Dear Facilitator

Firstly, a hearty thank you for facilitating the **Medical Device Code of Ethical Marketing and Business Practice** training programme.

This document that you are currently reviewing is called the Facilitator Guide and is one of 2 sections that form the Facilitator Toolkit. The Facilitator Toolkit is intended to assist in the preparation and the execution of this training programme. Let us take a closer look at the 2 sections of the Facilitator Toolkit.

Facilitator Toolkit Section 1: Facilitator Guide

a. This Facilitator Guide is the most comprehensive document within the toolkit as it incorporates the Code itself and the PowerPoint visuals as well as all Classwork and Group work activities along with recommended answers.

b. The Code is the source document based on which the Facilitator Guide and PowerPoint presentation was compiled. The flow of this training programme is aligned to the contents of the Code.

c. Please always check the SAMED website to ensure you have the most current version of the Code and Facilitator toolkit.

Section 2: Training presentation

A presentation slide-deck has been compiled as a tool for presenting information to the learners in a classroom setting and/or using relevant sections to guide feedback when using the blended learning approach (discussed below).

The presentation is animated to match the script in the Facilitator Guide and to provide an interesting learning experience. It is therefore suggested that the presentation be viewed as slide show from start to end along with the script as part of your preparation for this training programme.

There are two special icons within the PowerPoint slide deck: one for Classwork and the other for Group work as follows:

This icon indicates Classwork. Class work refers to activities/questions that are addressed to your learners as a general class discussion or brainstorm and are intended to provide variation to the teaching pace without consuming time.

This icon indicates Group work. Group work are activities/questions that are addressed by discussion between 2 or more learners within a given amount of time and provides an opportunity for learners to share experiences and to learn from each other.

Structure of training programme:

We understand that facilitators chosen at company level may be sales people and/or trainers. We do not wish to be prescriptive in this regard as we trust that companies will select the most appropriate person with the required expertise.

We have therefore developed a flexible training programme and encourage you to adapt your training methodology according to available time and experience level of audience. Here are a few different methodologies that can be applied to execute this training programme:

Class Room training

Execute a face-to-face session either as part of induction programme or as a specially organised event. We recommend duration of 4-8 hours depending on experience level of audience.

Blended learning approach

One of two strategies may be adopted:

Strategy One:

a. Email the Facilitator Guide to attendees and request them to review and complete all activities

b. Review all submissions for accuracy and completeness

c. Arrange a 2 hour session and use the PowerPoint presentation in your facilitator toolkit to consolidate knowledge gain, clarify inaccurate or incomplete responses and to have meaningful discussion around salient points

Strategy Two:

a. Break down the Facilitator Guide into chunk sizes and compile a schedule that indicates topics, submission deadlines and meeting dates. The meeting dates may be tagged onto planned one-on-one sessions or sales meetings.

b. Email the Facilitator Guide to attendees along with the Schedule.

c. Review all submissions for accuracy and completeness in a timely manner in preparation for planned meeting.

d. Meet as per schedule and use the PowerPoint slide deck to consolidate knowledge gain, clarify inaccurate or incomplete responses and to have meaningful discussion around salient points

Training Documentation

Complete attendance registers and evaluations forms per company procedure. You may generate internal certificates using company templates. This training programme prepares your staff to take the external SAMED assessment. Please ensure that a copy of this externally generated certificate is filed.

Evaluation of the Training Programme and feedback to SAMED

Lastly, with practical implementation of this workshop, there may be suggestions to improve the content of this workshop and we value your feedback, comments and suggestions. Please send feedback to info@samed.org.za.

We hope and trust that this facilitator guide will be a valuable tool for your successful implementation of this training programme and wish you the very best.

Regards

the SAMED Team

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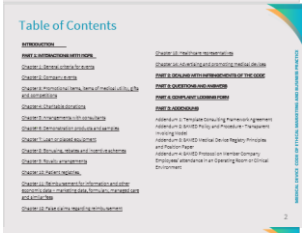
Introduction

Slide 1

Welcome to the Medical Device Code of Ethical Marketing and Business Practice training programme.

Either print the Code from the SAMED site or direct your audience to the link below to save an electronic version. https://samed.org.za/medical-device-code/

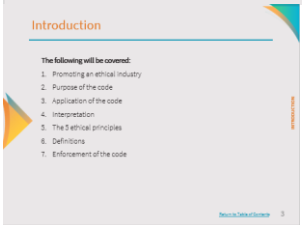
Slide 2



The following topics will be covered during the presentation. Allow your audience to review the slide.

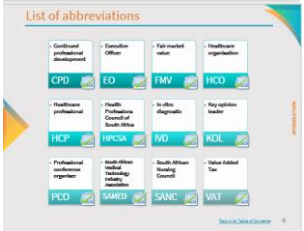
Note to Facilitator: to navigate through the slide deck, click on each topic to jump to the relevant slide and use the 'Table of Contents' button to return.

Slide 3



The next few slides provides an introduction and background to the code. The 7 topics that will be covered are listed on the slide.

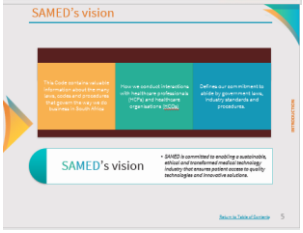
Slide 4



These are the abbreviations you will encounter. Please take a minute to familiarize yourself with these abbreviations.

Can someone give me an example of a HCO?

Slide 5



Promoting an ethical industry

As many of you know the healthcare, industry is one of the most carefully scrutinized industries in the world.

The Code contains valuable information about the many laws, codes and procedures that govern the way we, as a company, do business in South Africa. In particular, how we conduct interactions with HCPs and HCOs.

The Code helps to further define our commitment as a company operating within the healthcare industry by responsibly improving patient access to innovative medical devices.

Slide 6

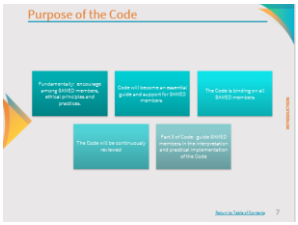
The Code is founded on the following ethical values:

Firstly, an industry that is socially responsible towards not only its customers, but to society at large and patients in particular.

Secondly, the desire to promote a spirit of co-operation and shared responsibility among both public and private HCPs and providers within the context of effective, efficient and transparent healthcare delivery.

In support of these values, the underpinning principle of the Code is that SAMED members will not offer any inappropriate inducement to any HCP or other customer in order to sell, lease, recommend or arrange for the sale or lease of their products.

Slide 7



Purpose and principles of the Code

•The fundamental purpose of the Code is to promote and encourage among SAMED members, ethical principles and practices.

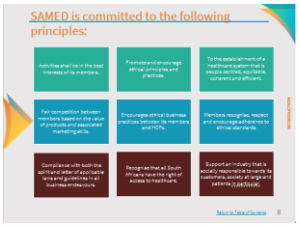
•As such it is envisaged that the Code will become an essential guide and support for SAMED members in their business and marketing interactions with their customers.

