

Department

Legal department

Administrative officer

Carl Braunerhielm

+46 08-563 085 38

carl.braunerhielm@uka.se

Date

7 November 2017

Reg. no.

31-00050-16

Karolinska Institutet
Board

Karolinska Institutet's handling of a number of issues related to Paolo Macchiarini's activities

Decision in short: The surgeon Paolo Macchiarini was employed by Karolinska Institutet (KI) in 2010 as a guest professor in regenerative surgery. The position was combined with a role of senior physician at Karolinska University Hospital. As such, Paolo Macchiarini conducted a number of transplantations using artificial tracheas. Afterwards, the transplantations have been criticised severely.

Paolo Macchiarini's activities at Karolinska Institutet and Karolinska University Hospital have been reviewed in several different ways, including a preliminary enquiry by the public prosecution authorities concerning the operations conducted in Sweden. This enquiry was concluded in October 2017. KI's responsibility for the activities has been examined in a review that was presented in a special report.

The purpose of the Swedish Higher Education Authority's (UKÄ) review has been to examine a number of questions falling under the purview of the Authority's supervisory responsibility. UKÄ's review was based largely on the report about Karolinska Institutet and an extensive complaint received by the Authority. UKÄ has also asked a number of questions to KI's board where the Authority has found there to be outstanding issues that need to be clarified.

UKÄ's review has included looking at how Karolinska Institutet has handled the reporting of secondary occupations, suspicions of research misconduct and Paolo Macchiarini's employments. UKÄ's assessments in the decision lead the Authority, in short, to express serious criticism of KI. Overall, the investigation into the case gives the impression that Karolinska Institutet wanted to protect Paolo Macchiarini's reputation as a researcher at all costs and retain him as an employee. The reasons for this assessment include KI:

- neglecting to fully examine his secondary occupations,
- not investigating several suspicions against him regarding research misconduct,
- insufficiently conducting the investigations of research misconduct that were actually initiated regarding him, and
- extending one of his employment contracts in contradiction to the higher education institution's appointments procedure.

The shortcomings discovered are such that UKÄ cannot be satisfied with this criticism. Therefore, in 2018 the Authority will follow up KI's work with its action plan and, in particular areas, UKÄ will review policy documents and cases at KI, the latter through special random controls.

MAILING ADDRESSBox 7703
SE-103 95 Stockholm**VISITING
ADDRESS**Löjtnantsgatan 21
Stockholm**PHONE**

+46 (0)8 563 085 00

CONTACT

registrator@uka.se www.uka.se

Background

The attention of the Swedish Higher Education Authority (UKÄ) has been called to the activities of researcher Paolo Macchiarini at Karolinska Institutet (KI) and Karolinska University Hospital (KUH) via information in the media. An extensive complaint lodged against KI has also been received from NN.

KI hired Paolo Macchiarini in 2010 as a guest professor in regenerative surgery, with placement in the Department of Clinical Science, Intervention and Technology (CLINTEC). The position included the role of senior physician at the ear, nose and throat clinic at KUH. He then conducted a number of transplantations using artificial tracheas in Sweden at KUH and abroad, primarily in Russia. Afterwards, the transplantations have been criticised severely. Prosecutors notified Paolo Macchiarini of suspected involuntary manslaughter, a felony, or causing bodily harm, a felony. However, the preliminary investigation was ended on 12 October 2017, motivated by the finding that it was not possible to demonstrate that a crime had been committed.

Paolo Macchiarini's positions at KI were limited in duration. The guest professorship was extended in 2013, and in 2015, he obtained a new position as senior researcher. However, his employment at KUH was not extended. On 4 February 2016, the vice-chancellor of KI announced that Paolo Macchiarini's position would not be renewed again. KI announced that same date via a press release on the website of the higher education institution (HEI) that the Board would initiate a review that would include the events at KI from the time of Paolo Macchiarini's recruitment as a guest professor in 2010 through 4 February 2016. In a response to the request for comment submitted to the HEI's Board on 9 February 2016, UKÄ requested that it be allowed to read the investigation in its entirety upon completion. In March 2016 KI decided to dismiss Paolo Macchiarini. On 15 September 2016, KI provided UKÄ with the report *Karolinska Institutet and the Macchiarini case – An external review – September 2016* (Heckscher, Sten, Carlberg, Ingrid and Gahmberg, Carl – hereafter referred to as 'the KI review') and KI's internal audit department's review, *Departmental review CLINTEC* (which comprised a basis for the KI review). The KI review noted several serious failings at the HEI.

In another press release published on KI's website on 7 September 2016, the Board announced that it had tasked the HEI's vice-chancellor with producing an action plan for rectifying the serious failings noted in the KI review. The press release also stated that the plan would be presented at a Board meeting on 10 October 2016. In a referral for comment on 8 September 2016 to KI's Board, UKÄ requested an account of the measures taken as a result of the KI review. On 28 October 2016 the HEI submitted to UKÄ the *Action plan implemented in response to the reviews carried out by KI due to the Macchiarini scandal*, henceforth referred to as the action plan.

In a decision taken 16 March 2017, UKÄ found that some questions in the case would be investigated through a special report for comment to the Board of KI. Furthermore, UKÄ noted that Harriet Wallberg, former vice-chancellor of Karolinska Institutet from 2004 – 2012, was the university chancellor and head of UKÄ from June 2014–September 2016. UKÄ expressed that, pursuant to Chapter 1, Section 9 of the Instrument of Government, administrative authorities and others who carry out public

administrative tasks in their operations are to consider the equality of all individuals before the law and exercise objectivity and impartiality. UKÄ also stated that according to Section 11, paragraph five of the Administrative Procedures Act, the individual who will handle a case is disqualified in the event of special circumstances that are likely to undermine confidence in the individual's impartiality in the matter. In light of this, UKÄ found that it was not appropriate for UKÄ to take any further action pertaining to what NN addressed in his emails, which were directly connected to the time period during which Harriet Wallberg was vice-chancellor of Karolinska Institutet, i.e., through the end of 2012. UKÄ noted that, instead, NN had the option to turn to the Parliamentary Ombudsmen (JO) for these components. The limitation of the investigation reported by UKÄ in the decision on 16 March 2017 also applies to the UKÄ's examination of the case in general.

The following provides an overview of the KI review's analysis and assessment of the elements of the course of events covered by UKÄ's examination. Subsequently, the KI review's recommendations and action plan in relevant sections are provided, followed by UKÄ's special referral for comment to KI's Board together with the HEI's response to each question in the referral, and comments on the HEI's response by the person who submitted the complaint. Lastly, UKÄ presents its assessment and the future supervisory measures deemed necessary.

Investigation

KI Review (investigation of Sten Heckscher et al.)

KI review of public laws

The beginning of the KI review states, among other things, that at an early phase, the investigation encountered problems related to how KI handles public documents. It concludes that many documents which are public and should be registered had not been registered. It seemed that external emails were essentially never registered, nor were internal emails when the case to which they pertained had concluded. Furthermore, according to what was expressed in the KI review, there were even several examples of inadequacies in the registration of such important documents as decision, employment, and delegation policies. In even more cases, the documents were registered long after they were received or drawn up within KI. The examples of deficiencies in registration which the KI review investigator encountered did not always originate with the departments and research operations. Even the university's Central Administration contained several examples of public documents being registered too late, as well as public documents in the form of emails not being registered at all (KI review p. 43 ff.).

The KI review's overall assessment in this area was that the inadequacies were severe in various formal regards and the administrative culture neglected its responsibilities. According to the KI review, it seemed that the regulations in the Freedom of the Press Act (1949:105) and the Public Access to Information and Secrecy Act (2009:400) regarding public documents and registration were in many ways unknown or matters of little interest, and observed only to a limited extent.

KI review of the extension of Paolo Macchiarini's employment in 2013

With respect to the extension of Paolo Macchiarini's employment in 2013, the KI review notes several formal hesitations regarding this decision. It is noted that neither the Higher Education Act (1992:1434) nor the Higher Education Ordinance (1993:100) in and of themselves require a guest professor to have primary employment elsewhere.

However, it is established that the applicable appointments procedure at KI in 2013 stipulates that a guest professor must have employment somewhere else. According to the KI review, Macchiarini did not have employment elsewhere when his position at the HEI was extended in 2013 – at that point, his position in Italy had concluded a year earlier. It was asserted that this was known by the CLINTEC department leadership, but the information was never passed on to the Recruitment Committee. According to the assessment in the KI review, KI's failure to check whether the requirement for other employment was still met was a deficiency (KI review 123).

KI review of an email message from Pierre Delaere on 16 July 2013

In the section on the extension of Paolo Macchiarini's employment in 2013, the KI review also addresses parts of an email written by Professor Pierre Delaere which was received by Anders Hamsten on 16 July 2013. The KI review states that in the email message, Professor Pierre Delaere pointed out, among other things, that he suspected that Paolo Macchiarini had been using prosthetic tracheas since 2008 without first conducting trials with animals. According to the KI review, Professor Pierre Delaere concluded with the words: 'We (and others) have been fighting the 'tissue-engineered airway' since 2008. We do hope that the Karolinska Institutet will also take actions to avoid further human experimentation with synthetic tracheas.' Subsequently, the KI review posits that according to Anders Hamsten, the message arrived when the decision had already been made not to carry out further transplantations with artificial tracheas at KI, which is why it was set aside. According to what was presented in the KI review, the letter did however pique a discussion and Anders Hamsten stated that Professor Pierre Delaere's objections contributed to the decision to arrange a research meeting that autumn to evaluate the scientific status of the field (KI review p. 112). The KI review's assessment (p. 123) establishes that the Recruitment Committee did not appear to have been informed of the research meeting to address Paolo Macchiarini's activities which the vice-chancellor considered necessary and which led, among other things, to the conclusion that 'the preclinical collection and experimental research' would be reviewed and 'reports submitted by Macchiarini' would be reread.

