CASE/0777/10/25

COMPLAINANT v ROCHE

Allegations regarding misleading data

CASE SUMMARY

This case was in relation to a slide in an Ocrevus (ocrelizumab) sales aid. The complainant alleged that a claim describing an annualised relapse rate (ARR) of 0.017 as being "equivalent to 1 relapse almost every 60 years" after 10 years of continuous treatment was inaccurate and misleading. Further allegations concerned the non-significance of data from Years 2 to 10, with the non-continuous arm performing better at 10 years of treatment, and that the ARR data was included in supplementary materials to the cited poster rather than within the body of the poster itself.

The outcome under the 2021 Code was:

Breach of Clause 5.1	**Failing to maintain high standards**
Breach of Clause 6.1	**Making a misleading claim**
Breach of Clause 14.4	**Not encouraging the rational use of the medicine by exaggerating its properties**

No Breach of Clause 2	**Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry**
No Breach of Clause 6.1 (x2)	**Requirement that information, claims and comparisons must not be misleading**
No Breach of Clause 6.2	**Requirement that information, claims and comparisons must be capable of substantiation**
No Breach of Clause 6.3	**Requirement that all artwork must conform to the letter and spirit of the Code**
No Breach of Clause 6.4	**Requirement that information and claims must reflect the available evidence regarding possible adverse reaction**
No Breach of Clause 14.2	**Requirement that clear references are given when promotional material refers to published studies**

This summary is not intended to be read in isolation.
For full details, please see the full case report below.

FULL CASE REPORT

A complaint was received about Roche from an anonymous, non-contactable complainant.

COMPLAINT

The complaint wording is reproduced below with some typographical errors corrected:

> "Roche have built a campaign for Ocrevus based on its long term safety and efficacy profile. Having seen the Ocrevus detail aid with efficacy data from their 10-year data from the OPERA follow up, I am concerned about misleading and inaccurate claims being made regarding the efficacy of Ocrevus and would recommend this promotion is stopped immediately. The slide in question suggests that after 10 years of continuous treatment, the ARR is 0.017 or equivalent to almost 1 relapse every 60 years. Basic maths will tell you an ARR is 0.017 is only equivalent to 1 relapse every 58.8 PATIENT years. Therefore, this claim is inaccurate and misleading for my colleagues. Further, this data is non-significant from years 2 to 10, and indeed the non-continuous arm performed better at 10 years of treatment. The reference for this claim is based on a poster presented at ECTRIMS 2023. Having re-read this poster, no ARR data is presented on this poster. I would suggest this is also misleading, with the ARR data found only in the supplementary materials. I believe there are breaches of clauses 5.1, 6.1, 6.2, 6.3, 6.4, 14.2, 14.4 and 2."

When writing to Roche, the PMCPA asked it to consider the requirements of Clauses 2, 5.1, 6.1, 6.2, 6.3, 6.4, 14.2, 14.4 of the 2024 Code.

ROCHE'S RESPONSE

The response from Roche is reproduced below:

> "Roche holds itself to the highest ethical standards, with adherence to the ABPI Code of Practice being fundamental to this commitment. We were therefore disappointed to receive the above-mentioned case and have set out our response below to explain why we believe we have maintained full compliance with the ABPI Code of Practice ("the Code").
>
> **Background to the material**
>
> The material referenced in the complaint relates to content from a sales aid concerning the Roche-marketed product Ocrevus (ocrelizumab). This version of the material is two iterations prior to the current version and was withdrawn in July 2024. Given that the 2024 Code only came into effect in October 2024, and in line with PMCPA agreement, we have therefore assessed this complaint under the provisions of the 2021 Code.
>
> Ocrelizumab is licensed in the UK for:
>
> ● the treatment of adult patients with relapsing forms of multiple sclerosis (RMS) with active disease defined by clinical or imaging features; and
>
> ● 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 Summary of Product Characteristics is attached for reference.

[Redacted information regarding ongoing inter-company dialogue]

Complaint details

The complainant refers to a claim made within an Ocrevus historic detail aid which displayed 10-year follow-up data from the OPERA study. The specific statement challenged is:

"After 10 years of continuous OCREVUS® treatment, the ARR (0.017) was equivalent to 1 RELAPSE ALMOST EVERY 60 YEARS."

The material (copy provided) was proactively withdrawn from use on 17 July 2024.

The complainant alleges breaches of Clauses 2, 5.1, 6.1, 6.2, 6.3, 6.4, 14.2, and 14.4 of the ABPI Code. As noted above, our detailed response to each relevant clause, as it applies to the 2021 Code, is set out below.

