

Case AUTH/3778/6/23

COMPLAINANT v DAIICHI SANKYO

Allegations about an article in Cardiac Rhythm News regarding atrial fibrillation

CASE SUMMARY

This case was in relation to an article published in Cardiac Rhythm News in August 2021, titled 'Exploring the potential of remote atrial fibrillation diagnosis through digital technology'. The complainant alleged that the article was disease awareness that had not been certified and that it did not make Daiichi Sankyo's involvement clear from the outset.

The outcome under the 2021 Code was:

Breach of Clause 5.1	Failing to maintain high standards
Breach of Clause 5.5	Failing to be sufficiently clear as to the company's role and involvement
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 8.3	Requirement to certify educational material for the public related to disease

**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 complainant, who became non-contactable, about Daiichi Sankyo.

COMPLAINT

The complaint wording is reproduced below:

"An article that had Daiichi Sankyo involvement did not make clear of the company influence from the outset of the article. The article in question was a disease education piece around atrial fibrillation. The article can be seen at: [link provided]. A reader could only see Daiichi Sankyo involvement at the very end of the article as there was a small statement below the references which stated 'The final version has been reviewed for accuracy and compliance by Daiichi Sankyo UK Ltd in line with the ABPI Code of Practice.' As this was a disease awareness article, the article should have been certified

but this could not be the case if the declaration of involvement had not been placed at the beginning of the piece. It was concerning that the spirit of the code had not been followed and one must wonder whether there was a dedicated signatory team function at Daiichi Sankyo to focus purely on approvals. There was breaches of clauses 5.1, 5.5, 8.3 and 2 of the ABPI code.”

When writing to Daiichi Sankyo, the Authority asked it to consider the requirements of Clauses 2, 5.1, 5.5 and 8.3 of the Code.

RESPONSE

The response from Daiichi Sankyo is reproduced below:

“Daiichi Sankyo UK (DSUK) takes its obligations under the ABPI Code of Practice very seriously, strives to maintain high standards and always behave responsibly and ethically and we are disappointed to receive this complaint.

This letter is the DSUK formal response to the alleged breaches.

Complainant allegations

The complainant has alleged the following breaches regarding an article in Cardiac Rhythm News, namely that entitled ‘***Exploring the potential of remote atrial fibrillation diagnosis through digital technology***’ (the article):

Clause 5.5 -

the article did not clearly indicate the role of DSUK

Clause 8.3 -

that the article was disease awareness and should have been certified

Clause 5.1 -

that high standards had not been maintained

Clause 2 -

that DSUK had brought discredit upon and reduced confidence in the pharmaceutical industry

Daiichi Sankyo Response

Background

In March 2021, DSUK issued a press release announcing a strategic partnership with a number of other organisations to develop initiatives using technology to improve the detection of atrial fibrillation.

As a result of this press release, the publication Cardiac Rhythm News approached DSUK offering the opportunity to develop an opinion article related to the partnership that was announced; this was a free editorial opportunity, and not a paid-for feature.

[Named] Director and Founder of one of the companies in the strategic partnership agreed to provide their views for the article, and DSUK agreed to facilitate the writing of the article jointly with [name] via a third party agency working on behalf of DSUK.

[Name] was not remunerated for their contribution to the article.

In response to the allegation of breach of Clause 5.5

As required by DSUK internal process, a concept discussion was held in relation to the details of the article and it was agreed that, because DSUK was examining the article for accuracy and compliance with the ABPI Code, this had to be made clear; the final article to be submitted to the publication would require examination by DSUK and it must contain a declaration of DSUK's involvement.

The initial draft version of the article DSC/21/0141 submitted in Promo Mats for approval contained a clear statement:

'This article has been facilitated by Daiichi Sankyo UK Ltd as part of its involvement in a strategic alliance between [organisation 1], [organisation 2] and [organisation 3]. The final version has been reviewed for accuracy and compliance with the ABPI Code of Practice'.

Unfortunately, between versions 0.2 and the final version in Promo Mats the declaration was amended removing the first sentence, to state only:

'The final version has been reviewed for accuracy and compliance by Daiichi Sankyo UK Ltd with the ABPI Code of Practice'.

Upon investigation, unfortunately it is clear that the initial sentence within the declaration was removed due to human error.

The article has now been withdrawn in Promo Mats and DSUK has requested the online article to be removed by Cardiac Rhythm.

DSUK is disappointed that the first statement of the declaration of DSUK involvement with the article was removed and that the final published piece therefore failed to fully clarify the extent of our involvement with, and influence on, the content.

DSUK also feel the positioning of the declaration was not as prominent as had been initially intended at concept.

We therefore acknowledge a breach of Clause 5.5 in that regard.

In response to the allegation of breach of Clause 8.3

Cardiac Rhythm News is an international newspaper for cardiac rhythm management specialists and the article was aimed with that readership in mind. It was non-promotional and made no reference, either directly or indirectly, to medicines. It was not aimed at the public or at patients.

It was therefore considered to be medical education and examined accordingly. It was not disease awareness as alleged by the complainant and would not therefore require certification; we therefore deny any breach of Clauses 8.3 in that regard.

In response to the allegation of breach of Clause 5.1 and 2

As previously stated, DSUK takes its obligations under the ABPI Code of Practice very seriously and strives to maintain high standards.

We do feel that in this case the article in question did fall below the High standards expected of a pharmaceutical company, and we therefore acknowledge a breach of Clause 5.1.

