

**CASE AUTH/3629/4/22**

## **COMPLAINANT v DAIICHI SANKYO**

**Allegations about a disease awareness campaign on a patient organisation's website**

### **CASE SUMMARY**

**This case was in relation to Daiichi Sankyo's relationship with a patient organisation and the arrangements for a disease awareness programme.**

**The Panel ruled a breach of the following Clauses of the 2021 Code following its decision that the arrangement was a contract for services and Daiichi Sankyo was responsible for the material; certain educational material for the public related to this disease awareness campaign had not been certified as required by the Code:**

<b>Breach of Clause 5.1</b>	<b>Failing to maintain high standards</b>
<b>Breach of Clause 8.3</b>	<b>Failing to certify educational material for the public related to disease</b>

**The Panel ruled no breach of the following Clauses of the 2021 Code as it had no evidence that the patient organisation had not included a declaration of Daiichi Sankyo's involvement on all materials related to the campaign:**

<b>No Breach of Clause 2</b>	<b>Requirement that activities or material must not bring discredit upon, or reduce confidence in, the pharmaceutical industry</b>
<b>No Breach of Clause 5.5</b>	<b>Requirement to be sufficiently clear as to the company's role and involvement</b>

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

### **FULL CASE REPORT**

**An anonymous contactable complainant stated that he/she was whistleblowing on a campaign where Daiichi Sankyo was not arm's length.**

### **COMPLAINT**

**The complainant alleged that Daiichi Sankyo had initiated and conducted a disease awareness campaign with a named patient organisation without certification of all material connected to that campaign.**

The complainant provided a link to a page on the patient organisation's website.

The complainant stated that as could be seen by the link, this campaign was a get a cholesterol test programme and the disclaimer at the top of the website page read as: *Daiichi Sankyo have assisted [patient organisation] by providing funding for this communication programme, and identification of areas of the country where people are living with high levels of cholesterol for [patient organisation] to reach out to. Daiichi Sankyo have had no input or influence over [patient organisation]'s materials used in this campaign.*

The complainant stated that this page and all subsequent material for the programme needed certification as Daiichi Sankyo had pointed the patient organisation in the direction of which patients to contact (identification of areas for the patient organisation to reach out to) meaning they were fully involved and not arm's length.

The complainant stated that the webpage was disease awareness considering it discussed that high cholesterol could lead to heart attacks and strokes and that a cholesterol test, along with other simple tests including a blood pressure test, BMI and waist measurement, would give a good idea of heart health and show you if any lifestyle changes or treatment was needed. It also stated that your doctor should also check another blood fat called triglycerides, as these also affect your heart health. The complainant alleged that none of the other material used for the campaign was certified by the internal review team. The complainant further alleged that the patient organisation had not made it clear on all materials (including when reaching out to patients) that there was funding and involvement from Daiichi Sankyo which was needed from the outset so that patients could have full understanding that a pharmaceutical organisation was involved and funding this campaign. The complainant alleged breaches of Clauses 8.3, 5.5, 5.1 and 2 of the 2021 Code.

When writing to Daiichi Sankyo, the Authority asked it to consider the requirements of Clauses 8.3, 5.5, 5.1 and 2 of the 2021 Code as cited by the complainant.

## **RESPONSE**

Daiichi Sankyo stated that it took its obligations under the Code seriously and strove to maintain high standards and behave responsibly and ethically at all times.

Daiichi Sankyo stated that its relationship with the named patient organisation was open, transparent and non-promotional in nature with no intention to influence the independence of the patient organisation in anyway. Daiichi Sankyo's relationship with the patient organisation included sponsorship of disease awareness campaigns, educational programmes and other non-promotional policy activities.

Daiichi Sankyo submitted that the allegations were unfounded; the complainant had made a series of assumptions and allegations without knowing the details of the nature of the agreement in place between the patient organisation and Daiichi Sankyo in relation to this campaign.

Daiichi Sankyo submitted that the objective of the patient organisation's disease awareness campaign was to build awareness amongst the general population particularly in specific high-risk groups for the importance of getting a cholesterol test and knowing how to manage their risk.

This initiative was instigated and disseminated by the patient organisation of which Daiichi Sankyo, upon being asked by the patient organisation, agreed to sponsorship. Furthermore, the responsibility of the relationship with the patient organisation sat with the medical department only and there was no link to any commercial activities.

