Collaboration between medical professionals and industry
Guidelines

Collaboration between medical professionals and industry

Approved by the Senate of the SAMS on 2 June 2022.
The German text is the authentic version.
The Swiss Professional Association for Nurses (SBK/ASI) recommends that its members and all other nurses should abide by these guidelines.

The Swiss Academy of Pharmaceutical Sciences (SAPhS) recommends that its members should abide by these guidelines.
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I. PREAMBLE

There is a long tradition of collaboration between physicians and industry. This is essentially in the interests of good healthcare, contributing to the growth of scientific knowledge, the development of new and improvement of existing treatments, and overall medical progress. At the same time, it may undermine independence and lead to conflicts of interest.

Mindful of these tensions, the Swiss Academy of Medical Sciences (SAMS) first published recommendations on “Collaboration between the medical profession and industry” in 2002. In 2005, these were partly revised and reissued as Guidelines, which came into effect in 2006 and were incorporated into the Code of the Swiss Medical Association (FMH). The Guidelines were revised in 2012: in particular, apart from the modification and expansion of various sections, a section on consultancy activities was added. Following the revision of Swiss therapeutic products legislation, the Guidelines were again thoroughly revised and updated.

The current version takes account of new developments and is therefore also addressed to a wider target group. The Guidelines are now no longer intended exclusively for physicians, but also include recommendations for other medical professionals collaborating with the pharmaceutical industry, the medical technology and IT industry, and commercial medical laboratories operating in the health sector.

The Guidelines complement binding legal regulations and the codes of conduct of the various professional organisations. They are designed to ensure that medical professionals declare any interests and can recognise and appropriately manage possible conflicts of interest arising from interactions with industry. In the longer term, however, the existing system should be replaced by new funding models, so as to reduce the risks of conflicts of interest. The aim should be that postgraduate training and continuing medical education are no longer financially supported by industry. Of particular importance in the research sector are initiatives promoting partnerships between industry and health organisations (e.g. health data sharing), based on a jointly developed conception of public welfare.

Guidelines can never offer solutions directly applicable to every individual case. In practice, all parties are to apply and comply with the spirit of the Guidelines to the best of their ability.
II. GUIDELINES

1. Scope
The Guidelines are addressed to medical professionals – in particular, physicians, dentists and pharmacists, but also nurses, medical practice assistants, midwives, physiotherapists and other persons who prescribe, dispense, use or purchase medicinal products and/or medical devices (therapeutic products) (hereinafter: medical professionals), and also to medical professionals in healthcare facilities or training and research centres which employ the above-mentioned persons (hereinafter: health organisations).

The Guidelines are not addressed to industry.

The Guidelines give concrete form to the legal framework and define professional ethical standards for interactions between medical professionals and the pharmaceutical industry, the medical technology and IT industry, and commercial medical laboratories operating in the health sector (hereinafter: industry).

2. Legal and self-regulatory framework
Collaboration between medical professionals, health organisations and industry is regulated by various legal provisions, professional rules and codes of conduct. Particular mention should be made of the Therapeutic Products Act (TPA), the Health Insurance Act, the Ordinance on Integrity and Transparency in relation to Therapeutic Products (TPITO), the Medicinal Products Advertising Ordinance, the Human Research Act (HRA), the Data Protection Act (FADP), the Medical Professions Act, the Health Professions Act, the Psychology Professions Act and the associated Ordinances. Also of particular relevance are the Pharma Code, the Pharma Cooperation Code and the Medtech Code. Medical professionals and health organisations have a duty to comply with the current legal regulations. The present Guidelines complement and give concrete form to these regulations.

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1 On being incorporated into the Code of the Swiss Medical Association (FMH), guidelines become binding for all members of the FMH.
2 In SAMS texts, the term medical is used in a broad sense. The term medical professional thus applies to all persons engaged in medical (sensu stricto), nursing, therapeutic or pharmaceutical tasks, whether in connection with the treatment and care of patients, in specific basic/postgraduate training and continuing education, or in research and consulting activities. The definition used here differs, for example, from that given in the Federal Act of 23 June 2006 on Medical Professions (SR 811.11).
3. **Ethical principles**

Medical conduct must always be guided by a concern for patient welfare and the interests of society. When medical professionals and health organisations collaborate with industry, personal interest and conflicts of interest may influence professional conduct and undermine the credibility of medical professionals and the trust placed in them. It is therefore essential that any interests should be declared, and that possible conflicts of interest should be recognised and managed in accordance with these Guidelines.

