CASE AUTH/3414/11/20

COMPLAINANT v NOVARTIS

Alleged promotion of pipeline products on company website

An anonymous, contactable complainant complained about the promotion of three pipeline products (QGE031, QMF149 and QVM149) on a Novartis Pharmaceuticals UK Ltd webpage.

The complainant noted the table of pipeline products on the webpage and alleged that one of the three pipeline products promoted was QGE031 (ligelizumab) subcutaneous injection which was an anti-IgE monoclonal antibody with the potential indication of chronic spontaneous urticaria which was in Trial Phase II with a planned filing date of 2021. The complainant stated that there was clear mention of indication, generic names and mechanism of action. The complainant concluded that his/her complaint was similar to Cases AUTH/3037/4/18 and AUTH/3274/10/19 and that as there was no restriction to members of the public and health professionals, there were many breaches of the Code.

The detailed response from Novartis is given below.

In the Panel's view, it was not necessarily unacceptable for a company to refer in general terms to its pipeline products on its corporate website, however, language, context, location, layout, intended audience and overall impression were important factors when deciding whether such references were acceptable. Such references should not, otherwise, constitute promotion of an unlicensed medicine.

The Panel noted Novartis' submission that the webpage at issue was not directed at health professionals and was not located in a promotional section of the Novartis website; it was hosted on the Novartis corporate website which had a broader intended audience solely for information purposes and to demonstrate its commitment to research in respiratory care. The company submitted that the Novartis' corporate website was not intended to be promotional. Access to the page required a reader to click through three different links; the webpage could be found by going to the Novartis UK website homepage, and clicking on 'Our Work', then 'Disease Area', then 'Our work in Respiratory and Inflammation'.

The Panel further noted Novartis' submission that a reader could also potentially be led to the webpage by carrying out a web search. It was, however, unclear to the Panel what search terms would be required for this to occur.

The Panel noted that three products were listed within the table namely: QGE031 (ligeliizumab), QMF149 (indacaterol, mometasone furoate in fixed-dose combination), and QVM149 (indacaterol, mometasone furoate, glycopyrronium bromide in fixed-dose combination).

The downloaded page from the link provided by the complainant that included the table of data was introduced by:

> **'At Novartis, we are focused on improving the lives of the millions of people affected by respiratory and inflammation diseases and continue to research, develop and launch innovative therapies which treat chronic obstructive pulmonary disease, chronic spontaneous urticaria and severe allergic asthma. The table below outlines our current research within respiratory and inflammation diseases.'**

The common name (non-proprietary name), mechanism of action, potential indication/disease area, route of administration, trial phase and planning filing dates for all three products were stated within the table.

The Panel noted that below the table it stated 'Click on the conditions for more information about our work' followed by the heading 'Asthma' beneath which it provided asthma statistics within the UK and stated, *inter alia*, that 'At Novartis, as well as furthering scientific research, we work to ensure people in need receive the most effective medicine for their condition as promptly as possible'. This was followed by some of the work that the company carried out including training for health professionals in severe allergic asthma and working with hospitals to conduct reviews and audits of their data on asthma exacerbations.

The Panel considered that whilst the style of the table was low key and included scientific information about what were, at the time of its publication, three potential products, the entire webpage might be seen as implying or claiming that QMF149 and QVM149 listed in the table were potentially effective, innovative treatments for severe allergic asthma. Whilst the reference to both products being in Phase III research might imply that their respective trials had not been successful and thus the planned filing in 2019 had not taken place, it might equally give the impression, in November 2020 at the time of the complaint, that the products were available or were likely to be available shortly. The information was, however, at the time of the complaint in November 2020, inaccurate as acknowledged by Novartis as both products were licensed.

The Panel considered that the information in the table within the context of the webpage, including the opening paragraph and information below the table, promoted QMF149 and QVM149 which were, at the time of the complaint, prescription only medicines to the public and breaches of the Code were ruled.

The Panel noted that QGE031 was not classified as a prescription only medicine at the time of the complaint. The Panel considered that the information provided in relation to QGE031 within the context of the opening paragraph and the inclusion of information on two of the company's products, which were licensed at the time of the complaint, promoted an unlicensed medicine and a breach of the Code was ruled.