•The Code is binding on all SAMED members and is a condition for new and ongoing membership.

•The Code will be continuously reviewed borrowing from best practice both locally and globally.

The Code also includes a set of questions and answers to assist SAMED members in the interpretation and practical implementation of the Code.

Slide 8



SAMED is committed to the following principles:

To ensure that all activities of SAMED shall be in the best interests of its members, provided that such shall not detract from the needs and rights of patients.

•To promote and encourage among its members ethical principles and practices, voluntarily agreed upon, and to this end, to ensure a Medical Device Code of Ethical Marketing and Business Practice which shall be binding on all members, is published.

•To the establishment of a healthcare system that is people centred, equitable, coherent and efficient and in particular to the contribution that high quality, cost-effective healthcare technology can make toward achieving good health outcomes.

•To promote fair competition between members based on the value of products and associated marketing skills, and not based on any unacceptable business practice.

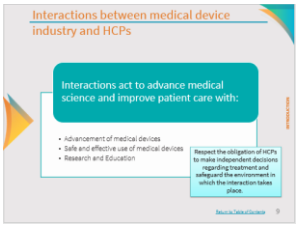
•SAMED encourages ethical business practices in interactions between its members and HCPs, in particular that members will not offer any inappropriate inducement to any HCP or other customer in order to sell, lease, recommend or arrange for the sale or lease of their products.

•Thus, in pursuing this mission, SAMED members ("members") recognise, respect and encourage adherence to ethical standards and compliance with both the spirit and letter of applicable laws and guidelines in all business endeavours.

•Members recognise that all South Africans have the right of access to healthcare, and that right should be progressively realised through cooperation and shared responsibility between the private and public healthcare sectors.

Members furthermore support an industry that is socially responsible towards not only its customers, but to society at large and patients in particular

Slide 9



Interactions between medical device industry and HCPs

There are many forms of interactions between the medical device industry and HCPs.

Such interactions act to advance medical science and improve patient care.

This is a distinguishing feature of the medical device and IVD industries and such interactions act as a backdrop to the following:

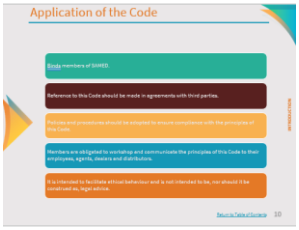
•Advancement of medical devices: The development of innovative medical devices and the improvement of existing products requires collaboration between industry and HCPs, often occurring outside the facilities of medical device companies.

•Safe and effective use of medical devices: The safe and effective use of medical devices requires that industry offers HCPs appropriate instruction, education, training, service and technical support. Regulators may also require this type of training as a condition of product approval.

•Research and Education: Industry's support of *bona fide* medical research, education, and enhancement of professional skills contributes to patient safety, improved patient outcomes and increased access to new technology.

In such interactions member companies must continue to respect the obligation of HCPs to make independent decisions regarding treatment and safeguard the environment in which the interaction takes place to ensure the integrity of the industry.

Slide 10

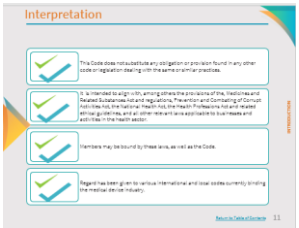


Application of the Code

This Code binds us as a SAMED member company as well as you as an employee, agent or contractor to this company.

- It is also binding to marketing agencies, advertising agencies, event management entities, commission agents or independent sales representatives, procurement or software entities, working for or on behalf of us as a SAMED member.
- We therefore should ensure that reference is made to this Code in agreements with third parties mentioned in this context.
- As a SAMED member we also have to adopt policies and procedures to ensure compliance with the principles of this Code, which includes, *inter alia*, mechanisms to ensure that all events, sponsorships, marketing and advertising campaigns are signed off by a responsible senior staff member / compliance officer.
- We are also under an obligation to workshop and communicate the principles of this Code to employees, agents, dealers and distributors as it is a requirement that they adhere to this Code. Hence, this training programme.
- Ultimately, this Code is intended to facilitate ethical behaviour and is not intended to be, nor should it be construed as, legal advice.

Slide 11



Interpretation and definitions

This Code does not substitute any obligation or provision found in any other code or legislation dealing with the same or similar practices.

In fact, it is and intended to align with, among others:

- the provisions of the Prevention and Combating of Corrupt Activities Act,
- the National Health Act, the Health Professionals Act and related ethical guidelines,
- the Medicines and Related Substances Act and all regulations and associated guidelines,
- the Competition Act,
- the Consumer Protection Act,
- King IV and all other relevant laws applicable to business and activities in the health sector.
- Members may be simultaneously bound by these laws, as well as the Code.

- In drafting the Code, regard has also been given to various international and local codes currently binding the medical device industry, and interpretations of this Code.

Slide 12

Any interpretation of the provisions of this Code, as well as members' interactions with HCPs not specifically addressed in this Code, should be made in light of the following 5 principles.

1. The Principle of Image and Perception

Members should, at all times, consider the image and perception of the medical device industry that will be projected to the public when interacting with HCPs.

Is it ok to play golf with an HCP even though you are not sponsoring the round of golf?

Possible Answer: No – to manage public perception recommend that this does not take place.

2. The Principle of Separation (patients best interest)

Interaction between industry and HCPs must not be misused to influence through undue or improper advantages, purchasing decisions, nor should such interaction be contingent upon sales transactions or use or recommendations of members' products.

Is it ok for members to hold positions on any executive committee or board of any medical association, society or other healthcare organization?

Possible Answer: No, a conflict of interest may occur.

3. The Principle of Transparency

Interaction between industry and HCPs must be transparent and comply with national and local laws, regulations and professional codes of conduct.

Class Work

Can you think of examples where you have had to apply these principles?

Note to Facilitator: Be open to different interpretations as there is no absolute right/wrong answer and considerable overlap across principles.

Possible answers: Financial support for third party organized educational events should be publicly disclosed, appropriate disclosure of information about company's clinical trials, e.g. in external public registries, promotional material sponsored by a company, should clearly indicate by whom it was sponsored.

4. The Principle of Equivalence

Where HCPs are engaged by a member to perform a service for or on behalf of a member, the remuneration paid by the member must be commensurate with, and represent a fair market value, for the services performed by the HCP.

Can you think of examples where you have had to apply these principles?

Note to Facilitator: Be open to different interpretations as there is no absolute right/wrong answer and considerable overlap across principles.

Possible answer: implementation of a company specific benchmark to remunerate HCPs who enter consultancy arrangement as speakers to ensure standardized remuneration.

5. The Principle of Documentation

For interactions between a member and a HCP, such as where services are performed by a HCP for or on behalf of a member, there must be a written agreement setting out, *inter alia*, the purpose of the interaction, the services to be performed, the method for reimbursement of expenses as well as the remuneration to be paid by the member.