3.1. **Definition of conflict of interest**

The Guidelines adopt the definition included in the SAMS Recommendations on the management of conflicts of interest in the development of guidelines and Choosing Wisely lists:5

“According to the definition proposed by the US Institute of Medicine (IOM)6 (Lo et al. 2009), which is based on previous work by Thompson (1993), a conflict of interest is ‘a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest.’ Personal interests may, but need not lead to conflicts of interest. Conflicts of interest may concern the individual or the institution on whose behalf the individual acts (‘institutional conflicts of interest’). [....] Conflicts of interest are not necessarily of a financial nature. Perceptions or behaviour may also be influenced by non-material conflicts of interest (e.g. participation in research or publication projects, enhancement or loss of status, confirmation or questioning of one’s own position, etc.). A distinction is sometimes drawn between direct financial and indirect conflicts of interest, which may ultimately lead to indirect financial gain, e.g. as a result of academic advancement (Schünemann et al. 2015). Relevant in each case are only those conflicts of interest which are related to the topic or task in question.”

3.2. **Principles of action**

The principles of action listed in this section should make it possible:
- to recognise conflicts of interest,
- to avoid conflicts of interest, and
- to manage conflicts of interest transparently and proactively.

3.2.1. **Principle of separation**

Medical action – in particular, vis-à-vis patients – must not be influenced by any benefits or advantages offered, promised or received. The processes and decisions in question are to be strictly separated.

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5 SAMS 2017, Section 3.1.
6 In 2015, the Institute of Medicine (IOM), a US non-profit institution, became the National Academy of Medicine (NAM), part of the National Academies of Sciences, Engineering and Medicine.
3.2.2. **Principle of transparency**
Interests and potential conflicts of interest arising therefrom are to be declared. Pecuniary benefits or advantages must be disclosed and the value of the pecuniary benefits received should be publicly accessible.7

3.2.3. **Principle of equivalence**
Conflicts of interest are to be avoided as far as possible. To prevent any incentives giving rise to conflicts of interest in the first place, benefits must always be proportionate to the services provided. When assessing the value of services provided, it is to be taken into account whether these are already remunerated via other payments provided for by law.

3.2.4. **“Two-pairs-of-eyes” principle**
Consequential decisions should not be taken by one person alone, especially if the individual concerned is subject to a potential conflict of interest. The aim is to reduce the risk of errors and abuses. All contracts concerning financial transactions with industry are to be signed by two persons at each institution.

3.2.5. **Principle of documentation**
The provision of pecuniary benefits and advantages is to be contractually agreed, so that it is clearly apparent what services are to be specifically performed and what remuneration is to be provided. If such agreements concern employees of health organisations, they are to be approved by the employees’ superiors.

3.2.6. **Principle of separation of accounts**
All financial contributions to support teaching and also basic/postgraduate training and continuing medical education are to be clearly and transparently deposited in an account established for this purpose.

3.2.7. **Principle of public perception**
If conflicts of interest are to be recognised as far as possible, self-critical reflection is essential with regard to relationships of dependence and personal interests. In assessing whether a conflict of interest could arise in a particular case, the external perspective must always be taken into consideration. Activities are to be designed in such a way that the public can obtain knowledge of them at any time.

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7 For the achievement of this goal, a transitional period is required. Disclosure must be appropriately structured, taking into account the various forms of collaboration. It must not lead to unjustified attacks on individual physicians.
3.3. Ban on gifts and exemptions therefrom

In a professional relationship, gifts are not appropriate, as they give rise to conflicts of interest. Gifts can take the form of payments in cash or in kind, specifically also items for promotional purposes. Not deemed to be gifts are “advantages of modest value”, i.e. with a maximum total value of CHF 300 per medical professional per year. Such an advantage must be of relevance to medical or pharmaceutical practice, i.e. be directly connected with the practice of the profession and of direct benefit to patients.8

4. Basic/postgraduate training and continuing medical education

Industry traditionally supports basic/postgraduate training and continuing medical education (CME) via endowed professorships, contributions to scholarship and fellowship programmes or grants to CME events and other medical education projects, such as e-learning or self-assessment programmes. In addition, product and procedure training events represent a special form of CME (cf. Section 4.4.). Depending on the circumstances, however, these may also be promotional events, in which case no payments may be made to participants.

