

CASE AUTH/3666/6/22

COMPLAINANT v DAIICHI SANKYO

Concerns about an article published in the Health Service Journal (HSJ)

CASE SUMMARY

This case was in relation to the alleged disguised promotion by Daiichi Sankyo UK Limited in the Health Service Journal (HSJ).

The Panel ruled a breach of the following Clauses of the 2019 Code as the fact the author was a senior employee of Daiichi-Sankyo should have appeared at the top of the article so that readers were aware of the extent of the company's involvement from the outset:

Breach of Clause 9.10	Failing to be sufficiently clear as to the company's role and involvement
Breach of Clause 9.1	Failing to maintain high standards

The Panel ruled no breach of the following Clauses of the 2019 Code because it did not consider that the complainant had established that:

- **the article promoted a specific Daiichi Sankyo medicine**
- **Daiichi Sankyo's compliance understanding, framework and application were severely poor as seen by the raft of breaches on a regular basis or that the compliance knowledge had serious gaps or that the compliance responsibilities and accountabilities were not improving as alleged**

No Breach of Clause 12.1	Requirement that promotional material and activities must not be disguised
No Breach of Clause 14.1	Requirement to certify promotional material
No Breach of Clause 9.1	Requirement to maintain high standards
No Breach of Clause 2	Requirement that activities or material must not bring discredit upon, or reduce confidence in, the pharmaceutical industry

**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 who described him/herself as a health professional, complained about disguised promotion in the Health Service Journal (HSJ) by Daiichi Sankyo UK Limited.

COMPLAINT

The complainant submitted that the compliance understanding, framework and application were severely poor at Daiichi Sankyo as seen by the raft of breaches on a regular basis. In addition, the compliance knowledge had serious gaps and the compliance responsibilities and accountabilities were not improving either.

The complainant provided a link to an article and alleged that it was fully funded and commissioned by Daiichi Sankyo but this was not set out at the start of the article to allow readers to understand Daiichi Sankyo's involvement. The complainant alleged breaches of Clauses 5.5 and 5.1 of the 2021 Code. The complainant alleged that there was disguised promotion within this article due to the following statement 'AF (atrial fibrillation) related stroke risk can be reduced by up to two thirds with the use of anticoagulants, yet these continue to be under-prescribed in the UK with around a quarter of eligible patients with AF not receiving NICE [The National Institute for Health and Care Excellence]-recommended anticoagulant drugs'. The complainant stated that Daiichi Sankyo had a product called Lixiana for AF and there was indirect promotional reference to this in the statement (AF + anticoagulant). Lixiana was also recommended as a potential option by NICE. The complainant alleged breaches of Clauses 3.6, 5.1 and 2 of the Code. The complainant stated that there was no prescribing information provided for Lixiana and alleged breaches of Clauses 12.1, 5.1 and 2 of the Code. The complainant further stated that the article had not been certified and alleged breaches of Clauses 8.1, 5.1 and 2 of the Code. The complainant considered that pre-vetting of materials was required to stop these compliance issues occurring on a regular basis.

When writing to Daiichi Sankyo, given the article referenced in the complaint was published in 2019, the Authority asked it to consider the requirements of Clauses 2, 4.1, 9.1, 9.10, 12.1 and 14.1 of the 2019 Code rather than the equivalent clauses of the 2021 Code cited by the complainant. Daiichi Sankyo was also asked to consider the requirements of Clause 9.1 in relation to the allegation about compliance and the alleged 'raft of cases on a regular basis'.

RESPONSE

Daiichi Sankyo submitted that it took its obligations under the ABPI Code of Practice seriously, strove to maintain high standards and always behaved responsibly and ethically.

Background information and response to individual breach allegations

Daiichi Sankyo submitted that the sponsored article, which was the subject of this complaint, was certified by a medical signatory for publication on 29 October 2019, to coincide with World Stroke Day.