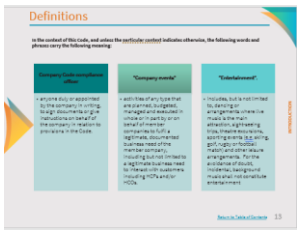
The activities envisaged by the agreement must be substantiated and evidenced by activity reports, financial records and the like.

Can you think of examples of documents that must be retained?

Answer: adequate documentation such as the agreement, related reports, invoices, etc. must be retained by the member to support the need for, and materiality of, the services as well as the reasonableness of the remuneration paid.

Note to Facilitator: Be open to different interpretations as there is no absolute right/wrong answer and considerable overlap across principles.

Slide 13



In your groups refer to the Code and review the meaning of the following words/phrases:

1. Company Code compliance officer
2. Company events
3. Third Party Organised (TPO) Educational Events
4. Entertainment
5. Healthcare organization (HCO)

***Possible Answers*:** ensure yellow highlighted words are included in answers

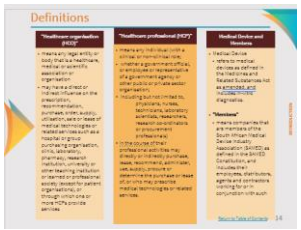
"Company Code compliance officer" means anyone duly authorised by the company, or appointed by the company in writing, to sign documents or give instructions on behalf of the company in relation to provisions in the Code.

Group Work

"Company events" means activities of any type that are planned, budgeted, managed and executed in whole or in part by or on behalf of member companies to fulfil a legitimate, documented business need of the member company, including but not limited to a legitimate business need to interact with customers including HCPs and/or HCOs.

"Entertainment" includes, but is not limited to, dancing or arrangements where live music is the main attraction, sight-seeing trips, theatre excursions, sporting events (eg skiing, golf, rugby or football match) and other leisure arrangements. For the avoidance of doubt, incidental, background music shall not constitute entertainment.

Slide 14



Healthcare organisation (HCO) means any legal entity or body (irrespective of its legal or organisational form) that is a healthcare, medical or scientific association or organisation which may have a direct or indirect influence on the prescription, recommendation, purchase, order, supply, utilisation, sale or lease of medical technologies or related services such as hospital or group purchasing organisation, clinic, laboratory, pharmacy, research institution, university or other teaching institution or learned or professional society (except for patient organisations), or through which one or more HCPs provide services.

Healthcare professional (HCP) means any individual (with a clinical or non-clinical role; whether a government official, or employee or representative of a government agency or other public or private sector organisation; including but not limited to, physicians, nurses, technicians, laboratory scientists, researchers, research co-ordinators or procurement professionals) that in the course of their professional activities may directly or indirectly purchase, lease, recommend, administer, use, supply, procure or determine the purchase or lease of, or who may prescribe medical technologies or related services.

Note: unless otherwise stipulated the term HCP includes and is applicable to HCOs.

Medical Device refers to medical devices as defined in the Medicines and Related Substances Act as amended, and includes in-vitro diagnostics.

Members means companies that are members of the South African Medical Device Industry Association (SAMED) as defined in the SAMED Constitution, and includes their employees, distributors, agents and contractors working for or in conjunction with such.

Slide 15

What are the differences between Third-party organized events Vs educational conferences Vs procedure training?

Possible Answers: ensure yellow highlighted words are included in answers.

"Third-party organised educational events": means activities of any type that are planned, budgeted, managed and executed in whole, or partly, by or on behalf of a person or entity other than a member company to fulfil HCPs medical educational needs.

"Third-party organised educational conferences": means a type of third-party organised educational event that is a genuine, independent, educational, scientific, or policy-making conference organised to promote scientific knowledge, medical advancement and/or the delivery of effective healthcare and are consistent with relevant guidelines established by professional societies or organisations for such educational meetings. These typically include conferences organised by national, regional, or specialty medical associations/societies, hospitals, professional conference organisers (PCOs), patient organisations or accredited continuing medical education providers.

Class Work

"Third-party organised procedure training": means a type of third-party organised educational event that is primarily intended to provide HCPs with information and training on the safe and effective performance of one or more clinical procedures in circumstances where the information and training concern:

- Specific therapeutic, diagnostic or rehabilitative procedures, namely clinical courses of action, methods or techniques (rather than the use of medical technologies).
- Practical demonstrations and/or training for HCPs, where the majority of the training programme is delivered in a clinical environment.

For the avoidance of doubt, proctorship and preceptorship are not considered to constitute third-party organised procedure training.

Slide 16

"Scientific meetings"

refers to meetings that are not generally open to the whole scientific community affected.

It includes meetings where pertinent clinical, healthcare or treatment issues are discussed which may relate to a particular issue (such as a treatment protocol for

a particular disease) , or which may be called by a member in order to advise the HCP on the impact or use of its specific technology, the clinical merits or place of the technology in treatment within a certain disease area, etc. They are not necessarily conducted under the auspices of an independent scientific committee.

Can you perhaps think of why some companies may opt to have a meeting 'disguised' as a scientific meeting? What could their intentions be?

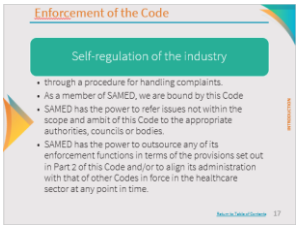
Possible answers: off-label 'promotion' with no genuine scientific interest in moving indication to on-label use; promoting and advocacy by KOLs if pre-selected committee (bias depending on who initiated and selected); business class travel permitted and consultancy arrangement permitted – this may be a disguised form of reimbursement.

Class Work

Therefore scientific meetings are scrutinized to ensure valid and genuine scientific dialogue along with associated documentation (agenda, minutes, who initiated, who selected and why, who present etc.).

"Unacceptable fees" refer to the payment of data, marketing, formulary, managed care or similar types of fees which are used to encourage or increase the purchase, loan or use of a medical device and which data, marketing or managed care is of no or limited value to the buyer or which services or information is not legitimately and actually in order to reward or secure a particular purchase or utilisation behaviour, whether under implicit or explicit conditions relating to such behavioural change or sustained behaviour.

Slide 17



Enforcement of the Code

The Code is based on the principle of self-regulation of the industry through a procedure for handling complaints. The process of enforcement is set out in Part 2 of this Code and we will cover this in more detail later on.

Please remember that as a member of SAMED, we are bound by this Code.

You must read this Code and should you become aware of a violation of this Code, you must report it in line with the provisions of Part 2 of this Code. Failure to report a violation is itself a violation.

SAMED has the power to refer issues not within the scope and ambit of this Code to the appropriate authorities, councils or bodies with the authority to deal with such issues.

SAMED has the power to outsource any of its enforcement functions in terms of the provisions set out in Part 2 of this Code and/or to align its administration with that of other Codes in force in the healthcare sector at any point in time.