KI review of the extension of Paolo Macchiarini's employment in 2015

The KI review notes that the final extension of Paolo Macchiarini's employment was carried out in such a way that he was appointed senior researcher. Prior to the appointment, based on the content of the KI review (p. 132 f.), Paolo Macchiarini had been assessed by experts, found to be a competent professor, and placed at the top of the list by all experts.

KI review of Paolo Macchiarini's secondary occupations

When it comes to the KI review of secondary occupations, it is noted in the KI review that all new employees must submit a report of any secondary occupations when they begin their position at KI. In addition, all staff are requested to submit a report each year of their secondary occupations on special forms, which, according to what emerged in the KI review, had been consistently carried out by the HEI with the exception of the years 2013-2014. According to representatives of KI, the reason the reports were not requested in those years was because they were redoing their system for the reports. The KI review argues in this context that it is highly unclear as to why this prevented reporting from taking place (KI review p. 152 f.).

With respect to Paolo Macchiarini's secondary occupation during his employment at KI, the KI review notes among other things that in spring 2015, a private individual notified the HEI of suspicions that Macchiarini was engaged with prohibited secondary

occupations. The person who submitted the complaint stated that the report of secondary occupations submitted by Paolo Macchiarini in 2012, in which he declared that he did not have any secondary occupations, would have been erroneous – in part because both Paolo Macchiarini and his coworkers had connections to a commercial company, and in part because he spent a significant portion of his work time in Russia and only a few days each month at KI. According to the KI review, the university director, with reference to this notification, tasked the head of the internal audit department with reviewing Paolo Macchiarini's secondary occupations. The review covered the years 2010–2015 and aimed to investigate whether there were transactions between KI and an external party that could be a violation of the principle of objectivity and entail a risk of being a secondary occupation that may damage confidence (KI review p. 153).

According to the KI review, the head internal auditor at the time judged in the report on 24 June 2015 that Paolo Macchiarini's account of his secondary occupations in 2012 was incorrect because he had not been informed that an English form with instructions was available and the error was not corrected in the subsequent follow-up. With regard to the report of secondary occupations for the year 2015, the head internal auditor felt that this was correct and complete (KI review p. 154 f.). The KI review states (p. 159) that six months earlier, the Committee for Staff Direct Responsibility at KI had concluded that the activities in Russia were not aligned with KI's fundamental values.

The KI review states that the fact that the internal audit department's investigation was limited to financial transactions that could be conflicts of interest entailed a risk that secondary occupations which may damage confidence for other reasons went unnoted (p. 158). The KI review concluded that a follow-up of secondary occupations also has to cover other circumstances than those included in the review. According to the KI review, the limited investigation also meant turning a blind eye to rather apparent risks of conflicts of interest, among other reasons, because visible transactions are not the only path for a commercial company to benefit in such a way that is problematic for KI's independence. Further, it was concluded that according to the Public Employment Act (1994:260), an employer is liable for intervening if an employee has a secondary occupation that may damage confidence and that there is no room for the employer to waive the requirement to prohibit secondary occupations that may damage confidence. Finally, the KI review noted in this section that an overview of the regulations and guidelines pertaining to employees' secondary occupations was underway at KI (p. 158 ff.).

KI review of KI's handling of complaints of misconduct

According to the KI review (p. 164) in April 2014, Thomas Fux received an email message from Professor Pierre Delaere in which he wrote, among other things, the following.

'Last Tuesday I attended a meeting on the bioengineered trachea in Paris. The Karolinska series was presented by Philippe Jungebluth. This day fully confirmed that the bioengineered trachea is a big lie and one of the most extreme examples of research misconduct in medical history.'

The KI review states that the email message was forwarded to Karl-Henrik Grinnemo who in turn forwarded it to head of unit Lars-Olaf Cardell, Urban Lendahl and head of department Li Felländer-Tsai. The latter then responded (KI review, p. 165):

'Thank you for your email with this serious information which we three have now discussed. There

Date

7 November 2017

Reg. no.

31-00050-16

are several different issues which you are addressing and which are handled via separate mechanisms. Please contact Professor Richard Kuylenstierna to review the patient information. This matter has already been discussed and Richard has been appointed the contact person for these issues. On 27 March 2014, Ulf Lockowandt was asked to contact Richard regarding this case in order to move forward... Publication questions may be addressed directly to the ethics counsel.'

The KI review concludes that subsequently, several complaints of suspected research misconduct were lodged against Paolo Macchiarini in 2014, including on 24 June 2014 and 25 June 2014, as well as 18 August 2014 (KI review p. 165 and 169 ff.). In the KI review, the handling of these complaints is summarised as follows (p. 169 ff.).

24 June 2014

Oscar E. Simonson, Matthias Corbascio and Grinnemo submitted a complaint pertaining to an article in Nature Communications, published in April 2014 (reg. no. 2-2184/2014). The article was about the transplantation of synthetic tracheal prostheses in rats in which Simonson had participated. Among other things, the persons who submitted the complaint stated that the pictures in the article were misleading.

Macchiarini was given the opportunity to comment on the complaint. An external expert, Professor Emeritus Bengt Gerdin, was subsequently tasked on 25 November 2014 with reviewing whether the criticized article could be considered an example of research misconduct. The external reviewer carried out the review on the basis of written material and submitted his special report on 13 May 2015. The reviewer concluded that the article contained departures from good practice in research. According to the external reviewer, this was evidence of negligence comprising scientific misconduct. However, the external reviewer felt that other deficiencies could be interpreted as examples of sloppiness, haste, ignorance or negligence. In these cases, there was no basis for unequivocally asserting that the deficiencies comprised a departure from good research practice. According to the external reviewer, as the main author, Macchiarini was responsible for the deficiencies.

All authors of the reviewed article were given the opportunity to comment on the external reviewer's report. The authors' statements were not shared with Gerdin; rather, a decision was made in the case. The vice-chancellor subsequently found in the decision on 28 August 2015 that Macchiarini demonstrated negligence, but was not, however, guilty of research misconduct.

In the justification for this decision, the vice-chancellor asserted that the authors' comments on the external review conveyed new material which had not been addressed in the special report and that this new material had crucial significance for the assessment of the complaint. For example, according to the vice-chancellor, the external reviewer's judgment that none of the authors had participated in a referenced CT scan was credibly disputed. The vice-chancellor also considered it important to note that Oscar Simonson had first left the writing process over to co-authors when the manuscript was accepted and in the proofreading stage. According to the vice-chancellor, other inadequacies did not represent unequivocal departures from good practice in research, but could rather be considered sloppiness, ignorance or negligence, but were expressions of inadequate quality in both the research process and the way in which the research and its findings were presented. The vice-chancellor also concluded in the decision that an initially coherent and functioning research environment had gradually broken down and that these conditions contributed to the resulting situation. With reference to KI's explicit policy to protect academic credibility and good practice in research, the vice-chancellor decided to take a number of actions, including that Macchiarini would submit erratum to the journal and that meetings with Macchiarini and his immediate manager would be held. The decision states that it is up to the head of the department to determine whether the decision should entail consequences for Macchiarini and the other authors of the article.

25 June 2014

The Belgian professor Delaere submitted a complaint of research misconduct against Macchiarini. Delaere attached an article that he had authored to the complaint, in which he calls into question Macchiarini's work with synthetic windpipes as described in four articles by Macchiarini (reg. no. 2-2167/2014).

After Macchiarini was given the opportunity to comment, on 22 December 2014 the vice-chancellor requested that KI's Ethics Counsel determine whether Macchiarini was guilty of research misconduct with regard to his work in regenerative medicine. The Ethics Council found in a report on 6 March 2015 that the accusations of scientific misconduct were unfounded. In light of what had been found in the case, the vice-chancellor decided on 7 April 2015 that Macchiarini was not guilty of research misconduct.

18 August 2014

Complaint from Corbascio, Thomas Fux, Grinnemo and Simonson against Macchiarini regarding six articles published in *The Lancet* in November 2011 and March 2012, in *Biomaterials* in March 2013 and April 2014, in *J Biomed Mater Res A* in August 2013 and in *Thorac Surg Clin* in February 2014 (reg. no. 2-2184/2014). All articles were about patients who had received synthetic trachea transplants. The persons who submitted the complaints asserted that the articles did not address the serious complications that had afflicted the patients; that patient records did not support the assertion that synthetic windpipes can develop into functioning tracheas; that no experiments on animals with synthetic tracheas had been carried out prior to the transplants; that some ethical permits had not been obtained prior to the transplants; that the surgeries could not be considered 'immediate or compassionate use'; that permits for use of the synthetic tracheas and certain medications had not been sought from the Medical Products Agency and that some biopsy findings were fabricated. The complaint was supplemented with additional documents on 24 September 2014.

Macchiarini was not given the opportunity to comment on this complaint or the supplementary documents until much later and not before the documents were submitted to the external expert, Professor Gerdin, on 25 November 2014. No separate referral for comment was circulated regarding this complaint; rather, the documents were submitted within the framework of the same task as the earlier complaint from Simonsson et al. Gerdin was tasked with reviewing whether the criticized articles could be considered expressions of research misconduct.

After receiving the task, the external reviewer had contact in January 2015 with the administrator of the vice-chancellor and with the department head. The external reviewer pointed out at that time that Macchiarini still had not been given the complaint from August 2014 and that this must happen promptly in order for Macchiarini to have the opportunity to comment. The external reviewer also gave the department head detailed information about what material he needed to be given.