World Stroke Day was an annual event in which disease awareness activities occurred to raise awareness of the burden of stroke on health systems and patients. The article was commissioned to present the views of Daiichi Sankyo UK and its senior employee on the topic of stroke, intended as a form of 'thought leadership'. It covered a wide range of issues

pertaining to national policy ambitions to improve stroke prevention through improvements in the detection, management and treatment of the stroke risk factors.

HSJ was a well-known publication aimed towards health system managers, leaders and policy makers which determine, and have an interest in, the way in which the health service operates, including delivery of its health policy priorities. HSJ was therefore a suitable audience for the theme and content of the article.

The intent of the article was non-promotional in its entirety and targeted specifically towards HSJ readers and subscribers.

Complainant allegation 1:

'This article was fully funded and commissioned by Daiichi Sankyo but this was not set out at the start of the article to allow readers to understand Daiichi Sankyo involvement'.

Daiichi Sankyo's response:

Daiichi Sankyo noted that the complainant alleged that Daiichi Sankyo's involvement was not made clear at the start of the article, thereby inferring a lack of transparency surrounding Daiichi Sankyo's authorship, funding, and commissioning. This was a refutable allegation which Daiichi-Sankyo strongly challenged.

The article made clear, below the title, that it was 'paid-for-content from commercial partners' external to the HSJ organisation and that the content was thereby not the responsibility of HSJ. This was displayed prominently before the first paragraph of the article. Additionally, the emboldened statement '*sponsored by*' alongside the corporate Daiichi Sankyo logo was prominently displayed towards the top of the article. The term 'sponsored by' was in line with HSJ's editorial style, but was sufficient in making it clear that Daiichi Sankyo was responsible for the content.

Moreover, it was wholly clear to the reader that the content was written by Daiichi Sankyo and there was no effort made to hide Daiichi Sankyo's involvement in sponsoring the article. The author of the article, the Daiichi Sankyo senior employee, was clearly presented by name and portrait, again to demonstrate clearly the fact that this material represented the views and opinions of the Daiichi Sankyo UK organisation, its employee and not of any other organisation.

Whilst a disclaimer was not displayed at the start or end of the article, Clause 9.10 of the 2019 Code did not state that it was a requirement that any statement was included at the beginning of an article. Rather, this clause stated that the '*material must clearly indicate the role of that pharmaceutical company and that the declaration of sponsorship must be sufficiently prominent to ensure that readers of sponsored material are aware of it at the outset*'. Daiichi Sankyo submitted that the role of Daiichi Sankyo as part of this content was clear and transparent, and no attempt was made to hide that this content was commissioned and written by a senior employee of a UK pharmaceutical company.

In line with the above responses, Daiichi Sankyo believed that its involvement with the article, both in its sponsorship and authorship, was both clear and transparent to all readers, fulfilled the requirements of the 2019 Code and no effort had been made to hide Daiichi-Sankyo's

responsibility for the content. Therefore, Daiichi Sankyo UK denied a breach of Clauses 9.10 and [9.1].

Complainant allegation 2:

'There was disguised promotion within this article due to the following statement - AF related stroke risk can be reduced by up to two thirds with the use of anticoagulants, yet these continue to be under-prescribed in the UK with around a quarter of eligible patients with AF not receiving NICE-recommended anticoagulant drugs. Daiichi Sankyo had a product called lixiana for AF and there was indirect promotional reference to this in the statement (AF + anticoagulant). Lixiana was also recommended as a potential option by NICE'.

Daiichi Sankyo UK's response:

Daiichi Sankyo UK strongly refuted any suggestion of disguised promotion through the publication of this article, and by association, breaches of Clauses 12.1, 9.1 and 2 of the 2019 Code.

The article was published to coincide with World Stroke Day, an annual event in which disease awareness activities occurred to raise awareness of the burden of stroke on health systems and patients. The article was commissioned to present the views of Daiichi Sankyo and one of its senior employees on the topic of stroke. It covered a wide range of issues pertaining to national policy ambitions to improve stroke prevention through improvements in the detection, management and treatment of the stroke risk factors.