Notes

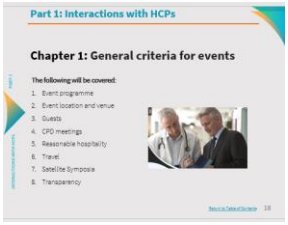
Part 1: Interactions with HCPs

Learning Outcomes

By the end of this module, you will:

1. Understand and apply the general criteria to events
2. Understand and apply criteria that will apply specifically to Company Events
3. Define and implement criteria that apply to Promotional items, items of medical utility, gifts and competitions
4. Understand criteria where Charitable donations are permitted
5. Understand various considerations when making arrangements with consultants
6. Understand the definitions of Demonstration products, Evaluation products and samples and implement various criteria that may apply to above.
7. Understand and implement various criteria that will apply to Loan or placed equipment
8. Understand considerations when implementing bonusing, rebates and incentive
9. Understand and implement Royalty arrangements
10. Understand concepts around Patient registries and able to maintain accordingly.
11. Understand criteria for Reimbursement for information and other economic data – marketing date, formulary, managed care and similar fees
12. Understand repercussions of making False claims regarding reimbursement
13. Understand and implement policy that applies to Healthcare representatives that enter OR/theatre
14. Understand and implement SAMED Guidelines for the utilisation of nursing professionals by member companies as independent contractors or as employees:
15. Understand and apply the rules that govern Advertising and promotion of medical technology

Slide 18



Chapter 1: General criteria for events

Probably the most relevant part in the Code is Part 1, which deals with interactions with HCPs. Remember; the definition of HCP includes medical or non-medical people and is anyone we can influence to purchase our products. Review Learning Outcomes.

These are the principles and criteria that will apply to all such events supported in any way by us, irrespective of who organises the event. Let's take a closer look at each criteria starting with the Event Programme.

Slide 19

Event programme

The Event programme need to adhere to these rules:

•Firstly, the event programme should directly relate to the specialty and/or medical practice of the HCPs who will attend the event or be sufficiently relevant to justify the attendance of the HCPs.

•We should not organise events, which include social, sporting and/or leisure activities or other forms of entertainment.

•The criteria for selection of attendees/invitees must be transparent and available on request for scrutiny.

•Advertisement and promotion at events is subject to relevant domestic legislation.

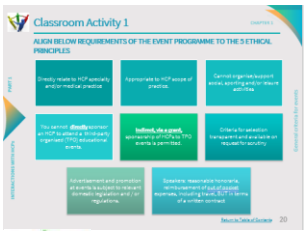
For third-party organised educational events, the agenda should be under the sole control and responsibility of the third-party organiser.

For third-party organised educational events, entertainment must be outside of the educational programme schedule and paid for separately by the HCPs.
Entertainment should not dominate or interfere with the overall scientific content of the programme and must be held during times that do not overlap with a scientific session. The entertainment should not be the main attraction of the event.

The meeting and event should be appropriate to all delegates' scope of practice.

Let's try to see how above requirement align to the 5 principles

Slide 20



1. Event programme

It is important that we recognise that all requirements set out in this Code, emanates from 5 ethical principles, which ultimately safeguard the rights, safety and well being of patients.

In your groups, try to link the requirements for event programmes to the 5 ethical principles.

Group Work

Note to Facilitator: Be open to different interpretations as there is no absolute right/wrong answer and considerable overlap across principles. Below are a few possible answers or points to stimulate discussion.

The Principle of Image and Perception: The event programme should directly relate to the specialty and/or medical practice of the HCPs who will attend the event or be sufficiently relevant to justify the attendance of the HCPs. A member company shall not organise events which include social, sporting and/or leisure activities or other forms of entertainment nor support such elements where part of third-

party organised educational events. These 2 requirements justify the presence of HCPs at events and eliminates the risk of the sponsorship being viewed as disguised sponsorship of recreational events. Sponsorship of HCPs to events is permitted. Note: as of 1 January 208, the direct sponsorship of HCPs to attend the third-party organised educational events is prohibited: the public will perceive that an HCP is more likely to recommend a particular product specifically because of sponsorship to such third party educational events.

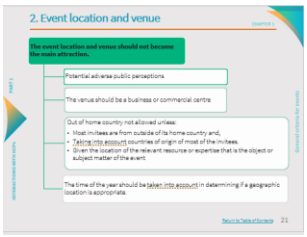
The Principle of Separation (patient best interest): The criteria for selection of attendees/invitees must be transparent and available on request for scrutiny.
Companies should have logical and ethically sound intentions for inviting HCPs to company arranged events and not invite particular HCPs as a reward for using company products or because such HCPs may positively , directly or indirectly, have undue influence of use of product.

The Principle of Transparency: The criteria for selection of attendees/invitees must be transparent and available on request for scrutiny. We should have logical and ethically sound intentions for inviting HCPs and not invite particular HCPs as a reward for using company products or because such HCPs may positively , directly or indirectly, have undue influence of use of product.
No payment may be made to the HCP for time spent at the event: by involving a third party organisation, this ensures transparency and eliminates the possibility of undue gain.

The Principle of Equivalence: For speakers, payment of reasonable honoraria and reimbursement of out of a company arranged event pocket expenses, including travel, are permissible provided it is in terms of a written contract.

The Principle of Documentation: The criteria for selection of attendees/invitees must be transparent and available on request for scrutiny.

Slide 21



2. Event location and venue

The event location and venue should not become the main attraction of the event. For the location and the venue, we must take into account at all times the following considerations:

- ✓ Potential adverse public perceptions of the location and venue for the event. The perceived image of the location and venue must not be luxury, or tourist/holiday-oriented, or that of an entertainment venue.
- ✓ The venue should be a business or commercial centre providing conference facilities conducive to the exchange of scientific and medical information and the transmission of knowledge.
- ✓ **No company may organise or sponsor an event that takes place outside its home country unless:**

- Most of the invitees are from outside of its home country and, given the countries of origin of most of the invitees, it makes greater logistical sense to hold the event in another country.
- Given the location of the relevant resource or expertise that is the object or subject matter of the event, it makes greater logistical sense to hold the event in another country (an “international event”).

The time of the year should be taken into account in determining if a geographic location is appropriate, especially considering the Principle of Image and Perception.

Slide 22

3. Guests

We are not permitted to pay for meals, travel, accommodation or other expenses for guests or spouses of HCPs.

In your groups, **discuss this prohibition in context of the 5 ethical principles.** *Note to Facilitator: Be open to different interpretations as there is no absolute right/wrong answer and considerable overlap across principles. Below are a few possible answers or points to stimulate discussion.*

Group Work

- The Principle of Image and Perception: may be seen as a perverse incentives to HCPs to recommend products; wasteful expenditure on part of companies yet products are expensive
- The Principle of Separation (patient best interest): HCP dealings with patients in particular must be independent of any material benefits promised or received. Sponsorship of spouse on any level is a material benefit to the HCP.
- Principle of transparency: Since such payments are prohibited, transparency may not apply but should a HCP pay for spouse to accompany him perhaps to control public perceptions per principle one, the invite or agenda or other appropriate document should incorporate a note to the effect: Company X does not sponsor spouses and/or other guests who may accompany invited delegates. The presence of spouses and /or guests is for the personal account of delegates. It is inappropriate for spouses to attend such events.
- Principle of equivalence: Benefits must not be disproportionate to the services provided in return. Sponsorship of guests is a perverse benefit and most certainly tilts the principle of equivalency.
- Principle of documentation: Since such payments are prohibited, documentation may not apply but should a HCP pay for spouse to accompany him/her then documentation as outlined above whilst not mandatory could be a risk mitigating process should a case arise out of a particular situation

Slide 23

4. CPD meetings

The number of diagnostic and therapeutic agents and procedures available to health care industry is constantly growing. Basic and postgraduate training and continuing education for physicians needs to be continuously adapted to these developments.

