Npof.

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Decision regarding research misconduct

Decision

The National Board for Assessment of Research Misconduct ("the Board" or "NPOF") finds [redacted] and [redacted] not guilty of research misconduct.

[redacted] not been included in the Board's investigation.

Background

On 30 August 2021, a report of alleged research misconduct was received by the Board from two researchers, [redacted] och [redacted]. In the report, research misconduct allegations are directed at the publication and marketing of results from the PLIANT study [redacted]

The complainants believe that the importance of the study's research results is enhanced when they have been published and marketed. Specifically, they point out that there is no evidence for a specific statement in the following article:

[redacted]

The statement in the article reads:

> *The effects are sufficiently strong and the lack of any indications of a tumour-protective effect is reassuring, motivating initiation of conclusive phase III trials.*

The complainants think [redacted] attitude is also reflected in a statement by him in a press release from PhedPharma, the company funding the study, on 29 March 2015:

> *This is, to my knowledge, the first study where a treatment has been shown to reduce side effects of this kind in a clinically meaningful manner.*

According to the complainants, this safety aspect has undoubtedly played a decisive role both in official approval being given and in the studies getting funded.

The complainants also think the PLIANT study design was defective and that no reliable conclusions could be drawn from it, as they say they told [redacted], among others. The complainants are also critical of the change in the primary goal.

The Board interprets the allegations reported as referring to suspected falsification.

[redacted] disputes that he is guilty of research misconduct. In his statement, he has told the Board that he believes there is ample support for the various statements made.

[redacted] also contests the accusation of research misconduct against her. She states that, to the best of her knowledge and experience as a co-author, the article contains a completely accurate account and discussion of the study's results.

The other authors have not been investigated, and have therefore not been invited to express themselves.

The Board has obtained an expert opinion on this matter. The expert[1] states that, with regard to the statement "*The effects are sufficiently strong and the lack of any indications of a tumour-protective effect reassuring, motivating initiation of conclusive phase III trials"*, it does not appear to be misconduct when the sentence is put in context. In his opinion, the primary goal was not achieved according to the researchers' presentation, but several other measurements demonstrated a difference. With this statement, the researchers also indicate that there is a need to confirm the results by means of a conclusive phase III study.

In the expert's assessment, the results therefore cannot be entirely reliable. He also points out that it is the European Medicines Agency and the Swedish Medicines Agency, not the authors of an article, that decide whether a phase III study is to be conducted or not. Regarding this allegation, the expert finds that the scientists have kept their statements within reasonable limits and that no misconduct occurred.

Regarding [redacted] statement, "This is, to my knowledge, the first study where a treatment has been shown to reduce side effects of this kind in a clinically meaningful manner […]", the expert's assessment is that [redacted], in his situation, had some significant data suggesting there was indeed a difference and a protective effect. The expert finds that the data have been processed correctly and that the statement does not entail a question of research misconduct.

According to the expert, the change in the primary goal was unfortunate. However, the study was still blinded when the switch was made and the data had not yet been analysed. He therefore thinks no research error has been committed.

[1] Professor Henrik Green, Department of Biomedical and Clinical Sciences, Linköping University.

Grounds for decision

Legal regulation

Under the Act (2019:504) on responsibility for good research practice and the examination of research misconduct ("the Act"), the Board is tasked to investigate issues of research misconduct. Section 2 of the Act defines research misconduct as a serious breach of good research practice in the form of fabrication, falsification or plagiarism, committed with intent or through gross negligence, in the planning, conduct or reporting of research.

Research covered

Under Section 3, the Act covers research carried out by higher education institutions and other bodies that have the state as the entity responsible, and which are subject to the Swedish Higher Education Act (1992:1434). Under certain conditions, the Act also covers research conducted by private companies.

[redacted] and [redacted] conducted their part of the research at Uppsala University and the Karolinska Institute respectively. Accordingly, Section 3 applies to their research and it must be examined by the Board.

In contrast, [redacted] och [redacted] participated in the research under way at companies that are not entities of the kind covered by Section 3. The other scientists conducted the research at responsible entities abroad, which are not covered by Section 3 either. Accordingly, none of these researchers are being investigated by the Board.

Planning, conduct or reporting of research

According to the definition in Section 2 of the Act, the breaches of good research practice that may constitute research misconduct must have been committed during the planning, implementation or reporting of research. The wording means, according to the preparatory work, that the concept of "misconduct" refers to breaches throughout the research process.[2] "Reporting" means both publishing and to other types of disclosure.[3]

The case concerns a published scientific article and statement in a press release concerning the study results. In the Board's assessment, this is an example of "reporting of research" that must be examined by the Board.

Fabrication, falsification or plagiarism

The Board's remit is to investigate three forms of research misconduct: fabrication, falsification and plagiarism. These terms are not defined by law, but are described in research ethics codes (codices) and guidelines, such as *The European Code of Conduct for Research Integrity*.[4,5] They are also explained in the Swedish Research Council's publication *Good Research Practice*.[6] Fabrication is often described as making up

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[2] Government Bill 2018/19:58, p. 100.
[3] Government Bill 2018/19:58, p. 49.
[4] *The European Code of Conduct for Research Integrity*, revised edition. Berlin: All European Academies (ALLEA); 2018, section 3.1.
[5] Government Bill 2018/19:58, pp. 45, 100.
[6] *Good Research Practice*, Swedish Research Council; 2017, Chapter 8.

results and documenting them as if they were real. Falsification refers to manipulation of research materials, equipment or processes, or unjustified alteration, omission or suppression of information or results.[7]

The statements to which the case refers to must be read in context. These statements have, as the expert also describes, been within reasonable limits and do not constitute falsification. Neither does the change of primary goal, in the way it happened, entail falsification.

Accordingly, in summary, the Board therefore finds [redacted] and [redacted] not guilty of research misconduct.

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The Board has made a decision in this matter, following a presentation by Office Manager Karin Nylén.

Catarina Barketorp
President

Karin Nylén
Office Manager

[7] Government Bill 2018/19:58, pp. 45, 100.