

CASE AUTH/3793/7/23

COMPLAINANT v DAIICHI SANKYO

Allegations regarding Daiichi Sankyo sponsored articles

CASE SUMMARY

This case was in relation to two articles on a charitable organisation’s website. The complainant alleged that the articles were disease awareness funded by Daiichi Sankyo that had not been certified and that Daiichi Sankyo’s involvement was only apparent at the end of reading the articles. The complainant made a further allegation about the organisational structure at Daiichi Sankyo in relation to the signatory team.

The outcome under the 2021 Code was:

Breach of Clause 5.1	Failing to maintain high standards
Breach of Clause 5.5 (x2)	Failing to have a sufficiently prominent declaration of sponsorship statement
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 5.1	Requirement to maintain high standards at all times
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 has since become non-contactable, about Daiichi Sankyo.

COMPLAINT

The complaint wording is reproduced below with typographical errors corrected:

“It is strongly evident that Daiichi Sankyo needed a dedicated signatory team to focus on approvals only, considering the number of breaches in recent times as there were further compliance breaches in regard to 2 [named charitable organisation] articles. It is remarkable that a dedicated signatory hub was not already in place to prevent breaches from occurring. Both articles are disease awareness pieces that Daiichi Sankyo had funded but this statement was only apparent at the end of reading the articles as

opposed to the beginning. At the end of the page, a statement stated, ‘The work for this project has been sponsored by Daiichi Sankyo’. As the pieces were disease awareness, these should have been certified. Breaches of following clauses had possibly taken place; 5.1, 5.5, 8.3 and 2. Articles can be viewed at: [weblinks provided]”.

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

DAIICHI SANKYO RESPONSE

The response from Daiichi Sankyo is reproduced below:

“Daiichi Sankyo UK Ltd (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 2 sponsored [named charitable organisation] articles (the ‘articles’):

- Clause 5.5 -
the articles did not have a prominent statement indicating the role of DSUK
- Clause 8.3 -
that the articles were 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 to the Sponsorship

On the 6th January 2022, DSUK received an email with a proposal from [named charitable organisation] outlining their plans to sponsor an activity entitled “Toolkit on cardiovascular disease for leaders to take action”. This had the stated aim of supporting local and national health leaders to take action to reduce Cardiovascular Disease (CVD) mortality and were seeking sponsorship from a number of partners from across the life sciences industry. This would take the production format of an online PDF report, along with commentary articles on the research, all of which were to be published on [named charitable organisation’s] website. DSUK were one of several organisations approached to sponsor the activity, and one of two which proceeded.

The sponsorship request was evaluated by DSUK based on its alignment with our organisational objectives, proposal merit, and compliance with ABPI Code of Practice. It

was deemed a suitable sponsorship request and the decision was taken to support this activity.

Between January and April 2022, the [named charitable organisation] drafted and circulated agreements with DSUK (as well as other third-party sponsors), during which time there were several email exchanges between DSUK and [named charitable organisation] to agree upon wording of an open, transparent and unambiguous disclaimer detailing DSUK's involvement as a company.

The initial [named charitable organisation] agreement was entitled a 'Service Agreement', which is their preferred terminology for third-party agreements. As DSUK believed the [named charitable organisation] to be a commercial organisation it was considered at the time of agreeing contractual terms and conditions that this would be appropriate. This matter is being addressed by Senior Leadership as a matter of priority.

Despite this use of contract terminology, DSUK would like to make clear to the PMCPA that this was always considered by both parties to better fit the spirit and wording of a third-party sponsorship arrangement, rather than a conventional services agreement. This is validated by email correspondence between both parties, which is enclosed as evidence.

Whilst initiating the payment process to the [named charitable organisation], it was identified on Tuesday 27th September 2022 that the [named charitable organisation] had been incorrectly categorised in DSUK's payments processing system as a Vendor rather than a third-party Organisation.

DSUK contacted the [named charitable organisation] immediately to highlight the error and provided [it] with a DSUK Agreement to review and sign. Following required legal reviews by both parties, the final DSUK Agreement was signed and certified on Thursday 20th October 2022.

The publications associated with the Sponsorship in question were published on the [named charitable organisation's] website on the following dates:

- *6th October 2022: A commentary blog: This outlines the rationale for the research project and explains that a report would be published in November 2022*
- *11th November 2022: The full research toolkit/report*

DSUK had no input into the 2 articles that are the subject of this complaint and does not therefore have any other copies other than the web captures.

