CASE AUTH/3663/6/22 ***NO BREACH OF THE CODE***

COMPLAINANT v ROCHE

Allegations about the promotion of Ocrevus on the Roche resources website

CASE SUMMARY

This case was in relation to allegations that Ocrevus (ocrelizumab) had been promoted for unlicensed indications on the congress and meetings landing page on the Roche resources website.

The Panel ruled no breach of the following Clauses of the 2021 Code, as it did not consider that the complainant had established that:

- **the congress and meetings landing page advertised prescription only medicines to the public,**
- **reference to COVID-19 in a meeting title 'COVID-19 in Ocrevus-treated patients – the story so far' was misleading or implied that Ocrevus was indicated for COVID-19, and**
- **the inclusion of a link to the Ocrevus prescribing information on the webpage, in itself, would imply to a health professional that the medicine was licensed for all the conditions and therapeutic areas mentioned within the congress/meeting tiles on that page.**

No Breach of Clause 2	**Requirement that material must not bring discredit upon, or reduce confidence in, the pharmaceutical industry**
No Breach of Clause 3.2	**Requirement not to advertise prescription only medicines to the public**
No Breach of Clause 5.1	**Requirement to maintain high standards**
No Breach of Clause 11.2	**Requirement not to promote a medicine for an unlicensed indication**

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 alleged off-label promotion of Ocrevus (ocrelizumab) on the Roche Products Ltd Resources website.

COMPLAINT

The complainant alleged that there was off-label promotion on the Roche resources website, specifically on the congresses and meetings webpage (M-GB-00006380 Date of preparation: March 2022). At the top of the webpage, prescribing information for Ocrevus was given.

However, on the page there were a number of references to non-small cell lung cancer, small cell lung cancer and breast cancer. The complainant believed that it was unacceptable to have Ocrevus prescribing information on this page, considering Ocrevus only had a licence for multiple sclerosis (MS), not lung cancer or breast cancer. Repeated mentions of lung cancer and breast cancer on the page, alongside mention of Ocrevus at the outset of the page, implied a licence for Ocrevus in lung and breast cancer. There was also reference to COVID-19 in the Ocrevus treated patients. This was, in the complainant's view, misleading as Ocrevus did not have a licence for COVID-19. The complainant alleged breaches of Clauses 3.2, 5.1 and 2. The complainant stated that initial and overall impressions had not been considered nor had the importance of on-label promotion considering health professionals were busy individuals. The complainant stated that the PMCPA ought to audit Roche considering the critical importance of promoting within licence and the lack of responsibility or accountability in allowing for this page to be published.

When writing to Roche, the Authority asked it to consider the requirements of Clauses 2, 3.2 and 5.1 of the Code, as cited by the complainant. The case preparation manager also asked Roche to respond in relation to Clause 11.2 of the 2021 Code.

RESPONSE

Roche stated that it was committed to the appropriate use of medicines, protecting the safety of patients and strove to maintain high standards in the ethical promotion of its medicines. It was therefore disappointed to receive a complaint of this nature.

The complainant referred to the Congress and Meetings landing page of the Roche Resources website which provided a link to highlights from a wide range of scientific meetings for areas related to medicines promoted by Roche. The complaint specifically highlighted the inclusion of Ocrevus prescribing information on this page. Ocrevus was a monoclonal antibody indicated for the treatment of adult patients with relapsing forms of multiple sclerosis (RMS) with active disease defined by clinical or imaging features. It was also indicated for the treatment of adult patients with early primary progressive multiple sclerosis (PPMS) in terms of disease duration and level of disability, and with imaging features characteristic of inflammatory activity.

In the complaint the complainant alleged breaches of the following clauses of the Code:

> Clause 2 – Activities or materials must never be such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry.
> Clause 3.2 – Prescription only medicines must not be advertised to the public.
> Clause 5.1 – High standards must be maintained at all times.

Roche submitted that given this was a current webpage and a contemporaneous complaint, it made the assumption that the complainant was referring to the 2021 Code so responded on this basis. It should be noted that whilst Roche was surprised by all of the accusations, Roche was particularly perplexed by the accusation of a breach of Clause 3.2 given the detail of the complaint lacked any reference towards promotion to the public apart from the clause reference itself.

Roche submitted that the Roche Resources website was a promotional website which included materials related to a number of Roche medicines. The website was clearly aimed at health

professionals. Upon accessing the page, users were asked whether they were a healthcare professional or a member of the public.

