Integrity in science

Guidelines of the SAMS for scientific integrity in medical and biomedical research and for the procedure to be followed in cases of misconduct

Preamble

In scientific research, the commitment to truthfulness is indispensable. It is the basis of all scientific activity. It is also a precondition for the credibility of science and the foundation for the privilege of freedom of scientific research.

Scientific misconduct puts confidence in science as a whole at risk. The increasing worldwide competitiveness of biomedical research, as well as the growing pressure on researchers to achieve results and to obtain financing make it necessary to establish standards for honest research work. As adherence to these standards can scarcely be assured by the law or by the state judiciary, primarily science itself has to provide its own regulations in this respect. Procedures for how to act in cases of alleged misconduct must be established.

At its meeting of 3 June 1999 the Senate of the Swiss Academy of Medical Sciences (SAMS) decided to create a *Committee for Scientific Integrity in Medical and Biomedical Research*, hereinafter called "CIS") and charged this committee with the drawing up of guidelines in regard to scientific integrity.

The CIS was also charged with proposing, at the level of the SAMS, an organisation which would be able to act as an appeal instance for future procedures and in special cases also to act as the sole authority for handling allegations of misconduct throughout Switzerland.

Guidelines

1. Area of application

These guidelines on research integrity are intended to regulate the conduct of researchers and scientific experts in public institutions in Switzerland where medical and biomedical research projects are carried out (hereinafter called "research institutions"), especially medical faculties, public hospitals and research institutes.

The guidelines furthermore apply to the conduct of researchers in the public as well as the private sectors, as far as they appear as authors of published works or apply for financing by public funding agencies.

These guidelines take into account foreign models, especially the current regulations in Germany [1], the United Kingdom [2, 3], North America [4] and Denmark [5]. They regulate neither questions relating to the political expediency of research projects nor ethical questions arising in connection with research projects involving humans or animals.

2. Scientific integrity in medical and biomedical research

The following rules of conduct are not conclusive. The SAMS recommends that the research institutions implement them considering the specific local conditions. These rules should constitute an integral part of the teaching and training of young scientists.

2.1. Priority of quality over quantity

In research, quality must take priority over quantitative aspects. For example, in principle more weight should be placed on the originality of the project, the importance of the conclusions, the accuracy of the basic data and the reliability of the findings than on the speed with which the results are obtained and the number of publications resulting from the research (see Para 2.5).

2.2. Planning of research

Even though the results of a research project cannot be predicted, the research work must be carefully planned. The research plan and any subsequent changes must be put down in writing. It must be clearly comprehensible for the members

Translated from the official version in German, June 2002

of the project team and for third parties who may wish to check the results of the research.

The plan must provide information on the persons responsible for the project, the financing, the financial sources and the handling of the basic data.

If a research project is financed by third parties it must be clearly stated to what extent the sponsor has influence on the research in question (planning, performance of the project, evaluation and publication).

If during the planning process it is considered possible for the results to be patented, this should be established in the planning phase by means of an agreement signed by all the participants. It is particularly important that all the researchers refrain from publishing their results until a patent application has been submitted. All such agreements must be attached to the research plan. If the possibility of patenting the findings only becomes evident in the course of the project, all the participants must come to a rapid agreement in this respect and must declare their intention not to publish their findings until a patent has been applied for.

2.3. Basic data

The original experimental results ("basic data") must be documented completely, clearly and accurately, in a manner that as far as possible excludes any damage or loss and any deliberate manipulation, namely by means of a bound laboratory protocol with numbered pages. This also applies to electronically stored data (back-ups on CD-ROM etc.) and to original documents on clinical research projects as described in the research protocol. All authorised persons must be allowed easy access to these records. They should not be accessible to unauthorised persons. In each project it must be established in advance which participants should have access to the basic data, even after they may have withdrawn from the project or institute in question, and for what purposes these data may be used.

Reports on special events occurring in the course of a series of experiments must provide information on any deviations from the original research plan and on unusual events which could become the source of errors, especially of misinterpretations. At the same time as the basic data are obtained, or as soon as possible thereafter, a summary or random assessment of the basic data is to be made, in order to detect, in good time, any possible errors in the design or execution of an experiment or the appearance of unusual outside influences, and to be able to take the necessary corrective measures.

The project leader is responsible for ensuring that the basic data are kept secure for at least ten years after completion of the study.

