

**CASE AUTH/3851/11/23**

## **COMPLAINANT v ROCHE**

**Alleged lack of declaration of Roche's involvement in a national ophthalmology database audit on Age-related macular degeneration (AMD)**

### **CASE SUMMARY**

This case was in relation to two published reports which had been funded by Roche. The complainant alleged that the first report, a full annual audit report on Age-related Macular Degeneration (AMD), did not declare Roche's funding at the beginning of the report. The complainant alleged that the second report, a patient summary of the full annual audit report on AMD, did not declare Roche's funding at all.

The outcome under the 2021 Code was:

<b>Breach of Clause 5.5</b>	<b>Failing to make sufficiently clear as to the company's role and involvement</b>
<b>Breach of Clause 23.2</b>	<b>Failing to include, in the written agreement for a donation or grant, a statement that all parties are fully aware that the donation or grant must be clearly acknowledged and apparent from the start</b>
<b>No Breach of Clause 2</b>	<b>Requirement that activities or materials 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 at all times</b>
<b>No Breach of Clause 5.5</b>	<b>Requirement to be sufficiently clear as to the company's role and involvement</b>

**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 from a contactable complainant who described themselves as a health professional about Roche Products Ltd.

### **COMPLAINT**

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

"To PMCPA director, A national ophthalmology database audit on AMD has been funded by Roche. However, the funding/involvement declaration regarding Roche has

not been disclosed from the beginning of this report. This was a requirement of the ABPI code of practice 2021. The report can be accessed at [link provided] The following breaches of ABPI code had occurred [5.5, 23.2, 5.1, 2] Transparency of a company involvement from the outset is mentioned several times within supplementary information too so it was unclear as to why the report did not disclose a statement from the start with regards to Roche funding/involvement. A patient summary of the AMD audit report was also produced and this did not mention Roche funding/involvement anywhere. A link to the summary of the report is [link provided] The following breaches of ABPI code had occurred [5.5, 23.2, 5.1, 2] It is concerning that healthcare professionals exposed to these reports were not provided with clear declarations from the outset of Roche involvement.”

When writing to Roche, the PMCPA asked it to consider the requirements of Clauses 2, 5.1, 5.5 and 23.2 of the 2021 Code as cited by the complainant and, in addition, Clause 10.9 of the 2021 Code.

## **ROCHE'S RESPONSE**

The response from Roche is reproduced below:

“Thank you for your letter dated 16th November 2023 regarding the above complaint.

Roche Products Ltd (**Roche**) would like to highlight its commitment to the maintenance of high standards and to provide assurance of the robust processes that Roche have in place to ensure that all activities meet the requirements of the ABPI Code of Practice. It is therefore unfortunate to receive a complaint of this nature.

### **Background**

The complaint relates to published outputs of a National Ophthalmology Database Audit, a large-scale audit for both cataract surgery and age-related macular degeneration, managed independently by the [named healthcare organisation]. The AMD audit specifically provides national benchmarks to enable sites to compare visual acuity outcomes and care process measures, both regionally and nationally, via publication of an annual report of aggregate data on the NOD Audit website.

On 17 May 2021, Roche entered into an Investigator Initiated Study agreement (the '**Agreement**') with the [healthcare organisation] (the '**Sponsor**') to provide financial support for '*Benchmarking and improving treatment outcomes for age-related macular degeneration through the [healthcare organisation] NOD AMD audit*' (the '**Study**'). The contractual terms of the Agreement (in particular clauses 4.10, 4.12 and 8.8, excerpts of which are set out below) for the Study clearly state it is the responsibility of the Sponsor to comply with applicable GxP regulations and the ABPI Code of Practice.

The complaint concerns Roche's appropriate disclosure of its funding for the Study on associated materials. Other than the provision of financial support, and certification of the NIS protocol, Roche had no involvement in the content or approval of the materials associated with this complaint and therefore do not have certificates of approval of the reports to provide the PMPCA as requested.

Before considering the particulars of the complaint, Roche would like to make reference to the following clauses in the Study Agreement [copy provided] that specify the Sponsor's obligations with regards to disclosure and transparency of Roche's support:

*Clause 4.10 - The Sponsor will ensure full and meaningful disclosure of Roche's support of the Study in accordance with all applicable laws and codes and will comply with all applicable laws, government or industry regulations and codes with respect to such support.*

*Clause 4.12 - The Sponsor will procure that the Investigator agrees and acknowledges that he or she is obliged, under the ABPI Code, to declare the existence of the Agreement and related services and participation, whenever he or she writes or speaks in public about a matter that is the subject of this Agreement or any other issue in relation to Roche.*

*Clause 8.8 - In accordance with the ABPI Code, if the Sponsor produces printed materials as a direct result of the support received from Roche pursuant to this Agreement, the Sponsor will identify Roche as the supporting company and include the wording 'Supported by Roche Products Limited' on any such materials.*

Roche would also like to provide context regarding navigation to the reports from both the [healthcare organisation] and Audit websites, along with the declarations of Roche's involvement that are apparent on both of these websites from the outset.