In addition to its comments above, the Panel noted that the webpage in question was neither directed to, nor limited to, an audience of health professionals and other relevant decision makers and thus was not advertising to that audience. The Panel, therefore, considered that the allegations relating to the promotion to health professionals were not relevant. The Panel ruled no breaches of the Code.

The Panel was very concerned to note that the webpage at issue, which had been issued in October 2016, had not been updated since then including when QMF149 and QVM149 received their marketing authorisations. The company had failed to maintain high standards in this regard and a breach of the Code was ruled as acknowledged by Novartis.

In the Panel's view, on balance, noting its comments above, the circumstances in this particular case did not warrant a ruling of a breach of Clause 2 which was a sign of particular censure and reserved for such. The Panel therefore ruled no breach of Clause 2.

An anonymous, contactable complainant complained about the promotion of three pipeline products (QGE031, QMF149 and QVM149) on a Novartis Pharmaceuticals UK Ltd webpage. The text on the webpage headed 'Our work in Respiratory and Inflammation' read:

> 'At Novartis, we are focused on improving the lives of the millions of people affected by respiratory and inflammation diseases and continue to research, develop and launch innovative therapies which treat chronic obstructive pulmonary disease, chronic spontaneous urticaria and severe allergic asthma. The table below outlines our current research within respiratory and inflammation diseases.'

COMPLAINT

The complainant noted the table of pipeline products and alleged that one of the three pipeline products promoted was QGE031 (ligelizumab) subcutaneous injection which was an anti-IgE monoclonal antibody with the potential indication of chronic spontaneous urticaria which was in Trial Phase II with a planned filing date of 2021. The complainant stated that there was clear mention of indication, generic names and mechanism of action. The complainant provided a screenshot of the webpage in question and concluded that his/her complaint was similar to Cases AUTH/3037/4/18 and AUTH/3274/10/19 and that there was no restriction to members of the public and health professionals meant that there were many breaches of the Code.

The complainant alleged breaches of Clauses 3.1, 4.1, 4.3, 9.1, 26.1, 26.2, 28.3 and 2.

RESPONSE

Novartis submitted that the webpage (released in October 2016) provided a brief and factual summation of the company's then current pipeline and was provided solely for information purposes and to demonstrate its commitment to research in that therapy area and, as such, it was treated as corporate advertising as stipulated under supplementary information under Clause 14.3 and examined in accordance with the Code. Novartis stated that, in its view, the brief summation information set out in the webpage was not a promotional activity (as defined in Clause 1 of the Code) but non-promotional in nature.

With regard to Clauses 3.1 and 2, Novartis reiterated that the webpage provided a brief summation of the company's then current pipeline. The information was factual and sufficiently succinct without any additional information pertaining to data on efficacy or safety of the products in development at the time. The facts were, therefore, different from those presented in Case AUTH/3037/4/18 referred to by the complainant.

Novartis submitted that the information provided described the company's commitment to the research of new treatments in respiratory care, and the webpage clearly explained that the information 'outlines our current research'. Further, only Novartis' logo was displayed on the webpage and the rest of the webpage was monotonal in nature which was consistent with the general corporate tone. Novartis did not consider that the information contained on the webpage would encourage a health professional to seek to use these products in development. At the time of release, the products described on the webpage were at Phase II and Phase III and not available as prescription-only medicines. As the webpage was not directed at health professionals and was not located in a promotional section of the Novartis website – the webpage was hosted on the Novartis corporate website which had a broader intended audience – the facts were, therefore, different to those presented in Case AUTH/3274/10/19. Novartis, therefore, did not consider that the information on the webpage constituted promotional activity and confirmed that there was no intention to promote any of the medicines prior to the grant of their marketing authorisations. Novartis thus denied any breach of Clauses 2 or 3.1.

With regard to Clauses 4.1 and 4.3, Novartis submitted that the webpage provided a brief and factual summation of the company's then current pipeline and was provided solely for information purposes to demonstrate its commitment to research in respiratory care. Therefore, the webpage was not promotional in nature, and Clauses 4.1 and 4.3 were not relevant.

With regard to Clause 9.1, Novartis stated that it reviewed its activities and materials to ensure compliance with the Code and believed that, prior to the release of the webpage, it had maintained the necessary high standards in accordance with Clause 9.1. However, as part of the Novartis' investigation into the complaint, it accepted that the information on the webpage was not up-to-date and it had subsequently removed the webpage from the site. With respect to this, Novartis accepted that it failed to maintain high standards in accordance with Clause 9.1 of the Code.