2.4. Openness

Within the project group, the participants must communicate to each other all information that may be important for the further advancement of the project.

During the course of the project, persons not belonging to the research group can only be given access to information that can be divulged according to the research plan and according to possible agreements made within the project group and with the sponsors.

After completion of the project and publication of the results, as a rule the necessary information should be made available to third parties who wish to repeat and verify the experiments. As far as this is possible, the material obtained in the course of the experiments and which is necessary in order to be able to repeat them must also be made available, provided such material is not obtainable on the open market and provided it is still in stock.

In the event of a procedure for alleged misconduct, the basic data must immediately be made available to the responsible authorities.

2.5. Scientific publications

A person who through his personal work has made a significant scientific contribution in the planning, performance, evaluation or control of the research work should be listed as an author. An executive function in the research institute or financial and organisational support of the project does not give anyone the right to appear as an author.

The head of the research project guarantees the overall accuracy of the content of the publication. The other authors are responsible for the accuracy of those statements that they are able to verify on the basis of their position in the project group.

The partial presentation in separate publications of the results obtained in the course of the project, for the sole purpose of adding to the number of an individual's published titles, and other procedures with the same intent, are not to be permitted.

To ensure optimal transparency and quality of publications in the field of biomedical research, the Vancouver recommendation [6], and for publications of controlled clinical studies the CONSORT Statement [7] should be respected.

2.6. Conflicts of interests and professional secrecy in the preparation of peer reviews

Persons who are contracted by publishers, editors, researchers, sponsors, search committees etc. as experts or peer reviewers to assess the research work or research projects of third parties that are in direct competition with their own work must either refuse the contract or declare the conflict of interests involved and leave it to the contractor to eventually call on the services of another expert.

The expert must treat the information contained in the work concerned as strictly confidential. He must not make use of such information without the consent of the authors.

3. Misconduct and fraud in scientific activity

3.1. Principles

In the event of serious infringements of the principles of scientific integrity which could prejudice the process of obtaining scientific knowledge, and such infringements that harm individual interests worthy of protection, an inquiry will be conducted in order to establish the existence or otherwise of misconduct.

Misconduct is blameworthy if it is intentional or due to negligence. Conduct is considered to be negligent if it violates the generally recognised duty of care, when the person concerned could in fact be expected to respect the rules of duty of care. If a person incites others, especially his/her subordinates, to misconduct, then this misconduct must also be imputed to the person who encouraged it.

In the event of impairment of the process of obtaining scientific information, the inquiry procedure may be initiated officially or on the basis of allegations by any person or persons. If the infringement only harms individual interests, then the inquiry procedure is initiated only at the request of a person who is him-/herself involved.

3.2. Infringements that can prejudice the processes of obtaining and publishing scientific knowledge

Particularly the following are considered as infringements that can prejudice the process of obtaining of scientific knowledge:

- invention of research results;
- deliberate falsification of basic data, false presentation and deliberately misleading processing of research findings, exclusion of basic data without declaration of this fact and without reasons being given (falsification, manipulation);
- removal of stored basic data from the archives before the prescribed retention time for the documentation expires, or after having taken note of requests by third parties for access to these data;
- refusal to grant access to the basic data to duly authorised third parties;
- concealment of the sources of data.

3.3. Infringements that harm individual interests

Particularly the following are considered as infringements that can harm individual interests:

3.3.1. In regard to the research work:

- copying of basic data and other information without the consent of the responsible project leader (data piracy);
- sabotage of the work of other researchers, within or outside one's own research group, namely by deliberately removing and rendering unusable research material, equipment, basic data and other recorded material;
- violation of professional secrecy.

3.3.2. In regard to publication:

- publication, under one's own name, of the results and discoveries of third parties (plagiarism);
- claim of co-authorship without having made any significant scientific contribution to the work;
- deliberate omission of the names of participants in the project who have made significant contributions; deliberate mention, as co-author, of a person who has not made a significant contribution to the work;
- deliberate failure to mention significant contributions to the subject of the research made by other authors;
- intentionally false citations from actual or alleged works of third parties;
- incorrect information on the publication status of one's own work (e.g. "Manuscript submitted", when a manuscript has not yet been submitted; "Publication in Press", when in fact the manuscript has not yet been accepted for publication).

