

**CASE AUTH/3626/3/22**

**COMPLAINANT v NOVARTIS**

**Promotion of Leqvio (inclisiran)**

**CASE SUMMARY**

This case was in relation to four articles that made up an online supplement titled '2021, Volume 28, Supplement 2: Inclisiran ▼ – its clinical position in lipid management' that was initiated and funded by Novartis which included the options to email and print it.

The Panel considered that the supplement constituted Leqvio promotional material for which Novartis would be responsible and ruled a breach of the following Clause of the 2021 Code as each of the four articles could be accessed without viewing the landing page which contained the black triangle and therefore should have included a black triangle as required by the Code and did not:

<b>Breach of Clause 5.1</b>	<b>Requirement to maintain high standards</b>
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The Panel ruled no breach of the following Clauses of the 2021 Code in relation to the online supplement because it did not consider that the complainant had established that a non-promotional Novartis employee authoring a promotional article was inappropriate and had not provided evidence that any of the four articles had been shared as alleged. The complainant had raised the Clause which related to the inclusion of a black triangle in abbreviated advertisements and was thus not relevant to the articles within the supplement at issue. Each of the four articles had been certified by a medical signatory as part of the supplement under one job code and the possibility of the articles being emailed was included within the job bag when the supplement was certified and the Panel therefore considered that, in the circumstances, there was no evidence that the certification requirements in relation to emails had not been met. The Panel considered that whilst it was unacceptable to omit the black triangle within each of the articles in question, it could, nonetheless, be viewed on the supplement landing page and on the prescribing information when accessed from the link within each of the four articles in question and, in the Panel's view, the ruling of a breach of Clause 5.1 adequately covered this matter and an additional ruling of a breach of Clause 2 would be disproportionate in the particular circumstances of this case:

<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 5.1</b>	<b>Requirement to maintain high standards</b>
<b>No Breach of Clause 8.1</b>	<b>Requirement to certify promotional material</b>
<b>No Breach of Clause 13.7</b>	<b>Requirement to show an inverted black equilateral triangle when required by the licensing authority on abbreviated advertisements</b>

<b>No Breach of Clause 15.5</b>	<b>Requirement to obtain permission from the recipient of promotional digital communications</b>
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The Panel ruled a breach of the following Clauses of the 2021 Code in relation to the printed articles as it appeared from Novartis' response that the printed articles would not have included prescribing information as required by the Code:

<b>Breach of Clause 5.1</b>	<b>Failing to maintain high standards</b>
<b>Breach of Clause 12.1</b>	<b>Failing to include up-to-date prescribing information</b>

The Panel ruled no breach of the following Clauses of the 2021 Code in relation to the printed articles as there was no evidence that the certification requirements in relation to the printed articles had not been met and whilst the printed articles would not have included prescribing information, it was, nonetheless, available via a single-click link on every page of the online supplement and was therefore accessible to individuals printing the webpage:

<b>No Breach of Clause 8.1</b>	<b>Requirement to certify promotional material</b>
<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>

**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 provided links to what he/she described as four promotional articles for Leqvio (inclisiran) funded and commissioned by Novartis.

### **COMPLAINT**

The complainant provided links to what he/she described as four promotional articles funded and commissioned by Novartis.

The complainant stated that he/she had been sent a promotional email from a colleague about Leqvio (inclisiran) which was a black triangle product. His/her colleague had been given the option to email it via a Novartis-initiated and -funded promotional webpage (Ref 133819, Date of preparation: September 2021). The complainant noted that, as could be seen by the link provided to the page, there was an option of emailing the promotional article. The complainant stated that he/she had not given permission for promotional emails nor did the email sent to him/her have an unsubscribe option. The complainant stated that Novartis had the responsibility for the option to email as it was a Novartis article with the email option directly beside the article on the webpage which should have been known to Novartis at the point of review and approval. The complainant alleged that as he/she had received a promotional email without permission, it was a breach of Clauses 15.5, 5.1 and 2. The complainant was concerned that the promotional email had not been certified by Novartis and alleged breaches of Clauses 8.1, 5.1 and 2. The complainant was very concerned that the article on the webpage

itself did not have a black triangle next to mention of Inclisiran and alleged breaches of Clauses 13.7, 5.1 and 2.