In response to the allegation of breach of Clause 5.5

DSUK is disappointed that despite the efforts made to ensure that the declaration of our sponsorship was open, transparent, and unambiguous; it was unfortunately not made clear in the subsequent agreements, or to the [named charitable organisation] directly, that the positioning of the declaration was equally as important and thus ensured that it be placed in a prominent position from the outset. DSUK has since contacted [named charitable organisation] to request amendments to the positioning of this disclaimer on all

associated published material from this project to ensure DSUK's involvement is clear at the outset.

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

In response to the allegation of breach of Clause 8.3

About [named charitable organisation]

The [named charitable organisation] is an independent charitable organisation and a leading health policy think tank, whose stated aim is to work to improve health and care in England. Its objectives are to produce content, research, analyses and recommendations aimed at health policymakers and leaders with decision-making responsibilities across the UK health system.

The "Toolkit" was designed to highlight the potential for evidence-based action on Cardiovascular Disease, to improve health and reduce health inequalities, supporting policy makers and commissioners with clear, information to aid strategic decision making.

The articles in question were aimed at 'national health leaders and policymakers across national and local government' and not therefore disease awareness as the complainant alleges. They were not aimed at patients or the public; they were non-promotional and made no reference, either directly or indirectly, to medicines.

The articles in question did not therefore require certification and we deny any breach of Clause 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 failure to ensure that the disclaimer in the articles was displayed in a prominent position at the outset does mean that High standards expected of a pharmaceutical company, have not been maintained and we therefore acknowledge a breach of Clause 5.1.

Upon receiving this complaint DSUK took immediate corrective action with the [named charitable organisation] to ensure that the disclaimer on both articles is now in a more prominent position at the outset.

As the arrangements of the activity were clear, documented and appropriate; DSUK do not feel that the error or omission brings into disrepute, or reduces confidence in, the industry, and we deny a breach of Clause 2.

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

We acknowledge that there are still 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 complaint related to two articles on [named charitable organisation’s] website. Article 1 was titled, ‘Tackling cardiovascular disease: why the urgency?’ and published on 6 October 2022. Article 2 was titled, ‘Cardiovascular disease in England: supporting leaders to take actions’ and published on 11 November 2022.

The Panel noted Daiichi Sankyo’s submission that in January 2022 it received an email from [named charitable organisation] requesting sponsorship for an activity titled “Toolkit on cardiovascular disease for leaders to take action”. Daiichi Sankyo stated that it was one of several organisations approached by [named charitable organisation] to sponsor the activity, and one of two which subsequently did.

Clause 1.22 stated that a company can provide sponsorship for an activity to certain organisations. ‘Sponsorship’ means a contribution, financial or otherwise, in whole or in part provided by or on behalf of a company, towards an activity (including an event/meeting or material) performed, organised, created etc by a healthcare organisation, patient organisation or other independent organisation.

The Panel took account of Daiichi Sankyo’s submission that neither article in question made a direct or indirect reference to any medicine and that [named charitable organisation] was an independent charitable organisation whose objectives were to produce content, research, analyses and recommendations aimed at health policymakers and leaders with decision-making responsibilities across the UK health system.

The Panel noted that the sponsorship request from [named charitable organisation] to Daiichi Sankyo stated that the material would be published on [named charitable organisation’s] website and promoted, including via [named charitable organisation] Twitter and LinkedIn accounts. The Panel considered that the audience of the material would therefore likely include the public.

Clause 8.3 included that educational material for the public issued by companies which relates to disease must be certified.

In determining whether Daiichi Sankyo was required to certify the articles in question, the Panel first had to determine the relationship between Daiichi Sankyo and [named charitable organisation].

The Panel considered that it was important that companies were clear about the classification of activities under the Code and that the classification should be consistently described across materials including written agreements.

The Panel noted that the written agreement executed in April 2022 was headed ‘Services agreement- provision of services by [named charitable organisation]’. However, the content of

the agreement referred to Daiichi Sankyo and another organisation as being 'sponsors' of the material, and described the statement that would be placed 'at the bottom of the relevant webpage' as:

'The work for this project was sponsored by Daiichi Sankyo and [second named organisation]. This output was independently developed, researched and written by [named charitable organisation]. The sponsors have not been involved in its development, research or creation and all views are the authors' own.'

The Panel noted that a contracted service had different requirements under the Code to that of sponsorship of an independent organisation's material. Importantly, a pharmaceutical company contracting an organisation to provide it with a service would mean that the pharmaceutical company was responsible for the material under the Code, including certification of the material if required. Whether a pharmaceutical company was responsible for materials produced as a result of a sponsorship would depend on the sponsorship arrangements. The Panel considered that a company could sponsor an independent organisation's educational material and not be responsible for certifying its content if the sponsorship was strictly arm's length.