3.3.3. In regard to the expert scientific appraisal (peer review) of the work of third parties:

- deliberate concealment of conflicts of interests;
- violation of professional secrecy;
- misjudgement of projects, programmes or manuscripts, either intentionally or through negligence;
- unsupportable appraisals made for one's own benefit or to the advantage of third parties.

4. Procedure in the event of allegations

A flow chart of the procedure to be followed in the event of an allegation of misconduct is to be found in the Appendix.

4.1. Responsibility

Primarily responsible for the assessment of allegations of misconduct are the competent authorities of those research institutes (Integrity Protection Organization, hereinafter "IPO", see definition: Para. 4.2.2.) in which the infringement is alleged to have occurred; secondary responsibility falls, if necessary, to the IPO of SAMS, in accordance with Para. 5.

4.2. Organisation

4.2.1. Base Institution

The Faculties as base institutions should set up an organisation (IPO) for the handling of allegations of scientific misconduct.

Independent research institutes may join forces, regionally or supraregionally, with various base institutions and jointly set up an IPO, or they may associate with the IPO established by a given university faculty.

4.2.2. Integrity Protection Organisation (IPO)

The members of the IPO are appointed by their base institution or by the Institution's Integrity Protection Commissioner (IPC). All these persons must be independent in respect of the handling of cases of misconduct. They are subject only to the corresponding guidelines and regulations.

The base institution must pay special attention to ensuring that only persons who are independent of any sponsors and who appear to be immune to pressure of any kind are appointed to the IPO.

Each base institution is in principle free to conceive the procedures for integrity protection according to its special circumstances and needs. However, the SAMS recommends that in all cases that can not already be settled by suspension of the procedure in the first phase, the respondent should be allowed a hearing, and that at least for the handling of serious cases the power to decide should be entrusted to persons who have not already been involved in determining the facts in the same case. The following presentation is not binding for the base institutions, but is intended to provide an example of how the procedure can be structured, in order to do justice to the aforementioned principles.

The IPO comprises two persons with long-term responsibility, namely the IPC, who leads the procedure, and the Ombudsman, who serves as contact person and as advisor and arbitrator in simple or minor cases. As long as the IPC has not been appointed, his tasks are incumbent upon the person entrusted with the management of the base institution.

4.2.3. Inquiry Panel

The inquiry panel, with responsibility for establishing the facts, comprises one or more persons. It is appointed by the IPC.

4.2.4. Deciding Authority

The deciding autority is instituted by the base institution, but it can include persons who do not belong to the base institution.

4.3. Conditions of the procedure

4.3.1. Documentation

Written minutes are kept on all steps of the procedure. All the documents are to be collected in a file relating to the case in question and held on record by the IPO or by the base institution.

4.3.2. Confidentiality

In principle, all the procedures are to be treated as confidential. The base institution decides on the time, form and content of a possible publication of facts and results.

Persons making an allegation (whistleblowers have the right to confidentiality. The base institution ensures that they are protected against reprisals or discrimination, especially if the person making the allegation is in a dependent relationship to the person incriminated.

4.3.3. Due process

At the beginning of each phase of the procedure (preliminary examination, determination of the facts, decision on the merits of the case) the respondent must be informed of the composition of each appointed panel. He is to be given the opportunity to challenge the appointment of certain persons because of their partiality. No persons should be allowed to participate in the procedure who may be considered to be potentially biased because of family relationship, close friendship, known animosity, a previous or present competitive situation, financial or organisational dependence on the respondent, the person making the allegation or on other directly or indirectly involved persons and institutions. Not only is actual partiality to be avoided, but also any appearance of partiality.

4.4. Ombudsman: Provision of advice, acceptance and preliminary examination of allegations

The Ombudsman is available to all persons seeking advice on questions of scientific misconduct. Unless expressly authorised by such persons, he treats all information obtained during the discussions as strictly confidential. He takes no action against persons who incriminate themselves in the course of the discussions, unless they authorise him expressly, in the sense of a self-denunciation.

He receives allegations and hears the allega-

tors and the respondent, but he undertakes no investigations.

He can verify, on his own initiative or on behalf of the organisation concerned, the suspicions and accusations made in public against researchers from his area of responsibility and, if appropriate, may propose to the IPC that an investigation be conducted.

In case of a dispute between individuals he attempts a conciliation. In case of minor violation of public interests he can settle the matter on the spot, deciding on the appropriate measures to be taken.

