CASE AUTH/3670/6/22

HEALTH PROFESSIONAL v NOVARTIS

Webinar registration page for Leqvio (inclisiran)

CASE SUMMARY

This case was in relation to the registration webpage for a webinar entitled 'Introducing an innovative approach to lipid management with inclisiran'.

The Panel ruled a breach of the following Clauses of the 2021 Code in relation to the adverse event reporting statement because its position and font size on the webpage itself was such that it was not sufficiently prominent:

Breach of Clause 5.1	**Failing to maintain high standards**
Breach of Clause 12.9	**Failing to include a prominent adverse event reporting statement**

The Panel ruled no breach of the following Clause of the 2021 in relation to the adverse event reporting statement as it considered that the rulings of breaches of Clauses 12.9 and 5.1 adequately covered this matter:

No Breach of Clause 2	**Requirement that activities or material must not bring discredit upon, or reduce confidence in, the pharmaceutical industry**

The Panel ruled no breach of the following Clauses of the 2021 Code on the basis that the complainant had not established that:

- **the title of the meeting misleadingly implied Leqvio was licensed for use for all types of lipid management and in children or was incapable of substantiation, and**
- **use of the word 'innovative' was a superlative or implied a special merit that could not be substantiated.**

No Breach of Clause 2	**Requirement that activities or material must not bring discredit upon, or reduce confidence in, the pharmaceutical industry**
No Breach of Clause 5.1	**Requirement to maintain high standards**
No Breach of Clause 6.1	**Requirement that claims must not be misleading**
No Breach of Clause 6.2	**Requirement that information must be capable of substantiation**
No Breach of Clause 11.2	**Requirement not to promote a medicine for an unlicensed indication**
No Breach of Clause 14.4	**Requirement that claims should not imply that a medicine or an active ingredient has some special merit, quality or property unless this can be substantiated.**

The Panel ruled no breach of the following Clauses of the 2021 Code in relation to the statement that allegedly solicited medical information questions on the basis that the complainant had not established that the inclusion of an invitation to contact Novartis for more information about inclisiran had resulted in responses that were not treated as promotional:

No Breach of Clause 2	**Requirement that activities or material must not bring discredit upon, or reduce confidence in, the pharmaceutical industry**
No Breach of Clause 5.1	**Requirement to maintain high standards**

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 themselves as a health professional complained about the Leqvio webinar hosting page (MAY 2021 I UK 121161).

COMPLAINT

The complainant alleged that the Leqvio (a black triangle product) webinar hosting page was inappropriate as the actual licensed indication for Leqvio was far narrower than claimed on the registration website. The title of the webinar was 'Introducing an innovative approach to lipid management with inclisiran'. The indication for inclisiran was:

> 'Leqvio is indicated in adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet:
>
> - in combination with a statin or statin with other lipid-lowering therapies in patients unable to reach LDL-C goals with the maximum tolerated dose of a statin, or
> - alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated.'

The complainant alleged that saying 'lipid management' and 'innovative' was misleading and gave the wrong impression that Leqvio could be used for all kinds of lipid management but Leqvio could only be used for primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia and also not in children. This important information was not presented on the webpage. The complainant alleged breaches of Clauses 6.1, 6.2, 5.1 and 2.

The complainant further alleged that the word innovative was a superlative and was a breach of Clause 14.4.

At the end of the webpage, the following text was given: 'If you have a question about the product, please contact Medical Information on [number provided] or by email at [email address provided]. Soliciting medical information questions was not maintaining high standards as they

should always be unsolicited'. The complainant stated this was a glaring error and breached Clauses 5.1 and 2.

Adverse event reporting was allegedly not prominent on this website which was crucial as Leqvio was a black triangle product. The complainant alleged breaches of Clauses 12.9, 5.1 and 2.

When writing to Novartis, the Authority asked it to consider the requirements of Clauses 2, 5.1, 6.1, 6.2, 12.9 and 14.4 of the 2021 Code as cited by the complainant and, in addition, the requirements of Clause 11.2.

RESPONSE

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

Novartis submitted Leqvio was a treatment used in lipid management and was indicated in people with primary hypercholesterolaemia. The page, which was the subject of the complaint, allowed health professionals to register and subsequently attend a promotional webinar providing medical education for health professionals.

The title of the webinar was 'Introducing an innovative approach to lipid management with inclisiran (Leqvio)'. This was then supplemented in the main substantive paragraph of the registration page which set out more information about the content. Namely, to educate the primary care clinical community of:

- Why lipid management was one of NHS England's priority areas.
- The challenges currently faced in managing lipids in primary care.
- How inclisiran (Leqvio) was set to be implemented via a national programme.
- Leqvio's key product data. The indication for use was clearly explained in the webinar.