Whilst a substantial proportion of CPD events are financially supported or organized by the pharmaceutical industry and the medical devices sector, the HCP and only the HCP is fully responsible for maintaining his/her accreditation.

To prevent dependencies or conflicts of interest that may arise from such sponsorships, CPD should provide the participants with objective and balanced knowledge and skills which are useful and necessary for patient care.

The principle of separation plays a huge part in CPD meetings: companies have a responsibility to separate 'education' from 'promotion' when sponsoring CPD events as their intention in this instance should be just to contribute to development of the industry in the interest of patient. Hence the following will apply:

1. No product promotion is allowed in the CPD meeting room.
2. Company-branded items/promotions are permissible.
3. Speakers should, in so far as possible, use the non-proprietary names of products during CPD events.

4. Companies must make it known to speakers that the use of trade names, in order to promote a particular product, is not permitted.

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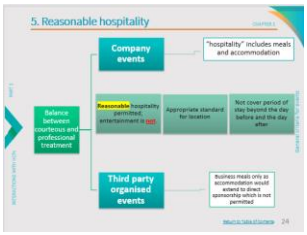


5. Reasonable Hospitality

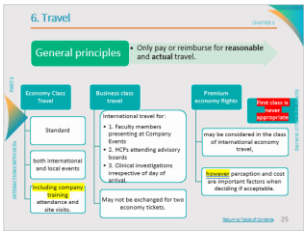
We may provide reasonable hospitality to HCPs in the context of company events and third-party organised educational events but any hospitality offered must be subordinate in time and focus to the event purpose.

- It is important that we find a balance between the courteous and professional treatment of HCPs by member companies, with the desire to avoid even the appearance that hospitality may be used by member companies as a means to induce HCPs to purchase, prescribe or recommend member companies' products. Accordingly, member companies must assess what is "reasonable" on any given situation and regional variations will apply.
- "Reasonable" should be interpreted as the appropriate standard for the given location and must comply with the national laws, regulations and professional codes of conduct.
- Accommodation and/or other services provided to HCPs should not cover a period of stay beyond the day before and the day after the official duration of the event.

Can you differentiate member between "hospitality" which is permitted and entertainment which is not?

Note to facilitator: "Hospitality" includes meals and accommodation and it is important that member companies differentiate between "hospitality" which is permitted and entertainment which is not.

Slide 25



6. Travel

General principles

We may only pay or reimburse for reasonable and actual travel. Travel may be arranged by the sponsoring company (or their designated travel agent.

Travel provided to HCPs should not cover a period of stay beyond the day before and the day after the official duration of the event.

International travel

We may sponsor business class travel for HCPs **only** for:

1. Faculty members presenting at a company organised event irrespective of day of arrival.
2. HCPs attending advisory boards and clinical investigations irrespective of day of arrival.

Business class airfares may not be exchanged for two economy tickets so that a companion/spouse may accompany the HCP.

For other international and local travel:

- For any other travel, economy class travel is the standard class of travel that companies may offer HCPs to attend both international and local events, including congress attendance and site visits.
- Premium economy flights may be considered in the class of international economy travel, however perception and cost are important factors when deciding whether premium economy flights may be acceptable.
- First class is never appropriate.

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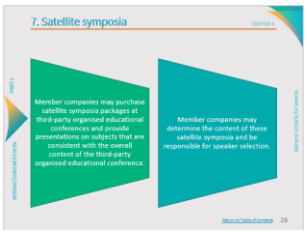

7. Satellite symposia

We may purchase satellite symposia packages at third-party organised educational conferences and provide presentations on subjects that are consistent with the overall content of the third-party organised educational conference.

We may determine the content of these satellite symposia and be responsible for speaker selection, but may not pay any expenses on behalf of the HCP for attending the TPEC.

Slide 27

8. Transparency

When meetings are sponsored by companies, other organisations or by individuals, the fact must be disclosed in the papers relating to the meetings and in any published proceedings. The declaration of sponsorship must be sufficiently prominent to ensure that readers are aware of it at the outset.

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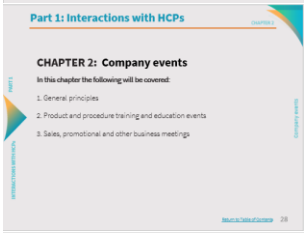

We have covered general criteria for events. Let us now cover Company Events specifically.

Slide 29

Chapter 2: Company events

Remember that company events should still continue to comply with the principles mentioned in Chapter 1: General criteria for events**.**

- **General principles**

We may invite HCPs to company events where there is a legitimate business purpose.

Such **events** include:

- Product and procedure training and education events.
- Sales, promotional, product launch and other business meetings.

Where there is legitimate business purpose, company events may include or take place in member company's premises, manufacturing plant or HCOs used by the member company as reference centres.

- **Product and procedure training and education events.**

  Where appropriate, in order to facilitate the safe and effective use of medical technologies, therapies and/or services, member companies should make the product and procedure training and education available to relevant HCPs. Member companies shall ensure that personnel conducting the product and procedure training and education events have the appropriate expertise to conduct such training.

- **Sales, promotional, product launch and other business meetings.**

Where it is appropriate, member companies may organize sales, promotional, product launches and other business meetings where the objective is to discuss product and related services, features and benefits, conduct contract negotiations or discuss sales terms.

In addition sales, promotional and other business meetings should, as a general rule, occur at or close to the HCPs place of business.

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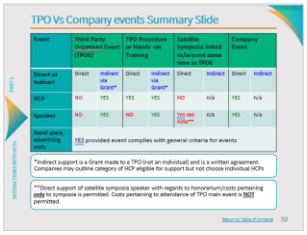

Our industry is still fully committed to supporting medical education. We will now do this at arms' length through independent third-parties. The independent third party will decide which HCPs receive the funding, aligned with pre-determined selection criteria.

What does this mean in practical terms?

1. For third-party organised conferences (main programme): Companies will not be able to directly support an HCP, neither as a delegate nor as a speaker.
2. For company-organised events in the framework of third-party organised conferences (e.g. satellite symposia): Companies may directly support speakers (i.e. their consultants) but not delegates.
3. For third-party organised procedure/hands-on trainings: Companies may support delegates but not speakers, the latter being independent.
4. For company-organised product/procedure trainings: Companies may directly support an HCP either as a delegate and/or as a speaker.