In the report submitted by Gerdin on 13 May 2015, he determined in summary that there were departures from good research practice in all six articles; that the main author Macchiarini should have been aware that the clinical conditions were described incorrectly; that important information was omitted and that Macchiarini was therefore guilty of research misconduct.

All authors of the reviewed article, including Macchiarini, were subsequently given the opportunity to comment on the complaint and the external reviewer's report. These comments were not given to the reviewer; rather, a decision was made in the case.

The vice-chancellor subsequently found in a decision on 28 August 2015 that Professor Macchiarini was not guilty of research misconduct, but that some conditions emerged regarding his practices

demonstrating that they did not fulfil in all respects the high requirements for quality. In the justification for this decision, the vice-chancellor asserted that the authors' comments on the external review conveyed new material which had not been addressed in the special report and that this material had crucial significance for the assessment of the complaint. The vice-chancellor felt that the comments could credibly dispute the main features of the complaint's criticism and the external reviewer's assessments of the central questions that comprised the foundation of the finding that research misconduct had occurred. With regard to the other deficiencies discussed by the external reviewer, the vice-chancellor agreed that they were not to be considered misconduct. The decision also noted that some significant clinical data had been omitted in the reports and that an initially coherent and functioning research environment had gradually broken down, which contributed to the resulting situation. With reference to KI's explicit policy to protect academic credibility and good practice in research, the vice-chancellor decided to take a number of actions, including meetings, a review of procedures, regulations and support structures for clinical trials, clinical treatment research and clinical studies.

The KI review's assessment stated that the right of HEIs to take decisions in cases of misconduct is legislated and constitutes the exercise of public authority, which means special administrative law is applicable. It was also stressed that an individual who is a party in a case is entitled to be made aware of everything supplied for the case; to comment on data provided by someone else before the case is determined; and that decisions in misconduct cases must be satisfactorily justified. Moreover, it was stressed that these regulations are intended to support precision and the rule of law.

The KI review concluded that the complaints of scientific misconduct lodged against Paolo Macchiarini were handled and investigated in various ways. It was stated that it is not inherently out of the ordinary for different cases to be handled differently as a result of differing characteristics and complexity. But the KI review states it was difficult to discern a line of thought or any clear reasons for these variations – rather, the handling of the cases indicated inadequate procedures, which made it difficult to predict which cases were of such a character that they should result in one action or another.

It was noted that Professor Pierre Delaere's complaint in June 2014, for example, was passed for comment to KI's Ethics Council, while the complaint from Corbascio et al. in August 2014 was sent to an external reviewer, even though these complaints, at least to some extent, revolved around the same matter. Moreover, according to the KI review, in none of the reported cases did KI contact the expert group for misconduct at the Central Ethical Review Board – the body which is explicitly referenced in the Higher Education Ordinance (KI review p. 174 f.).

With regard specifically to the complaints of misconduct submitted by Simonson et al. on 24 June 2014 and Corbascio et al. on 18 August 2014, the KI review mainly made the following assessment.

Even though the complaint submitted by Corbascio et.al. in August 2014 was with regard to a different matter and other articles than the complaint submitted by Simonson et al. in June 2014, both complaints were registered under the same registration number and thus became one rather than two cases. The cases were partially handled together, but led to two distinct decisions with the same registration number. Even if this does not entail a formal mistake, the procedure involved a lack of clarity and inadequate opportunities for overview and follow-up.

Macchiarini was made aware of and permitted to comment on the complaint submitted by Simonson et al. in June 2014. However, he was not made aware of the complaint from Corbascio et al. in

Date

7 November 2017

Reg. no.

31-00050-16

August 2014 until the investigation by the external reviewer. The review has determined no reasonable explanation for why the complaint from August 2014 was not communicated to Macchiarini in conjunction with its submission. From an administrative law perspective, the most important practice is above all for the party to be made aware of and given the chance to comment on the information that could form the basis of the decision before it is made. The handling and delays in this case, however, are not acceptable. Good handling requires that the relevant individual is informed of the complaint essentially immediately. In addition, the procedure contributed to the handling of this case in a backward fashion. See further below.

The vice-chancellor's written assignment to the external reviewer on 25 November 2014 was not clearly formulated. In it, the investigation is described as being precipitated by the complaint submitted by Simonson, Corbascio and Grinnemo on 24 June 2014 regarding the article about the transplantation of oesophagi in rats in Nature Communications. Indeed, the assignment stated that this complaint had been supplemented with additional documents in August 2014 and that 'the task is to review the article and based on other documents in the case assess whether research misconduct has occurred'. But it was not until after the external reviewer's conversation with the vice-chancellor and the legal department at KI that it was clarified that the task also included the investigation of the significantly larger complaint submitted 18 August 2014 pertaining to six articles about patients who had received synthetic tracheas. The insufficient clarity is unfortunate, among other reasons because it could be interpreted as an attempt to conceal the latter and more substantial of the two complaints.

The regulations regarding the handling of cases in the Administrative Procedures Act are intentionally flexible to make it possible to handle cases in the most suitable way. Even so, the handling of the complaint lodged against Macchiarini in August 2014 is unsatisfactory.

First of all, Macchiarini should have been notified of the complaint so he could comment as soon as possible, at least since immediate action had been taken as a result of the complaint, such as securing certain material. Once the comments were received or the time to do so had expired, the complaint and any comments from Macchiarini should have been submitted to the external reviewer for his consideration. Then Macchiarini should have been given the opportunity to comment on the external reviewer's report. Depending on the content of the comments, further correspondence may have been appropriate before the vice-chancellor made a decision.

This is where the process was backwards. Macchiarini was not notified of the complaint until about six months later, when the external reviewer pointed out that this must happen. Nor was he given the opportunity to comment at that time. KI did not receive Macchiarini's comments until after the investigation by the external reviewer. However, the reviewer was not notified of Macchiarini's comments, even though the vice-chancellor, as a crucial factor, stated in the decision that these comments contained new material. Furthermore it appears likely that the reviewer, when he began his investigation, was not provided with all the material he requested. In an email to the vice-chancellor in December 2015, he wrote:

Now in retrospect as I compare my request with the documents which were actually eventually handed over from the research group via PM, and what was in retrospect mentioned in various comments, I realise that a significant amount of the original material was not provided. This includes all communication with Iceland about the patient's condition, or about the studies carried out there and where the material was communicated to PM or Jungebluth for analysis. I found no reason to suspect that PM did not do what I requested as an investigator, i.e. to provide "all documentation pertaining to the alleged misconduct".-.-. I find PM's omission of original material for the investigation remarkable and damning and in addition, as such, this conduct has de facto sabotaged the investigation. Considering the very clear language which I as

an investigator used in my request, I cannot interpret the omission as anything other than intentional.

From our point of view, we cannot interpret the material in any other way than that KI did not ensure that the external reviewer would be provided with all the material he requested. This is not acceptable.

Thus, the external reviewer was not given the opportunity to read and comment on the authors' replies before the vice-chancellor made a decision in the misconduct cases in August 2015. It is true that reviewer was not a party in the case. Thus, there is no definitive requirement that he should be given the opportunity to comment. In the situation that took place in 2015, when the vice-chancellor abandoned the clear position of the external reviewer following the replies, it would have however been suitable to do so, especially as the vice-chancellor, as an important factor in his decision, asserted that new material had emerged through the replies. The email exchange between the reviewer and the vice-chancellor in December 2015 also shows that the reviewer had several views on the statements from the reported individuals which could have enriched the case. It is not possible to argue that the vice-chancellor made a formal error which prevented the external reviewer from commenting on the statements from Macchiarini and his other co-authors. We assess this, however, as inappropriate.

We also believe the vice-chancellor's decisions in the misconduct cases taken in August 2015, after the comments from the external reviewer, are inadequately justified. This applies particularly to the most extensive case pertaining to six articles.

The explanation of a decision should state what circumstances were significant for the authority's decision and how the circumstances were evaluated. The reasons for a decision should be able to be read and understood independently.

In the vice-chancellor's decision on 28 August 2015 regarding the more extensive complaint lodged against Macchiarini, the external reviewer's comments and the co-authors' responses were described fairly comprehensively. Meanwhile, in the section comprising Karolinska Institutet's considerations and assessments, it cannot be seen how the arguments in the comments and the arguments in the responses were weighed against each other. It merely states that 'the comments received from Macchiarini and several co-authors could credibly dispute the main features of the complaint's criticism and the external reviewer's assessments of the central questions, which comprise the foundation of the finding that research misconduct had occurred.' We do not believe this describes with sufficient clarity what conditions led to the actual decision. As a reader, one does not understand how the conclusion has been reached. Consequently, the explanation is insufficient.

From both the decisions from 28 August 2015, it can be seen that the external reviewer was accused of having a conflict of interest. Both decisions asserted that the reviewer does not have a conflict of interest. Meanwhile, the reader knows neither what the objection was nor the basis for KI's assessment. This is not satisfactory.

Earlier in this chapter, we noted that there was discord between Macchiarini and his research group on one hand, and Grinnemo and his research group on the other. The reason we have done so is because it is addressed in the explanation of the vice-chancellor's decision. In it, he concludes that 'an initially coherent and functioning research environment (ACTREM) had gradually broken down and that these conditions contributed to the resulting situation.' Meanwhile, it is unclear what significance the vice-chancellor believes this has nor why it is included in the decision. The question emerges of whether this is because the vice-chancellor considered it significant in order to assess the matter of misconduct with Macchiarini and others. Nevertheless, this should not be relevant to the assessment of the assertions of misconduct in Macchiarini's research.