Daiichi Sankyo stated that it was happy to provide the context and evidence to demonstrate that no breach of Clauses 8.3, 5.5, 5.1 or Clause 2 of the Code had occurred.

Case AUTH/3594/12/2 was a previous complaint whereby Daiichi Sankyo took a similar approach to the sponsorship of the patient organisation's disease awareness campaign in 2020. The company submitted that there might be some overlap with this case.

### **Complainant allegation 1:**

Daiichi Sankyo submitted that it agreed to sponsorship of the project through the provision of funds and of a 'Cholesterol heatmap' report, as per the request of the patient organisation; this was outlined in the certified and signed agreement between Daiichi Sankyo and the patient organisation. The cholesterol heatmap report was a resource information containing publicly available data that identified areas of high disease burden across England. It provided information which could assist the patient organisation to understand how they could effectively carry out their campaign to geographic areas where CVD burden was greatest. This material was provided to the patient organisation as requested and they were never under any obligation to use it. Full details of the nature of contributions of both parties could be found in the signed agreement. Therefore, Daiichi Sankyo submitted that it did not initiate and conduct this campaign.

The complainant alleged that Daiichi Sankyo 'were not arms length'. Daiichi Sankyo submitted that it did not have editorial control and had no input into the development of the campaign materials; Daiichi Sankyo contributed as part of the sponsorship, funding and cholesterol heatmap report to the patient organisation as requested. In compliance with Clause 5.5 Daiichi Sankyo submitted that it was fully transparent and declared clearly its involvement as shown in the disclaimer statement:

'Daiichi Sankyo have assisted [patient organisation] by providing funding for this communication programme, and identification of areas of the country where people are living with high levels of cholesterol for [patient organisation] to reach out to. Daiichi Sankyo have had no input or influence over [patient organisation]'s materials used in this campaign'.

To add to this, as Daiichi Sankyo had no editorial input or control on the materials for the campaign, the decision was made to certify the disclaimer which appeared on the landing page of the patient organisation webpage to ensure compliance and an accurate reflection of Daiichi Sankyo's contribution and role within the context of this campaign was clear and apparent to all.

As this campaign was solely owned by the patient organisation, with full disclosure into Daiichi Sankyo's level of involvement provided in the approved disclaimer and in line with the signed and certified agreement, Daiichi Sankyo submitted that there was no requirement for it to certify

the patient organisation's campaign materials as part of this arrangement. Daiichi Sankyo denied a breach of Clauses 5.5 and 8.3.

### **Complainant allegation 2:**

As stated above in response to allegation 1, Daiichi Sankyo submitted that it provided sponsorship in the form of both funding and provision of a 'Cholesterol heatmap' report and had no editorial input or influence on the materials produced by the patient organisation. As a result, the decision was taken to only certify Daiichi Sankyo's involvement disclaimer to be used on different platforms including the website landing page.

Daiichi Sankyo submitted that its involvement did not extend beyond the terms of the certified agreement. Daiichi Sankyo had no input into the content of the campaign or how the patient organisation chose to utilise the reactive resources provided.

In line with the agreement, Daiichi Sankyo had no access to any individual identifiable data and therefore disagreed with the allegation that Daiichi Sankyo 'had pointed [patient organisation] in the direction of which patients to contact'. This campaign was solely owned by the patient organisation: Daiichi Sankyo did not have input on how the patient organisation used the heatmaps report, nor any influence on areas targeted. Daiichi-Sankyo submitted there was no requirement for it to certify the patient organisation's campaign materials as part of this sponsorship. Therefore, Daiichi Sankyo refuted the complainant's allegation 'meaning they were fully involved and not arms length', as a consequence, Daiichi Sankyo denied a breach of Clauses 5.5 and 8.3.

### **Complainant allegation 3:**

Daiichi Sankyo submitted as explained above, that there was no requirement for Daiichi Sankyo to certify the patient organisation's campaign materials as part of this arrangement since Daiichi Sankyo had no editorial input or influence over the patient organisation's materials used in the campaign. Thus, Daiichi Sankyo denied a breach of Clauses 5.5 and 8.3.

### **Complainant allegation 4**

Daiichi Sankyo submitted that the requirement for disclosure of involvement was communicated to the patient organisation and formed a main component of the agreement which was signed by both parties. Daiichi Sankyo referred to a section of the contract re: disclosure that stated:

'The patient organisation must always declare and acknowledge support provided by Daiichi Sankyo and must be clearly acknowledged from the outset. Also advertising of a particular prescription only medicines to the public is prohibited.'