The complainant stated that there was an option to print the article which was concerning as the final form of the printed version had not been certified by Novartis and there was no prescribing information available on the printed format. The complainant alleged a breach of Clauses 8.1, 12.1, 5.1 and 2.

The complainant noted that one of the authors of the promotional piece was a Novartis employee in a non-promotional role and alleged that it was inappropriate for an individual in a non-promotional role to write a promotional article and this was in breach of Clauses 5.1 and 2. The named employee was not a medical signatory but a PhD background and hence it seemed as though he/she was not aware of compliance considerations considering the cocktail of compliance errors with this article, including basics such as no black triangle being present.

The complainant alleged that another article on the same website, again funded and written by Novartis, had the same issues (link provided). No black triangle had been mentioned next to the brand name. There was a link to prescribing information, so it was clearly a promotional article. The complainant alleged that the article on the website could not have been certified as the reference code and date of preparation was exactly the same as the previous article; he/she mentioned that this could not be possible as the final form of the two articles would mean different reference codes and date of preparation on each. This article had the option to email and print the article which had the same issues as mentioned for the previous article. The complainant alleged breaches of Clauses 8.1, 5.1, 13.7 and 2. In addition for being able to email the article that had not been certified and without prior permission, breaches of Clauses 8.1, 15.5, 5.1 and 2 were also alleged. For being able to print the article which had no prescribing information, breaches of Clauses 8.1, 12.1 and 2 were alleged.

The complainant stated that another two articles had the same issues as the previous two articles (links provided). The complainant requested the Panel apply the same breaches that he/she had mentioned in the previous two articles for these two articles (not being certified, no black triangle, no permission to email, no prescribing information on hard copy).

The complainant concluded that there were four promotional articles about inclisiran which had not been certified, had no black triangle and were able to be printed and emailed out without certification/permissions/lack of prescribing information on hard copy. The complainant stated that this was shocking and demonstrated how low the compliance knowledge was in the medical team at senior level. Breaches of Clause 2 on multiple occasions were alleged.

In response to a request from the case preparation manager for clarification, the complainant stated that in terms of the promotional email, it was sent to him/her by a colleague from the website page, as there was an option to email on the webpage. As a result, the complainant received the email. The complainant stated that this page should have been reviewed and certified by Novartis considering Novartis had a promotional article on it, so it was the company's responsibility for providing the email option on the webpage. The complainant stated that this was the same principle as a promotional email sent by a company where there was the option of forwarding within the email and the company would be responsible for providing the option to send the promotional content onto others. The complainant stated that

he/she deleted the email after submitting the complaint so did not have the copy he/she received from his/her colleague.

When writing to Novartis, the Authority asked it to consider the requirements of Clauses 2, 5.1, 8.1, 12.1, 13.7 and 15.5 of the Code.

## **RESPONSE**

Novartis stated that the complaint caused it concern and the company had taken it seriously; it was committed to operating in accordance with the required standards and meeting the relevant requirements and expectations.

The relevant background to the supplement was that Novartis was approached by a publisher to fund the production of a supplement to be published online on its existing platform in The British Journal of Cardiology ('BJC'). The BJC was a specialist journal predominately subscribed to by healthcare providers with an interest in cardiometabolic disease. The publisher had produced pharma industry-supported supplements (both in print and online) for many years in a similar manner. The supplement at issue was published on 9 September 2021 and was removed from the website on 19 April 2022 whilst the complaint was being investigated.