The Panel was concerned that the April 2022 contract referred to the arrangement as a services agreement and 'provision of services by [named charitable organisation]' and then later referred to Daiichi Sankyo as being a sponsor.

A new written agreement was executed and certified in October 2022, using a Daiichi Sankyo 'sponsorship agreement' template.

The Panel noted that both the April 2022 and October 2022 contracts stated that [named charitable organisation] would share a draft of the main toolkit with both sponsors ahead of publication, which was "not for comment" as this was "an independent piece of work and [named charitable organisation] retains full editorial control".

On the evidence before it, despite the incorrect terminology in the contract executed in April 2022 which referred to a services agreement, the Panel considered that the arrangements appeared such that Daiichi Sankyo had sponsored [the named charitable organisation] articles at arm's length. In making this decision the Panel bore in mind that the articles made no reference to Daiichi Sankyo medicines and there was no evidence that Daiichi Sankyo had either: initiated the articles/concept, influenced the content, chose or directly paid the individual authors, influenced where the material was sent, used the material, or received anything in return for the funding.

Noting the Panel's determination that the articles were sponsored at arm's length, the Panel considered that the articles themselves did not require certification by Daiichi Sankyo and the Panel ruled **no breach of Clause 8.3 in relation to each article**.

Regarding the declaration of involvement statement, the Panel noted that this appeared towards the bottom of Article 1 and stated, "The work for this project has been sponsored by Daiichi Sankyo and [second named organisation]. The associated report, which will be published in November 2022, has been independently developed, researched and written by [named charitable organisation]. The sponsors have not been involved in its development, research or creation and all views are the author's own."

A similar declaration of involvement statement appeared towards the bottom of Article 2 and stated, “The work for this project was sponsored by Daiichi Sankyo and [second named organisation]. This output was independently developed, researched and written by [named charitable organisation]. The sponsors have not been involved in its development, research or creation and all views are the author’s/authors’ own”.

Clause 5.5 stated 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 this clause included that 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 that the length of the continuously scrolling webpage for each article was such that the statement of involvement by Daiichi Sankyo would not appear until the reader had scrolled down at least three screens worth of content to the bottom of each article. The Panel considered, given the length of each article, it was entirely possible that a reader could miss the declaration of Daiichi Sankyo’s involvement. The Panel considered that Daiichi Sankyo’s declaration of sponsorship was not sufficiently prominent to ensure that readers were aware at the outset and the Panel ruled **a breach of Clause 5.5 in relation to each article, as acknowledged by Daiichi Sankyo.**

The Panel noted that the first contract executed in April 2022 stated that sponsors’ involvement would be recognised “through a statement at the bottom of the relevant webpage”. The second contract, executed and certified in October 2022, included the same provision. The Panel was concerned that the Daiichi Sankyo employees that signed each contract, and the Daiichi Sankyo employee who certified the October 2022 contract, did not request that the agreement was amended to make clear that the declaration of Daiichi Sankyo’s sponsorship must be sufficiently prominent to ensure that readers were aware at the outset and that inclusion ‘at the bottom of the relevant webpage’ would be insufficient. The Panel considered that Daiichi Sankyo had not made the requirements of the Code regarding declaration of sponsorship clear to [named charitable organisation] and had failed to maintain high standards in this regard. The Panel therefore ruled **a breach of Clause 5.1, as acknowledged by Daiichi Sankyo.**

The Panel noted the complainant’s concerns regarding the need for a dedicated signatory team to focus on approvals only, to prevent breaches of the Code. The Panel considered that the Code required companies to have nominated signatories to certify certain materials and activities as referred to in Clause 8, however, the Code did not mandate that such an individual’s job role be confined to certification only. It was not for the Panel to mandate how a pharmaceutical company should organise its operations. The Panel noted that Daiichi Sankyo had provided the PMCPA with a list of its nominated signatories when responding to this complaint. The Panel considered that the complainant had not established that Daiichi Sankyo’s organisational structure was such that it had failed to maintain high standards and the Panel ruled **no breach of Clause 5.1 in that regard.**

Clause 2 was a sign of particular censure and reserved for such use. The Panel accepted that there was a declaration of Daiichi Sankyo’s sponsorship on each article and the contracts referred to the requirement for a declaration, albeit it was not made clear to [named charitable organisation] that the declaration must be sufficiently prominent to ensure that readers were aware at the outset. The Panel considered that the complainant had not established that the

matter was such as to bring discredit upon or reduce confidence in the industry and the Panel therefore ruled **no breach of Clause 2**.

Complaint received **5 July 2023**

Case completed **28 August 2024**