By supporting basic/postgraduate training and CME, industry makes an important contribution to knowledge and technology transfer. To date, relationships of dependence and conflicts of interest which may arise as a result of such support have been discussed primarily in relation to CME which is a legal requirement for physicians. Increasingly, however, this topic also concerns other medical professionals, for whom the following remarks are therefore also applicable.

Professional integrity in connection with support for basic/postgraduate training and CME activities means that:
- the educational content and speakers are selected independently of the organisations providing support;
- topics are dealt with objectively and on the basis of scientific criteria;
- collaboration with industry is based on written agreements;
- support provided by industry is also disclosed by the event organiser;
- CME events are supported by more than one company (mono-sponsorship permissible only in justified exceptional cases, cf. section 4.3.5).

4.1. Basic training

Medical professionals are to be made aware at an early stage that conflicts of interest may arise in the exercise of their profession, and they should learn how to manage such conflicts appropriately. Those responsible for basic training should ensure that online events and recommended e-learning tools do not contain any profes-

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8 Based on Art. 55 para. 2 TPA and Art. 3 TPITO.
sional promotion. Information and education materials, items and software provided by industry for educational purposes may only be of modest financial value (cf. section 3.3).

With regard to industry-supported professorships, attention is drawn to the responsibility of higher education institutions (self-regulation). Freedom of research and teaching must be guaranteed at all times.

4.2. Scholarship and fellowship programmes
If scholarship and fellowship programmes are supported by industry, it must be ensured that the sponsor has no influence of any kind on the scientific activities or on the selection of the professionals benefiting from this support. The support must be regulated by a contract.

4.3. Postgraduate training and continuing medical education

4.3.1. Organisation
On the scientific programme committee of a postgraduate training or CME event, the majority of members should be medical professionals. The programme managers should decide independently on the nature of the event and the topics to be covered, and on the selection of participants and speakers. Agreements with industry must be made in writing.

Participants must be given an opportunity to evaluate and provide feedback on the event.

4.3.2. Declaration of interests
Postgraduate training/CME event organisers and speakers must declare any interests, especially financial ties to industry, and specifically consulting activities or research collaborations, in any applications for accreditation, at the start of a presentation, in the invitation and in the programme. The organisations providing support are to be mentioned by name in the preliminary and main programme, in the event documentation, and in presentations and e-learning materials.

4.3.3. Programme
The organisers (cf. section 4.3.1) define the programme and select the speakers. Any accompanying programme is not part of the CME event and is not to be included in the scientific programme. Financial support for accompanying programmes, even if these are of secondary importance, is not permissible. Satellite symposia organised by industry are to be designated as such and do not count as accredited CME events (cf. section 4.3.9).
Topics should be discussed objectively in line with the current state of scientific knowledge and as far as possible from an interdisciplinary perspective. Diagnostic and therapeutic options should be presented comprehensively and essentially in accordance with the criteria of evidence-based medicine. In presentations, medicines are generally to be referred to by their generic names.9

4.3.4. Event venue and virtual events10
The venue (location, accommodation) should be selected on the basis of practical considerations (suitable premises, accessible by public transport) rather than on the basis of attractiveness as a tourist resort.

In the case of virtual events for which credits are awarded, the participants must also register, pay a contribution to the costs, and be invited to evaluate and provide feedback on the event. Wherever possible and appropriate, interactive formats are to be chosen. Promotional displays are only permitted during breaks. In addition, all the guidelines contained in this document are also applicable for virtual events.

4.3.5. Financing
Events are generally to be financed by contributions from participants, the host institution, an association or the professional society, and supported by contributions from industry. In order to avoid undue dependence, support should be sought from a number of mutually independent companies (multi-sponsorship), whose contributions should as far as possible be evenly balanced. Exceptions to multi-sponsorship (e.g. for rare diseases) must be justifiable.