**The [healthcare organisation] website** includes a section titled 'National Ophthalmology Database Audit' [copy provided], which provides an introduction to the NOD, a link to the NOD Audit website and a prominent section [screenshot provided] which links to information about funding of the project.

**Screenshot 1:** Information regarding funding of the UK AMD Audit on the [healthcare organisation] website, accessed from [link provided]

Clicking onto 'Read More' (Screenshot 1) opens a page titled '[title provided]' (copy provided - [healthcare organisation] website [title provided]), which provides a clear statement highlighting Roche's (and other pharmaceutical companies') support, as shown in Screenshot 2.

**Screenshot 2:** Declaration of funding on the [healthcare organisation] website, accessed from [link provided]

**The NOD Audit website** hosts both the NOD AMD Audit Full Annual Report 2023 and the NOD AMD Audit Patient Summary 2023, which can be accessed from the page titled 'First NOD Age-related macular degeneration (AMD) audit annual report published' (copy provided - NOD website First NOD Age-related macular degeneration (AMD) audit annual report published section).

On this section of the NOD website, Roche's (and other pharmaceutical companies') support is highlighted immediately preceding the links to both the NOD AMD Audit Full Annual Report 2023 and the NOD AMD Audit Patient Summary 2023, as shown in Screenshot 3.

**Screenshot 3:** *NOD website with links to both reports, accessed from [link provided]*

The above demonstrates Roche's clear and transparent involvement in providing financial support for the development of the NOD Audit. This ensures that users are informed from the outset as they navigate through the content and/or access associated materials.

### **The Complaint**

The complaint relates to two reports which are published on the NOD Audit website by the Sponsor as outputs from the Study:

1. NOD AMD Audit Full Annual Report 2023 or the '**Annual Report**' [copy provided]
2. NOD AMD Audit Patient Summary 2023 or the '**Patient Summary**' [copy provided],

#### **1. National Ophthalmology Database Year One Report of the Age-related Macular Degeneration Audit 2023**

The complainant alleges that the declaration of Roche's support has not been disclosed from the beginning of the Annual Report, and therefore is not clear at the outset. As such, breaches of clauses 5.5, 23.2, 5.1 and 2 are alleged.

The Annual Report is accessed through the NOD Audit website, which, as described above, clearly discloses Roche's support. In addition, the Annual Report itself contains two sections that acknowledge Roche's support:

- a. The 'Forewords' section on page 5 includes a paragraph clearly acknowledging Roche's funding from the outset, as shown in Screenshot 4.

**Screenshot 4:** *Audit report declaration of funding in the Foreword*

- b. A specific section dedicated to 'Funding' on page 45 also acknowledges Roche's funding of the Audit, as illustrated in Screenshot 5. This 'Funding' section is prominently listed in bold on the 'Contents' page, at page 3 from the outset.

**Screenshot 5:** *Audit report section titled 'Funding'*

Taking into consideration the transparency requirements in the Study Agreement, the clear signposts on the website declaring Roche's support of the NOD Audit, as well as two clear statements in the Annual Report, Roche considers its involvement in the NOD Audit, as well as the material in question, to be abundantly clear.

As such, Roche strongly refutes any breaches of clauses 5.5 and 23.2, as well as any failure to maintain high standards (clause 5.1) or bring the industry into disrepute (clause 2).

#### **2. 2023 Patient Summary of the AMD Audit Report [copy provided]**

The complainant alleges that the Patient Summary does not mention Roche's funding / involvement anywhere and as such alleges breaches of clauses 5.5, 23.2, 5.1 and 2.

As demonstrated above, the NOD Audit website contains clear statements declaring Roche's (and other pharmaceutical companies') support. Clause 23.2 includes requirements for a written agreement to be in place for the provision of grants / donations. The supplementary information also includes specific requirements for the content of such agreements. In this instance, the Study Agreement specifies the Sponsor's obligations concerning disclosure and transparency of Roche's support (in particular clauses 4.10, 4.12 and 8.8, excerpts of which are set out above). Consequently, Roche does not consider there to be a breach of Clauses 23.2, 5.1 and 2.

Clause 5.5 states that: *'Material relating to medicines and their uses, whether promotional or not, and information relating to human health or diseases which is sponsored by a pharmaceutical company or in which a pharmaceutical company has any other involvement, must clearly indicate the role of that pharmaceutical company'*. Roche acknowledges that although the provision of funding support was explicitly stated on the NOD Audit website and in a statement immediately preceding the link to the Patient Summary, no such statement was included in the Patient Summary itself. Consequently, Roche recognises a breach of Clause 5.5 of the 2021 ABPI Code of Practice in this instance. Roche do consider that high standards have been maintained however, and therefore do not consider there to be a breach of Clause 5.1 or 2 in this regard.