We do not however, feel that the error or omission brings into disrepute, or reduces confidence in, the industry, and we deny a breach of Clause 2.

This article was approved for use on 02/08/2021.

As the PMCPA will know DSUK has been on a significant compliance improvement journey over the past 3 years and has made considerable progress in improving our processes, policies and training.

We acknowledge that there are still some improvements to be made, and these are very much being addressed as an absolute priority at Senior Management Level.

DSUK wish to absolutely reaffirm to you their commitment to self-regulation and the high standards set by the ABPI.”

PANEL RULING

The article at issue in Cardiac Rhythm News was titled ‘Exploring the potential of remote atrial fibrillation diagnosis through digital technology’, published in August 2021.

The Panel took account of Daiichi Sankyo’s submission that the publisher had approached it following the issue of a Daiichi Sankyo UK press release in March 2021. The press release had referred to Daiichi Sankyo entering into partnership with three technology companies to offer digital solutions for detection and diagnosis of atrial fibrillation. Cardiac Rhythm News offered Daiichi Sankyo the opportunity to develop an opinion article related to the partnership. It was a free editorial opportunity and not a paid-for feature. The director/founder of one of the technology companies in the partnership agreed to provide their views for the article and Daiichi Sankyo agreed to facilitate the writing of the article via a third party agency working on Daiichi Sankyo’s behalf.

Daiichi Sankyo submitted that the initial draft version of the article reviewed in the company’s approval system included the following declaration statement:

‘This article has been facilitated by Daiichi Sankyo UK Ltd as part of its involvement in a strategic alliance between [organisation 1], [organisation 2] and [organisation 3]. The final version has been reviewed for accuracy and compliance with the ABPI Code of Practice’.

The Panel noted that this statement was positioned towards the end of the article, in the same font size as the core article text, prior to the references.

Daiichi Sankyo submitted, however, that the initial sentence of this declaration was removed due to human error and the final version of the article approved by Daiichi Sankyo and published stated:

'The final version has been reviewed for accuracy and compliance by Daiichi Sankyo UK Ltd with the ABPI Code of Practice.'

The Panel noted that this statement was now positioned at the end of the article, after the references, in italicised font which was of much smaller size than the core article text.

The Panel considered the layout of the article and the immediate and overall impression to the reader. The Panel noted the article was hosted on an independent news site and that reference to Daiichi Sankyo's involvement in the article was only included at the very end of the article, after the references section, in a font size much smaller than that of the core text.

The Panel noted Clause 5.5 included that material relating to medicines and their uses, whether promotional or not, and information relating to human health or diseases which is sponsored by a pharmaceutical company or in which a pharmaceutical company has any other involvement, must clearly indicate the role of that pharmaceutical company.

The supplementary information to Clause 5.5 stated that the wording of the declaration of involvement must be unambiguous so that readers are immediately able to understand the extent of the company's involvement and influence. This is particularly important when companies are involved in the production of material which is circulated by an otherwise wholly independent party, such as supplements to health professional journals. The declaration of sponsorship must be sufficiently prominent to ensure that readers of sponsored material are aware of it at the outset.

The Panel considered the declaration that the article had been 'reviewed for accuracy and compliance by Daiichi Sankyo UK Ltd with the ABPI Code of Practice' was an ambiguous and inaccurate description of the company's involvement in facilitating the writing of the article. In the Panel's view, the lesser prominence of the declaration statement compared with the core article text, and its positioning at the very end of the article after the references, was such that Daiichi Sankyo's involvement in the article was not sufficiently prominent nor clear to readers at the outset. The Panel therefore ruled **a breach of Clause 5.5** of the Code as acknowledged by Daiichi Sankyo.

With regard to the complainant's allegation that this was a disease awareness article that should have been certified under Clause 8.3, the Panel noted that the certificate from the company's approval system showed that the article had been examined and approved by a signatory as a corporate press release. However, in its response, Daiichi Sankyo submitted that the article was medical education that was not aimed at the public or patients.

Clause 8.3 stipulated the materials that required certification under this clause including educational material for the public or patients. The supplementary information to Clause 8.3 stated that material issued by companies which is not required to be certified under the Code should be examined by a signatory or an appropriately qualified person, who needs not be a signatory, to ensure that it does not contravene the Code or the relevant statutory requirements.

The Panel noted Daiichi Sankyo's submission that Cardiac Rhythm News was an international newspaper for cardiac rhythm management specialists and the article was aimed with that readership in mind. The Panel did not have before it the readership of Cardiac Rhythm News but considered, on the balance of probabilities, it was an independent site intended for health

professionals and other relevant decision makers. Daiichi Sankyo submitted that the article was non-promotional and made no reference, either directly or indirectly, to medicines.

The Panel considered that the article was non-promotional information intended for health professionals and other relevant decision makers which did not require certification under Clause 8.3. The Panel therefore ruled **no breach of Clause 8.3** accordingly.

Overall, the Panel was concerned that the article had been approved by Daiichi Sankyo despite having an inadequate declaration of involvement statement, which was not sufficiently prominent at the outset. The Panel considered Daiichi Sankyo had failed to maintain high standards in this regard and **a breach of Clause 5.1 was ruled**, as acknowledged by the company.

Clause 2 was a sign of particular censure and reserved for such use. The Panel considered that the matter in relation to declaration of involvement in the article was adequately dealt with by its rulings of breaches of the Code above. The Panel ruled **no breach of Clause 2** accordingly.

Complaint received **19 June 2023**

Case completed **28 June 2024**