This change now means that the onus is on independent third parties to manage indirect grants received from the industry.

How the rules for educational grants will change?

1. Grants can only be provided to third parties e.g. professional associations but never to individuals.
2. Grants will also require a written contract.
3. Companies may define the category of HCPs eligible for financial support but not choose individual HCPs.

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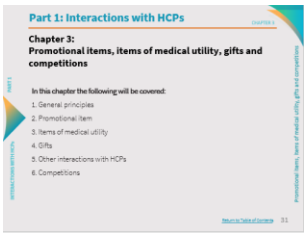

Chapter 3. Promotional items, items of medical utility, gifts and competitions.

Moving on to Chapter 3. Promotional items, items of medical utility, gifts and competitions. These are the topics we will cover in chapter 3.

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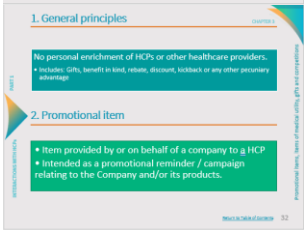

1. General principles

There should be no personal enrichment of HCPs or other healthcare providers.

No gift, benefit in kind, rebate, discount, kickback or any other pecuniary advantage to HCPs, administrative staff, government officials or the general public as an inducement to prescribe, lease, loan, supply, stock, dispense, administer or buy any medical device.

2. Promotional items

Definition: An item that is provided by or on behalf of a Member to another person or organization and is intended as a **promotional reminder / campaign** relating to the Company and its products. (Records of all promotional campaigns must be kept for a period of five years).

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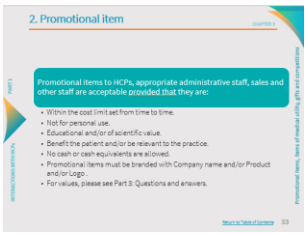

Promotional items to HCPs, appropriate administrative staff, sales and other staff are acceptable provided that they are:

- Within the cost limit set from time to time by SAMED.
- Not for personal use eg. no entertainment CDs/DVDs, electronic items for entertainment, tickets to attend sporting events or other forms of entertainment.

- Educational and/or of scientific value, benefit the patient and/or be relevant to the practice.
- No cash or cash equivalents (eg. vouchers) are allowed.
- Promotional items must be branded with Company name and/or Product and/or Logo .
- The value as set by SAMED Board for promotional items and items of medical utility to an individual HCP is R300 incl VAT/per item and for a unit / department within a hospital (ie. not a practice) is R1000 incl VAT/per item.

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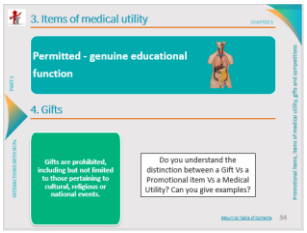

3. Items of medical utility

Definition:

An item that is provided by or on behalf of a Member to another person or organization, which has a **genuine educational function** that is intended to aid in the medical care of patients.

Classwork: now that you understand the definition, can you think of examples:

Possible answers: Items of medical utility generally include items that are beneficial to enhancing the provision of medical services and patient care, and have no personal benefit to the HCP. Items of medical utility including, informational and educational materials, scientific medical reference books, journals, periodicals and anatomical models intended for teaching or patient benefit are allowed to be provided to HCPs within the cost limit set from time to time by SAMED.

Class Work

For values note the maximum value for scientific medical reference books / journals and periodicals:

- Individual practicing HCP or practices, the value should not exceed R2 500 incl VAT/year.
- Training or academic institutions, the values should not exceed R10 000 incl VAT/year.

4. Gifts

We may not give gifts **of any nature**, including but not limited to those pertaining to cultural, religious or national events.

Can you differentiate between a Gift and a Promotional Item?

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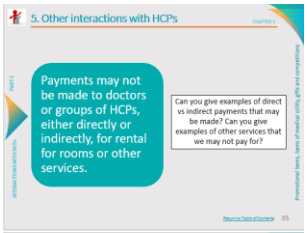

5. Other interactions with HCPs

Payments may not be made to doctors or groups of HCPs, either directly or indirectly, for rental for rooms or other services.

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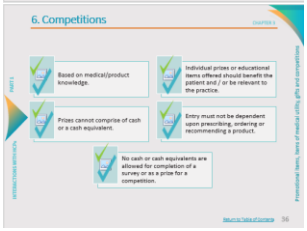

6. Competitions

Competitions should fulfil the following criteria:

- Firstly, the competition is based on medical/product knowledge or the acquisition of scientific knowledge.
- Individual prizes or educational items offered should benefit the patient and / or be relevant to the practice; and within the cost limit set from time to time by SAMED.
- The prize cannot comprise of cash or a cash equivalent (eg vouchers).
    - Entry into a competition must not be dependent upon prescribing, ordering or recommending of a product and no such condition shall be made or implied.
    - No cash or cash equivalents (eg. vouchers) are allowed for completion of a survey or as a prize for a competition.
    - If the prize is congress sponsorship, it will cover *bona fide* conference fees, accommodation and travel for the winner only. Note: In accordance with the prohibition of direct sponsorship to HCPs to third party arranged events, a prize in the form of congress sponsorship is prohibited as of 1 January 2018.

That concludes chapter 3. We covered Promotional items, items of medical utility, gifts and competitions. We will now move on to Chapter 4, charitable donations.

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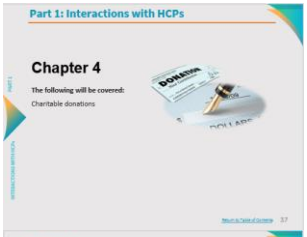

Chapter 4 covers charitable donations. The Code recognizes the need to do social good but makes provisions for such contributions to be genuine contributions without being disguised perverse incentives.

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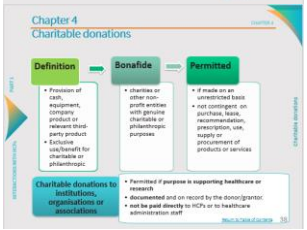

Chapter 4: Charitable donations

Charitable donations means provision of cash, equipment, company product or relevant third-party product, for exclusive use for charitable or philanthropic purposes and/or to benefit a charitable or philanthropic cause.

Charitable donations may only be made on an unrestricted basis and to *bona fide* charities or other non-profit entities or bodies whose main objects are genuine charitable or philanthropic purposes.

Charitable donations shall not be contingent in any way on past, present or potential future purchase, lease, recommendation, prescription, use, supply or procurement of the member company's products or services. It is important that support of charitable and/or philanthropic programmes and activities by Us is not viewed as a price concession, reward to favoured customers or as an inducement to purchase, lease, recommend, prescribe, use, supply or procure Our products or services.

We should implement an independent decision-making/review process to identify, prevent and mitigate against potential bribery and corruption risks arising in connection with the provision of a charitable donation to a specific prospective recipient. The process shall include a documented, prior evaluation of any such associated risks and of the relevant information concerning the intended recipient organisation or entity.

