development of the "Interactive Lipid Management Pathway" guideline document. In the Panel's view, given that the material at issue was not the subject of either sponsorship agreement, the requirement to declare the company's involvement did not arise.

The Panel noted that Daiichi Sankyo's promotional NICE technology appraisal guidance TA694 (company reference BEM/21/0086) has been the subject of case AUTH/3611/2/22, whereby the Panel ruled breaches of the Code for failing to make immediately apparent to health professionals there was a contraindication regarding concomitant use with simvastatin >40mg daily.

The Panel noted Daiichi Sankyo's submission that it was not aware of, and did not direct the inclusion of, the screenshots of BEM/21/0086 in the material at issue. BEM/21/0086 was certified for promotional use with health professionals, payers and policy makers and provided to Daiichi Sankyo representatives to distribute via email. The intended audience did not include patient organisations. The Panel also noted that neither the patient organisation nor the NHS had sought permission from Daiichi Sankyo to use BEM/21/0086. In the Panel's view there was no evidence that Daiichi-Sankyo had facilitated, directly or indirectly, reproduction of its promotional material by the health organisation that provided the material at issue or whose names appeared on its front page such that Daiichi-Sankyo was responsible for it.

The Panel concluded that the material at issue was not the subject of a sponsorship agreement between Daiichi Sankyo and the patient organisation, and Daiichi Sankyo was not responsible for the inclusion of BEM/21/0086 in the material at issue. The Panel therefore did not consider

the material at issue promotional material for which Daiichi Sankyo was responsible and ruled **no breach of Clauses 2, 5.5, 6.1, 6.2, 8.1 and 12.1**.

Complaint received **08 June 2023**

Case completed **27 November 2024**