In case of an obviously unfounded allegation he takes no further action. The person making the allegation can, in the sense of an appeal, submit the Ombudsman's decision to reject the allegation to the IPC within 30 days after its notification.

If, on the basis of a preliminary study, the ombudsman considers that a procedure is justified, he refers the matter to the competent inquiry panel or, if one has not been permanently established, to the IPC. In this latter case, the Commissioner designates an inquiry panel, to which the case is referred.

4.5. Fact finding

The inquiry panel conducts the necessary investigations. It gives the respondent the opportunity to speak about the allegation made against him, to submit documentary evidence and to ask for additional investigations. It must listen to the person making the allegation, especially if he asserts that the alleged misconduct has injured him in his individual interests.

In case of allegations of misconduct in connection with publications based on research work in the private sector, the investigation is limited to publicly accessible facts in the public domain.

4.5.1. Suspension of the proceedings

If the investigation reveals that the allegation is unfounded, the inquiry panel calls on the IPC to terminate the procedure.

Upon receipt of a request for suspension of the proceedings, the IPC then hears the views of the respondent and the person making the allegation. He can then suspend the proceedings or refer the case to the deciding authority. Should the respondent request the transfer of the file on to the deciding authority, the IPC must comply with such request, so that the respondent can be formally acquitted and, if appropriate, malicious conduct on the part of the person making the allegation can be officially established.

4.5.2. Referral to the deciding authority

If the investigation reveals that the allegation is fully or partly justified, the inquiry panel refers the dossier directly to the deciding authority or, if one is not permanently established, to the IPC. In this latter case, the IPC requests the base institution to establish an ad hoc deciding authority, to which he then hands over the matter.

4.6. Arriving at a decision on the issue

The deciding authority examines the file and hears the respondent and the person making the allegation.

If new aspects are presented, the deciding authority can ask the inquiry panel to carry out further investigations and to add new findings to the file.

The deciding authority does not itself carry out any investigations, but arrives at its decisions on the basis of the evidence provided by the inquiry panel and the personal hearing of the respondent and, if appropiate, of the person making the allegation.

The respondent and, if appropriate, also the person making the allegation are given the opportunity to present their opinions regarding any new findings.

4.6.1. "Verdict of acquittal"

If the allegation proves to be unfounded ("acquittal"), the decision may also contain observations that, and to what extent, the conduct of the person making the allegation may have been malicious.

4.6.2. "Verdict of guilty"

In case of a fully or partly justified allegation ("verdict of guilty") the decision is limited to establishing which person or persons have committed the misconduct, to noting the nature of the misconduct and of the blame. If necessary, it may also be established within the framework of the decision to what extent the acquisition of scientific knowledge was put at risk or individual interests were damaged.

It is left to the discretion of the deciding authority to complement its decision with a proposal to the base institution, on sanctions that could be imposed against the respondent.

Moreover, the deciding authority can suggest to the base institution measures pertaining to persons or organisational matters in order to reduce the future risk of misconduct. Provided such measures are not addressed either directly or indirectly to the person under investigation, they do not need to be included in the decision, but may be communicated in another way, also in confidential form.

4.6.3. Notification

The deciding authority notifies the respondent, the base institution, and any other such institutions of its decision, together with the justification; in the case of allegations for injury to individual interests it also notifies the person making the allegation.

4.7. Appeal

Persons who, as respondent or as the individually injured party who made the allegation, are aggrieved by the final decision of the deciding authority may appeal the decision to the deciding authority of the SAMS within 30 days of its notification.

5. Integrity Protection Organisation (IPO) of SAMS

The SAMS designates an appeal instance to assess the final decisions of local IPOs.

Furthermore, the SAMS appoints an Ombudsman for the handling of special cases and an IPC, who if necessary convenes an inquiry panel and requests the Executive Committee of the SAMS to set up a deciding authority. The responsibility of these bodies is restricted to cases for which no other assessment organisation is responsible in Switzerland, and to cases that are referred to the SAMS at the request of primarily responsible local or regional assessment organisations, because for an important reason the organisation in question cannot deal with the case itself.

The CIS may be approached for advice at any time by the local organisations – the Ombudsman, the IPC, inquiry panels, and deciding authorities.

6. Recommendations to promoters and sponsors of research

Promoters and sponsors of research must inform all applicants and institutions of their requirements in regard to scientific integrity and their intentions in the case of misconduct in a project that they support [8]. In particular, promoters and sponsors must define their attitude to projects that are carried out in research institutions which do not prescribe guidelines on research integrity for their members and do not have an adequate infrastructure to enable them to investigate cases of alleged misconduct.