Novartis submitted that the publisher proposed the objectives of each article within the supplement, which were then finalised in collaboration with Novartis. The publisher was responsible for appointing and liaising with faculty authors, although Novartis was able to suggest authors for consideration. The four papers in the supplement were prepared by the faculty authors. Two members of the faculty were Novartis employees with expert knowledge of an implementation research study that was the topic of one of the articles. Novartis reviewed the content of the supplement for factual accuracy and compliance requirements and certified the content as it was deemed to be promotional. Novartis was not responsible for creating or approving the BJC platform on which the content was hosted, which was pre-existing property of the publisher. As with many other websites hosting online articles, or promotional emails, functionality was available for the reader to forward the content or print individual pages; this functionality was standard practice.

The printing or emailing of content by individuals unassociated with a pharmaceutical company and not working on their behalf, was not included within the definition of promotion in Clause 1.17 of the Code. Novartis submitted that this was supported by digital communications guidance provided on the PMCPA website which advised that statements such as 'Forward to a colleague' would indicate a company's direction and make them responsible under the Code for forwarded content. In addition, where an independent health professional had taken a decision to forward published content, the outcomes of such a decision was beyond Novartis' responsibility.

Due to the similarity of complaints across the four items, the allegations had been summarized by clause and Novartis' responses are given below.

### **1 Clauses 2 and 5.1**

**One article in the supplement was authored by a Novartis employee in a non-promotional role. It was inappropriate for such an employee to write a promotional article.**

Novartis submitted that there was no prohibition within the Code against the authorship of promotional materials by associates in non-promotional roles. The individual at Novartis running the implementation research study was the appropriate subject matter expert to author an article about this research. As an author, the individual was not responsible for the compliance review of the article.

Novartis submitted that the complainant's suggestion, that the individual's PhD qualification (as opposed to a medical qualification) might, in some way, make him/her insufficiently aware of the relevant compliance considerations, demonstrated a fundamental misunderstanding of the requirements of the Code.

Novartis stated that, as all other allegations of breaches of Clauses 2 and 5.1 also alleged breaches of other clauses, these were addressed below.

## **2 Clauses 8.1, 12.1 and 15.5**

**Four articles in the online supplement had not been certified in their final forms (Clause 8.1).**

Novartis submitted that the content of the digital supplement was certified by a medical signatory, in accordance with this clause and its supplementary information on certifying dynamic content. Screenshots were included as attachments to the job bag showing the context within which the content would appear.

**The complainant received a promotional email despite not having provided permission (Clause 15.5). The email had not been certified by Novartis (Clause 8.1) and did not have an unsubscribe link (Clause 15.5).**

Novartis submitted that the email was sent without direction from Novartis hence there had been no breaches of these clauses. Furthermore, as the email in question had not been provided, Novartis' position was that the complainant had not proved their complaint and no ruling could be made on these clauses.

**The option to print the four online articles was provided, however, the printed forms had not been certified (Clause 8.1) and did not contain prescribing information (Clause 12.1).**

Novartis submitted that prescribing information was available via a single-click link on every page of the online supplement and was therefore accessible to individuals printing the webpage. Novartis did not direct the pages to be printed, therefore neither certification nor prescribing information were required on the resulting printed documents.

## **3 Clause 13.7**

**Four articles in the online supplement did not have a black triangle next to the mention of inclisiran.**

Novartis submitted that when originally approved, it was thought that readers would need to browse to the landing page of the supplement, which included the black triangle, prior to reaching any of the individual articles; thus, the mentions of inclisiran on these pages were not considered the first or most prominent mention of the product necessitating a black triangle. As

a result of this complaint, it had become apparent that, while unlikely to happen in practice, the individual articles were reachable without first browsing to the landing page. Clause 13.7 related specifically to the requirement for a black triangle on abbreviated advertisements and was not relevant to an online supplement. Novartis, therefore, believed there had been no breach of this clause. However, Novartis appreciated the concern regarding the lack of a black triangle in each article and took this matter very seriously. Novartis' due diligence regarding black triangles and patient safety were of utmost importance to the company and Novartis agreed that, in the event of a reader not using the proposed front page of the supplement, a black triangle on each of the individual articles would be appropriate. As previously described, the supplement had since been removed from the website, black triangles would be added if it was to be republished online.