Alleged Breach of Clauses 6.1 and 14.4

The complainant states the claim "equivalent to almost 1 relapse every 60 years" for an Annualised Relapse Rate (ARR) of 0.017 is mathematically inaccurate (equivalent to 58.8 patient years) and therefore misleading. Furthermore, the data is non-significant from years 2 to 10, and the non-continuous arm performed numerically better (ARR 0.009).

The ARR figure of 0.017 for the Ocrevus continuous treatment arm (OCR-OCR) at 10 years of follow-up is factually correct and directly derived from the supporting study data. The value 1/0.017 equates to 58.8 patient years per relapse. The phrase "equivalent to 1 relapse almost every 60 years" was used as a contextual descriptor to help busy healthcare professionals (HCPs) quickly grasp the clinical relevance of the ARR value. The use of the word 'almost' clearly indicates that the figure is a close approximation, not an exact mathematical equivalence. Crucially, the exact ARR value (0.017) is stated immediately before the descriptive phrase and a clear footnote on the slide defines the calculation method of ARR, ensuring transparency. Furthermore, anecdotal feedback from HCPs working in the therapy area, who had seen this material during its use, did note that expressing the data in this way provided relevant clinical context to otherwise quite obtuse numerical values. Roche believes this contextual rounding does not render the information inaccurate or misleading to the degree required for a breach of Clauses 6.1 or 14.4, particularly as the base data is accurate and supplied.

The statement is presented as an absolute, observational finding of the Ocrevus continuous treatment arm ("After 10 years of continuous OCREVUS treatment..."). It is not presented as a comparative claim of superiority against the other study arm. Therefore, the numerical difference between the two arms (ARR 0.017 vs. 0.009) or the non-significant nature of the data is not relevant to the interpretation of the isolated, non-comparative statement.

Roche maintains that the core data is accurate, and the contextual description is a

reasonable approximation of a low ARR, supported by the exact figure and definition and therefore does not breach Clauses 6.1 or 14.4.

Alleged Breach of Clauses 6.2 and 14.2

The complainant states that the reference cited (Weber MS et al. ECTRIMS 2023, Poster P302) (copy provided) does not contain the ARR data, which is only found in the supplementary materials, suggesting the referencing is misleading and the claim is not capable of substantiation.

The artwork is clearly stated as being "Adapted from Weber MS et al, 2023.1" and the full citation is provided. The ARR data (0.017) is contained within the supplementary slides accompanying the cited poster (P302) presentation at ECTRIMS 2023.

It is a standard and accepted practice to cite the primary abstract/poster reference when utilising data contained within the associated materials, including the supplementary slides, which form an integral part of the overall presentation. The cited reference directs the reviewer to the original source, and the data is readily accessible from this source, meaning the claim is capable of substantiation in line with Clause 14.2.

The claim is fully substantiated by the cited abstract/poster and its supplementary materials; therefore, Roche does not consider this to constitute a breach of Clauses 6.2 or 14.2.

Alleged Breach of Clause 6.3

The complainant states that the presentation of the data is unbalanced, potentially by excluding context such as the non-significant nature of the results or the other treatment arm's lower ARR.

The detail aid page displays a graph derived directly from the Weber et al. study, showing the ARR data over 10 years for both the continuous Ocrevus arm (OCR-OCR) and the switch arm (IFN-OCR). The ARR of 0.017 is clearly labelled the OCR-OCR arm. The presentation is a clear and accurate depiction of the observational data from the study, providing the necessary context and not masking the figures for the other arm.

Roche does not consider this to constitute a breach of the Code. The artwork had been prepared with due regard to accuracy and balance, accurately reflecting the underlying study data, and included explicit references to the supporting information. Accordingly, Roche maintains that there is no breach of Clause 6.3.

Alleged Breach of Clause 5.1

The complainant alleged technical inaccuracy in the calculation and misleading nature of the claim fall short of the high standards required by Clause 5.1.

While Roche acknowledges the complainant's concern regarding the rounding of 58.8 patient years to "almost 60 years," we respectfully submit that the matter relates to a

non-material rounding used for contextual communication. Given that the underlying ARR figure (0.017) is correct, the calculation methodology is referenced, and the word 'almost' is used, this practice does not represent a failure to maintain the high standards required by Clause 5.1.

The provision of appropriate clinical context to accompany mathematical figures does not constitute a failure to maintain high standards. Accordingly, Roche does not consider this to be in breach of Clause 5.1.

Alleged Breach of Clause 6.4 and Clause 2

The complaint focuses entirely on efficacy claims (ARR) and raises no specific concerns regarding the accuracy or completeness of the safety information provided in the material. There is no information to suggest a breach of Clause 6.4.