Novartis noted that when the webpage was released it clearly stated that the products mentioned were currently in either Phase II or Phase III of clinical trials, and therefore were not yet licensed. As a result, and technically, the medicines could not be classified as prescription-only medicines, but in any event, the information that was presented was non-promotional in nature, factual and succinct. Additionally, as Novartis did not deem the content on the webpage to be promotional in nature, and bearing in mind that the factual summary was for information purposes to the public, the company did not deem it necessary to limit the content only to health professionals and other relevant decision makers.

Novartis submitted that at the time of this response (17 November 2020):

i) QGE031 remained unlicensed and therefore technically it could not be classified as a prescription-only medicine; and

ii) QMF149 (Atectura Breezhaler (indacaterol plus mometasone)) and QVM149 (Enerzair Breezhaler (indacaterol plus glycopyrronium plus mometasone) were now licensed. Despite the licensing of these products and considering the summary format of the information and indication on the webpage that the products were in trial phase, the webpage did not advertise or promote the medicines to the public nor did it encourage any member of the public to ask their health professional to prescribe nor raise hopes of the public of a successful treatment. The information was factual and balanced, with minimum detail and did not contain any detail regarding either the

efficacy or safety of the products in question and was always regarded as corporate advertising. Novartis therefore did not believe that the information would raise unfounded hopes of successful treatment or mislead with respect to the safety of the product.

Therefore, based on the above, Novartis submitted that there was no breach of Clauses 26.1, 26.2 or 28.3.

Novartis submitted that the materials on the webpage were published on 10 October 2016. The materials were directed at the public and, as such, this was corporate advertising as stipulated under the supplementary information to Clause 14.3 and examined in accordance with the Code. Novartis provided a copy of the certificate of examination and details of its signatories to the material. The company also provided copies of the summaries of product characteristics (SPC) for Atectura Breezhaler and Enerzair Breezhaler. As QGE031 was not yet licensed, no SPC was available.

Novartis explained that the webpage could be found by going to the http://www.novartis.co.uk homepage, and clicking on 'Our Work', then 'Disease Area', then 'Our work in Respiratory and Inflammation', therefore, the reader would be required to go through the UK Novartis corporate website to reach the information. The webpage was not accessible from the homepage. The 'Click on the conditions for more information about our work' expanded the section for that condition and provided more information on the condition (copy provided). There were no separate hyperlinks.

Novartis noted that the webpage was also automatically marked as being included in the Search Index (so this was something that Novartis would not manually turn on), so potentially, a reader could be led to the webpage by carrying out a web search.

Novartis noted its comments above and denied breaches of Clauses 2, 3.1, 4.1, 4.3, 26.1, 26.2 and 28.3 of the Code, but acknowledged a breach of Clause 9.1.

PANEL RULING

In the Panel's view, it was not necessarily unacceptable for a company to refer, in general terms, to its pipeline products on its corporate website, however, language, context, location, layout, intended audience and overall impression were important factors when deciding whether such references were acceptable. Such references should not otherwise constitute promotion of an unlicensed medicine. The supplementary information to Clause 13.1 of the Code stated that companies must include on the homepage of their website details of where their clinical trials could be found.

The Panel noted Novartis' submission that the webpage at issue was not directed at health professionals and was not located in a promotional section of the Novartis website; it was hosted on the Novartis corporate website which had a broader intended audience solely for information purposes and to demonstrate its commitment to research in respiratory care.

The webpage was located within a section of Novartis' corporate website which the company submitted was not intended to be promotional. Access to the page required a reader to click through three different links; the webpage could be found by going to the Novartis UK website

homepage, and clicking on ‘Our Work’, then ‘Disease Area’, then ‘Our work in Respiratory and Inflammation’.

The Panel further noted Novartis’ submission that a reader could also potentially be led to the webpage by carrying out a web search. It was, however, unclear to the Panel what search terms would be required for this to occur.

The Panel noted that three products were listed within the table namely: QGE031 (ligeliizumab), QMF149 (indacaterol, mometasone furoate in fixed-dose combination), and QVM149 (indacaterol, mometasone furoate, glycopyrronium bromide in fixed-dose combination).