With regard to the queries raised by the case preparation manager, Novartis submitted:

- 1 A colour copy of the online supplement at issue.**
- 2 The approval certificate** and stated that the content of the supplement was certified, and the job bag included a gallery item showing how the content would be rendered within the British Journal of Cardiology website as final form. Qualifications of the signatory were given.
- 3 Leqvio (Inclisiran) SPC (summary product characteristics).**
- 4 Explanation of Novartis' role in relation to each article.**
- 5 Checks on who the articles could be emailed to:** The supplement was published in a relevant, independently produced, electronic journal intended for health professionals and each page was clearly labelled as intended for health professionals as required by the Code. Content emailed without Novartis' direction was not included within the definition of promotion and therefore did not require certification nor prescribing information. In addition, where an independent health professional had taken a decision to forward published content, such a decision was beyond Novartis' responsibility. The intended audience of the supplement was clear to any individual intentionally, or inadvertently, browsing to the site and Novartis' view was that further checks beyond the above were not warranted in the circumstances.

In light of the above, Novartis' opinion was that Novartis had not breached Clauses 2, 5.1, 8.1, 12.1, 13.7 and 15.5 of the Code.

In response to a request for further information, Novartis provided a copy of the Leqvio (inclisiran) prescribing information which was available via a single click link on every page of the online supplement in question.

## **PANEL RULING**

The Panel noted that the four articles in question appeared to be part of an online supplement titled '2021, Volume 28, Supplement 2: Inclisiran ▼ – its clinical position in lipid management' (ref 133819, Date of preparation: September 2021). The sponsorship statement at the beginning of the supplement and each article stated 'This sponsored supplement was initiated and funded by Novartis Pharmaceuticals UK Ltd. Editorial control was retained by the authors and editors, however, Novartis reviewed the supplement for technical accuracy and compliance with relevant regulatory requirements. Leqvio® (inclisiran) prescribing information is available on the Novartis website'.

The Panel noted Novartis' submission with regard to its involvement in the production of the supplement which was published on the publisher's existing online platform, including that the objectives of each article were finalised by the publisher in collaboration with Novartis, Novartis was able to suggest authors for consideration by the publisher which was responsible for appointing and liaising with faculty authors, two members of the faculty were Novartis employees, one of which was an author of one of the articles. The Panel noted that the supplement including the four articles in question was certified by Novartis under one job code (ref 133819) on 7 September 2021 as the content was deemed by it to be promotional. Noting the above, the Panel considered that the supplement constituted Leqvio promotional material for which Novartis would be responsible.

The Panel did not consider that it was necessarily unacceptable for an individual in a non-promotional role to write a promotional article as alleged. The Panel noted Novartis' submission that the individual was the appropriate subject matter expert to author an article about the research he/she was running. The Panel did not consider that the complainant had established that the non-promotional Novartis employee authoring a promotional article was inappropriate as alleged and **no breach of Clauses 5.1 and 2** were ruled.

The Panel noted the complainant's allegation that the second article 'New opportunity for cholesterol lowering: inclisran' could not have been certified as the reference code and date of preparation was exactly the same as the previous article 'Inclisran: testing a population health management methodology to implement a novel lipid treatment'. The Panel noted that each of the four articles had been certified by a medical signatory as part of the supplement under one job code and the Panel therefore ruled **no breach of Clause 8.1**.

The Panel noted that on the side of each of the four articles hosted on the British Journal of Cardiology website, there was the option to share them via email. Whilst the Panel noted that Novartis might not be responsible for creating or approving the publisher's platform on which the content was hosted, in its view, Novartis was responsible for the context in which Novartis promotional material, such as the supplement including the four articles in question, appeared. The Panel noted Novartis' submission that the job bag included a gallery item showing how the content would be rendered within the BJC website as final form.