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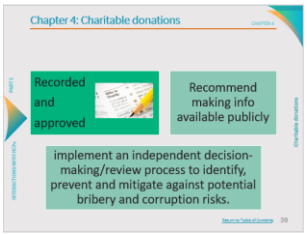


Financial donations to charities or other institutions may be made if properly recorded and approved by the responsible person(s) in each company or organisation.

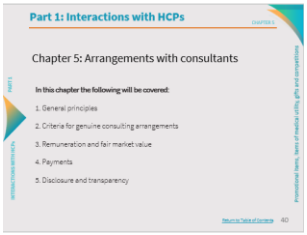
Donations, grants and benefits in kind to institutions, organisations or associations are only allowed provided:

- They are made for the purpose of supporting healthcare or research.
- They are documented and kept on record by the donor/grantor.
- Donations must not be paid directly to HCPs or to healthcare administration staff.

Companies are encouraged to make available publicly, information about donations, grants or benefits in kind made by them as covered in this section.

Let's move on to chapter 5: Arrangements with consultants.

Slide 40



Chapter 5: arrangements with consultants. In this chapter, we will cover the following:

1. General principles
2. Criteria for genuine consulting arrangements.
3. Remuneration and fair market value
4. Payments
5. Disclosure and transparency

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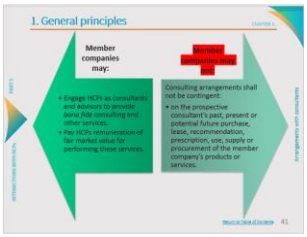

1. General principles

We may engage HCPs as consultants and advisors to provide *bona fide* consulting and other services, including but not limited to research, participation on advisory boards, presentations at company events and product development.

The following principles will apply and importantly, these principles are applicable even when a consultant HCP declines a fee for provision of their services:

- We may pay HCPs remuneration of fair market value for performing services.
- In all cases, consulting arrangements must be permitted under the laws and regulations of the country where the HCP is licensed to practise and be consistent with applicable professional codes of conduct in that country.

Can you think of professional codes that places restrictions on members in terms of being able to act as a consultant?

Possible answers: Dental Council – real dentist not permitted to appear in ads. Pharmacy Council: only real pharmacists can appear on ads.

- Consulting arrangements shall not be contingent in any way on the prospective consultant's past, present or potential future purchase, lease, recommendation, prescription, use, supply or procurement of the member company's products or services.
- When selecting consultants, we shall implement an independent decision-making/review process to identify, prevent and mitigate against potential bribery and corruption risks arising in connection with use of consultants. This process shall include a documented prior evaluation of any such associated risks and of the relevant background information concerning each prospective consultant.

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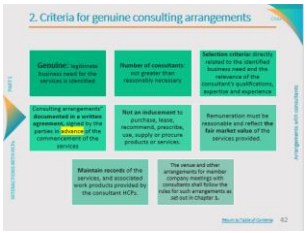

2. Criteria for genuine consulting arrangements

In addition to the general principles above, the arrangements which cover genuine consultancy or other services must, to the extent relevant to the particular arrangement, fulfil all the following criteria:

- Consulting arrangements must be entered into only where a legitimate business need for the services is identified in advance.
- The number of consultants retained must not be greater than the number reasonably necessary to achieve the identified business need.
- Selection of consultants must be based on criteria directly related to the identified business need and the relevance of the consultant's qualifications, expertise and experience to address the identified need. The volume or value of business generated by a prospective consultant or the HCO where s/he performs her/his professional activity is not a relevant criterion.
- Consulting arrangements with HCPs must be documented in a written agreement, signed by the parties in advance of the commencement of the services, which must specify the nature of the services to be provided and the basis for payment for those services. See Addendum 1, Article 1 for an example template of a consultancy agreement.
- The hiring of the consultant must not be an inducement to purchase, lease, recommend, prescribe, use, supply or procure the member company's products or services.
- The remuneration for the services rendered must be reasonable and reflect the fair market value of the services provided.
- Member companies must maintain records of the services, and associated work products provided by the consultant HCPs and of the use made of those services by the member company.
- The venue and other arrangements (eg hospitality, travel etc) for member company meetings with consultants shall follow the rules for such arrangements as set out in Chapter 1: General Criteria for Events

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3. Remuneration and fair market value

The remuneration paid to HCPs engaged as consultants should reflect fair market value for the services provided.

It shall not in any way be contingent upon the value of products or services which consultants may purchase, lease, recommend, prescribe, use, supply or procure in the course of their own professional practice or that may be purchased, leased, recommended, prescribed, used, supplied or procured by HCOs where they perform their professional activities.

Fair market value (FMV) definition

Fair market value is the value of the specified consultancy services which would be paid by the member company to the consultant, each dealing at arm's length in an open and unrestricted market, and when neither party is under any compulsion to buy or sell, and both parties have reasonable knowledge of the relevant facts.

Commercial reasonableness

In addition to the establishment of a value for services, such services should also be commercially reasonable where the agreement would make commercial sense if entered into by reasonable parties, even if there were no potential for additional business. For example, a company may be paying a HCP fair market value for a study, but is that study really necessary?

Valuation elements

Business needs: Assess the need relative to the resource deployed. For example, the need for more than four HCPs on an Advisory Board.

Terms of agreement: Assess what services will be provided and the manner in which parties will be compensated.

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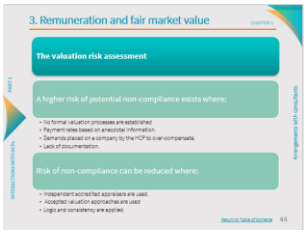

The valuation risk assessment

It is essential that any risk related to any agreement be minimised.

A higher risk of potential non-compliance exists where:

- No formal valuation processes are established.
- Payment rates are based upon anecdotal information about what other companies are paying.
- Demands placed on a company by the HCP to over-compensate.
- Lack of documentation.

Risk of non-compliance can be reduced where:

- Independent accredited appraisers are used.
- Accepted valuation approaches are used.

Logic and consistency are applied.

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Assessing FMV for HCPs and Key Opinion Leaders (KOLs)

Compensation earned by a HCP in his/her practice may not be directly comparable to the compensation associated with providing services to a member company.

Compensation should be based on an objective and consistent methodology including:

- Specific requirements of the company, product group or department engaging with the HCP.
- The specific services required.
- The HCP's experience and expertise.
- The time requirements for the engagement.
- The HCP's clinical specialty.

- HCPs versus KOLs

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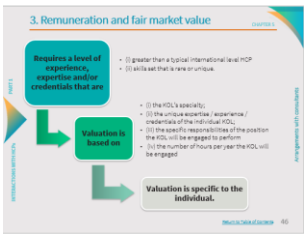

KOLs – Key Opinion Learners

- Can include physicians, nurses, technicians, pharmacists, academic researchers, administrators etc.
- Range in expertise and experience from local-level expert.

KOLs requires a level of experience, expertise and/or credentials that are:

(i) greater than a typical international level HCP or a
(ii) skills set that is rare or unique.