HSJ was a well-known publication aimed towards health system managers, leaders and policy makers which determined, and had an interest in, the way in which the health service operated, including delivery of its health policy priorities. It was therefore a suitable audience for the theme and content of the article.

Daiichi Sankyo submitted that at no point did the article refer to a Daiichi Sankyo medicine or a medicinal class which featured a Daiichi-Sankyo medicine. 'NICE-recommended anticoagulant drugs' covered a broad range of medicines and medicinal categories, including vitamin K antagonists, Direct Oral Anticoagulants (DOACs) and Low Molecular Weight Heparins (LMW). Daiichi Sankyo did market a NICE-recommended medicine in the DOAC category. However, the article did not state this, or reference DOACs at all. Neither did it provide any link to material or resources in which this fact could be discovered, or by association, result in the promotion or uptake of this medicinal class.

At the time of publication, increasing access to anticoagulant medicines, as well as reducing unwarranted variation of care, to help meet national stroke prevention ambitions was a well-recognised policy objective and Daiichi Sankyo UK did not accept that general reference to such ambitions to improve patient care constituted disguised promotional activity.

Daiichi Sankyo noted that the Code stated that 'the term promotion does not apply to information relating to human health or diseases provided there is no reference, either direct or indirect, to specific medicines'. Daiichi Sankyo submitted that this was the case with this article which was intended to raise awareness of the burden of stroke on health systems and patients.

Daiichi Sankyo UK did not believe that such a statement, considered in the context and intent of the article, could be construed as disguised promotion, and refuted the allegation of breaches of Clauses 12.1, 9.1 and 2 of the 2019 Code.

Complainant allegation 3:

'There was no prescribing information provided for Lixiana'.

Daiichi Sankyo UK's response:

In line with response to allegation 2, Daiichi Sankyo UK refuted the allegation that this was material which was promotional and thus required the inclusion of prescribing information. As this was certified as non-promotional material, intended for a non-promotional audience, which did not name a Daiichi Sankyo medicine, its medicinal class, or include a promotional claim, no prescribing information was therefore required and would have been wholly inappropriate to include. Thus, Daiichi Sankyo UK denied a breach of Clause 4.1.

Complainant allegation 4:

'The article had not been certified'.

Daiichi Sankyo UK's response:

This was a factually inaccurate allegation. The article had been certified by a qualified medical signatory. Daiichi Sankyo provided the certificate approving 'WSD HSJ article on AF management DSC/19/0024'. Daiichi Sankyo UK denied a breach of Clause 14.1 of the 2019 Code.

Daiichi Sankyo UK recognised that it was best practice to ensure that all materials had clearly identifiable job codes and dates of preparation displayed. Whilst it was not a requirement in the 2019 Code for job codes to be displayed, Daiichi Sankyo UK, as a matter of internal policy, now mandated that all materials, including articles published and circulated on third-party platforms, prominently and clearly included such metadata to ensure best practice.

In relation to the allegation about compliance and the alleged 'raft of cases on a regular basis', the issue of complaints received by the PMCPA was a wider issue for the pharmaceutical industry and not specific to Daiichi Sankyo UK. That said, Daiichi Sankyo UK took compliance very seriously and strove to maintain high standards at all times, and consequently denied a breach of Clause 9.1 in relation to this allegation.

Conclusion

Daiichi Sankyo submitted that it trusted that the PMCPA would see that, based on the evidence provided above, it had acted in line with the requirements of the ABPI Code of Practice, maintained high standards, and had not brought discredit upon, or reduced confidence in, the industry.

PANEL RULING

The Panel noted that the material at issue was an article hosted on The Health Service Journal (HSJ) online which had been published on World Stroke Day, 29 October 2019, and was titled 'Addressing variations in the diagnosis and treatment of atrial fibrillation is key to the NHS achieving its stroke care target'.

