

FASMED Code of Business Conduct

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1. Foreword

The goal of high quality, comprehensive medical treatment financed in a socially sound manner also carries with it a high degree of responsibility for the medical devices industry.

In the Swiss Health Insurance Act (*Krankenversicherungsgesetz – KVG*), the Therapeutic Products Act (*Heilmittelgesetz – HMG*) and the Medical Devices Ordinance (*Medizinprodukteverordnung – MepV*), the legislature enacted regulations which are of considerable significance for the medical devices in the health care market. An objective of the various enactments includes the elimination of false incentives in relations with the persons involved in health care (Art. 56 KVG and Art. 33 HMG)–i.e. incentives which do not primarily promote the optimal medical treatment of the individual.

Through a **Code of Business Conduct**, the Federation of Swiss Medical Devices Trade and Industry Associations desires to provide its members guidelines for interactions with health care professionals in keeping with underlying legal principles. The interaction of members with health care professionals should be transparent and easy to follow.

The members of FASMED, the Federation of Swiss Medical Devices Trade and Industry Associations, approved this **Code of Business Conduct** at the membership meeting on May 26, 2010 in Bern. This **Code of Business Conduct** replaces the Code of Business Conduct of May 27, 2003 from this date. The **Code of Business Conduct** should be regarded by all members as a guideline in their interaction with health care professionals. Each member will receive a written version of the **Code of Business Conduct**. A copy is being sent to the agencies Federal Social Insurance Office (BSV) and Swissmedic and to the associations FMH, FMS, H+, economiesuisse and SAMW. In addition, the **Code of Business Conduct** will be published on the home page of Fasmед (www.fasmed.ch).

2. General Section

2.1 Definitions

Professional(s) (in health care): Persons (with clinical or non-clinical, self-employed or non self-employed occupations, such as physicians, nurses, medical technical assistants and research coordinators, including closely related persons, such as spouses and business friends) or organizations (hospitals, clinics, residential facilities, laboratories and purchasing pools) who/which directly or indirectly use products.

Use of / using products: Using, purchasing, leasing, recommending, arranging the purchase or lease of and prescribing products in the past, present and future.

Interaction(s): Contacts between professionals and members.

Products: Medical devices and services of the members.

2.2 Scope of application

The **Code of Business Conduct** applies to the members and their interactions with professionals admitted to practice a profession in Switzerland or elsewhere. Should local laws and regulations or the applicable industry code deviate from the principles established in this **Code of Business Conduct**, either the **Code of Business Conduct** or the local regulations should be followed, depending on which provisions are more restrictive.

The members should take appropriate measures to ensure compliance with the **Code of Business Conduct**.

The members should require that the principles of the **Code of Business Conduct** are also followed by parties with whom they contract.

2.3 Reporting violations

Violations of the **Code of Business Conduct** may be reported by anyone, even directly to FASMED. Anonymous reports will not be pursued. Reports that are received will be forwarded for further processing to the person who has been registered as responsible for the member concerned (or to the CEO if no person has been registered accordingly).

2.4 Basic principles

2.4.1 Separation principle

The interaction may not be exploited by granting an undue benefit to influence the decisions of the professionals with regard to the products, nor may the interaction be made dependent on use of the products.

2.4.2 Transparency principle

The interaction should be transparent and consistent with local laws, regulations and professional rules.

2.4.3 Equivalence principle

When a member engages a professional to perform a service for or on behalf of the member, the compensation paid for the service rendered must be reasonable and in accord with its fair market value.

2.4.4 Documentation principle:

A written agreement must be entered into for interactions and shall include provisions on the purpose of the interaction, the services to be performed, the compensation and reimbursement of expenses. The intended activities must be substantiated and evidenced by activity reports or the like. Documents such as the agreement, reports and invoices must be retained by the member in order to document the need and the materiality of the services as well as the reasonableness of the compensation.

3. Special Section

3.1 Corruption

The members may not directly or indirectly make, offer or promise payments of money or other non-cash benefits to professionals so that they will use the products or to obtain orders or other benefits. Professionals may not demand, permit the promising of nor accept such direct or indirect payments of money or other non-cash benefits.

Acceptable, however, are non-cash benefits of nominal value which are of relevance to the medical or pharmaceutical practice as well as customary and commercially justified discounts which directly affect the price.