In addition to the clauses cited by the complainant, the PMCPA case manager asked Roche to also consider the requirements of Clause 10.9 of the 2012 Code\* in our response.

*\*Roche assumes this refers to clause 10.9 of the 2021 Code, which states, 'When events/meetings are sponsored by pharmaceutical companies, that fact must be disclosed in all the material relating to the events/meetings and in any published proceedings. The declaration of sponsorship must be sufficiently prominent to ensure that readers are aware of it at the outset'.*

The definition of 'Events' is set out in Clause 1.7, which states *'Events' includes all professional, promotional, scientific and educational meetings, congresses, conferences, symposia, and other similar events (including, but not limited to, advisory board meetings, visits to research or manufacturing facilities, and planning, training or investigator meetings for clinical trials and non-interventional studies) organised or sponsored by or on behalf of a company (further examples can be found in the supplementary information to Clause 10.1).'* As per this definition, Roche believes that this clause does not apply since this activity concerns funding of a study and associated outputs and is not related to any events / meetings. Roche therefore refutes any breach of clause 10.9.

Please do let me know if you require any further information to inform consideration of this case."

## **PANEL RULING**

A complaint was received about two reports which were published on the National Ophthalmology Database (NOD) Audit website and which had been funded by Roche. The complainant alleged that the first report, a full annual audit report on Age-related Macular

Degeneration (AMD), did not declare Roche's funding at the beginning of the report. The complainant alleged that the second report, a patient summary of the full annual audit report on AMD, did not declare Roche's funding at all.

The Panel was provided with a copy of both reports. Roche confirmed, in their submissions, that both reports were accessible through a link on the NOD Audit website as well as the [healthcare organisation] website, who were responsible for the study. The Panel accepted Roche's submissions that a declaration of their involvement was prominent on both websites. The Panel was of the view that both reports, despite being accessible through the websites needed to stand alone and not rely on the declarations of company involvement on the website.

#### First report: Full annual audit report on Age-related Macular Degeneration (AMD)

The Panel noted that pages 1-4 of the first report included a cover page, a short paragraph on the [healthcare organisation] and two pages of contents which included at number 13 "Funding". Page 5 of the first report was titled Foreword which included a thank you to "all those who funded this work including...Roche".

On page 45 of the first report under its own heading "Funding" it stated "The [healthcare organisation] NOD Age-related Macular Degeneration (AMD) Audit is currently funded by...Roche". The Panel noted that the reader could skip straight to this page of the report from the contents page should they wish.

The Panel considered that the declaration of Roche's involvement was unambiguous and clear to readers. They considered the foreword to be at the outset of the report before the reader reached any detail of the report itself. The Panel believed that this report could stand alone and Roche's involvement was clear from the start. The Panel ruled **no breach of Clause 5.5**.

#### Second report: 2023 Patient Summary of the AMD Audit Report

The Panel noted that this report had also been funded in part by Roche through the same grant agreement as the full annual audit report. The Panel observed that there was no mention within the second report itself of Roche's involvement. Although the website where the report could be accessed provided a declaration of funding received with the link to access the report, this was material which the Panel considered could be downloaded and disseminated without needing to access the website containing the relevant declarations of pharmaceutical company funding. The Panel considered that the report itself also needed to contain a transparent declaration of Roche's involvement. The Panel ruled a **breach of Clause 5.5** as acknowledged by Roche.

#### The Agreement

The Panel was provided with a copy of the agreement between Roche and the [healthcare organisation] who were responsible for the study, setting out the terms of the funding, which reflected Roche's description in their submissions. This included a requirement at Clause 4.10 to:

"ensure full and meaningful disclosure of Roche's support of the Study in accordance with all applicable laws and codes and will comply with all applicable laws, government or industry regulations and codes with respect to such support."

The Panel reminded itself of the requirements of Clause 23.2 and its supplementary information which further refers to Clause 27.2 and the arrangements for written agreements with patient

organisations. This includes that the written agreement should include a statement that all parties are fully aware that the donation or grant must be clearly acknowledged and apparent from the start. The Panel considered that written agreements should be unequivocal about the requirements regarding declarations of involvement by companies. Whilst in this case there was a written agreement between parties, which referred to the need to acknowledge the companies' involvement, it did not state that it must also be apparent from the start. On that basis, the Panel ruled a **breach of Clause 23.2**.

The Panel was concerned that Roche did not notice that the written agreement did not meet the above requirement of the Code. Nonetheless, there was a reference in the written agreement to the requirement for a declaration of involvement statement; in that regard, the Panel did not consider that Roche had failed to maintain high standards and ruled **no breach of Clause 5.1**. It follows that the Panel ruled **no breach of Clause 2**.

The burden of proof is on the complainant to provide evidence to support the allegations. The Panel considered that there was no allegation set out regarding Clause 10.9 and therefore did not rule on it.

**Complaint received**      **13 November 2023**

**Case completed**        **10 February 2025**