The Panel noted that above the article title in smaller font it stated HSJ Partners. Below the article title, there was a picture of the author, with their name and the date of the publication followed by a banner which stated 'HSJ partners SPONSORED – This is paid-for content from our commercial partners. Find out more', which was hyperlinked. The left-hand side of the third paragraph of the article contained an image which stated 'Sponsored by Daiichi Sankyo' and included the company logo. The authors' name appeared again at the end of the article, before the references, this time the authors job title and company were included; this was repeated again after the references. In the Panel's view, it would not have been clear to readers until the end of the article, that it had been written by a senior Daiichi Sankyo employee and was therefore Daiichi-Sankyo material.

The Panel noted that Clause 9.10 of the 2019 Code 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 must clearly indicate that it had been sponsored by that company. The supplementary information to that clause stated that the declaration of sponsorship must be sufficiently prominent to ensure that readers of sponsored material were aware of it at the outset. The wording of the declaration must be unambiguous so that readers will immediately understand the extent of the company's involvement and influence over the material. The supplementary information stated that this was particularly important when companies were involved in the production of material which was circulated by an otherwise wholly independent party.

The Panel disagreed with Daiichi Sankyo's submission that the term 'sponsored by' was sufficient in making clear that Daiichi Sankyo was responsible for the content of the article.

In the Panel's view, the fact the author was a senior employee of Daiichi-Sankyo should have appeared at the top of the article so that readers were aware of the extent of the company's involvement from the outset. The Daiichi Sankyo logo was insufficient in this regard.

The Panel noted its comments above and considered that the requirements of Clause 9.10 had not been met and **a breach of Clause 9.10 of the 2019 Code** was ruled. Daiichi Sankyo had failed to maintain high standards in this regard and **a breach of Clause 9.1 of the 2019 Code** was ruled.

The Panel noted Daiichi Sankyo's submission that the article was published to coincide with World Stroke Day and was commissioned to present the views of Daiichi Sankyo and one of its senior employees on the topic of stroke covering a wide range of issues pertaining to national policy ambitions to improve stroke prevention through improvements in the detection, management and treatment of the stroke risk factors. The Panel further noted Daiichi Sankyo's submission that at no point did the article refer to a Daiichi Sankyo medicine or a medicinal class which featured a Daiichi Sankyo medicine and 'NICE-recommended anticoagulant drugs' covered a broad range of medicines and medicinal categories, including vitamin K antagonists, Direct Oral Anticoagulants (DOACs) and Low Molecular Weight Heparins (LMW). Daiichi Sankyo did market a NICE-recommended medicine in the DOAC category but the article did not

state this, or reference DOACs at all. Neither did it provide any link to material or resources in which this fact could be discovered.

The Panel noted that although Daiichi Sankyo marketed a direct-acting oral anticoagulant, so did a number of other companies and the article referred to anticoagulants without mentioning a specific class. The Panel noted that the complainant bore the burden of proof and did not consider that the complainant had established that the article promoted a specific Daiichi Sankyo medicine and therefore that prescribing information for any specific medicine was required as alleged. The Panel therefore ruled **no breach of Clause 4.1** and consequently ruled **no breach of Clauses 9.1 and 2 of the 2019 Code**.

Clause 14.1 related to the certification of promotional material. The Panel noted its comments and rulings with regard to the article. The Panel further noted Daiichi Sankyo's submission that the article had been certified by a qualified medical signatory as non-promotional material. The Panel noted its comments above and therefore ruled **no breach of Clause 14.1** and consequently ruled **no breach of Clauses 9.1 and 2 of the 2019 Code**.

Noting its comments and rulings above, the Panel considered that the article did not constitute disguised promotion as alleged and **no breach of Clause 12.1** and consequently ruled **no breach of Clauses 9.1 and 2 of the 2019 Code**.

The Panel noted that the complainant bore the burden of proof and did not consider that he/she had established that Daiichi Sankyo's compliance understanding, framework and application were severely poor as seen by the raft of breaches on a regular basis, that the compliance knowledge had serious gaps or that the compliance responsibilities and accountabilities were not improving as alleged. The Panel therefore ruled **no breach of Clause 9.1 of the 2019 Code** in this regard.

Complaint received 27 June 2022

Case completed 2 June 2023