Daiichi Sankyo submitted that it applied full due diligence to ensure that its involvement was fully transparent in line with the requirements of Clause 5.5. By certifying the PAG agreement and disclaimer, Daiichi Sankyo's involvement was prominent in the disclaimer. Beyond this, Daiichi Sankyo had no input into the contents of the campaign and relied upon the patient organisation to fulfil their contractual obligations in line with the signed agreement.

### **Summary**

Daiichi Sankyo submitted that this was a disease awareness campaign solely produced by the patient organisation and sponsored by Daiichi Sankyo. Daiichi Sankyo had had no editorial input or influence over the patient organisation's materials used in the campaign, as a result, there was no obligation for Daiichi Sankyo to certify materials as part of this campaign. Daiichi Sankyo denied a breach of Clause 8.3.

As communicated previously in Case AUTH/3594/12/21, Daiichi Sankyo submitted that it had been fully transparent with the nature of the involvement in accordance with the requirements of Clause 5.5; Daiichi Sankyo submitted that it had fulfilled this requirement by certifying the appropriate disclaimer for use in the campaign as well as including this obligation of disclosure in the certified signed agreement with the patient organisation. Therefore, Daiichi Sankyo denied a breach of Clause 5.5. As there was no evidence to suggest that high standards had not been maintained, Daiichi Sankyo denied a breach of Clause 5.1 and as a consequence, denied a breach of Clause 2.

### **PANEL RULING**

The Panel noted that the link provided by the complainant led to a page on the patient organisation site, Get a cholesterol test. The first paragraph stated:

'Daiichi Sankyo have assisted [patient organisation] by providing funding for this communication programme, and identification of areas of the country where people are living with high levels of cholesterol for [patient organisation] to reach out to. Daiichi Sankyo have had no input or influence over [patient organisation]'s materials used in this campaign. CVD/21/0226 September 2021'.

Beneath this it stated, *inter alia*, that high cholesterol could affect anyone at any age and if left unchecked could lead to serious health issues such as heart disease, heart attacks and strokes and that the only way of knowing if you have high cholesterol was to take a test.

The Panel noted Daiichi Sankyo's submission that the objective of the patient organisation's disease awareness campaign was to build awareness amongst the general population particularly in specific high-risk groups for the importance of getting a cholesterol test and knowing how to manage their risk. The Panel further noted Daiichi Sankyo's submission that this initiative was instigated and disseminated by the patient organisation and Daiichi Sankyo had agreed to sponsorship.

The Panel noted the agreement provided by Daiichi Sankyo was titled 'Collaboration Agreement'. The agreement referred to the patient organisation as a 'Partner' and stated that Daiichi Sankyo 'wishes to engage the services of the Partner'. The footer of the agreement was referred to as a 'PAG Service Agreement'. The agreement set out the services that the patient organisation would provide to Daiichi Sankyo.

Section 8.2 of the agreement stated, 'Unless otherwise agreed between the Parties in Appendix 1, the Partner [patient organisation] assigns to the Company [Daiichi Sankyo] all of its Intellectual Property Rights on materials and products developed or prepared for the Company by the Partner in connection with the Services performed hereunder.'

Appendix 1 of the agreement (description of services etc.) referred to the activity as 'Cholesterol Awareness Campaign 2021' with a start date in June 2021 and a completion date of 1 March 2022.

The contributions of the patient organisation were stated to include: Audience setup on social media i.e. Facebook and Google, Campaign landing page setup – to include DSUK disclaimer for transparency purposes, Negotiating with pharmacies to participate in cholesterol testing, Manage advertising budget, create auto-responder email and Reporting.

It was stated that Daiichi Sankyo would have no input into the content of the campaign but would provide funding and the cholesterol heatmap report to target campaign by geography. It further stated that Daiichi Sankyo would have quarterly updates on the campaign programme and access to data analytics which would include:

- Where the social media had most success
- The number of people engaged with the social media messages
- How many people saw the social media posts
- Where in the country did people access the campaign page
- The age and gender profile of people engaged on social media and on the website
- The number of people receiving Cholesterol e-News
- The number of people downloading a voucher/discount code for a cholesterol test
- The age and gender of Cholesterol e-News subscribers

It was stated that all data were to be anonymised and non- identifiable.