Date

7 November 2017

Reg. no.

31-00050-16

Our conclusion in this part of our review is that KI's handling of the cases of alleged research misconduct were unsatisfactory in various ways and merits criticism.

KI review's recommendations for KI and action plan

The sections of the KI review presented above include the following recommendations to KI (KI review, p. 189 f.). Under each recommendation, KI's planned measures are described according to the action plan submitted by KI to UKÄ on 28 October 2016 (action plan p. 7 ff.).

Recommendation

- KI should ensure that staff receive the necessary information about the rules regarding public documents, the principle of public access to official documents, documentation and registration.

Measure

An analysis will be carried out on the knowledge needs of the various roles. The university's Central Administration is to have the appropriate expertise, while other to provide the sufficient knowledge base on the person and the person's role.

Recommendation

- KI must ensure that employees who work with case management understand the applicable regulations, for example regarding communication, explanation of decisions and documentation of documents and collected information.

Measure

A new, university-wide procedure for case management will be formulated and implemented through training initiatives aimed at the relevant staff categories.

Recommendation

- KI should establish guidelines and procedures for handling cases of research misconduct.

Measure

Mostly carried out; completed 31 December 2016.

Recommendation

- KI should review procedures for assessment of employees' secondary occupations.

Measure

New regulations were decided by the vice-chancellor on 14 September 2016. Secondary employment reporting was to be done in October 2016.

The Swedish Higher Education Authority's special referral for comment to the KI Board UKÄ's special referral for comment to KI's Board has aimed to gather additional information in light of the KI review and action plan, among other things. The questions in the document were asked based on the KI review and the complaint from NN in which UKÄ found that there are remaining questions in need of clarification.

1. The email messages from Professor Pierre Delaere

On 16 July 2013, the vice-chancellor of Karolinska Institutet at the time received an email from Professor Pierre Delaere. UKÄ has read the email via the informational copy of Harriet Wallberg's complaint to the Parliamentary Ombudsmen (JO) received by the Authority. In this email message, Pierre Delaere states the following.

“-P. Macchiarini and co use a tracheal prosthesis soaked in bone marrow cells. They mislead the scientific community with the unrealistic prospect that the prosthesis will regenerate into a living trachea induced by ‘stem cells’ (!!).

-Macchiarini and co have been using these prostheses since 2008 in patients without any previous animal research.

-The outcome is disastrous as is predictable with our knowledge on prosthetic replacements of the trachea. Half of the patients died. The others are in a palliative setting with a self-expandable metallic airway stent (temporary airway support with major complications leading to death of the patient). We can not find one word of evidence that points to regeneration induced by stem cells.

-The Lancet (by publishing of several papers and editorials) and Karolinska Institute (homepage and internal brochures) help promote this unethical approach.

-This information not only damages research on tracheal replacement but also harms the field of regenerative medicine [sic].

We (and others) have been fighting the ‘tissue-engineered airway’ since 2008. We do hope that the Karolinska Institute will also take actions to avoid further human experimentation with synthetic tracheas (which are announced as ‘tissue-engineered tracheal transplants’).”

From the KI review (p. 164 f.) it can also be seen that Karolinska Institutet received another email from Pierre Delaere in April 2014. The email message specifies, as it is presented in the KI review, among other things, the following.

‘Last Tuesday I attended a meeting on the bioengineered trachea in Paris. The Karolinska series was presented by Philippe Jungebluth. This day fully confirmed that the bioengineered trachea is a big lie and one of the most extreme examples of research misconduct in medical history’

Chapter 1, Section 16, paragraph one, of the Higher Education Ordinance states that a higher education institution which, via complaint or in some other way, is made aware of suspected research misconduct is to investigate these suspicions.

- a) Karolinska Institutet is requested to respond to why no investigation of the research misconduct took place as a result of the email from Professor Pierre Delaere to the HEI on 16 July 2013. Karolinska Institutet is also asked to respond to whether the HEI now believes such an investigation should have been carried out.
- b) Karolinska Institutet is further requested to respond to why no investigation of the research misconduct took place as a result of the email from Professor Pierre Delaere to the HEI in April 2014. Karolinska Institutet is also asked to respond to whether the HEI now believes such an investigation should have been carried out.

2. Complaints of research misconduct

The KI review explains the handling of the complaints of research misconduct which were received on 24 June 2014 and 18 August 2014 (reg. no. 2-2184/2014) with respect to articles authored by Paolo Macchiarini, among others. From the review, the following can be seen, among other things (p. 169 ff.).

An external expert was tasked with reviewing whether the criticized articles could be considered expressions of research misconduct. The external reviewer carried out the review on the basis of written material and submitted his special report on 13 May 2015. The external reviewer's assessment was that research misconduct was found concerning all reported articles. All authors of the articles were given the opportunity to comment on the external reviewer's report. The comments were not shared with the external reviewer; rather, a decision was made in the case. In a decision on 28 August 2015, the vice-chancellor found that Paolo Macchiarini was not guilty of research misconduct. In the justification for this decision, the vice-chancellor asserted that the authors' comments conveyed new material which had not been addressed in the special report and that this material had crucial significance for the assessments of the complaints.

- a) Karolinska Institutet is asked to respond to why the external reviewer was not given the opportunity to respond to the authors' comments on the review before a decision was made in the case.
- b) Karolinska Institutet is asked, on the basis of Section 17 of the Administrative Procedures Act (1986:223), to respond to why the persons who submitted the complaint were not given the opportunity to respond to the authors' comments.
- c) The HEI is also asked to provide the procedure for handling complaints of research misconduct applicable to the years 2013-2015.
- d) Karolinska Institutet is also asked to provide the guidelines and procedures for handling complaints of research misconduct which, according to the action plan (p. 8) would be completed on 31 December 2016.

3. Extension of Paolo Macchiarini's employment in 2013

The KI review (p. 119 f.) states among other things the following with regard to the extension of Macchiarini's employment in 2013.

'On 20 November 2013 the Recruitment Committee (decision of the chair) decided to approve the proposal to renew Macchiarini's position as guest professor of regenerative surgery at CLINTEC. According to the approval, the position would be 60 per cent for a period of two years, however only for the period during which Macchiarini was employed at Azienda Ospedaliero-Universitaria Careggi.'

[...] At the time of the extension, the appointments procedure's regulations for guest professorships included a requirement for other employment. [...]

As previously noted, since autumn 2012 Macchiarini no longer held a position at Careggi. Macchiarini had informed the department head and unit head at CLINTEC of this himself. However, this factor was not known to the Recruitment Committee upon taking the decision. No new permission was obtained from the main employer; rather, the permission submitted to KI in 2010 formed the foundation for this decision as well.

'On 14 January 2014, the vice-chancellor took the decision to renew the employment of Macchiarini

as a guest professor. The previous joint employment changed to a straightforward position as guest professor in regenerative surgery at KI. The position was for the period of 1 December 2013–30 November 2015 and covered 60 per cent of full-time working hours. However, the vice-chancellor's decision did not contain the terms for the position at the university in Careggi which were included in the Recruitment Committee's decision to approve the extension.'

- a) Karolinska Institutet is requested to comment on the fact that Paolo Macchiarini's employment as a guest professor was extended even though he had no other employment.
- b) The HEI is also asked to provide a copy of the applicable appointments procedure at the time of the extension of employment.

4. Extension of Paolo Macchiarini's employment in 2015

The KI review states the following with regard to the extension of Macchiarini's employment in 2015 (p. 128 ff.).

'In 2014, discussions continued about the form of Macchiarini's continued employment. The plan was now to create the permanent professorship for Macchiarini which had previously been suggested. [...] The professorship was announced on 23 June 2014. Macchiarini and three other individuals applied for the position. [...] In October 2014, three experts were tasked with ranking the three applicants. All experts determined that Macchiarini was most suited to the position. However, the position was never appointed. The vice-chancellor opted to stop the process in January 2015 as a result of the ongoing investigation into accusations of fraud. [...] On 17 November 2015, a new employment contract was signed with Macchiarini, this time for a position as senior researcher.'

Karolinska Institutet is requested to respond to whether the senior researcher position was announced as available in accordance with the regulations in section 6 of the Employment Ordinance and, with reference to relevant regulatory provisions, to otherwise account for the handling of the employment case.

5. Secondary occupations

Finally, Karolinska Institutet is asked to provide the new regulations for assessing employees' secondary occupations as decided by the vice-chancellor on 14 September 2016 (compare with action plan p. 9).

Statement of the KI Board to the Swedish Higher Education Authority

In a statement to UKÄ, KI's Board has primarily argued the following.

In the response to the referral for comment, the Board has chosen to divide the answers to each question into a report and an assessment. The information and facts comprising the content of the report have been obtained from the individuals who were involved with KI at the time of the event. The sitting Board of KI has supplied the assessment section.

Therefore, the explanations regarding the different cases to which UKÄ is seeking supplementary responses have been obtained from the vice-chancellor at that time, Anders Hamsten; former department head Li Felländer-Tsai; administrative head Pille Ann Härmat; unit head Lars-Olaf Cardell (all three from Department of Clinical Science, Intervention and Technology [CLINTEC]); HR director Mats Engelbrektsson; unit head Peter Gustafsson (both from the HR department); and lawyer Lisen Samuelsson (legal department).

The Board considers it crucial to also take the opportunity to describe how KI is currently actively working with the consequences of the events related to Paolo Macchiarini. KI is well aware that the work includes many different dimensions with a variety of time lines. The responsibility of the Board is to continuously raise issues pertaining to regulations and compliance to ensure awareness in the organisation. The ultimate goal is to minimise the risk of such an event ever occurring again.