Promoters and sponsors of research must commit their experts or peer reviewers to respect the confidential nature of the documents submitted to them.

Research proposal must contain a statement on the nature of the guidelines on research integrity to be followed. They must also indicate who has jurisdiction in the case of allegation of misconduct. This is particularly important in the case of collaborative, joint projects.

7. Concluding provisions

These guidelines were adopted by the Senate of the SAMS at its meeting of 23 May 2002. They come into effect on 1 June 2002.

Members of the committee responsible for the formulation of these guidelines: Prof. Michel R. Cuénod, Lausanne, Chairman; Prof. André Blum, Lausanne; Prof. Christian Brückner, Basel; Prof. Max M. Burger, Basel; Prof. Käthi Geering, Lausanne; Prof. Christian Hess, Berne; Lic. iur. Michelle Salathé, Basel (ex officio); Prof. Andreas Schaffner, Zurich; Prof. Peter M. Suter, Geneva; Prof. Ewald R. Weibel, Berne

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8 See also Art. 32 Para. 3 of the Regulations of the Swiss National Fund on the Granting of Contributions (Schweizerischer Nationalfonds über die Gewährung von Beiträgen), http://www.snf.ch

Appendix

Definitions

CIS: Committee for Scientific Integrity in Medicine and Biomedicine of the Swiss Academy of Medical Sciences (SAMS).

Deciding authority: makes the final determinations on allegations in a procedure to scientific misconduct (see Para. 4.6).

Inquiry panel: carries out the investigations in a procedure on alleged misconduct (see Para. 4.5).

Research institutions: Institutions where medical

and biomedical research projects are carried out, that is, especially medical faculties, public hospitals and research institutes (see Para. 1).

Integrity Protection Commissioner (IPC): As a permanent member of the Integrity Protection Organisation, he is responsible for leading the procedures undertaken in cases of alleged scientific misconduct (see Paras. 4.2.2 and 4.4).

Guidelines on Research Integrity: These present guidelines, drawn up by the CIS, with rules of conduct for researchers and experts and a description of the procedures in case of allegations of scientific misconduct.

Integrity Protection Organisation (IPO): The members of the IPO are appointed by their superior academic institutions (Base Institutions such as University Faculties) or by the corresponding IPC. Each IPO comprises two persons with long-term responsibility, the IPC and the Ombudsman.

Ombudsman: A permanent member of the IPO, available to all persons who seek his advice in matters relating to scientific misconduct (see Para. 4.4). In cases of alleged misconduct, he undertakes a preliminary investigation (see below).