Agreed services and consideration shall be shown on the invoice or otherwise documented in writing.

3.2 Product training and advanced training by the members

In order to facilitate the safe and effective use of the products, the members may offer product training and advanced training for professionals. However, care must be taken that such events are held in an appropriate setting with consideration given to the convenience of the participants and the type of event.

In particular, the following should be considered:

Events should be held in a setting that is appropriate for effectively imparting information and for any necessary practical training. These include, independent of location, clinics, educational facilities, conference rooms or other suitable places such as the member's own premises or commercial conference venues.

The persons providing training should have the necessary expertise for conducting such an event.

Members may offer the participants reasonable meals in conjunction with the event and also overnight accommodations for training or advanced training events. Additional hospitality may be appropriate. All hospitality should range within reasonable financial limits and be secondary to the purpose of the event from the standpoint of time and subject matter.

Members may pay the participant's reasonable and actual cost of travel and accommodations.

Members shall not pay the cost of meals, travel and lodging or other expenses of the professional's spouse or other guests or other persons who have no work-related interest in the information imparted at the event.

3.3 Support of the educational conferences by third parties

If permitted under the guidelines of professional associations or organizations responsible for such conferences, members may support independent, educational, scientific or guideline-drafting conferences that promote scientific expertise, medical advances and the provision of effective health care.

Members may support such events with financial, scientific, technical, organizational and/or logistical assistance as follows:

- a. **Sponsoring professionals:** Members may absorb the cost of participation by a particular professional. The defrayal of such costs should be limited to the participation fee and reasonable and actual meals, travel and lodging costs arising in connection with the participation in the conference. Applicable disclosure requirements must be observed or necessary approvals obtained. In each case, the members should maintain appropriate transparency by obtaining the prior written consent of the hospital administration, the professional's superior or another responsible agency with complete disclosure of the purpose and scope of the sponsoring.
- b. **Advertising and demonstrations:** Members may purchase advertising and rent booths for demonstrating products at conferences.
- c. **Conference grants:** Members may provide direct financial support to the organizer in order to reduce the cost of the participants. Consequently, they may provide grants for reasonable fees and for the reasonable and actual cost of meals, travel and lodging of professionals who have a work-related interest in the information imparted at the event. The organizer must make a written request and the support must be paid directly to the organizer or educational institution. The members may be involved in specifying the content of the event only to the extent of recommending speakers or commenting on the program upon appropriate request.
- d. **Parallel conference:** Members may support parallel conferences and hold presentations on topics which fit the overall context of the event, provided that the information is fair, balanced and scientifically correct.
- e. **Scholarships:** Members may also make educational grants to educational institutions, health care institutions or professional associations for medical education programs. The selection of the recipient shall be made by the institution. The scholarship shall be paid to the institution and not to the recipient unless the institution has consented in advance in writing. In no event may the support be tied to the use of products.

3.4 Meetings for marketing, promotion and other business purposes

Meetings with professionals to discuss features or sales terms or to conduct contract negotiations should as a basic rule take place at or near the location of the professional. In connection with such meetings, members may pay for reasonable meals in a setting which promotes the exchange of information. If factory tours or demonstrations are necessary for non-portable devices, members may also pay the participant's reasonable and actual cost of travel and accommodations. However, members shall not defray the cost of meals, travel and lodging or other expenses of the spouse or other guests of the professionals or other persons who have no work-related interest in the information imparted at the meeting.

3.5 Consulting agreements with professionals

Members work with professionals in a broad spectrum of consulting services which are regulated through various types of agreements—e.g. agreements for research, product development, development or assignment of intellectual property rights, marketing, participation on advisory boards, presentations in the context of member-supported training or for other services. Members may pay consultants a reasonable fee for this type of services.