It was also in light of this that in February 2016 the then Board took the decision to allow the implementation of an external review of the case regarding surgeon Paolo Macchiarini. At the same time, the acting vice-chancellor and the acting pro-vice-chancellor launched internal efforts to review the organisation for defects and deficiencies. In September 2016, the KI review was presented. The Board immediately took the decision to instruct the acting vice-chancellor to develop an action plan based on the content of the KI review, other external investigations of Paolo Macchiarini, and its own internal review. The focus of the action plan was on measures for ensuring regulatory compliance and a necessary shift in internal culture, starting with leadership. The action plan was formulated, presented to the Board, communicated internally and externally, and is now continually reported on to the current Board.

1. a) Email message on 16 July 2013 from Professor Pierre Delaere

The Board's report:

Pierre Delaere conveyed the view that synthetic prosthetic tracheas filled with bone marrow-derived cells lack the conditions to develop into functioning tracheas through regenerative processes induced by stem cells. He urges KI to ensure that what he considers an unrealistic and thus unethical form of experimental treatment ceases.

Barely one week before Pierre Delaere's email on 11 July 2013, the vice-chancellor and hospital director met to discuss the future of surgery with prosthetic tracheas at KUH.

The Board's assessment:

The Board at KI has not successfully found any satisfactory explanation for why Pierre

Delaere's email to the HEI on 16 July 2013 did not cause any response of any form or the obvious decision to investigate suspected research misconduct. It is therefore impossible to provide a response as to why no investigation was launched. On the other hand, it can be stated that the current Board considers KI's actions at that time to be remarkable.

The Board asserts that the email message from 16 July 2013 contains more than enough information for KI to have taken action immediately. The Board believes that KI should have launched an investigation at that time into suspected research misconduct in light of the indications that emerged.

1. b) Email message April 2014 from Professor Pierre Delaere

The Board's report:

This email message was sent to Thomas Fux, who forwarded it to Karl-Henrik Grinnemo. He, in turn, sent it to the department head, unit head, and coordinator of regenerative medicine at KI. At that time, an investigation had already been launched at KI and KI's department CLINTEC. The investigation began after a meeting on 2 February 2014 between the vice-chancellor, department head, unit head and the coordinator of regenerative medicine. A case of suspected plagiarism was discussed at the meeting. The meeting also came to address the publication covering oesophagus transplants (rat oesophagi) and the discrepancies perceived by Karl-Henrik Grinnemo and other colleagues between the medical records describing the three patients' clinical courses of events and the clinically-oriented scientific work.

Between March and June 2014, several exchanges took place between Karl-Henrik Grinnemo and colleagues, KI's vice-chancellor, the department head, unit head, and the coordinator of regenerative medicine. These exchanges pertained to one of the Macchiarini group's experimental projects with oesophagus transplants in rats and the conditions of the three Swedish patients who had undergone surgery to receive a prosthetic trachea, and how this was presented by Paolo Macchiarini and his colleagues in several articles and oral presentations.

The department head, unit head and coordinator of regenerative medicine considered Pierre Delaere's information about the challenged patient data to be serious. Therefore, after consulting with the vice-chancellor on 25 March 2014, the department head contacted the senior manager at the Thorax clinic at KUH to contact the senior manager at the ear, nose and throat clinic at KUH to gain an understanding of the patient data.

On 25 June 2014, Pierre Delaere submitted a complaint regarding Paolo Macchiarini and research misconduct. This complaint was handled according to the KI procedure for dealing with suspected research misconduct that was in place at that time.

The Board's assessment:

After reading the accounts of people involved at that time, The Board's understanding is that the handling of the case and the specific email message demonstrate clear deficiencies in structure, responsibility, and regulatory compliance. If regulations and a functioning management procedure exist and are followed, then the fact that many parties were involved from both KI's management and from the CLINTEC department, combined with the fact that several different questions were discussed, should not pose an obstacle to the relevant email message reaching the vice-chancellor without delay and thus being presumed to have been handled properly, in accordance with the applicable regulations.

The Board's interpretation of the respondents is that an investigation had already begun in February 2014. However, as the Board understands the respondents, this investigation did not include research misconduct. Nor is it clear to the Board if the already launched investigation included the assertions made in Pierre Delaere's email message from April 2014.

The Board believes that the content of the relevant email message from April 2014 should have resulted in the immediate launch of an investigation into research misconduct.

2. Complaints of research misconduct

The Board's account of the background

The questions below pertain to the handling of complaints received on 24 June 2014 (research related to experiments with animals that resulted in an academic article in the journal Nature Communications in 2014), and 18 August and 24 September 2014, respectively, (six academic articles about patients who received synthetic trachea transplants – The Lancet 2011 and 2012, Biomaterials 2013 and 2014, J Biomed Mater Res A 2013 and Thorac Surg Clin 2014), reg. no. 2-1284/2014.

After certain introductory measures, the vice-chancellor tasked Professor emeritus Bengt Gerdin, as an external expert, with reviewing whether the criticized articles constituted research misconduct. After Bengt Gerdin submitted his special report on 13 May 2015, all authors of the six articles were given the opportunity to comment on it. On 28 August 2015, the vice-chancellor made a decision in the case.

2. a) Why was the external reviewer not given the opportunity to comment on the authors' comments on the review before a decision was made in the case?

The Board's report:

The question of whether the external reviewer should have been given the opportunity to comment on the authors' responses to the criticism presented in the review was discussed by the vice-chancellor, university director, head lawyer and the lawyer in charge of the case. However, the consensus was that the external reviewer had completed his task upon submitting his report on 13 May 2015.

The Board's assessment:

The Board asserts that KI is obligated, in accordance with the regulations of the Higher Education Ordinance, to investigate suspected research misconduct. From KI's internal procedures for such cases, it follows that it is the vice-chancellor who makes a decision in the case. As it is a matter of the exercise of public authority, those who are accused are considered parties in terms of administrative law, which means they have the right to be made aware of what has been supplied in the case and to be given the opportunity to comment before the case is decided. However, an external reviewer assisting in an investigation is not formally considered a party.

The Board cannot however, in light of the provided information, respond to or explain why the vice-chancellor at the time chose not to give the external reviewer Bengt Gerdin the opportunity to be informed of, and the opportunity to comment on, the responses from the authors. The Board can, however, conclude that it naturally would have been appropriate to give the external reviewer these opportunities if for no other reason than to lend credibility and legitimacy to the decision the vice-chancellor had to make.

2. b) Why were the persons who submitted the complaint not given the opportunity to comment on the authors' comments?

The Board's assessment:

The Board's understanding is that this question does not appear to have been discussed. According to the main rule, a person who submits a complaint that initiates proceedings requiring an authority to take action about a given condition is not considered a party. As stated in the section Assessment 2 a), KI is obligated to investigate suspected research misconduct.

As the Board understands it, at the time, an assessment was made that in this case, the persons who submitted the complaints could not be deemed to have such a justified interest in the case as to be a real party in interest and thereby be treated as a party according to the provisions of Sections 16 and 17 of the Administrative Procedures Act.

The Board asserts, however, that even if these regulations guided the decision at the time to not permit the persons who submitted the complaints to comment, these regulations do not prevent KI from holding a dialogue with the persons who submitted the complaints. The Board therefore states that it would have been appropriate if such had taken place.

3. Extension of Paolo Macchiarini's employment in 2013

3. a) Comment on the fact that Paolo Macchiarini's employment as a guest professor was extended even though he had no other employment

The Board's report:

According to the applicable handling procedure at that time, consent was obtained from Paolo Macchiarini's 'main employer' in part to ensure that he had other employment, and in part to ensure that the 'main employer' provided approval of Paolo Macchiarini's part-time employment as a guest professor at KI. The proposals which the department head and unit head at CLINTEC submitted to the Recruitment Committee included this consent. From the consent issued by Azienda Ospedaliero-Universitaria Careggi on 27 August 2010 it can be seen that Paolo Macchiarini was permitted to hold a position as guest professor for a period totalling five years. The relevant extension of the position as a part-time guest professor included the last two years of that five-year period. This was the same consent included with the application in 2010, when Paolo Macchiarini was first hired.

When the case for renewed employment of Paolo Macchiarini as a part-time guest professor at KI was presented by the administrators of the HR department on 14 January 2014 to the vice-chancellor, it was not stated that Macchiarini's employment at Careggi had ended.

The Board's assessment:

The Board's assessment is that this case was mishandled. Even if at this point in time there were no statutory requirements, i.e. in the Higher Education Act or in the Higher Education Ordinance, stipulating that a guest professorship required the individual to hold primary employment at another HEI, this requirement was clearly included in KI's appointments procedure.

The Board's understanding is therefore that the decision to extend Paolo Macchiarini's guest professorship never should have been made. Nor could the decision have been made if the vice-chancellor had complied with KI's applicable appointments procedure.

The Board considers one of its most important tasks to not only ensure the conditions for regulatory compliance within KI, but also to ensure adequate regulations are in place in the organisation that can prevent errors such as this from occurring again.

4. Extension of Paolo Macchiarini's employment in 2015

The Board's report:

The vice-chancellor informed Paolo Macchiarini at a personal meeting that there would be no extension of the part-time guest professorship, but that under the prevailing conditions, he could be employed in a temporary one-year position as a researcher. The conditions concerned were the vice-chancellor's decision in the misconduct case and the vice-chancellor's request to reconsider the decision to discontinue payment to KI of funding for the project in which Paolo Macchiarini was project manager, several doctoral students and one large research group. The department head of CLINTEC was present when the vice-chancellor gave Paolo Macchiarini this information. Based on this, and with labour union cooperation, the department produced an employment agreement in line with the vice-chancellor's decision.

