Collaboration between medical professionals and industry

Guidelines of the Swiss Academy of Medical Sciences *

«A useful criterion in determining acceptable activities and relationships is: would you be willing to have these arrangements generally known?»

Guidelines of the American College of Physicians, 1990

Contents

*Approved by the Senate on 24 November 2005. These guidelines replace the recommendations of the SAMS on ”Collaboration between the medical profession and industry” from the year 2002. The German version is binding.

Preamble

The collaboration between physicians and industry has long been established, is fundamental for good medical care and contributes considerably to the increase of knowledge. Over the past few years this cooperation has intensified even further, not least because of the partial withdrawal of public involvement.. In itself and particularly within the frame of existing legal requirements and national as well as international codices (see Appendix), this collaboration can lead to conflicts of interest, to financial and professional dependence, or, in exceptional cases, even to conflicts with the law.

For the physicians concerned, be they in research, hospital- or general practice, this collaboration with industry is not only a question of law, but constitutes a central question of professional ethics. In confirmation, and under the title "No more free lunches", an Editorial in the British Medical Journal, states: "There is growing evidence that doctors' prescribing habits are influenced by drug companies, either through discussions with sales representatives or through sales drives dressed up as medical education".[1]

In drawing up its own guidelines, which refine and complement the existing regulations, the medical profession underlines its desire for independence and credibility.

In 2002 the SAMS published, for the first time, its "Recommendations for the collaboration between the medical profession and industry"; as was stated from the outset, they were checked and partially revised after two years, i.e. in the summer of 2004. Along with minor editorial corrections in Chapter I, major changes were made in Chapter II, "Graduate medical training, postgraduate medical training and continuing medical education", and a new Chapter III, "Acceptance of payments in cash or in kind" was added. In addition, the title was changed from "Recommendations" to "Guidelines", and the present guidelines of the FMH (Swiss Medical Association) on the certification of events for continuing medical education in the framework of the FBO (Regulations on Continuing Education) have been incorporated.[2]

The following guidelines apply for the relations between the medical profession and the commercial suppliers of the health-care market, in particular the pharmaceuticals and medicinal products industries, in the fields of clinical research, graduate medical training, postgraduate medical training and continuing medical education, and also in regard to the acceptance of payments in cash or in kind. They are not intended to forbid, but rather to contribute to the promotion of objectivity, quality, transparency, the prevention of dependence and to the proper handling of conflicts of interests.

[1] BMJ 2003; 326: 1155
[2] SÄZ 2004; 85: 16

I. Clinical Research

Introduction

The aim of clinical research is to understand human diseases on a scientific basis and to make this knowledge available for practical application in the development of effective diagnostic and therapeutic methods. Clinical research is the indispensable basis for every advance in medicine.

Clinical research is a complex process over many stages and many years, with the aim of developing better and safer preventive, diagnostic and therapeutic products and procedures; it is carried out in universities, hospitals, research institutes and in general practice. The research conforms to strict scientific, ethical and legal requirements, mainly aimed at ensuring the protection of the trial subjects (see Appendix).

In many areas, the collaboration of clinical research physicians with industry or with research institutes contracted by industry is an important precondition for innovative research. The prospect of financial gain or of gaining publicity with a clinical trial or its results can, however, induce certain investigators to act incorrectly in the planning, performance or evaluation of a trial. The current rules for guaranteeing the quality of research projects and for the protection of the trial subjects taking part in them[3] therefore need to be supplemented by guidelines that contribute to the objectivity of the research, to the prevention of dependence and to the proper handling of conflicts of interests.

[3] Law on Drugs (HMG), Regulations on Clinical Trials (VKlin), Guidelines on Good Clinical Practice (GCP)

Guidelines

1. **Clinical trials are carried out according to the principles of "Good Clinical Practice".**

   Every clinical trial must meet the current scientific and ethical requirements and the existing legal regulations and must conform to the internationally recognised principles of Good Clinical Practice (GCP)[4].