The registration webpage was published on 3 June 2021 and the webinar ran on the 1 July 2021, according to Novartis.

Novartis submitted that the title of this meeting accurately reflected the content of the webinar, where approaches to lipid management were discussed, referencing multiple available medicines of varying indications. The focus was on tackling health inequalities using population health management approaches. Leqvio was discussed as an emerging therapy within the lipid management space. The title did not mention any lipid diseases or patient populations and it was unreasonable to suggest that the use of 'lipid management' or 'innovative' in the title promoted Leqvio's use for lipid diseases or patient populations other than those for which it was indicated.

Novartis submitted that contrary to the apparent view of the complainant, the inclusion of the full licensed indication on promotional material was not required by the Code. The title in question was not inconsistent with the marketing authorization, in addition, the Code required (as per Clause 12.4) a single click link to prescribing information, where the licensed indication could be found. This single click link was prominently displayed and fully accessible to health professionals.

The complainant's assertion that the use of the words 'innovative' and 'lipid management' in the title '*gave the wrong impression*' was objectively not supported by the evidence the complainant presented.

Novartis submitted that the word innovative was not a superlative, it was an adjective. The complainant had failed to provide any evidence that innovative was a superlative or that Novartis' use of this word in the context, in which it appeared, was inappropriate.

Novartis considered it reasonable to include contact details for its medical information department in health professional/other relevant decision maker-facing materials such as this. Novartis' view was that the inclusion of such contact details maintained and upheld high standards. Indeed, Clause 18.1 of the Code required a company promptly to provide health professionals and other relevant decision makers with accurate and relevant information about the medicines which the company marketed upon reasonable request. Soliciting queries about a company's medicines was not prohibited by the Code.

Novartis acknowledged that the adverse event reporting wording on this page was in a slightly smaller font than the title and description of the webinar. However, it had been displayed in an easy-to-read font, with black text on a white background. The inclusion of the black triangle in the main body of the registration page was clear and could reasonably be expected to alert health professionals to the requirement for additional monitoring. As this was digital material, the viewer could easily increase the size of the wording if there was a need to do so (for example, pinching to zoom on a phone or tablet screen). Novartis' view was that the adverse event reporting wording was sufficiently prominent in this material to comply with the requirements of the Code.

A colour copy of the webpage at issue was provided. Health professionals who were invited to attend the webinar would click on a link that would take them to this registration page where they could subsequently register and attend the webinar. In addition, the approval certificate and qualifications of the signatory were provided as well as the Leqvio (Inclisiran) summary product characteristics (SPC).

In light of the above, Novartis strongly refuted any breach of Clauses 6.1, 6.2, 11.2, 12.9, 14.4, 5.1 or 2 of the Code.

PANEL RULING

The Panel noted that the webpage at issue was a registration page for health professionals to register for a Novartis promotional webinar which took place in July 2021; the webpage was headed with a large Novartis logo followed by 'this meeting is intended for UK healthcare professionals only'.

Beneath this within an image was the Leqvio (inclisiran) brand logo followed by the title of the webinar 'INTRODUCING AN INNOVATIVE APPROACH **TO LIPID MANAGEMENT WITH INCLISIRAN (LEQVIO)**' which was followed by the title repeated, the date and time of the webinar and details of areas to be discussed during the webinar which included:

- why lipid management is one of NHS England's priority areas,
- the challenges currently faced in managing lipids in primary care,
- how inclisiran (Leqvio) is set to be implemented via a national programme,

- overview of Novartis' key product data.

The Panel noted Novartis' submission that health professionals who were invited to attend the webinar would click on a link that would take them to this registration page where they could subsequently register and attend the webinar.

The Panel noted Novartis' submission that different approaches to lipid management were discussed and multiple available medicines of varying indications were referenced. The Panel noted, however, that this was not clear from the details of what was to be discussed as provided on the registration webpage. The Panel further noted Novartis' submission that Leqvio, as an emerging therapy within the lipid management space and its key data including a clear explanation of the indication for use was also discussed. The Panel had no information before it with regard to the content of the webinar itself. The subject of the complaint was the registration webpage and it was on this basis that the Panel made its rulings.

With regard to the complainant's allegation that the licensed indication for Leqvio was narrower than shown on the webinar registration webpage, the Panel noted that the complainant referred to the title of webinar in this regard; the complainant alleged that use of the terms 'lipid management' and 'innovative' in conjunction with the name of the medicine created a misleading impression that Leqvio could be used for all kinds of lipid management which was not the case.