Contributions to support the organisation of an event and advertising income (cf. section 4.3.6) are to be deposited in a dedicated account held by the organiser (university, institution, foundation, professional society, cantonal medical association, agency engaged by the organiser, etc.) and to be used for the organisation of the event and to defray speakers’ fees and expenses. Finances are to be controlled by the event organiser. Budgets and accounts are to be disclosed on request to the professional societies, the Swiss Institute for Postgraduate Training & Continuing Medical Education (SIWF) or the corresponding institutions11 of the professional group in question and to industry sponsors (but cf. section 4.3.6). Any surplus must be used for the purposes of basic/postgraduate training or CME.

10 Cf. SIWF 2021; Scienceindustries 2021.
11 By analogy – for example, in the case of events for pharmacists – these would be the Institute for Pharmaceutical Postgraduate Training and Continuing Education (FPH) or the Swiss Professional Society for Pharmacy and the Swiss Pharmacists Association.
4.3.6. Sales of (online) advertising space and stand rental
Income from sales of (online) advertising space and rental of stands and time slots for industry symposia is to be recorded on an aggregate basis in the event budget. There is no obligation vis-à-vis third parties to break down the contributions or to name the counterparties.

4.3.7. Costs of participation
For events lasting more than a half-day, participants are to make a personal contribution to the costs amounting to at least a third of the event costs\(^{12}\) attributable to them in the case of CME, and at least a fifth in the case of postgraduate training.\(^{13}\)

The costs of any fringe events, extended hotel stays and trips or other activities are to be borne in full by the participants.

Not permissible are full or partial reimbursement of the personal contribution to the costs and/or compensation for participants’ indirect costs (loss of working time or income) by industry.

Information materials and items, including pens and pads, provided for the participants by industry must be of modest value.

4.3.8. Speakers’ fees
Speakers’ fees should be appropriate.\(^{14}\) The assessment of what is appropriate is to be made on a case-by-case basis. Factors to be taken into consideration are the extent of the agreed services, the speaker’s qualifications and the time involved. Whether a speaker is already receiving compensation as part of an existing employment or engagement relationship may additionally be taken into consideration.

4.3.9. Accreditation of continuing medical education events
If a CME event is to count towards the fulfilment of mandatory CME requirements, it must be accredited in advance. The organiser is responsible for applying to the competent body for accreditation. Accreditation will only be granted for CME events which fully comply with the present Guidelines. For CME events to count towards the fulfilment of mandatory CME requirements (credit points), they must be accredited by the competent (national or supranational) professional society or organisation, the cantonal medical association or the SIWF. Accredited postgraduate training centres can award credit points independently.

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12 Cf. Art. 6 TPITO. Calculation: costs of the event including any travel, meal and accommodation costs.
13 Permissible, according to the Pharma Code, is payment for meals (including beverages) on a reasonable and modest scale, subject to a maximum amount of CHF 100 per healthcare professional per meal, but only in direct relation to an event held in Switzerland.
14 Cf. Art. 7 TPITO.
As part of the accreditation process, it must be determined whether the event complies with the goals and requirements of the CME Regulations (FBO) of the SIWF, the CME programmes of the professional societies and the present Guidelines. The accreditation of a CME event (i.e. approval of credit points) must be settled before invitations are sent out. Enquiries concerning credit points must be dealt with by the competent bodies within a period of four weeks. To avoid unnecessary administrative effort, professional societies or the SIWF may grant global or advance accreditation to CME events regularly conducted by the societies themselves or by hospitals or hospital departments; in such cases, however, a written assurance that the entire series of CME events complies with the present Guidelines is required from the professional society or hospital concerned.

4.4. Product and procedure training events
Product and procedure training events offered by industry may have the character of CME or postgraduate training, but may also be promotional events. Particularly for the medical technology and IT sector, they are often a prerequisite for appropriate use of the products concerned. Participation is only permissible if the setting is appropriate. It must be ensured that medical professionals are not unduly influenced.

5. Research and development
Collaboration of researchers with industry or with contract research organisations takes various forms. Research may be supported by financial contributions and the provision of products and/or technical equipment for specific research purposes, or it may be conducted within the framework of strategic partnerships (e.g. endowed professorships) or as paid contract research.