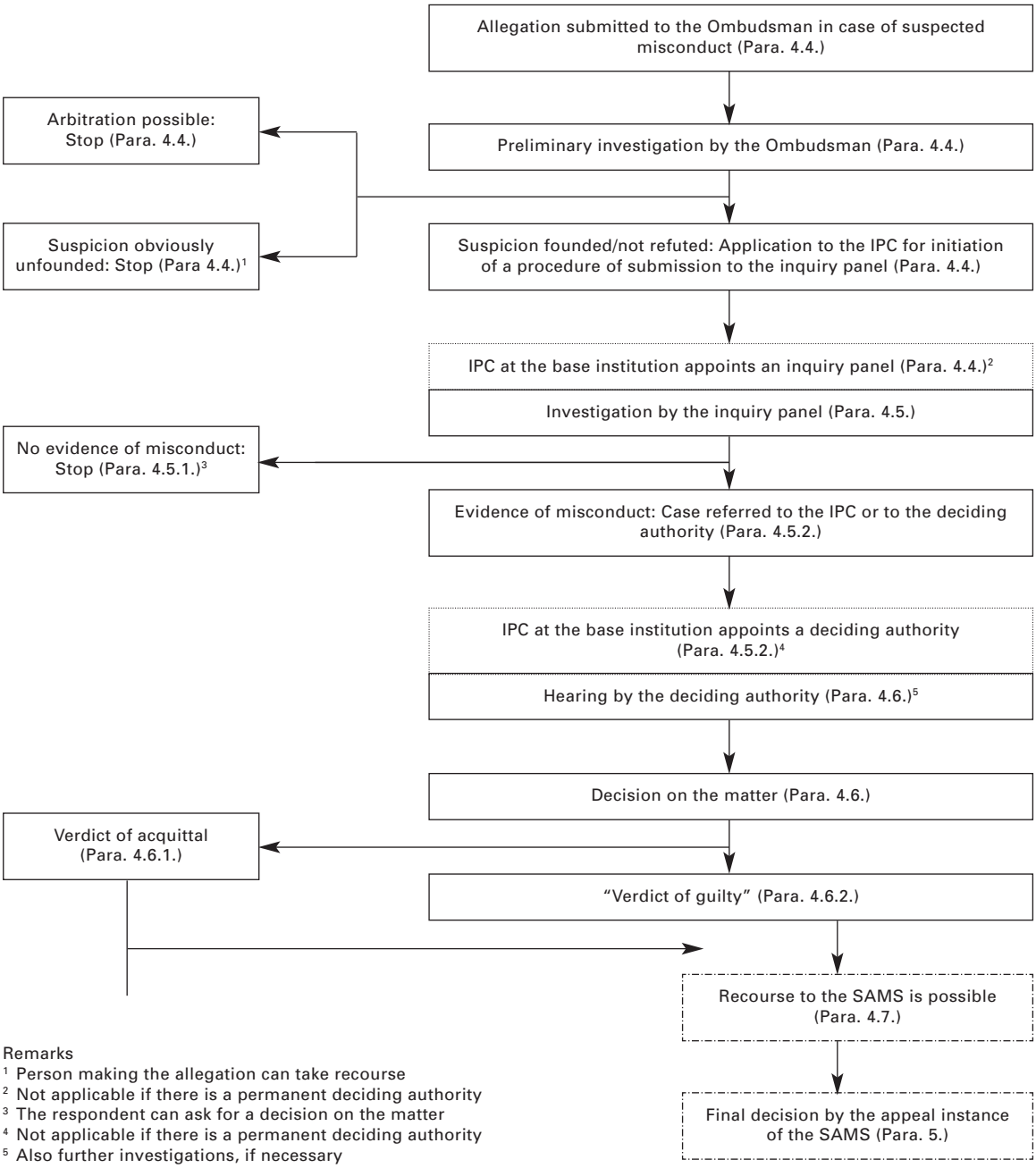
Appeal instance: The deciding authoritiy of the SAMS, part of the CIS, is the appeal instance for final decisions that have been made by local deciding authorities (see Para. 4.7).

Respondent: subject of an allegation of misconduct

Base institution: The medical faculties are as a rule the base institutions of the IPO. Several different faculties may combine to form one base institution for this purpose (see Para. 4.2.1).

Preliminary investigation: An inquiry carried out by the Ombudsman in the case of allegations of scientific misconduct (see Para. 4.4).

Flow chart: Procedures to be followed in the case of alleged misconduct.



Remarks
[1] Person making the allegation can take recourse
[2] Not applicable if there is a permanent deciding authority
[3] The respondent can ask for a decision on the matter
[4] Not applicable if there is a permanent deciding authority
[5] Also further investigations, if necessary

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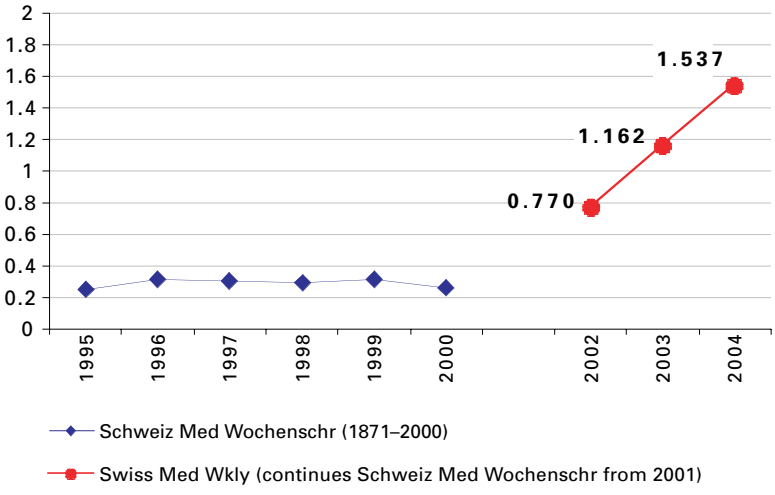

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