Roche stated that it was very clear that Roche Resources was aimed at health professionals and, on this basis, denied a breach of Clause 3.2. On this basis, Roche further denied any breach of Clause 5.1 or 2.

In the detail of the complaint the complainant stated that by including Ocrevus prescribing information Roche had implied that Ocrevus was indicated for a number of potential conditions, including lung cancer and breast cancer.

Roche strongly refuted any suggestion that the inclusion of prescribing information for Ocrevus could mislead health professionals into thinking its licence was broader than it was. The Ocrevus prescribing information was included on this page (via a prominent one click link) due to the fact that one of the presentations referenced Ocrevus and another referenced multiple sclerosis in their titles. The inclusion of the treatment name and therapy area were relevant to allow users to understand whether this content would be of interest to them. Given the reference to both brand name and therapy area on the same page, and the potential for this to be construed as a product claim, prescribing information was included to ensure any health professional could appraise themselves of key product information. No other Roche product was mentioned directly on this page hence no other prescribing information was made available for any other medicine. The prescribing information was very clear that Ocrevus was indicated for:

- The treatment of adult patients with relapsing forms of multiple sclerosis (RMS) with active disease defined by clinical or imaging features.
- The treatment of adult patients with early primary progressive multiple sclerosis (PPMS) in terms of disease duration and level of disability, and with imaging features characteristic of inflammatory activity.

Based on the balance of the information on the webpage and with the support of the prescribing information, Roche believed that there was no risk that a health professional would be misled to believe that Ocrevus was indicated for any condition outside of MS.

Roche stated that the complaint highlighted one of the Ocrevus webinars focused on COVID-19 in people receiving Ocrevus. This was an area of significant interest to health professionals treating multiple sclerosis, given the impact of anti-CD20 treatments on immune function. The prescribing information of Ocrevus included a clear precaution around treatment of patients with active infections. Even without this information, Roche did not believe that any specialist health professional, who were the target of this website, would be misled by the content into believing that Ocrevus was an appropriate treatment for COVID-19. Roche noted that the complaint had no uncertainty over the indications for Ocrevus.

In light of the above, Roche concluded that at no time had the company promoted Ocrevus to members of the public. Furthermore, Roche refuted the sentiment expressed in the additional comments of the complaint. Considering all aspects of the complaint, Roche believed that it had maintained high standards at all times and had taken no actions which might reduce confidence in the industry.

PANEL RULING

The Panel noted that Ocrevus was indicated for the treatment of adult patients with relapsing forms of multiple sclerosis (RMS) with active disease defined by clinical or imaging features; or for the treatment of adult patients with early primary progressive multiple sclerosis (PPMS) in terms of disease duration and level of disability, and with imaging features characteristic of inflammatory activity.

The Panel noted that the complaint concerned the inclusion of Ocrevus prescribing information on the congress and meetings landing page of the Roche Resources website and whether this meant Ocrevus had been promoted outside its licensed indication, given that the webpage mentioned a number of therapeutic areas and conditions such as lung cancer, breast cancer and COVID-19 where Ocrevus was not licensed.

The complainant raised Clause 3.2. Clause 3.2 stated that 'Prescription only medicines must not be advertised to the public'. The supplementary information to Clause 16.1 stated, amongst other things, that 'Unless access to promotional material about prescription only medicines is limited to health professionals and other relevant decision makers, a pharmaceutical company website or a company sponsored website must provide information for the public as well as promotion to health professionals with the sections for each target audience clearly separated and the intended audience identified'.

The Panel noted that the congress and meetings webpage at issue contained a fixed menu bar with tabs identifying the different sections of the Roche Resources website and the range of information it contained: Home, Roche Medicines, Therapy Areas, Congress and Meetings, HCP Materials, FAQs, Prescribing Information and Adverse Event Reporting. Beneath these tabs was the statement 'This website is intended for healthcare professionals (HCPs) only. If you are an HCP, register free to access the full content'.

The Panel noted Roche's submission that the Roche Resources website was a promotional website which included materials relating to a number of Roche medicines. According to Roche, upon accessing the website, users were presented with text to inform the visitor that Roche Resources was intended for UK healthcare professionals only and by entering the website the visitor was confirming that they were a UK healthcare professional by clicking the 'I am a healthcare professional' tab or alternatively the visitor could select 'I am a member of the public'. It was not clear where visitors would navigate to if the 'I am a member of the public' tab was selected, and Roche made no submission in that regard.