According to Section 6 of the Employment Ordinance (1994:373), an authority must announce in a suitable way that it intends to hire an employee so that individuals can notify the authority of their interest within a certain period. This information does not need to be provided if there are special reasons to the contrary.

The position was not announced as vacant since there were special reasons that rendered doing so unnecessary. It seemed obvious that the position could not be filled by another applicant because it was based on the continuation of an ongoing research project.

The Board's assessment:

The Board asserts that there is no doubt that the decision to extend the employment of Paolo Macchiarini in November 2015 never should have been made. At the time of the presentation of a new employment agreement, the vice-chancellor should have had sufficient documentation, knowledge and familiarity with Paolo Macchiarini to prompt KI not to extend his employment. The Board asserts that no information submitted by individuals involved at the time or facts that emerged later on were enough to justify the decision to extend his employment in 2015.

In light of what has occurred, the Board can however highlight the importance of both a functioning framework and clear and functioning leadership, in which there is consensus in the organisation on ethics and morals. It is therefore with satisfaction that the Board is closely following the current leadership's dedicated efforts to improve leadership at KI to achieve a necessary cultural change and prevent history from repeating itself.

KI has attached to its report for UKÄ *Rules for handling cases of research misconduct* (reg. no. 1-551/2014), *Appointments procedure for teachers at Karolinska institutet* (reg. no. 4976/2012-200) and *Rules pertaining to secondary occupations* (reg. no. 1-627/2016).

The persons who submitted the complaint comments on the Board's statement In response to KI's statement, NN has conveyed essentially the following.

Points 2a and 2b in the document deal with why the external reviewer (2a) and the persons who submitted the complaints (2b) were not given the opportunity to comment on the authors' views on the review before a decision was made in the case.

He feels that the failure on the part of KI and Anders Hamsten to allow the external reviewer and persons who submitted the complaints to read the authors' comments before a decision in the case was taken must be considered extremely remarkable and, indeed, the question is whether this is not a violation of the law. What the Board has written on this issue in its statement to UKÄ must, according to him, be strongly questioned.

He says that it is especially remarkable that the Board does not believe KI made a formal error when they failed to provide the persons who submitted the complaints with the comments on Bengt Gerdin's report. He recommends that UKÄ asks the persons who submitted the complaints what level of interest they had in the case. If they are not to be considered 'applicants, appellants or another party' then who is?

According to him, it can be seen from the Board's statement that the decision to extend Paolo Macchiarini's guest professorship never should have been taken. On the other hand, he feels that nothing is said about – as in general with regard to this entire case – how accountability will be demanded from those responsible. As the Board points out, it is even more remarkable that Paolo Macchiarini's employment at KI was extended yet again, this time not as a guest professor, but as a senior researcher. His starting point is that UKÄ will critically review what the Board presents in its statement and take into consideration in this context that several of its members had significant responsibility for the scandal that took place. According to him, they can thus be thought to be disqualified due to a conflict of interest in the matter, which the statement does not address overall. He also assumes UKÄ is doing everything possible to demand true accountability from those responsible for the scandal, which seriously damaged the reputation of both KI and Swedish medicine not only nationally but also internationally.

Another item which he believes the Board's statement barely addresses is how KI's leadership failed to act promptly and sufficiently, not only with regard to the complaint of suspected research misconduct received in August/September 2014, but also regarding the many other warnings received from various sources both before and afterward. He asks UKÄ to review the extent to which vice-chancellor Anders Hamsten's behaviour in this regard should be considered a violation of Section 14 of the Administrative Procedures Act (oral procedure). According to him, there is also reason to review the extent to which Anders Hamsten, Li Tsai, Lars-Olaf Cardell and/or Urban Lendahl, following their meetings with Karl-Henrik Grinnemo, complied with Section 15 of the Administrative Procedures Act and recorded official notes of information submitted orally.

He points out that in addition, it was not long before both the Swedish and international press began writing about the suspicions of research fraud lodged at Macchiarini. One of the first newspapers to address the matter was the New York Times in an article from 24 November 2014. According to him, this obviously caused bad blood within KI's leadership and according to an email message from clinical director Bo Tideholm at the ear, nose and throat clinic in Huddinge, KI's press secretary contacted the New York Times editorial staff to determine who leaked the story. He asserts this information would have confirmed that Karl-Henrik Grinnemo, one of the persons who submitted the complaints, gave the information to the newspaper. If this is true – which there is no reason to doubt – he asks UKÄ to review the extent to which, on the part of KI, this amounts to a violation of the freedom of disclosure as stipulated in Chapter 1, Section 1, paragraph three of the Freedom of the Press Act and in Chapter 1, Section 2 of the Fundamental Law on Freedom of Expression.

He considers the first true action to have been in late November 2014, when, after having received a written complaint about Paolo Macchiarini in August, Anders Hamsten appointed Bengt Gerdin as external reviewer. Thereafter, according to him, it took several more months before KI could present the requested documentation. As he stated previously, however, Bengt Gerdin never received a large portion of the documentation that existed and which he had requested.

He asks UKÄ to determine whether this handling of serious verbal warnings of illegal activities (police reports from the Medical Products Agency and the Health and Social Care Inspectorate) which seriously harmed a number of patients and caused their deaths should not lead to reports to the police of the responsible individuals among KI's leadership.

The Swedish Higher Education Authority's conclusion

Scope of the Swedish Higher Education Authority's inquiry

UKÄ's task in its capacity as a regulatory authority for higher education institutions is to ensure that HEIs comply with the regulations applicable to their operations. The Authority cannot, however, change or retry the decision of a higher education institution. Nor does UKÄ investigate issues that belong to other agencies' areas of responsibility.

Matters of crime are investigated by the Swedish Police Authority. NN's contention that KI employees are guilty of a crime and that UKÄ should investigate whether the handling of verbal warnings of illegal activities should lead to the responsible members of KI's leadership being reported to the police will therefore not result in any action by the Authority. This also applies to NN's assertion that KI violated the freedom of disclosure, because it is the Chancellor of Justice that is responsible for investigating matters of criminal violations of the Freedom of the Press Act and the Fundamental Law on Freedom of Expression. NN may notify the Swedish Police Authority and the Chancellor of Justice himself.

UKÄ does not typically comment on an HEI's application of the law without the HEI having the opportunity to comment on the matter. NN asserts that a conflict of interest has occurred in conjunction with the KI board submitting comments to UKÄ. However, UKÄ does not find any reason to request a statement from KI on this matter. NN's assertion about a conflict of interest will therefore not result in any further statements or actions from UKÄ.

With respect to NN's statement about demanding accountability, UKÄ would like to emphasise the following. According to Section 1 of the Ordinance containing Instructions for the Swedish Higher Education Authority (2012:810), the Authority is responsible, among other things, for tasks regarding oversight of the higher education institutions included in the Higher Education Act (1992:1434). According to Section 6 of the same ordinance, the agency is to supervise operations within its area of responsibility. However, the Parliamentary Ombudsmen (JO) oversees government authorities as such, including public higher education institutions, but also individual officials at these authorities; compare with Section 2 the Act (1986:765) with instructions for the Parliamentary Ombudsmen. JO may also report an official to be the subject of disciplinary review, deprivation of office or dismissal (see Section 6 of the instructions named above). NN may contact JO with his statement.

With respect to NN's assertion that some officials at KI would not have met the requirements of Sections 14 and 15 of the Administrative Procedures Act (on oral procedure and official notes), UKÄ has the following considerations. UKÄ's investigation in this case has focused on the issues which the Authority has found most pressing from a regulatory perspective. These issues include how KI handled written complaints of research misconduct and several email messages from Professor Pierre Delaere in some specific respects. In light of this, UKÄ will not take any action with reference to NN's assertions of insufficient compliance with the requirements of Sections 14 and 15 of the Administrative Procedures Act (1986:223).

Basis for the inquiry into the case

In its investigation, the KI review has identified a number of problems at KI, which were related in one way or another to Paolo Macchiarini and his activities at the HEI. Below, UKÄ will describe the Authority's assessment of what emerged from the KI review in light of the elements referred to above, and in light of KI's response to the Authority's special referral for comment to the HEI. UKÄ has thus operated from the assumption that KI considers the information presented in the KI review to be correct.

UKÄ cannot comment on the surgeries carried out by Paolo Macchiarini at Karolinska University Hospital because the hospital is not supervised by UKÄ.

Finally, it can be noted in this section that Paolo Macchiarini was employed at KI from 2010–2016. However, UKÄ's inquiry does not include, as reported in the *Background* section, anything with a direct connection to the time period when former head of UKÄ Harriet Wallberg was vice-chancellor of Karolinska Institutet, i.e. through the end of 2012.

Public documents and registration, etc.

It has emerged from the KI review that at an early phase, the investigation encountered problems related to how KI handles public documents. The problems included the fact that many public documents that should have been registered were not registered and that documents were registered long after they were received or prepared by KI. A document is public if it is stored with an agency and can be considered to have been received or prepared by the agency (Chapter 2, Section 2, paragraph one, Freedom of the Press Act). Public documents, with a few exceptions that are not relevant to this section, are to be registered as soon as they have been received or prepared by an agency; compare with Chapter 5, Section 1, paragraph one of the Public Access to Information and Secrecy Act (2009:400). The KI review's overall assessment was that the inadequacies were severe in various formal regards, and the administrative culture was neglectful. The KI review concluded that the regulations in the Freedom of the Press Act and the Public Access to Information and Secrecy Act regarding public documents and registration appeared to be, in many respects, unknown or matters of little interest and observed only to a limited extent.