2. **Institutions that carry out clinical research regularly evaluate the quality of the research.**

   The scientific quality of clinical trials has to be assessed on the basis of their originality and methodology, as well as on their results. In this assessment, the quality of the publication, the patentability of the product or the importance of the knowledge arising from the research and its significance for medical practice have to be considered.

3. **All clinical trials are recorded in a central register[5].**

   The purpose of this recording is:

   - to ensure the correct and complete publication of the results, and
   - to exclude subsequent changes to the trial protocol that do not conform to the principle of GCP.

   The register is to be kept by an appropriate public institution and is to be accessible to the public. It is to provide the information on the relevant parameters of a trial.

4. **The responsible investigator and his/her co-workers have no financial interest in the trial or in the results.**

   The investigators who are involved in a trial inform the institution for which they are working of the financial interests associated with their participation. In particular, an investigator who is responsible for a clinical trial and his co-workers may not at the same time be proprietor, partner, member of the board of management or a significant shareholder or consultant of a firm that uses the procedure or manufactures the product that is to be investigated. Any justified exceptions to this rule must be approved by the institution for which the investigator is working.

[4] In addition, in accordance with Art. 9. Para. 2Bst. l of the Regulations on Clinical Research and Drugs (VKlin), the investigator must have the necessary training or experience in the Good Clinical Practice of clinical trials.

[5] Today there exists in Switzerland only one register, managed by Swissmedic (Swiss Agency for Therapeutic Products), in which all the trials with drugs and medicinal products are recorded; this register is intended exclusively for use by the relevant authorities. The SAMS and the FMH (Swiss Medical Association) support the creation of a register that is accessible to the public, according to the Anglo-Saxon model, which records all the clinical trials taking place in Switzerland.

5. The performance and financing of clinical trials is regulated contractually.

Each trial that is carried out on behalf of a sponsor by whom it is financed is covered by a written contract. The contract is to be signed by the responsible investigator (a hospital physician or general practitioner), when appropriate by the responsible representative of the institution for which the investigator is working, and by the sponsor.

The following are to be defined in the contract:

- the clinical trial which is the object of the contract;
- the relation between work performed and compensations in the execution and financing of the trial;
- the remuneration of the responsible investigator, whereby the amount of this should be commensurate with the work performed;
- the access of the responsible investigators to all the data relevant for the carrying out of the trial and for the protection of the participating trial subjects;
- the obligation to publish the results of the trial or to make them accessible to the public;
- the conditions under which the trial can, if necessary, be discontinued; as a rule, this should be for medical-ethical reasons.

6. The payment for the trials is made to special institutional accounts for acquired funds.

All financial contributions by sponsors in connection with clinical trials are paid into accounts that are specifically intended for this. The institution (university, department, hospital, foundation etc.), for which the responsible investigator is working controls access to these accounts.

7. The performance of clinical trials and the purchase of the sponsor's products are independent of each other.

The carrying out of clinical trials may not be dependent, either directly or indirectly, on the purchase of products, nor on agreed conditions of purchase. Likewise, the institution where the clinical trials are to be carried out may not make its decision on the purchase of products dependent, either directly or indirectly, on the carrying out of the clinical trials.

Members of committees that are responsible for the purchase of drugs and medicinal products must make known those of their mandates that could lead to conflicts of interests (management mandates, participation in firms, consultancy contracts, responsibility for, or collaboration in, clinical trials etc.). If conflicts of interests can be foreseen, the committee member concerned may not take part in the decision.

8. In the case of publication and presentation of the results, the financing of a trial must be declared.

In the publications of trial results, an annotation or a footnote must make it clear to the reader who, as sponsor, has financed the trial. When trial results are presented at con-

ferences, congresses and similar events, this fact must be made clear, as must any financial interests of the authors.

9. The interpretation of the results of a trial must be independent of the sponsor's interests.

In the interpretation of trial results in publications and in presentations at conferences, care must be taken to avoid conflicts of interests. The responsible investigator must therefore take special care

- to discuss, in a factual and critical manner, the wanted or unwanted effects of a product or of a procedure that were observed in the course of a clinical trial;
- to present the cost/benefit ratio of the product or procedure investigated as objectively as possible.