The Panel noted the navigation to the webpage at issue as described by Roche and considered that, on the evidence before it, the complainant had not established that the webpage advertised prescription only medicines to the public and **no breach of Clause 3.2** was ruled.

The Panel noted that within the congress and meetings webpage at issue, the links to the prescribing information for Ocrevus appeared towards the top of the webpage and immediately above tiles containing information on the highlights from various national and international congresses, across multiple therapy areas including haematology, breast cancer and neurology. Below this were further tiles signposting to information about Roche-organised meetings and sponsored symposia, again in a number of different therapeutic areas of interest to Roche. A brief description of the content was provided for each meeting to enable viewers to determine whether the content within the tile would be of interest to them and a link to more information was provided. The Panel noted that, apart from Ocrevus, no other Roche medicines were

named on this landing page. The Panel noted that it had been provided with very limited information by either party and had no information before it regarding the content accessible from within each meeting link. Whilst it was clear that some congress/meetings links would contain data on Roche medicines, it was not clear exactly what data was being discussed within other links.

The Panel considered the overall impression created by the congress and meetings landing page of the Roche Resources website. In the Panel's view, the positioning of the webpage as a distinct section of the website, separate from any specific therapy area or medicine, and the layout of the page with labelled tiles and descriptions of the content from the various meetings, had been designed to create the impression of a hub resource where health professionals would find information aligned to specific-named congresses, rather than information for a specific medicine. Nonetheless, whilst context was important, the Panel noted that any claims on the landing page should be capable of standing alone in relation to the requirements of the Code.

Regarding the issue of off-label promotion of Ocrevus, the Panel noted that Clause 11.2 stated, among other things, that 'the promotion of a medicine must not be inconsistent with the particulars listed in its summary of product characteristics' and the supplementary information stated that 'The promotion of indications not covered by the marketing authorisation for a medicine is prohibited'.

The Panel noted that it had to consider whether the inclusion of the Ocrevus prescribing information on the webpage suggested that it was indicated for use in lung cancer, breast cancer or COVID-19, as alleged, and therefore if Roche had promoted Ocrevus for indications not covered by its marketing authorisation, regardless of whether this had been Roche's intention.

The Panel noted that in the 'Roche organised Meetings and Sponsored Symposia' section of the webpage at issue, one of the tiles had the title 'COVID-19 in OCREVUS (ocrelizumab) treated patients – the story so far' and another tile had the title 'Multiple Sclerosis: impact of COVID-19 and vaccination'. These two tiles were linked visually insofar as they both used the same colours and font. Roche asserted that reference to both brand name (Ocrevus) and therapy area (multiple sclerosis) on the webpage at issue had the potential to be construed as a product claim, and therefore the Ocrevus prescribing information had been included to ensure any health professional could appraise themselves of key product information.

The Panel noted that there had been a lot of interest in the impact of the COVID-19 pandemic on patients with pre-existing medical conditions. In the Panel's view, health professionals would understand that the meetings concerned the impact of COVID-19 (and its vaccination) for patients with multiple sclerosis, including those patients treated with Ocrevus. The Panel considered that the complainant had not established that the reference to COVID-19 in Ocrevus-treated patients was misleading or implied that Ocrevus was indicated for COVID-19, as alleged, and the Panel ruled **no breach of Clause 11.2**.

Regarding the mention of non-small cell lung cancer, small cell lung cancer and breast cancer on the webpage at issue, having taken account of the layout of the congress and events landing page, the Panel considered that it was unlikely that a health professional would make a connection between the tiles for the various oncology congresses/meetings and the tiles for Ocrevus given the use of different colour schemes and clearly defined tile borders.

The Panel queried the placement of the links to the Ocrevus prescribing information, distant from the meetings it related to, and with unrelated content in between. Nonetheless, in the Panel's view, the complainant had not established, on the balance of probabilities, that the inclusion of a link to the Ocrevus prescribing information on the webpage, in itself, would imply to a health professional that the medicine was licensed for all the conditions and therapeutic areas mentioned within the various congress/meeting tiles on that page. The Panel therefore ruled **no breach of Clause 11.2**.

Noting its rulings of no breaches above, the Panel consequently ruled **no breach of Clause 5.1** and, accordingly, **no breach of Clause 2**.

Complaint received **19 June 2022**

Case completed **14 June 2023**