

## **SAMED Code of Marketing and Business Practice** **effective 1 January 2010**

### **Summary**

#### **A. Introduction**

- The updated Code has been approved by the Board of SAMED. We urge you to read the document in detail. However, a few of the more important issues are outlined underneath.
- The fundamental purpose of the Code is to promote and encourage among SAMED Members, ethical principles and practices.
- The underpinning principle of the Code is that SAMED Members will not offer any inappropriate inducement to an HCP or other customer in order to sell, lease, recommend, or arrange for the sale or lease of their products.

#### **B. COMPANY SPONSORED PRODUCT TRAINING AND EDUCATION**

- Programs and events should be conducted in clinical, educational, conference, or other settings, including hotel or other commercially available meeting facilities conducive to the effective transmission of knowledge.
- Programs requiring “hands on” training in medical procedures should be held at training facilities, medical institutions, laboratories, or other appropriate facilities. All training staff should have the proper qualifications and expertise to conduct such training.
- Members may provide HCP attendees with modest meals and refreshments. These should be subordinate in time and focus to the educational or training purpose of the meeting.
- Where there are objective reasons to support the need for out-of-town travel to efficiently deliver Training and Education on Medical Technologies, Members may pay for reasonable travel, economy class fares and modest lodging costs of the attending HCPs who reside outside of the main centre or centres where such training takes place. It is not appropriate for Members to pay for the meals, refreshments, travel, or other expenses for guests or spouses/partners of HCPs or for any other person who does not form part of the trainees or invited attendees at such a meeting.

## C. CONGRESSES AND EDUCATIONAL CONFERENCES

### 1. Educational Grants for International Conferences

- Members may sponsor HCPs, both qualified and in training, to attend International events like congresses, conferences and scientific meetings, subject to the following:
- Members may pay registration fees and may only offer **economy travel, modest accommodation and meals**. The level of accommodation offered must be appropriate, modest in nature, and the costs involved must not exceed that level that the recipients would normally adopt when paying for themselves.
- No monies may be paid **directly to an HCP** other than reimbursement of monies paid on congress expenditure, on production of original invoices. Conference fees and other expenses related to the conference should be paid directly to the Conference organizers.
- **Spouses** and other accompanying persons, unless qualified as HCPs, **may not attend the actual meeting and may not receive any associated meals and refreshment at the company's expense**; the entire costs which their presence involves are the responsibility of those they accompany;
- Members may pay only for congress organized events e.g. an opening dinner, **but not for any add-on events, such as sporting events (ski, golf, etc), sight-seeing tours, etc.**
- Members may pay for business class flights only for both incoming and outgoing faculty presenting on the day of arrival.

### 2. Educational Grants for Local Conferences

- **Members may only sponsor HCPs in training, registrars, nursing staff and technicians and other deserving persons to attend local CPD accredited events like congresses, conferences and scientific meetings.**
- Members may only provide a grant directly to the entity under whose auspices the conference is taking place to reduce or defray conference costs and may also choose to make such grant directly to a training institution, or to the attendee's employer to allow attendance of such conference or training by HCPs in training, registrars, nursing staff and technicians.

- **No monies may be paid directly to the sponsored individual.**

### Conference Meals and Refreshments

- Any meals and refreshments should be modest in value, subordinate in time and focus to the purpose of the conference and clearly separate from the continuing medical education portion of the conference.

### Faculty Expenses for HCPs visiting South Africa

- Members may make grants to conference sponsors to cover the costs of reasonable honoraria, travel, lodging, and meals for HCPs visiting South Africa who are *bona fide* conference attendees and/or speakers.
- While Members are encouraged not to reimburse HCPs directly for costs incurred directly related to the scientific components of the Conference, it is realized that there may be *bona fide* occasions where direct payments are justified. Reimbursement of expenses may only be made on production of original invoices.

### Interactions with HCPs

- During conferences (local and international) the organizers will often make provision for interaction between Industry and delegates e.g. a free evening. The following principles will apply to such interactions:
- Members' interactions should be professional in nature and should facilitate the exchange of medical or scientific information that will benefit patient care. To ensure the appropriate focus on an educational and/or informational exchange and to avoid the appearance of impropriety, a Company may provide and pay for a meal and refreshments only if such hospitality is subordinate in time and purpose to the exchange of medical or scientific information. **Entertainment of any nature is prohibited.**
- Events or interactions may not be organised at the same time as congress related events.