10. Investigators who take part in clinical trials are not to be involved in the marketing of the products investigated.

Investigators responsible for, or taking part in a trial may not put their credibility in question by taking part in marketing promotions for the product or procedure investigated.

II. Graduate medical training, postgraduate medical training and continuing medical education

Introduction

More and more diagnostic and therapeutic drugs and procedures are being made available to medicine. The undergraduate medical training, postgraduate medical training and continuing medical education of medical doctors must be constantly adapted to this development. Postgraduate training and continuing education should provide the participants with objective and balanced knowledge, skills and abilities which are useful and necessary for the care of the patients; they are a precondition for proper medical practice.

The continuing medical education prescribed by law implies a considerable additional effort on the part of the physicians. To be considered in this connection are the financial cost for the events of continuing medical education, the loss of working hours and the loss of income. The financing of these costs is not ensured, either at hospitals of for the practising physicians. However, continuing education should not be looked upon as an obligation only; new knowledge constitutes a considerable enrichment for medical activity and is therefore also in the interest of the individual physician.

A significant part of the events for continuing medical education are supported financially (sponsored) or are even organised by the pharmaceuticals industry and the medicinal-products sector (hereinafter called “industry” or “firms”). For many physicians and institutions this has become a matter of course, but it can lead to dependence and conflicts of interests. Guidelines are therefore also useful and practical for this area[6] – all the more so since there are no state regulations on the financing of events of continuing medical education (apart from the disposition in the Regulations on Advertising of Drugs of 17.10.2001[7]).

The considerations regarding support by the industry detailed here for continuing education apply also for graduate and postgraduate medical training.

[6] For details see also Kuhn HP. Disclosure helps – but is not panacea. Schweiz. Ärztezeitung 2002; 83: 2429-2439.

[7] Art. 11, Para. 1 of the Regulations on the Advertising of Drugs: “The costs of representation in connection with scientific congresses or promotional events must be kept within reasonable limits and must be of secondary significance in relation to the main purpose of the event”

Guidelines

1. **The application for recognition of an event for continuing medical education is submitted to the relevant professional association by the physicians or the medical committee responsible for the event.**

   It is the task of the organiser of the event to apply to the relevant professional association for recognition. Such recognition is granted only for events which completely meet the requirements of the present guidelines. The event's contents are to be in agreement with the aims of the Regulations concerning continuing medical education (FBO) of the FMH (Swiss Medical Association) and with the corresponding programmes of the professional associations.

2. **Events for continuing medical education will only be accredited if their contents and schedules are defined, in full, by physicians or a medical committee.**

   In this connection the following conditions, in particular, are applicable:

   - The organisers of the events are, in principle, organisations, institutions or persons competent in the particular specialist field, and not the industry.
   - Financial support is provided by several firms. In exceptional cases requiring justification, sponsoring by a single firm may be acceptable.
   - As a rule a participant's fee is levied. However, for shorter (half-day) events or for in-hospital events, this fee may be waived.
   - Agreements between organisers of events and sponsors must be set down in writing.
   - The organisers of the event, and not the sponsors, draw up the programme (content and schedule) and choose the speakers.
   - The participants must be offered the opportunity to evaluate events of continuing medical education.
   - An eventual social component of the event is to be of minor importance: at least 80% of the time is to be reserved for the scientific an professional part of the event and the relative costs of the two pats reflect this ratio. The social and the scientific part of the event must be kept clearly separate.

   In order to prevent unnecessary administrative procedures, the professional associations can accredit regularly held events of their own, or regularly held in-hospital continuing medical education en bloc and in advance; however, this requires the assurance, in writing, of the professional association or the hospitals concerned, that these courses of continuing medical education meet the requirements of the present guidelines.

3. **The possibilities for prevention, diagnosis and therapy are presented, as far as possible, in accordance with the criteria of evidence-based medicine (EBM) and taking into account their effectiveness and their efficiency, also from an economic viewpoint.**

   The various topics must be handled objectively according to the present state of scientific knowledge and from different (interdisciplinary) viewpoints. The diagnostic and therapeutic possibilities should as a rule be presented exhaustively, and as far as possible, in accordance with the criteria of EBM.