The Panel noted that the licensed indication for Leqvio, as stated in Section 4.1 of the SPC, was for adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet:

- in combination with a statin or statin with other lipid-lowering therapies in patients unable to reach LDL-C goals with the maximum tolerated dose of a statin, or
- alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated.

The Panel noted that Clause 11.2 required that promotion of a medicine must be in accordance with the terms of its marketing authorisation and must not be inconsistent with the SPC.

The Panel considered that whether the full licensed indication needed to be included in promotional material depended on a consideration of all the circumstances including the content, layout, audience and intended use of the material.

The Panel noted Novartis' submission that the webinar title did not mention any lipid diseases or patient populations. In the Panel's view, the title of the webinar 'Introducing an innovative approach to lipid management with inclisiran (Leqvio)' referred to Leqvio as one pharmacological approach to the management of lipids.

Whilst the Panel considered that Leqvio was a black triangle product and health professionals might be less familiar with the details of its licensed indication and it would have been helpful to have included it on the registration webpage at issue, the Panel considered it unlikely that health professionals would interpret the title of the meeting as the therapeutic indication for Leqvio. In the Panel's view, the complainant had not established that the title of the meeting misleadingly implied that Leqvio was licensed for use for all types of lipid management and in children as alleged. The Panel therefore ruled **no breach of Clauses 6.1 and 11.2**. The Panel did not

consider that the complainant had established that the title of the meeting was incapable of substantiation and the Panel ruled **no breach of Clause 6.2**. It followed that the Panel ruled **no breach of Clauses 5.1 and 2**.

Whilst the Panel considered that companies should be cautious when using terms such as 'innovative', the Panel did not consider this to be a superlative as alleged, nor did the Panel consider that the complainant had established that it implied a special merit that could not be substantiated. Based on the very narrow allegation, the Panel ruled **no breach of Clause 14.4**.

The Panel noted the complainant's allegation that the inclusion of the following text: 'If you have a question about the product, please contact Medical Information on [number provided] or by email at [email address provided]' meant that Novartis had solicited medical information questions and therefore had failed to maintain high standards. The Panel noted that this text appeared in small font at the bottom of the webpage following the adverse event reporting statement.

The Panel noted that Clause 1.17 of the Code stated, *inter alia*, that replies made in response to individual enquiries from members of the health professions or other relevant decision makers were exempt from the definition of promotion only if they related solely to the subject matter of the enquiry, were accurate and did not mislead and were not promotional in nature. The supplementary information to this clause stated that the exemption related to unsolicited enquiries only, which were those without any prompting from the company. The supplementary information further stated that a solicited enquiry would be one where a company invited a person to make a request, for example, material offering further information to readers would be soliciting a request for that information.

The Panel noted that whilst providing general contact details on a website was good practice, it considered that by inviting readers to contact the company for more information about 'the product', which would be considered to be inclisiran, on a promotional webpage, Novartis might have solicited requests about inclisiran and therefore the responses given by the company, in this regard, would not be exempt from the definition of promotion. However, the Panel had no information before it as to what, if any, questions were received via the registration webpage and whether such responses were treated as promotional or not. The Panel noted that the complainant bore the burden of proof and did not consider that he/she had established that Novartis had breached the Code as alleged. The Panel therefore ruled **no breach of Clauses 5.1 and 2**.

The Panel noted that Clause 12.9 required that all promotional material must include the **prominent** statement 'Adverse events should be reported. Reporting forms and information can be found at [website address which links directly to the MHRA Yellow Card site]. Adverse events should also be reported to [relevant pharmaceutical company]'.

The Panel noted that below the paragraph regarding what was to be discussed, and prior to the list of speakers it stated in the same size font 'Prescribing information and adverse event reporting information can be found here' which included a link to both the Great Britain and Northern Ireland prescribing information containing the relevant adverse event reporting statement. Regardless of its inclusion in the prescribing information, Clause 12.9 required that the statement was included as part of the material itself. In this regard, the Panel noted that the adverse event reporting statement appeared at the bottom of the webpage in a smaller font size than the text in the main body of the webpage.

In the Panel's view, the position and font size of the statement on the webpage itself was such that it was not sufficiently prominent and **a breach of Clause 12.9** was ruled. Noting that Leqvio was a black triangle medicine, subject to additional monitoring, 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 its comments and rulings above and although it considered the importance of prominently displaying the adverse event reporting statement, it considered that the rulings of breaches of Clauses 12.9 and 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 **30 June 2022**

Case completed **14 July 2023**