The problems described in the KI review are noteworthy. The KI review recommends that the HEI should ensure that staff receive the necessary information about, among other things, regulations regarding public documents and registration. In its action plan, KI has stated that an analysis will be carried out on the needs for knowledge among the various job roles; that expertise is to be found centrally at the HEI; and that sufficient knowledge is to be provided to others based on the individual and position. UKÄ will follow up this work and carry out random controls to check compliance with the Freedom of the Press Act and Public Access to Information and Secrecy Act at KI.

Extension of Paolo Macchiarini's employment in 2013

It has emerged from the KI review that Paolo Macchiarini's appointment as guest professor was extended in 2013 even though he was not employed elsewhere at that time, despite the fact that this was a requirement of KI's applicable appointments procedure at that time. The KI review also asserts that this was known to the department leaders at CLINTEC, but that this information was never passed on to the Recruitment Committee. According to the assessment in the KI review, KI's failure to check whether the requirement for other employment was still fulfilled was a deficiency.

UKÄ has obtained from KI the relevant appointments procedure, which specifies the following under '3.3 Guest professorship' (p. 6).

'A guest professor at KI is to be employed at another university, whether Swedish or non-Swedish, company or some other agency or organisation.'

In its statement to UKÄ, KI has admitted that the case was handled improperly. The HEI has also asserted that even if at this point in time were no statutory requirements, i.e. in the Higher Education Act or in the Higher Education Ordinance (1993:100), stipulating that a guest professorship demanded that the individual had primary employment at another HEI, this requirement was clearly included in KI's appointments procedure.

UKÄ concludes that KI has violated its own appointments procedure. KI is to be criticized for this.

Paolo Macchiarini's employment as senior researcher in 2015

The KI review notes that the final position held by Paolo Macchiarini at KI was a position as senior researcher. It is also noted that he was offered this position after he was assessed by experts, found to be competent as a professor, and placed at the top of the list by all experts.

However, it has not emerged from the KI review whether this position was announced as vacant in accordance with Section 6 of the Employment Ordinance (1994:373).

Paragraph one of the aforementioned regulation states that an authority that intends to hire an employee must suitably announce this information so that those who are interested in the position can inform the authority within a certain amount of time. According to Section 6, paragraph three of the Employment Ordinance, however, information about a position according to paragraph one does not need to be provided if there are special reasons to the contrary.

KI has argued that the position was not announced as vacant because the HEI determined that special reasons rendered the announcement unnecessary. According to KI, it seemed obvious that the position could not be filled by another applicant because it was based on the continuation of an ongoing research project.

UKÄ notes that it has now emerged that in 2015, in conjunction with Paolo Macchiarini's appointment to his final position at KI, then as a senior researcher, KI decided that there were special reasons that rendered such an announcement unnecessary. As mentioned in the *Scope of the Swedish Higher Education Authority's inquiry* section, UKÄ cannot re-examine a decision by an HEI and the Authority therefore will not comment on KI's decision not to announce the available position as vacant.

Reporting of secondary occupations

The KI review notes that all staff at KI are encouraged to submit a report each year of their secondary occupations via a special form. However, this does not appear to have been done for the years 2013–2014, which according to KI is because the system for reporting was being overhauled. The KI review considered it to be highly unclear as to why this prevented reporting from taking place. The Authority finds it remarkable that no reporting was requested for the years 2013–2014.

With regard to Paolo Macchiarini's secondary occupations in particular, the KI review reveals, in summary, that in 2015, KI received an anonymous complaint pertaining to suspicions of prohibited secondary occupations, whereupon the internal audit department was tasked with investigating whether there were transactions between KI and an external party that could be a violation of the principle of objectivity and entail a risk of being a secondary occupation that may damage confidence. According to the KI review, the internal auditors determined that reports of secondary occupations for the year 2015 were correct and complete. However, the KI review did state that six months later, the Committee for Staff Direct Responsibility at KI concluded that the activities in Russia were not aligned with KI's fundamental values.

The KI review judged the fact that, since the internal audit department's investigation was limited to financial transactions that could be conflicts of interest, this resulted in a risk that secondary occupations which may damage confidence for other reasons went unobserved. Further, the review noted that the limited investigation also entailed turning a blind eye to rather apparent risks of conflicts of interest. The KI review concluded that according to the Public Employment Act (1994:260), an employer is liable for intervening if an employee has a secondary occupation that may damage confidence and that there is no leeway for the employer to waive the prohibition of secondary occupations that may damage confidence.

According to Chapter 3, Section 7 of the Higher Education Act, in parallel with their teaching posts, teachers at HEIs may undertake employment or assignments or pursue activities relating to research and development work within the subject area of their posts, if in doing so they do not undermine the confidence of the general public in the HEI. Such secondary occupations, according to the same regulation, are to be kept clearly separate from the tasks assigned to teachers within their posts. Otherwise, issues relating to secondary occupations are also subject to the provisions stipulated in the Public Employment Act, LOA. According to Section 7 of LOA, an employee may not hold any position or pursue any assignments or activities that may adversely affect confidence in his or any other employee's impartiality in the work or that may harm the reputation of the authority. This ban includes secondary occupations that constitute a conflict of

interest pursuant to Section 11 of the Administrative Procedures Act. Section 7 c of LOA stipulates that an employer is to decide that an employee who has or intends to undertake a secondary occupation that is not compatible with Section 7 is to cease with or not undertake such a secondary occupation. The ban on public employees engaging in secondary occupations that may damage confidence serves an important function in maintaining the public's trust, as does the system that exists to monitor the secondary occupations of public servants (see Govt. Bill 2000/01:147 p. 10).

UKÄ concurs with the views conveyed in the KI review and is critical of the inadequate review of Paolo Macchiarini's secondary occupations.

The KI review recommended in this section that KI should review the procedures for assessing employees' secondary occupations. The action plan states that new regulations in this regard were decided by the vice-chancellor on 14 September 2016. UKÄ has obtained these regulations from KI (Regulations pertaining to secondary occupations, reg. no. 1-627/2016). The Authority concludes that the regulations appear to be fit for purpose. However, UKÄ intends to follow up KI's handling of secondary occupations and to carry out random controls with KI to monitor compliance with these regulations.

The email messages from Professor Pierre Delaere

Email message from 16 July 2013

The email message from Professor Pierre Delaere to KI's vice-chancellor at the time, Anders Hamsten, is discussed in detail in the KI review in the section on the extension of Paolo Macchiarini's employment in 2013. It mainly states that Professor Pierre Delaere pointed out, among other things, that he suspected that Paolo Macchiarini had been using prosthetic tracheas since 2008 without first conducting trials with animals. Moreover, the KI review states that Professor Pierre Delaere concluded the email with the words:

'We (and others) have been fighting the "tissue-engineered airway" since 2008. We do hope that the Karolinska Institute will also take actions to avoid further human experimentation with synthetic tracheas.'

From the KI review it can be seen that according to Anders Hamsten, the message arrived when the decision had already been taken not to carry out further artificial trachea transplants at KI, which is why it was set aside. It also states that the message did, however, initiate a discussion and Anders Hamsten stated that Professor Pierre Delaere's objections contributed to the decision to arrange a research meeting that autumn to evaluate the scientific status of the field. However, the email message was neither mentioned nor commented on otherwise any further in the assessment in the KI review.

From the email message, the primary content of which is described in greater detail in the referral for comment from UKÄ to KI referenced above, it can be seen, in summary, that Professor Pierre Delaere felt that Paolo Macchiarini misled the research community with the unrealistic possibility that prosthetic tracheas were transformed into living tracheas; that Paolo Macchiarini had been using these prostheses in patients since 2008 without first conducting trials with animals; that the results for patients were catastrophic and that, among other things, KI participated in promoting this unethical approach.

According to Chapter 1, Section 3 of the Higher Education Act, academic credibility and good research practice are to be upheld in the operations of higher education institutions. According to Chapter 1, Section 16 of the Higher Education Ordinance, a higher education institution which, via complaint or in some other way, is made aware of suspected research misconduct must investigate these suspicions. This means that an explicit complaint of research misconduct need not exist for a higher education institution to be obligated to investigate a matter of misconduct. It is sufficient for a higher education institution to be aware of suspected misconduct for the institution to be obligated to initiate an investigation.

In its statement to UKÄ, KI asserted that the Board of the HEI has not managed to find any satisfactory explanation for why Pierre Delaere's email on 16 July 2013 did not cause any action of any kind, or the obvious decision, according to the Board, to investigate suspected research misconduct. KI considers the HEI's behaviour at this point in time remarkable, and asserts that the email message contains more than enough information for KI to have taken action immediately. KI has conveyed that the HEI should therefore have launched an investigation into suspected research misconduct in light of the indications that emerged.

UKÄ shares the KI Board's assessment that an investigation should have been launched. KI is to be criticized for its failure to investigate the suspicions of research misconduct raised in Pierre Delaere's email message to the HEI on 16 July 2013.

Email message in April 2014

From the KI review, it can be seen that in another email message in April 2014, Pierre Delaere stated the following.

'Last Tuesday I attended a meeting on the bioengineered trachea in Paris. The Karolinska series was presented by Philippe Jungebluth. This day fully confirmed that the bioengineered trachea is a big lie and one of the most extreme examples of research misconduct in medical history'

The KI review noted that this email message was received by Thomas Fux and forwarded to Karl-Henrik Grinnemo, who in turn forwarded it to the unit head Lars-Olaf Cardell, Urban Lendahl and department head Li Felländer-Tsai. The KI review notes that Li Felländer-Tsai then gave the following response:

'Thank you for your email with this serious information which we three have now discussed. There are several different issues which you are addressing and which are handled via separate mechanisms. Please contact Professor Richard Kuylenstierna to review the patient information. This matter has already been discussed and Richard has been appointed the contact person for these issues. On 27 March 2014, Ulf Lockowandt was asked to contact Richard regarding this case in order to move forward... Publication questions may be addressed directly to the ethics counsel.'