The downloaded page from the link provided by the complainant, that included the table of data, was introduced by:

> ‘At Novartis, we are focused on improving the lives of the millions of people affected by respiratory and inflammation diseases and continue to research, develop and launch innovative therapies which treat chronic obstructive pulmonary disease, chronic spontaneous urticaria and severe allergic asthma. The table below outlines our current research within respiratory and inflammation diseases.’

The common name (non-proprietary name), mechanism of action, potential indication/disease area, route of administration, trial phase and planning filing dates for all three products were stated within the table.

The Panel noted that below the table it stated ‘Click on the conditions for more information about our work’ followed by the heading ‘Asthma’ beneath which it provided asthma statistics within the UK and stated, *inter alia*, that ‘At Novartis, as well as furthering scientific research, we work to ensure people in need receive the most effective medicine for their condition as promptly as possible’. This was followed by some of the work that the company carried out including training for health professionals in severe allergic asthma and working with hospital departments to conduct reviews and audits of their data on asthma exacerbations. The complainant did not specifically refer to this further information in his/her complaint.

The Panel considered that whilst the style of the table was low key and included scientific information about what were at the time of its publication, three potential products, the entire webpage might be seen as implying or claiming that QMF149 and QVM149 listed in the table were potentially effective, innovative treatments for severe allergic asthma. Whilst the reference to the planned filing dates of 2019 and that both products were in Phase III research might imply that their respective trials had not been successful and thus the planned filing in 2019 had not taken place, it might equally give the impression, in November 2020 at the time of the complaint, that the products were available or were likely to be available shortly. The Panel noted that the information was, however, at the time of the complaint in November 2020, inaccurate as acknowledged by Novartis as both products were licensed.

The Panel noted that Clause 3.1 prohibited the promotion of a medicine prior to the grant of its marketing authorisation. Once the marketing authorisation had been granted Clause 26.1 prohibited the promotion of prescription only medicines to the public.

The Panel noted Novartis’ submission that QMF149 and QVM149 were both licensed at the time of the complaint. The Panel, therefore, ruled no breach of Clause 3.1 in relation to each.

However, the Panel considered that the information in the table within the context of the webpage, including the opening paragraph and information below the table, promoted the two products which were, at the time of the complaint, prescription only medicines to the public and a breach of Clauses 26.1 and 26.2 were ruled.

The Panel noted that QGE031 was not classified as a prescription only medicine at the time of the complaint. Clauses 26.1 and 26.2 only applied to prescription only medicines. On that very narrow technical point, the Panel ruled no breach of Clauses 26.1 and 26.2. The Panel considered, however, that the information provided in relation to QGE031 within the context of the opening paragraph and the inclusion of information on two of the company's products, which were licensed at the time of the complaint, promoted an unlicensed medicine and a breach of Clause 3.1 was ruled.

In addition to its comments above, the Panel noted that the webpage in question was neither directed to, nor limited to, an audience of health professionals and other relevant decision makers and thus was not advertising to that audience. The Panel therefore considered that the allegations relating to the promotion to health professionals were not relevant. The Panel ruled no breach of Clauses 4.1 and 4.3.

The Panel was very concerned to note that the webpage at issue, which had been issued in October 2016, had not been updated since then including when QMF149 and QVM149 received their marketing authorisations. The company had failed to maintain high standards in this regard and a breach of Clause 9.1 was ruled as acknowledged by Novartis.

The Panel noted that Clause 28.3 required that information about medicines on the internet which was intended for members of the public must comply with Clause 26.2. The Panel noted its comments and rulings above and consequently ruled a breach of Clause 28.3.

Whilst the Panel was concerned that the webpage had not been updated since it was first published and about the context in which the table appeared and queried whether all of the detail within it was necessary, it noted that the style of the table was low key and scientific. The Panel further noted that whilst the webpage was potentially accessible via a web search, there was no information before the Panel regarding the relevant search terms required for this to occur and visitors to Novartis' website would have to actively click through three separate links to access the webpage at issue. The supplementary information to Clause 2 listed examples of activities likely to be in breach of Clause 2, which included promotion of a medicine prior to the grant of its marketing authorisation. However, in the Panel's view, on balance, noting its comments above, the circumstances in this particular case did not warrant a ruling of a breach of Clause 2 which was a sign of particular censure and reserved for such. The Panel therefore ruled no breach of Clause 2.

Complaint received **4 November 2020**

Case completed **16 July 2021**