4. **If several different effective drugs, medicinal products or procedures are available for the proposed prevention, diagnosis or therapy, these must be compared as objectively as possible.**

   In the conferences and presentations, drugs are, in principle, to be referred to by their internationally recognised generic name.

5. **Funds obtained through sponsoring are deposited in a special account designated by the organiser (university, institution, foundation, professional association, regional medical association etc.) and are to be used for the organisation of courses for continuing education and for the payment of speakers' fees and expenses.**

   Events to be held in hospitals (lasting one or several days) and which are supported by industry must be approved by the management of the hospital or the department concerned, or by the appropriate institutional authority.

   The control of the finances is the responsibility of the organiser. Budgets and accounts are to be submitted to sponsors and the professional associations, on request.

6. **Physicians taking part in events for continuing education as listeners (i.e. without active participation or presentation of papers or posters) make an appropriate contribution to the costs.**

   In the interests of their independence, the participants in an event for continuing education pay

   a) a participation fee;

   b) an appropriate personal contribution towards the costs for travelling and hotel expenses[8].

   The calculation of the amount of their contribution is based mainly on the duration of the event and the distance between the venue and the participant's place of residence, and also takes into account his/her professional position. For doctors in postgraduate training, exemption from costs by the organiser or payment of the contribution by the employer are justifiable.

   Employed physicians, whose participation in an event for continuing education, a firm wishes to support,, inform their employer of the extent of the support they are receiving

[8] Contributions of CHF 500.- for European events and CHF 1000.- for events outside Europe have proved to be adequate. Full or partial refund of contributions to the costs or remuneration of the indirect costs (loss of working-time and/or loss of income) by firms is not permitted.

and the identity of the sponsor. For doctors in postgraduate training, the invitation is as a rule addressed to the institution, which makes the final decision regarding their participation.

The costs for additional hotel accommodation, travelling or other activities not directly related to the event concerned, are charged, in full, to the participants and to any other persons accompanying them.

7. Speakers and organisers are to make known any personal or institutional commercial interests, financial connections with the sponsor, consultancy on behalf of the sponsor or support of their research provided by the sponsor.

Speakers' fees must be appropriate.

All the sponsors are to be listed in the programme and in the documentation of the event.

Speakers are to make their interests known, in an appropriate manner, to the organiser, to the professional association and, before the start of their presentation, to the participants.

III. Acceptance of payments in cash or in kind

Introduction

Article 38 of the Professional Regulations of the Swiss Medical Association (FMH) states that "acceptance of gifts […] or other benefits [...] from third parties, which may influence the physician in his/her medical decisions and which exceed customary minor recognition of services rendered [...] is not permitted".

Dispositions relevant to this topic have also been included in various laws (Article 33 of the Law on Drugs; Article 56, Para. 3 of the Law on Health Insurance; Article. 322ter ff of the Swiss Civil Code; various cantonal regulations). The following guidelines are to be understood and considered as aids to practical implementation of these requirements.

Guidelines

Physicians in hospitals, in private practice and in research do not accept personal payments, in cash or in kind, which exceed customary minor recognition of services rendered, without a corresponding contract or without adequate service rendered on their part.

In public hospitals, internal rules usually regulate the acceptance of payments in cash or in kind. They determine, within the institution, which gifts are to be approved by, and which only have to be reported to, the superior authority (e.g. by the setting of upper limits or by the preparation of a "positive list").

For all major purchases and orders, a collective signature is required ("four eyes" principle). The acceptance of payments in cash or in kind and the purchasing operations of the institution are to be kept strictly separate from one another.

All agreements on the acceptance of payments in cash or in kind that exceed the upper limits established within the institution are to be drawn up in writing. These agreements also include the assurance that no secondary agreements (oral or implied) have been made. In addition, the purposes for which funds placed in the donor account may be used, are also laid down. The authority to dispose of funds through this account is given according to existing institutional rules.