The Panel noted that the archived PMCPA digital guidance dated March 2016, provided by Novartis, stated 'Promotional emails should not include the statement "Forward to a colleague" or similar. The Authority is concerned that suggesting to recipients the possibility of forwarding the email to a colleague would not comply with the need to ensure prior permission from the onward recipient before the promotional email is resent. In forwarding the email original recipients would be acting at the company's direction in that regard and so the company would be responsible under the Code for their action'. In the Panel's view, the option to email the promotional articles in question would similarly encourage recipients to forward the article to a colleague which would have been known to Novartis when certifying the supplement.

The supplementary information to Clause 15.5 states that 'where permission to use emails for promotional purposes has been given by a recipient, each email sent should inform the recipient how to unsubscribe'.

The Panel, noting its comments above, considered that the emailing of the promotional articles would constitute the promotion of Novartis' medicine for which Novartis would be responsible.

The Panel, however, noted that the complainant bore the burden of proof and had not provided evidence that any of the four articles had been shared as alleged and thus the Panel ruled **no breach of Clauses 15.5, 5.1 and 2** in this regard in relation to each of the four articles.

The Panel noted its comment above that the complainant had not provided evidence that any of the four articles had been shared via email as alleged. Nonetheless, the Panel noted that the possibility of the articles being emailed was included within the job bag when the supplement was certified. The Panel therefore considered that, in the circumstances, there was no evidence that the certification requirements in relation to emails had not been met and **no breach of Clauses 8.1, 5.1 and 2** were ruled in this regard.

The Panel similarly noted that the option to print the articles was included within the job bag when the supplement was certified. There was no evidence that the certification requirements in relation to the printed articles had not been met and **no breach of Clause 8.1** was ruled. The Panel noted that whilst, according to Novartis, prescribing information was available via a single-click link on every page of the online supplement and was therefore accessible to individuals printing the webpage, the articles could be downloaded and therefore, as standalone items, needed to comply with the requirements of the Code. It appeared from Novartis' response that the printed articles would not have included prescribing information as required by the Code and **a breach of Clause 12.1** was ruled in relation to each as alleged. The Panel considered that high standards had not been maintained in this regard and **a breach of Clause 5.1** was ruled. The Panel noted that the prescribing information was, nonetheless, available via a single-click link on every page of the online supplement and was therefore accessible to individuals printing the webpage and **no breach of Clause 2** was ruled.

The Panel noted Novartis' submission that when the supplement was originally approved, it was thought that readers would need to browse the landing page of the supplement, which included the black triangle, prior to reaching any of the individual articles; thus, the mentions of inclisiran on these pages were not considered the first or most prominent mention of the product necessitating a black triangle. As a result of this complaint, it has become apparent that, while unlikely to happen in practice, the individual articles were reachable without first browsing to the landing page. Novartis agreed that, in the event of a reader not using the proposed front page of the supplement, a black triangle on each of the individual articles would be appropriate. The Panel noted that the complainant had raised Clause 13.7 which related to the inclusion of a black triangle in abbreviated advertisements and was thus not relevant to the articles within the supplement at issue. The Panel therefore ruled **no breach of Clause 13.7**. The relevant Clause was Clause 12.10 which had not been raised and the Panel therefore considered the matter under Clause 5.1. The Panel noted that each of the four articles could be accessed without viewing the landing page which contained the black triangle and therefore should have included a black triangle as required by Clause 12.10 and did not. The Panel therefore ruled a **breach of Clause 5.1** in relation to each of the four articles. The Panel noted its rulings above and although it considered that it was unacceptable to omit the black triangle within each of the articles in question, it could, nonetheless, be viewed on the supplement landing page and on the prescribing information when accessed from the link within each of the four articles in question. The Panel noted Novartis' submission that the supplement had since been removed from the website, black triangles would be added if it was to be republished online. The Panel considered that the ruling of a breach of Clause 5.1 adequately covered this matter and an additional ruling of a breach of Clause 2 would be disproportionate in the particular circumstances of this case. A ruling of a breach of Clause 2 was used as a sign of particular censure and reserved for such use and the Panel, on balance, ruled **no breach of Clause 2**.



**Complaint received**      **31 March 2022**

**Case completed**        **29 March 2023**