Roche notes that a breach of Clause 2 is reserved for cases that would be likely to bring discredit upon, or reduce confidence in, the pharmaceutical industry. Roche strongly maintains that the technical matter of providing relevant context to an absolute risk reduction (ARR), where the underlying data are accurate and appropriately referenced, does not meet the threshold required for a breach of this clause.

Conclusion

Roche respectfully submits that the claims made in the material in question are not in breach of the ABPI Code of Practice as alleged. The claim is a non-comparative, contextual statement supported by accurate and substantiated data.

Roche appreciates the PMCPA's consideration of this response and would be pleased to provide any further information to assist in the review of this case."

PANEL RULING

This case was in relation to a slide for Ocrevus (ocrelizumab) in a sales aid. The complainant alleged that a claim describing an annualised relapse rate (ARR) of 0.017 as being "equivalent to 1 relapse almost every 60 years" after 10 years of continuous treatment was inaccurate and misleading. The complainant further raised concerns that the data from Years 2 to 10 was non-significant, with the non-continuous arm performing better at 10 years of treatment, and that the cited reference, which was a poster, did not present ARR data within the poster itself, with the data only appearing in supplementary materials.

Ocrevus (ocrelizumab) was indicated for the treatment of adult patients with relapsing forms of multiple sclerosis (RMS) with active disease defined by clinical or imaging features, and 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 slide at issue appeared as the first substantive slide in the efficacy section of the sales aid and was headed 'Ocrevus patients experienced consistently low relapse rates over 10 years in the OPERA trials and long-term follow up' followed by a blue bar containing the claim 'After 10 years of continuous OCREVUS treatment, the ARR (0.017) was equivalent to **1 RELAPSE ALMOST EVERY 60 YEARS'**. The remainder of the slide comprised a bar chart; the y-axis

showed the adjusted ARR and the x-axis showed the timeline in years up to Year 10 with bars representing two treatment arms. The chart compared patients receiving continuous Ocrevus with patients initially treated with high-dose Rebif who switched to Ocrevus upon entry into the open label extension (OLE) phase at Year 2. The chart included patient numbers, p-values and ARRs for each time point, with the analyses from Year 2 onwards, which had a marker identifying the 'Start of OLE', labelled as 'non-confirmatory'. A footnote section provided the calculation method for the ARR, acronyms and details of the reference cited to support the content which was a poster presented at an international scientific conference for multiple sclerosis (Weber MS et al., ECTRIMS 2023).

Roche submitted the sales aid had been withdrawn in July 2024, which, the Panel noted, was some 15 months prior to the submission of the complaint. As the 2021 Code was in place at the time the material was 'live', the Panel made its rulings in relation to the 2021 Code.

The complainant's allegations solely concerned the slide they had provided and the claim 'After 10 years of continuous treatment, the ARR (0.017) was equivalent to **1 relapse almost every 60 years'** (emphasis as per the material). The Panel therefore restricted its deliberations to this slide.

The ARR claim

The Panel noted that annualised relapse rates (ARRs) were an established efficacy outcome measure in multiple sclerosis studies.

The complainant alleged that the ARR claim was inaccurate and misleading because the ARR of 0.017 equated to 1 relapse every 58.8 patient-years and not one relapse every 60 years. In this regard, the Panel understood the complainant's concerns to be that the figure stated had been rounded up and that the rate had been expressed in years rather than patient years.

Clause 6.1 of the Code required claims to be "accurate, balanced, fair, objective and unambiguous", that "they must not mislead either directly or by implication, by distortion, exaggeration or undue emphasis" and that they "must be sufficiently complete to enable recipients to form their own opinion of the therapeutic value of the medicine". Clause 14.4, amongst other things, prohibited exaggerated claims.

The Panel noted Roche's submission that the ARR figure of 0.017 at 10 years of continuous treatment with Ocrevus was mathematically equivalent to one relapse per 58.8 patient years and that use of the word 'almost' indicated that the figure was a close approximation rather than an exact mathematical equivalence.

The Panel accepted that use of the word 'almost', which was emboldened within the claim, indicated that the number was an approximation. The Panel calculated that one relapse every 60 patient-years provided an ARR of approximately 0.0167. In the Panel's view, the complainant had not established that the degree of approximation used in the claim was misleading.
The Panel was concerned, however, that the claim expressed the annualised relapse rate in terms of 'years' rather than 'patient-years'. In the Panel's view, this materially impacted the meaning of the claim and might have misleadingly implied that an individual patient could expect to experience one relapse approximately every 60 years, rather than one relapse being observed across 60 patient-years. The Panel considered the claim was ambiguous such that it had the potential to mislead and exaggerate the effect of the medicine if interpreted incorrectly.

The Panel therefore ruled a **breach of Clauses 6.1 and 14.4**.