Glossary

Clinical trial	A study carried out in humans, with which the safety, the efficacy or other properties of a medicine or its bioavailability are investigated systematically (Article 5 Bst. a of the Regulations on Clinical Trials - VKlin).
Continuing medical education	Continuous updating and broadening of professional qualification after completion of postgraduate training; the aim is to ensure the quality of professional practice.
Drugs	Products of chemical or biological origin which are intended for medical application on the human or animal organism or are recommended especially for the detection, prevention or treatment of diseases, injuries and physical disabilities; blood and blood products are also classified as drugs (Article 4, Para. 1 Bst. a, of the Law on Drugs - HMG)
Education	Basic university education (medical studies)
Further-training event	e.g. congresses, conferences, meetings of medical doctors for exchange of experiences (“Quality discussion circles“), Internet-based further training.
GCP	Good Clinical Practice; guidelines for good practice in clinical trials, which are intended on the one hand to ensure the protection of the trial subjects and on the other to guarantee the quality of the results.
Generic name	Internationally recognised active-substance designation (International Non-proprietary Name [INN]; Dénomination commune internationale [DCI])
Gifts	Gifts made without agreement regarding payment and without determination of their purpose.
Institution	e.g. university, hospital, network.
Investigator	A person who is responsible for the practical performance of a clinical trial and for protection of the health and wellbeing of the trial subjects; if an investigator personally starts a clinical trial and undertakes complete responsibility for it, he or she is then at the same time the sponsor (Article 5 Bst. c of the Regulations on Clinical Trials - VKlin).
Medicinal products	Products, including instruments, apparatuses, in-vitro diagnostics, software and other articles or substances, defined, which are intended or recommended for medical use, and whose main effect is not achieved through the use of a drug. (Article 4. Para. 1 Bst. b of the Law on Drugs - HMG).
Medicines	General term for drugs and medicinal products.
Postgraduate training	An evaluable activity, organised according to duration and content, which is intended to deepen and broaden acquired knowledge, skills and abilities, with a view to independent practice of the medical profession; it follows the completion of medical studies.
Sponsor	A person or organisation that undertakes responsibility for the initiation, the management or the financing of a clinical trial.
Sponsoring	Financial support of an event, a project, a publication or other activities without direct equivalent remuneration, but with definition of the purpose, with or without conditions regarding the declaration.
Third-party financing	Financial support which is made available to a person or an institution by an external agency, with agreement on direct remuneration (purpose-oriented financing of projects) and which has the same value for both parties (in comparison with sponsoring).
Trial subjects	Persons who take part in a clinical trial, in whom the investigational medicine is used or who are allocated to a control-group (Article 5 Bst. d of the Regulations on Clinical Trials - VKlin).

Relevant provisions and authorities

Re. I. Clinical research

- National and international regulations for the performance of clinical trials:
  - Forschungsuntersuchungen am Menschen. Medizinisch-ethische Richtlinien der SAMW (Research investigations in humans. Medical-ethical guidelines of the SAMS) (1997)
    http://www.samw.ch/content/Richtlinien/d_Forschungsunters.pdf
  - Integrität in der Wissenschaft. Richtlinien der SAMW für wissenschaftliche Integrität in der medizinischen und biomedizinischen Forschung und für das Verfahren bei Fällen von Unlauterkeit (Integrity in science. Guidelines of the SAMS for scientific integrity in medical and biomedical research and for the procedure in cases of dishonesty) (2002)
    http://www.samw.ch/content/Dokumente/d_CIS_RL.pdf
  - Declaration of the World Medical Association, Helsinki: "Ethical principles for medical research in humans" (revised version, October 2000)

    Original text: http://www.wma.net/e/policy/17-c_e.html
    German: http://www.bundesaerztekammer.de/30/Auslandsdienst/92Helsinki2000.pdf
  - Guideline for Good Clinical Practice, International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)
    Original text: http://www.ifpma.org/pdfifpma/e6.pdf
    German: http://www.amgen.de/apotheker/arbeit/gcp/gcp5.pdf
  - Convention for the protection of human rights and dignity with regard to the application of biology and medicine (Bioethic Convention)
    Original text: http://conventions.coe.int/treaty/en/treaties/html/164.htm
    German: http://www.ruhr-uni-bochum.de/zme/Europarat.htm#dt-0298
  - The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomised trials.
    The Lancet 2001; 357: 1191-1194
  - International Committee of Medical Journals Editors: Uniform requirements for manuscripts submitted to biomedical journals.
    New England Journal of Medicine 1997; 336: 309-315.
  - Clinical Trial Registration: A Statement from the International Committee of Medical Journal Editors. Editorial. Annals of Internal Medicine 2004; 141: 477-478.