The agreement further stated:

*'Agreements and materials in relation to working with the Partner must be agreed between the Parties and certified in advance of the commencement of the activity or service. The exception being where funding is provided as a grants and donations or it is stipulated in the contract that the Company has had no input or involvement in the content. This does not preclude the company from correcting factual inaccuracies.'*

*'The Patient organisation is strongly encouraged to declare that they have been provided paid services by the company whenever those concerned write or speak in public about a matter that is the subject of this agreement, or any other issue relating to Daiichi Sankyo.'*

The agreement was certified and signed by both parties in June 2021.

Whilst the Panel noted Daiichi Sankyo's submission that the initiative was instigated by the patient organisation, no documentation had been provided to this effect. It was not clear to the Panel what correspondence had taken place between the two organisations prior to the written agreement being made.

The Panel considered that there was conflicting terminology within the contract and between the contract and Daiichi Sankyo's response to the complaint with regard to the relationship between Daiichi Sankyo and the patient organisation. The contract predominantly referred to the relationship as a contract for services save in three instances where it referred to derivatives of the word 'collaboration'. Daiichi Sankyo's response to this complaint consistently referred to the

relationship as 'sponsorship'. The Panel noted that under the Code there were very different requirements with regard to sponsorship, contract for services and collaborative working.

In a previous case, Case AUTH 3594/12/21, which was related to Daiichi Sankyo's relationship with the patient organisation and a different disease awareness campaign in 2020, the Panel had noted that the master services agreement referred to ownership of materials remaining with the patient organisation, which the Panel had noted appeared to be inconsistent with a contract for services. The Panel in that case, in the absence of a clear and unambiguous classification of the relationship between the parties in the documents provided, and noting the ownership of materials by the patient organisation and Daiichi-Sankyo's submission that it was a sponsorship, decided, on balance, that the arrangements were to be considered a sponsorship which was not at arm's length and thus in that case Daiichi-Sankyo was responsible for the content of the materials and the Panel made its rulings on that basis.

Turning to the current case, Case AUTH 3629/4/22, the Panel noted that the contract between the patient organisation and Daiichi Sankyo made no reference to the term sponsorship, however, the term 'service' was stated 53 times. Notably, the contract referred to the patient organisation assigning to Daiichi Sankyo all of its Intellectual Property Rights on materials and products developed or prepared for Daiichi Sankyo by the patient organisation in connection with 'the Services'. This was inconsistent with sponsorship of patient organisation material.

A contracted service had different requirements under the Code to that of sponsorship of patient organisation material. Importantly, a pharmaceutical company contracting a patient organisation to provide it with a service would mean that the pharmaceutical company was responsible for the activity and materials under the Code. Whether a pharmaceutical company was responsible for materials produced as a result of a sponsorship would depend on the sponsorship arrangements. The Panel noted that companies could sponsor patient organisation material and not be responsible for its content but only if the sponsorship was arm's length. The Panel noted that the contract referred to Daiichi Sankyo, in addition to the provision of funds, providing the Cholesterol heatmap report to target campaign by geography and that Daiichi Sankyo would receive quarterly updates on the campaign programme and have access to data analytics which included where in the country people had accessed the campaign, the age and gender profile of people who had engaged on social media and on the website, how many people had received the e-News and how many had downloaded the voucher/discount code for a cholesterol test. It thus appeared to the Panel that the arrangement was not arm's length and therefore, in the Panel's view, Daiichi Sankyo would be responsible for the content even if the company had classified it as sponsorship of patient organisation material.

Nonetheless, the Panel noted that the contract set out the legal basis of the arrangements between the parties and in this regard noted that the contract predominantly referred to a contract for services and that the intellectual property rights of the materials developed in connection with the service would be assigned from the patient organisation to Daiichi Sankyo. Noting the content of the contract, the Panel decided that the arrangements were to be considered a contract for services; Daiichi Sankyo was responsible for the content of the materials and the Panel made its rulings on that basis.

The Panel noted the complainant's statement that the 'get a cholesterol test' webpage and all material related to the programme required certification.

The Panel noted its decision above that the arrangement was a contract for services and Daiichi Sankyo was responsible for the material; therefore, all the educational material for the public required certification. The Panel noted Daiichi Sankyo's submission that it had certified the disclaimer which appeared on the landing page of the patient organisation's webpage.