### Sponsoring congress related events

- Members may sponsor congress related events (excluding recreational and sporting events) e.g. opening address, gala dinner provided:

1. The event is organised by the congress organisers and
2. Attendance is open to all registered delegates

## D. MODEST MEALS ASSOCIATED WITH HCP BUSINESS INTERACTIONS

Modest meals may be provided as an occasional business courtesy

- Purpose. The meal should be incidental to the bona fide presentation of scientific, educational, or business information and provided in a manner conducive to the presentation of such information.
- Setting and Location. Meals should be in a setting that is conducive to bona fide scientific, educational, or business discussions. Meals may occur at the HCPs place of business.

However, in some cases the place of business may be a patient care setting that is not available for, or conducive to, such scientific, educational, or business discussions. In other cases, it may be impractical or inappropriate to provide meals at the HCPs place of business, for example, (1) where the Medical Technology cannot easily be transported to the HCPs location, (2) when it is necessary to discuss confidential product development or improvement information, or (3) where a private space cannot be obtained on-site.

- Participants. A Company may provide a meal only to HCPs who actually attend the meeting. A Company may not provide a meal for an entire office staff where everyone does not attend the meeting. A Company also may not provide a meal where its representative is not present. **A Company may not pay for meals for guests of HCPs or for any other person who does not have a bona fide professional interest in the information being shared at the meeting.**

## E. PROHIBITION OF ENTERTAINMENT AND RECREATION

- Company interactions with HCPs should be professional in nature and should facilitate the exchange of medical or scientific information that will benefit patient care. **To ensure the appropriate focus on an educational and/or informational exchange and to avoid the appearance of impropriety, a Company should not provide or pay for any entertainment or recreational event or activity for any HCP. Such activities include, for example, theatre / movie tickets, sporting events, golf, skiing, hunting, and leisure or vacation trips.**
- Such entertainment or recreational events, activities, or items should not be provided, regardless of: (1) their value; (2) whether the Company engages the HCP as a speaker or consultant; or (3) whether the entertainment or recreation is secondary to an educational purpose.

## F. CONSULTING AGREEMENTS

Companies should comply with the following standards in connection with consulting arrangement with HCPs.

- Consulting agreements should be **written** and describe all services to be provided. When a Member contracts with a consultant to conduct clinical research services, there must also be a written research protocol.

## G. GIFTS

- Members may provide modest gifts to HCPs and staff, to a **maximum value per annum** as set from time to time. Scientific medical reference books and medical periodicals are not subject to the value restriction providing these would be relevant to the practice, facility or clinical department.
- Gifts may not be personal in nature, and should be of relevance to the healthcare practice or healthcare facility.
- Members may occasionally give HCPs branded promotional items of minimal value related to the HCPs work or for the benefit of patients.
- Gifts may not be given in the form of cash or cash equivalents (e.g. gift vouchers), as these are by their very nature personal and without any guarantee as to their use.

## H. CLINICAL TRIALS

AN HCP may receive compensation for his/her work in the trial subject to the following:

- A formal financial agreement between the sponsor and investigator/institution needs to be documented, and submitted as part of the ethics approval process.
- This financial agreement should be transparent, and clearly show the method and quantum of payment from the sponsor to the investigator.
- The compensation of whatever kind must be related to the work done, and must be disclosed to the ethics committee reviewing the study protocol.
- The compensation must not be linked to any expected result of the study.
- This financial agreement should be transparent, and clearly show the method and quantum of payment from the sponsor to the investigator.

## I. PRODUCT EVALUATIONS

- No payment may be made to the healthcare provider involved in the evaluation. If any payments are made, the evaluation must be done in full compliance with the rules of Clinical Trials/Product Registries, as stipulated in the Code.

## J. TRANSPARENT INVOICING

- Members should provide accurate, transparent and responsible billing information to HCPs, reimbursement authorities and other payers.
- No Member may offer a bonus, rebate (e.g. an off invoice discount) or other incentive scheme to an HCP in relation to the acquisition of goods and services in contravention of regulations to be issued in terms of section 18A and B of the Medicines and Related Substances Act, with particular reference to the Amendments as contained in Act 72 of 2008.
- Members are expected to follow the principles of acceptable invoicing procedures as detailed in the SAMED Policy on Transparent Invoicing.

## K. COMPETITION LAW

- Both individual Members and the Association have to comply fully with South African Competition law. Part D contains guidelines which will help ensure compliance and which are applicable to SAMED, its Members and its sub-committees.

## L. Infringements of the Code

### Sanctions

- Should the Ethics Committee find that the Member has breached the Code the Ethics Committee may impose certain sanctions on the Member.

### Powers of SAMED

- SAMED may cancel or refuse Membership to any company that:

1. is unwilling to commit to the standards and values reflected in the code and/or
2. fails to conduct its affairs in a manner consistent with the code

- Such cancellation or refusal of Membership shall be made only after review by the SAMED Board of Directors, and in line with the provisions of the SAMED Dispute Resolution Procedure and the Articles of Association.