Professional integrity in connection with industry-supported research means that:
- the rules of good scientific practice (Good Laboratory Practice, Good Clinical Practice, etc.) are complied with; in particular, the planning and conduct of a research project and the analysis of data must not be subject to conditions and requirements which influence the results and the publication;
- researchers disclose to the institution where they work, and in the application to the competent research ethics committee, any interests associated with their participation in a research project;
- support is agreed in writing and contributions are deposited in a dedicated account for third-party funds;

15 This is to be distinguished from so-called professional promotion.
16 Cf. Annex 1 Clinical Trials Ordinance.
– any kind of support for research is declared in scientific presentations and publications;\(^{17}\)
– third parties (medical writers\(^{18}\)) involved in the preparation of a publication are mentioned by name and any ties to industry are disclosed.

5.1. **Strategic research partnerships**

Partnerships for joint research projects involving industry and health organisations are of substantial mutual benefit, but they also pose risks. There is a risk of loss of academic freedom or scientific independence if sponsors exert a direct influence on research.

Health organisations should therefore disclose strategic research partnerships on their website and be able to provide information at any time on the extent of support received for research and development.\(^{19}\) Withdrawal from contracts must be legally possible at any time, particularly if the independence of research, the health organisation’s autonomy and reputation, or the freedom of teaching, research and publication are jeopardised as a result of a collaboration. Should this occur, financial support provided in advance is to be repaid on a pro rata basis. When a contract is entered into, attention should be paid to the practicability of such a withdrawal.

5.2. **Clinical research**

Clinical research is comprehensively regulated by the Human Research Act and the associated ordinances. If research projects are supported by industry, this must be contractually agreed. Contracts are to be signed by the researcher responsible (investigator or project leader) and – where appropriate – by the competent representative of the institution where the researcher is employed. Financial contributions are to be deposited in a dedicated account for third-party funds; access must be clearly regulated and verifiable.

5.3. **Start-ups, spin-offs and licensing agreements in the medical devices sector**

Medical professionals may – individually or as part of a group – develop or improve medical devices and technologies, for which, for example, patent applications are filed. In the clinical testing of new medical devices or procedures, a person or group with an intellectual involvement and/or financial interest may participate in the development of criteria for indications and contraindications. It must, however, be excluded that they are involved in establishing the indication for the use of a medical device or procedure in an individual patient before it has been ap-

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\(^{17}\) Cf. Art. 55 para. 2 let. b TPA; Art. 4 TPITO.
\(^{18}\) Cf. Swiss Academies of Arts and Sciences 2013, section 3.2.2; Swiss Academies of Arts and Sciences 2021, section 5.2.5.
\(^{19}\) For the achievement of this goal, a transitional period is required.
proved. Clinical testing of the medical device or procedure should be carried out independently – i.e. by other professionals/groups and ideally at a different institution. In particular cases, it may be appropriate for the “inventors” to be involved in an advisory capacity, as they have the expertise which is required to ensure the necessary quality of testing.

Agreements on the payment of royalties by industry must be made in writing. Royalties paid in exchange for intellectual property must not be subject to a requirement that the products, services or medical technologies produced as a result of the development project be purchased, leased, recommended, prescribed or used by the licensor.

Researchers who are at the same time an owner, partner, board member or significant shareholder of a company which is developing the medical device or procedure to be reviewed must inform the competent research ethics committee accordingly when submitting an application.

Health organisations should require all employees to have any secondary occupations approved and to disclose any interests associated with start-ups, spin-offs or licensing agreements.

5.4. Studies of authorised medicinal products and medical devices

Post-marketing studies of medicinal products or user evaluations of medical devices must investigate a question of scientific relevance. It is permissible to make available products to be evaluated in exchange for a user evaluation. Medical professionals and health organisations must not be inappropriately compensated by the provision of products for evaluation and associated services and/or encouraged to purchase, lease, recommend, prescribe or use the products or services (cf. section 6.2). Medical professionals are not to participate in studies conducted purely for marketing purposes.
6. **Medical services**

Medical services in a broad sense encompass all activities in which medical professionals make their expertise available – in treating patients or developing professional guidelines, but also as members of advisory bodies. In all these activities, interactions with industry are unavoidable. It must be ensured that:

- treatment decisions, particularly also the prescription of medicinal products, are always based on recognised medical (and pharmaceutical) sciences;
- consultancy agreements are made in writing;
- interests are disclosed (e.g. in collaboration agreements);
- consultancy fees are proportionate to the effort involved and payments are effected transparently (“two-pairs-of-eyes” principle); direct payments are to be avoided;
- consultancy functions are based on objective criteria and are independent of previous, current or possible future commercial relationships.