The Panel noted that the webpage that was certified by Daiichi Sankyo in September 2021 contained differences to the webpage that was accessed by the case preparation manager in the link provided by the complainant in April 2022. The main difference was that the certified version referred to '10%+ off a cholesterol test' or a 'completely free cholesterol test' and directed readers to register their email address to receive a discount code and a link to a map with pharmacies taking part where the reader could book a test. This was not on the version accessed by the case preparation manager in April 2022, however, the Panel noted from the agreement that the campaign was due to end on 1 March 2022. Both the certified version and the version accessed by the case preparation manager in April 2022 had the Daiichi Sankyo declaration statement noted above.

Nonetheless, it appeared to the Panel that the complainant's allegation was in relation to certification of material other than the landing page as he/she stated '...none of the **other** material used for the campaign was certified ... (emphasis added by the Panel).' In this regard, the Panel noted that the complainant did not identify any specific materials but made a general reference to all material within the disease awareness programme. The Panel noted that the contract referred to other materials including Cholesterol eNews and social media posts. The Panel noted Daiichi Sankyo's submission that there was no requirement for it to certify the campaign materials as part of the arrangement and that Daiichi Sankyo took the decision to only certify its involvement disclaimer to be used on different platforms including the website landing page. On the evidence before it, it appeared to the Panel, on the balance of probabilities, that certain educational material for the public related to this disease awareness campaign had not been certified as required by the Code and thus **a breach of Clause 8.3** was ruled.

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 referred to the declaration being sufficiently prominent so that readers were aware at the outset.

The Panel noted the complainant's allegation that the patient organisation had not made it clear at the outset on all materials (including when reaching out to patients) that there was funding and involvement from Daiichi Sankyo. The complainant did not provide any specific examples, but it appeared that he/she was referring to the social media posts as part of the campaign as referred to in the contract.

The Panel noted that the body of the 'get a cholesterol test' landing page stated at the top:

'Daiichi Sankyo have assisted [patient organisation] by providing funding for this communication programme, and identification of areas of the country where people are living with high levels of cholesterol for [patient organisation] to reach out to. Daiichi Sankyo have had no input or influence over [patient organisation]'s materials used in this campaign'.



Whilst the Panel had concerns about the wording of the declaration of involvement based on the nature of the contract between the two parties, it nonetheless noted that the complainant's allegation was not in relation to this landing page, but that the patient organisation had not made it clear on '...all materials (including when reaching out to patients)...' (emphasis added by the Panel). It appeared that the allegation was in relation to a declaration of involvement being on all material related to the campaign rather than the wording of the declaration per se.

The Panel noted Daiichi Sankyo's submission that the contract stated, 'The patient organisation must always declare and acknowledge support provided by Daiichi Sankyo and must be clearly acknowledged from the outset'. The Panel further noted Daiichi Sankyo's submission that it certified the agreement and the disclaimer which it requested the patient organisation to use and then relied upon the patient organisation to fulfil their contractual obligations.

The only disease awareness material provided by either party was the website landing page. The Panel had no evidence before it to suggest that the patient organisation had not included a declaration of Daiichi Sankyo's involvement on all other materials related to the campaign, including when reaching out to patients. The Panel was not an investigatory body; based on the narrow allegation and the lack of evidence before it, the Panel ruled **no breach of Clause 5.5**.

The Panel noted its comments above and was concerned that Daiichi Sankyo had failed to understand that its arrangements with the patient organisation meant that Daiichi Sankyo was responsible for the disease awareness materials and it appeared that Daiichi Sankyo did not have adequate oversight over all the materials, including the social media posts sent by the patient organisation, and **a breach of Clause 5.1** was ruled in this regard.

Clause 2 was a sign of particular censure and reserved for such use. Whilst the Panel had concerns about the relationship between Daiichi Sankyo and the patient organisation in relation to this disease awareness campaign as set out above, on balance, noting the limited material provided by the complainant, it did not consider that the complainant had established that Daiichi Sankyo had brought discredit upon the industry and **no breach of Clause 2** was ruled.

\* \* \* \* \*

During the consideration of this case, the Panel noted that the certified webpage included an offer of 'a minimum of 10% off a cholesterol test' or a free cholesterol test. There was no allegation in this regard and the Panel did not have sufficient information to understand the appropriateness of this benefit. The Panel requested that Daiichi Sankyo be advised of its concerns in this regard.

**Complaint received**      **11 April 2022**

**Case completed**        **30 March 2023**