In particular, the following should be considered:

- a. Consulting agreements may only be entered into when a legitimate need for the corresponding services was identified in advance.
- b. The consultant should be selected based on his qualifications and specialized knowledge in the field of the defined project and not based on his use of the products.
- c. Consulting agreements must be recorded in writing, signed by both parties and the services and consideration to be provided described. This also applies when only a brief engagement is involved.
- d. The consultant's compensation should correspond with the applicable market value and reasonable consideration for the services rendered. The compensation may not be made dependent on the use of products in any case. Members may pay the consultant's reasonable and actual expenses that arise in connection with his consulting (e.g. costs for meals, travel and lodging based on meetings with or on behalf of the member). The written consulting agreement should list all expenses which the consultant may request in connection with his service.
- e. Applicable disclosure requirements must be observed or necessary approvals obtained. In each case, members should maintain appropriate transparency by obtaining the prior written consent of the hospital administration, the professional's superior or another responsible agency with complete disclosure of the purpose and scope of the consulting agreement.
- f. Meetings between consultants and members should be held in a setting which is appropriate for the consultation and suited to an effective exchange of information. These include clinics, educational facilities, conference rooms or other suitable places such as the member's own premises or commercial conference venues.
- g. Costs paid by the member for hospitality in connection with meetings with a consultant should range within reasonable financial limits and be secondary to the primary purpose of the meeting from the standpoint of time and subject matter.
- h. When a member contracts with a consultant for clinical research studies, a written research protocol or written work timetable must be on hand as well.
- i. When a member contracts with a consultant for the development of intellectual property, the fee may not also be tied to the use of the product which includes the intellectual property.

3.6 Hospitality in the context of business contacts with professionals

Invitations for dining or for another occasion should bear a reasonable relation with the role and function of the professional and thus not be primarily for pleasure or entertainment. The scientific and medical discussion or the discussion of products should be paramount. The setting and overall cost should be reasonable under these aspects.

3.7 Gifts

The giving of gifts and other benefits to professionals is fundamentally improper.

Acceptable, however, are promotional gifts—i.e. objects of nominal value up to CHF 300.00—that are labeled with a permanent and clearly visible identification of the advertiser or manufacturer of the product.

Also acceptable are non-cash benefits of nominal value—i.e. valued up to CHF 300.00—which have relevance to the medical or pharmaceutical practice. Purely monetary payments and cash-like gifts (such as coupons, for example) are improper. Acceptable, however, are free samples and providing the use of specialist books without charge.

This subparagraph does not refer to the acceptable practice of making products available for evaluation and demonstration.

3.8 Information concerning insurance coverage, reimbursement of costs and other commercial information

Members should support accurate and responsible billing to insurance companies and other payers by providing the professionals information on economic efficiency and reimbursements regarding their products. This information should be restricted to determining the appropriate coverage, coding and invoicing of the products or to facilitating the correct procedure for use of these products or the economically efficient delivery of the products.

This subparagraph does not refer to the acceptable practice of offering technical or other support concerning the correct use or installation of the products.

3.9 Donations for charitable or nonprofit purposes

Members may make donations for exclusively charitable or nonprofit purposes, provided that the recipient is allowed to accept such donations under applicable law. Donations may be made for the general activities of a charitable or nonprofit organization or to support general fundraising for projects of such organizations.

Donations may not be tied to the use of the products in any way.

All donations must be properly documented.

Donations may not be made at the request of a professional unless the professional is an employee of this organization and makes the request on behalf of the organization. The professional's preferred organization should not be supported thereby at the request of such professional.

Members should have no control over the actual use of their donations.

3.10 Research and educational grants

Members may make research grants to support independent medical research. Research grants to support customer-initiated studies are possible for studies which concern clinical or nonclinical research in areas in which the member has a legitimate interest. The member may absorb documented expenses, render in-kind benefits or provide free products in order to support clearly defined independent research activities. All requests for such grants must be made in writing, naming the type and goal of the research activity. No support should be granted until the written agreement is signed. If appropriate, the agreement should provide for incident reporting. Complete disclosure to the hospital administration or the professional's superior or another responsible agency is necessary and the recipient should promise to mention the support of the research by the member in all oral and written presentations of the results.

Members may make educational grants to support the advancement of medical science or medical education (see subparagraph 3.3) or to inform patients or the public concerning important health care topics.

Grants may not be misused for price reductions or rewards for preferred customers or tied to the use of the products and must be properly documented.

The recipients of such grants must be entitled to receive such grants under applicable law. The grants should not be awarded to an individual professional.

Bern, May 26, 2010

FASMED



President
N. Markwalder



Secretary
Dr. M. Buchs