The email message from Pierre Delaere in April 2014 was also neither addressed nor commented on any further in the assessments in the KI review.

In its comment to UKÄ in this section, KI's Board has in summary stated that their interpretation of information and facts having been obtained from the individuals involved with KI at the time of the event is that an inquiry had already begun in February 2014. KI has stated that it understands, however, from the informants, that the review did not include research misconduct. Nor is it clear, according to KI, if the already launched investigation included the assertions made in Pierre Delaere's email message from April 2014. Meanwhile, KI believes that the content of the relevant email message should have resulted in the immediate launch of an investigation into research misconduct.

UKÄ concurs with KI's assessment that an investigation should have been launched immediately. The Authority believes the formulation: '[...] the bioengineered trachea is a big lie and one of the most extreme examples of research misconduct in medical history' in the relevant email message must obviously be thought to have contained accusations of research misconduct. The investigation in the case has not indicated that the email message resulted in an investigation of research misconduct. KI therefore deserves criticism of the handling of Professor Pierre Delaere's email message in April 2014.

KI's handling of the complaints of research misconduct on 24 June 2014, 25 June 2014 and 18 August 2014

The section *KI's handling of complaints of misconduct* above provides an account of what emerged from the KI review about how KI handled the complaints of research misconduct submitted by Corbascio et al. and Simonson et al. (reg. no. 2-2184/2014) as well as by Professor Pierre Delaere (reg. no 2-2167/2014). The section also presents the KI review's assessment of how it handled these complaints. This assessment was made based on the provisions in the Higher Education Ordinance on investigating suspected research misconduct (Chapter 1, Section 16 of the Higher Education Ordinance) and the provisions in the Administrative Procedures Act on the parties' right to information and a justification of the decision.

UKÄ observes that pursuant to the regulations of the Administrative Procedures Act, an applicant, appellant or another party is entitled to know the information that has been supplied in the case, if this involves the exercise of public authority in relation to an individual (Section 16 of the Administrative Procedures Act). Moreover, a case may not be decided without the applicant, appellant or other party being notified of information that has been supplied in the case by someone other than himself or herself, and he or she has been given an opportunity to comment on this information, if the case involves the exercise of public authority in relation to an individual. The authority may however make a decision in the case without this having occurred if the decision is not adverse to the party, if the information is not significant, or if the measures for any other reason are obviously unnecessary (Section 17 of the Administrative Procedures Act). A decision whereby a matter is determined by an authority is to include the reasons that settled the outcome when the matter concerns the exercise of public authority in relation to an individual. The provisions stated above from Chapter 1, Section 16 of the Higher Education Ordinance mean that an HEI is obligated to ensure that a case of research misconduct is satisfactorily investigated.

The conclusions of the KI review were that the university's handling of the cases of alleged research misconduct were unsatisfactory in various ways and merited criticism. The inadequacies established in the KI review were, in summary, that no consistent procedures for case management seemed to have existed; that KI did not ensure that the external reviewer was provided with the material he requested; that the decision from August 2015 was not sufficiently justified; and that the handling of the case received in August 2014 contained several mistakes. These mistakes pertained, among other things, to the formulation of the assignment to the external reviewer and the fact that too much time passed before Paolo Macchiarini was notified of the complaint.

UKÄ concurs with the criticism of the handling of the misconduct cases expressed in the KI review in the areas mentioned in the preceding paragraph.

With regard to the case with reg. no. 2-2184/2014 in particular, UKÄ notes that the KI review assessed that it was not possible to argue that the vice-chancellor made a formal error when he did not give the external reviewer the opportunity to comment on statements from Paolo Macchiarini and the other co-authors. However, the KI review judged this to be inappropriate (see above under the section *KI's handling of complaints of misconduct*).

Regarding this matter, in the special referral for comment to KI, UKÄ asked the HEI to state why the external reviewer was not given the opportunity to comment on the reported authors' views of the review before a decision was made in the case. In its response, KI reported that the matter was discussed by the vice-chancellor, the university director, the head lawyer and the lawyer in charge of the case, but the consensus was that the external reviewer had completed his task upon submitting his opinion on 13 May 2015. Furthermore, KI stated that an external reviewer who assists in an investigation is not considered a formal party, but that it naturally would have been appropriate to give the external reviewer these opportunities if for no other reason than to lend credibility and legitimacy to the decision the vice-chancellor had to make. The HEI has not, however, in light of the provided information, been able to respond to or explain why the vice-chancellor at the time chose not to give the external reviewer the opportunity to be informed of, and the opportunity to comment on, the responses from the authors.

UKÄ shares KI's understanding that the external reviewer was not a party and there was thus no formal obligation, according to the Administrative Procedures Act, to give him the chance to comment on the statements of Paolo Macchiarini and the other co-authors. Nevertheless, KI must uphold good research practice and did have an obligation, according to the Higher Education Ordinance, to investigate the suspicions of research misconduct conveyed by the persons who submitted the complaints. To carry out this obligation, KI chose to engage an external reviewer, who stated in the report that he believed research misconduct had occurred. In the responses from the reported individuals to the external reviewer's statements, according to the assessment in KI's decision, new material emerged that served as the basis for KI's conclusion that research misconduct had not occurred. In light of KI's obligation to conduct an investigation in accordance with the Higher Education Ordinance, it seems remarkable that the external reviewer was not given the opportunity to comment on the new material provided by the reported individuals before the case was decided.

The Authority has also asked KI to respond to why the persons who submitted the

complaints in the case reg. no. 2-2184/2014 were not given the opportunity to comment on the authors' comments. KI responded that this question did not seem to have been discussed, but they understand that at the time, an assessment was made that in this case, the persons who submitted the complaints could not be deemed to have such a justified interest in the case as to be a real party in interest and thereby be treated as a party according to the provisions of Sections 16 and 17 of the Administrative Procedures Act. KI has also stated that even if these regulations guided the decision at the time to not permit the persons who submitted the complaints to comment, they did not prevent the HEI from holding a dialogue with the persons who submitted the complaints and asserted that it therefore would have been appropriate for this to have occurred.

Concerning this matter, UKÄ finds cause to express the following. If a regulatory authority can intervene *ex officio*, then anyone at all, through a complaint, can direct the attention of the authority to a certain condition. The main rule is therefore that a person who submitted the complaint is not considered a party (see i.e. Strömberg, Håkan and Lundell, Bengt, General administrative law, 26u, 2015, p. 90). From Chapter 1, Section 16 of the Higher Education Ordinance, it follows that an HEI is obligated to investigate suspected research misconduct *ex officio*. UKÄ therefore finds, like KI, that the HEI had no formal obligation according to Section 17 of the Administrative Procedures Act to give the persons who submitted the complaints the chance to comment on the reported authors' statements. NN's assertions in relation to this matter do not provide cause for UKÄ to change its assessment. Meanwhile, like KI, the Authority believes it would have been appropriate to give the persons who submitted the complaints the opportunity to submit their views on the reported authors' statements – especially with reference to, as was reported above, the crucial importance given to the authors' comments in KI's decision that no research misconduct had occurred.

The KI review recommended that KI establish guidelines and procedures for handling cases of research misconduct. In the action plan, KI stated that this has essentially been implemented and would be completed on 31 December 2016. In the special referral for comment, UKÄ asked KI to submit the relevant guidelines and procedures. KI informed UKÄ that they are not yet completed. The Authority therefore intends to review the guidelines and procedures in a special order at a later date.

Concluding assessments

Paolo Macchiarini's activities at KI and Karolinska University Hospital have been addressed in many different ways, including in an extensive preliminary investigation by the Swedish Prosecution Authority.

UKÄ is tasked with reviewing the issues that fall within the framework of the Authority's supervisory activities, i.e., how KI has complied with the applicable formal regulations related to Paolo Macchiarini and his activities at the HEI. The assessments made by UKÄ in this supervisory decision lead the Authority, in summary, to express severe criticism of KI. Overall, the investigation into the case gives the impression that KI wanted to protect Paolo Macchiarini's reputation as a researcher at all costs and retain him as an employee. The reasons for this assessment include KI:

- neglecting to fully examine his secondary occupations,
- not investigating several suspicions against him regarding research misconduct,
- insufficiently conducting the investigations of research misconduct that were actually initiated regarding him, and

- extending one of his employment contracts in contradiction to the higher education institution's appointments procedure.

The shortcomings discovered are such that UKÄ cannot be satisfied with this criticism. Therefore, in 2018 the Authority will follow up KI's work with its action plan and, in particular areas, UKÄ will review policy documents and cases at KI, the latter through special random controls. The special review areas will include:

- compliance with the Freedom of the Press Act and Public Access to Information and Secrecy Act,
- reporting of secondary occupations,
- guidelines for handling complaints of research misconduct, and
- employment cases

A copy of the decision will be submitted to the Ministry of Education and Research for its information. The case is concluded with these notifications and the severe criticism expressed above.

The decision in the case has been taken by general director Anders Söderholm following the presentation by legal officer Carl Braunerhielm in the presence of chief legal adviser Christian Sjöstrand, strategy and planning manager Per Westman, and communications manager Agneta Rolfer.

Anders Söderholm

Carl Braunerhielm

Copy to:

Government Office, Ministry of Education and Research

NN