6.1. **Purchase, prescription, dispensing and use of medicinal products**

The management of discounts and rebates in connection with the purchase, prescription, dispensing or use of prescription-only medicinal products is regulated in detail in the Therapeutic Products Act. Unless an agreement exists in accordance with Art. 56 para. 3bis Health Insurance Act, all price reductions relating to the List of Medicines with Tariffs and the List of Pharmaceutical Specialities (SL) are to be passed on.

“Persons who prescribe, dispense, use or purchase for this purpose prescription-only medicinal products, and organisations employing such persons shall not claim, be promised or accept any undue advantage for themselves or for the benefit of a third party.”[20] This does not apply to “advantages of modest value”.[21]

Also regulated by law is professional promotion,[22] which is required to be fair, balanced and appropriate. The promotional claims must therefore meet high standards of integrity, and scientific statements must be correct and appropriately referenced.

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20 Cf. Art. 55 para.1 TPA.
21 Cf. Art. 55 para. 2 let. a TPA.
22 Cf. Art. 31 and 32 TPA and the Ordinance on the Advertising of Medicinal Products (SR 812.212.5).
6.2. Free samples

Free sample packages are a recognised method of advertising for medicinal products. They are designed to familiarise medical professionals with, and enable them to gain experience with the use of, new medicinal products. Medical professionals must however be aware that free samples may influence professional conduct. The management of free samples is regulated by law. Under Art. 9 TPITO, free samples as defined in Art. 10 of the Medicinal Products Advertising Ordinance may not be sold by professionals who receive them.

6.3. Medical device samples

Companies may make available, free of charge, an appropriate number of medical device samples to medical professionals or medical institutions, so that they can familiarise themselves with and gain experience with safe and effective use of the device or medical service in clinical practice.

Medical institutions must clearly document their use of medical device samples and undertake not to charge the patient/health insurer for them.

6.4. Advisory bodies and professional guidelines

Before a medical professional agrees to serve on an industry advisory body, the need and justification for a consultancy activity of this kind must be assessed. The professional’s own expertise must be sufficient to permit an adequate expression of views on the subject in question. Individual remuneration must always be proportionate to the effort involved (fair value principle). If any conflicts of interest would arise with the individual’s primary professional activity as a result of service on the advisory body, then the role is not to be undertaken. Medical professionals are not to serve on an advisory body established exclusively for marketing purposes. Employees of health organisations are to be required to disclose any engagements if they speak in public about matters which are the subject of an engagement or are otherwise related to the industry by which they have been engaged.

With regard to the development of professional guidelines, reference is made to the SAMS Recommendations on the management of conflicts of interest in the development of guidelines and Choosing Wisely lists.

23 Cf. Art. 9 TPITO.
24 Cf. SAMS 2017, section 3.2.
25 Cf. SAMS 2017, section 3.3.
III. ANNEX

References

**Swiss Academies of Arts and Sciences.**

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**Scienceindustries.**

**Scienceindustries.**

**Scienceindustries.**

**Swiss Medtech.**
IV. INFORMATION ON THE PREPARATION OF THESE GUIDELINES

Mandate
At the end of August 2019, the Central Ethics Committee (CEC) of the SAMS decided that the guidelines on “Collaboration between the medical profession and industry” (2013) were to be revised. For this purpose, an interprofessional working group was appointed.

Composition of the working group
Professor Daniel Scheidegger, SAMS Vice President, Arlesheim (Chair)
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Consultation procedure
On 25 November 2021, the Senate of the SAMS approved a draft version of these guidelines to be submitted for consultation to professional associations, organisations and other interested parties. The comments received have been taken into account in the final version.

Approval
The final version of these guidelines was approved by the Senate of the SAMS on 2 June 2022.