Presentation of efficacy data

The complainant further alleged that the data was misleading because the data was non-significant from years 2 to 10 and because the non-continuous arm performed better at 10 years of treatment.

The Panel considered the content, layout and overall impression created by the claim, graphic and slide as a whole.

The Panel noted that the 10-year ARR claim appeared prominently within a blue banner and did not expressly state that it was derived from the long-term follow-up period following entry into the OLE. The Panel further had no information in relation to how representatives had been instructed to present the sales aid data to health professionals.

While the Panel considered it might have been helpful for the claim itself to make clear the nature of the underlying data, it nonetheless considered that sufficient context had been provided on the slide. The title of the slide referred to results from the "OPERA trials and long-term follow up" and the graph included a prominent marker identifying the "Start of OLE" at Year 2. The Panel further noted the graph displayed ARR values, patient numbers and p-values for both treatment arms throughout the follow-up period with each time point being labelled "as non-confirmatory" after Year 2.

In relation to the complainant's comments that the non-continuous treatment arm had performed better at Year 10 of treatment, the Panel noted that the graph displayed the ARR values for both treatment arms throughout the follow-up period and included the corresponding p-values. At Year 10, the ARR was 0.09 for the non-continuous, high-dose Rebif-Ocrevus arm compared to 0.017 for the continuous Ocrevus arm. The Panel noted the comparison was accompanied by a p-value of 0.41 and was labelled as "non-confirmatory".

In the Panel's view, the claim at issue made clear the ARR was "after 10 years of continuous OCREVUS treatment" and the Panel accepted Roche's submission that the claim was presented as an observational finding of the Ocrevus continuous treatment arm rather than a comparative claim of superiority against the other treatment arm.

Taking all the circumstances into account, the Panel did not consider it had been established that the claim, graph or slide was misleading in relation to the statistical significance of the data nor that they represented implied superiority of the continuous Ocrevus treatment arm over the non-continuous treatment arm. The Panel therefore ruled **no breach of Clauses 6.1 and 6.3.**

Safety

The Panel noted the complainant had raised Clause 6.4 however it did not consider that there was an allegation relating to safety information and consequently ruled **no breach of Clause 6.4.**

Reference & substantiation

The Panel understood the complainant's allegation to be that the ARR claim was misleading

and not capable of substantiation because the ARR data was not included within the cited poster itself but could only be found in the supplementary materials.

The slide cited Weber MS et al. ECTRIMS 2023, Poster P302 and stated that the graph had been “Adapted from Weber MS et al, 2023.”

The Panel noted that while the data underpinning the slide at issue did not appear within the main body of the cited poster it appeared within the supplementary material as part of the same document provided by Roche.

The Panel queried the prominence given to the ARR claim and accompanying graph as the first information presented within the efficacy section of the sales aid, given that the underlying data did not appear within the core poster itself nor the pivotal OPERA studies. The Panel further considered that it would have been helpful for the reference to have indicated that the data appeared within the supplementary information. However, the matter before the Panel was whether the information presented was misleading and incapable of substantiation because the underlying data appeared within supplementary materials rather than within the poster itself.

Clause 6.2 required that information must be capable of substantiation. Clause 14.2 required when material refers to published studies, clear references must be given.

The Panel noted that the supporting ARR data appeared as the fourth slide within the accompanying supplementary information of the poster provided by Roche. Whilst it had no information before it as to whether the supplementary material formed an integral part of the poster and would accompany it in all circumstances, the Panel did not consider it had been established that the claim was incapable of substantiation. Nor did the Panel consider that it had been established that the citation of the poster was misleading or unclear because the supporting ARR data appeared within its supplementary material. The Panel therefore ruled **no breach of Clauses 6.1, 6.2 and 14.2.**

High Standards

Clause 5.1 required companies to maintain high standards at all times.

The Panel noted that the claim ‘After 10 years of continuous OCREVUS treatment, the ARR (0.017) was equivalent to **1 RELAPSE ALMOST EVERY 60 YEARS’** appeared as the principal efficacy message on the first substantive slide within the efficacy section of the sales aid. The Panel also noted its finding that the use of ‘years’ rather than ‘patient years’ had the potential to materially impact the meaning of the annualised relapse rate and exaggerate the treatment effect. Taking all the circumstances into account, the Panel considered that, on balance, Roche had failed to maintain high standards in this regard. The Panel ruled a **breach of Clause 5.1**.

Clause 2

A breach of Clause 2 was a sign of particular censure and was reserved for such use. Having considered its rulings and comments above, the Panel considered that the failings in this case were adequately covered by its above rulings and were not such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry and accordingly ruled **no breach of Clause 2.**

Complaint received	**15 October 2025**
Case completed	**18 June 2026**