- Drug-licensing authorities, laws and other regulations:
  - *Switzerland:* Swissmedic – Swiss Agency for Therapeutic Products,
    www.swissmedic.ch

    Federal Law on Drugs and Medicinal Products (HMG)
    http://www.admin.ch/ch/d/sr/c812_21.html

Regulations of 17 October 2001 on clinical trials and drugs (VKlin)
http://www.admin.ch/ch/d/sr/c812_214_2.html

- *European Union:* European Medical Evaluation Agency, EMEA
  http://www.emea.eu.int/

  Guideline 2001/20/EC of the European Parliament and Council of 4 October 2001 on the adjustment of the legal and administrative regulations of the member states on the application of good clinical practice in the performance of clinical trials with drugs for humans
  http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=DE&numdoc=32001L0020&model=guichett

- *USA:* Food and Drug Administration, FDA
  http://www.fda.gov/

  Good Clinical Practice in FDA Regulated Clinical Trials
  http://www.fda.gov/oc/gcp/default.htm

- Codices of industry:
  - Behaviour Codex of the pharmaceuticals industry in Switzerland (Pharmakodex) of 4 December 2003

    http://www.sgci.ch/plugin/template/sgci/*11386
  - Codex of the FASMED (medicinal-products industry)

    http://www.fasmed.co/uploads/Fasmed code-of-conduct.pdf

Re. II. Undergraduate medical training, postgraduate medical training and continuing medical education

- Foreign recommendations and guidelines:
  - Canadian Medical Association. CMA Policy. Physicians and the Pharmaceutical Industry. Update 2001. www.cma.ca
  - Physician-Industry Relations. Part 1: Individual Physicians. Ann Int Med; 2002, 136: 396, Physician-Industry Relations. Part 2: Organizational Issues. Ann Int Med 2002; 136: 403

- Codices of industry:
  - Behaviour Codex of the pharmaceuticals industry in Switzerland (Pharmakodex) of 4 December 2003

    http://www.sgci.ch/plugin/template/sgci/*11386
  - Codex of the FASMED (medicinal-products industry)

    http://www.fasmed.com/uploads/fasmed_code-of-conduct.pdf

Ad III. Acceptance of payments in cash or in kind (monetary-value advantages, privileges)

- Relevant legal texts:
  - Article 33 of the Federal Law on Drugs and Medicinal Products (HMG) of 12.12.2000
  - Article 322ter ff. of the Swiss Legal Code (StGB) of 21.12.1937
  - Article 56, Para. 3 of the Federal Law on Health Insurance (KVG) of 18.3.1994

Members of the working-group responsible for the elaboration of these guidelines

Dr. Hermann Amstad, SAMW, Basel

Prof. Christoph Beglinger, University Hospital, Basel

Prof. Jérôme Biollaz, University Hospital, Lausanne

Dr. Max Giger, FMH, Winterthur

Dr. iur. Dieter Grauer, SGCI Chemie Pharma Schweiz, Zurich

Attorney Hanspeter Kuhn, FMH, Bern

Prof. Urban Laffer, Regional Hospital, Biel/Bienne

Prof. Thomas Lüscher, University Hospital, Zurich

Dr. iur. Jürg Müller, Legal Services, University Hospital, Basel

Lic.iur. Michelle Salathé, SAMS, Basel

Prof. Werner Stauffacher, SAMS, Basel

Dr. Urs Strebel, District Hospital, Männedorf

Contact address

Swiss Academy of Medical Sciences
Petersplatz 13
CH-4051 Basel
Tel. ++41 61 269 90 30
Fax ++41 61 269 90 39
E-Mail mail@samw.ch
www.samw.ch