Valuation is based on:

(i) the KOL's specialty;
(ii) the unique expertise / experience / credentials of the individual KOL;
(iii) the specific responsibilities of the position the KOL will be engaged to perform;
(iv) the number of hours per year the KOL will be engaged.

Therefore, valuation is specific to the individual.

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4. Payments

All payments made for services must comply with all applicable tax and other legal requirements. We may pay for expenses reasonably incurred by consultants in providing the services which are the subject of the consulting agreement.

These may include: reasonable travel, meals and accommodation expenses incurred by consultants if attending meetings with or on behalf of us.

The written consulting agreement must detail which expenses can be claimed by the consultant in relation to the provision of the services and the basis for payment of these by the member company.

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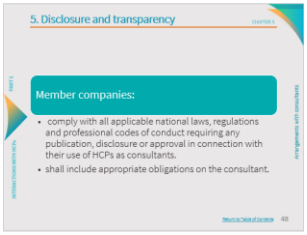

5. Disclosure and transparency

We should ensure they fully comply with all applicable national laws, regulations and professional codes of conduct requiring any publication, disclosure or approval in connection with their use of HCPs as consultants.

All required consents and approvals shall be obtained, including from the hospital or other HCO administration or from the HCP's superior (or designated competent authority), as applicable.

We should include appropriate obligations on the consultant to ensure that the individual's status as a consultant for the member company and his/her involvement in the research for, or the preparation of, material for scientific publication is disclosed at the time of any publication or presentation.

With that, we now conclude chapter 5. In this chapter we have covered general principles, criteria for genuine consulting arrangements, remuneration and fair market value and payments as well as disclosure and transparency.

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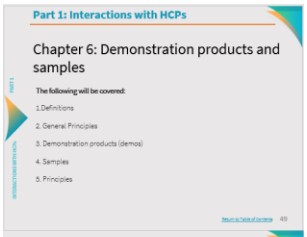

Chapter 6: Demonstration products and samples

We will now move on to Chapter 6: Demonstration products and samples. This chapter is limited to the provision of demonstration products and/or evaluation products and/or samples and related services at no charge.

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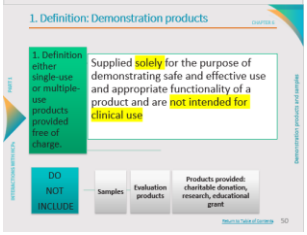

Demonstration products (demos): means either single-use or multiple-use products provided free of charge by or on behalf of a member company to HCOs or HCPs, who are equipped and qualified to use them.

Demos are supplied solely for the purpose of demonstrating safe and effective use and appropriate functionality of a product and are not intended for clinical use.

Demos do not include the following:

- Samples.
- Evaluation products.
- Products provided at no charge as part of a charitable donation or as part of a research or educational grant.
- Products provided at no additional charge as part of the overall purchase price in a commercial supply arrangement, eg. as part of an agreed discount arrangement, or as substitute products provided pursuant to a warranty agreement.

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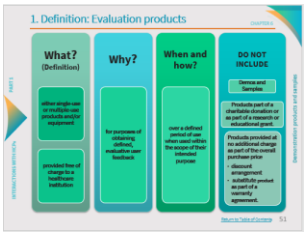

Evaluation products: means either single-use or multiple-use products and/or equipment provided free of charge to a healthcare institution by or on behalf of a member company for purposes of obtaining defined, evaluative user feedback over a defined period of use when used within the scope of their intended purpose.

Evaluation products do not include the following:

- Demos.
- Samples.
- Products provided at no charge as part of a charitable donation or as part of a research or educational grant.
- Products provided at no additional charge as part of the overall purchase price in a commercial supply arrangement, eg as part of an agreed discount arrangement, or as substitute products provided pursuant to a warranty agreement.

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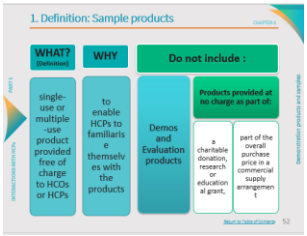

Samples: means single-use or multiple-use products provided free of charge by or on behalf of a member company to HCOs or HCPs who are equipped and qualified to use them in order to enable HCPs to familiarise themselves with the products in clinical use.

Samples do not include the following:

- Demos.
- Evaluation products.

- Products provided at no charge as part of a charitable donation or as part of a research or educational grant.
- Products provided at no additional charge as part of the overall purchase price in a commercial supply arrangement, eg as part of an agreed discount arrangement, or as substitute products provided pursuant to a warranty agreement.

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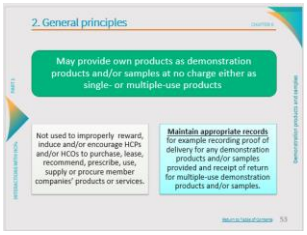

We should ensure we fully comply with all applicable national laws, regulations and professional codes of conduct requiring any publication, disclosure or approval in connection with their use of HCPs as consultants.

All required consents and approvals shall be obtained, including from the hospital or other HCO administration or from the HCP's superior (or designated competent authority), as applicable.

We should include appropriate obligations on the consultant to ensure that the individual's status as a consultant for the member company and his/her involvement in the research for, or the preparation of, material for scientific publication is disclosed at the time of any publication or presentation.

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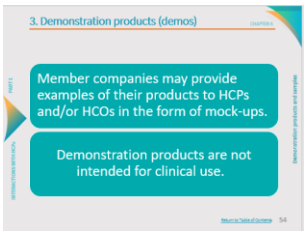

Member companies may provide their own products as demonstration products and/or samples (see the definitions above) at no charge in order to enable HCPs and/or HCOs (as applicable) to evaluate and/or familiarise themselves with the safe, effective and appropriate use and functionality of the product and/or related service and to determine whether, or when, to use, order,

purchase, prescribe or recommend the product and/or service in the future.

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Demonstration products and/or samples may be either single- or multiple-use products. Member companies may also provide products from another company in conjunction with the member company's own demonstration products and/or samples on an exceptional basis if those other company's products are required in order to properly and effectively demonstrate, evaluate or use the member company's products, eg. computer hardware and software produced by a company other than the member company.

Provision of demonstration products and/or samples must not improperly reward, induce and/or encourage HCPs and/or HCOs to purchase, lease, recommend, prescribe, use, supply or procure member companies' products or services. Any offer and/or supply of such products shall always be done in full compliance with applicable national laws, regulations and industry and professional codes of conduct.

We should in all cases maintain appropriate records in relation to the provision of demonstration products and/or samples to HCPs and/or HCOs, for example recording proof of delivery for any demonstration products and/or samples provided and receipt of return for multiple-use demonstration products and/or samples. We should clearly record in the member company's records as well as clearly disclose to HCPs and/or HCOs the no-charge basis and other conditions applicable for the supply of such demonstration products and/or samples no later than the time of the supply. The disclosure to HCPs and HCOs shall be in writing.

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4. Samples

Member companies may provide a reasonable number of samples at no charge to:

- allow HCPs and/or HCOs to familiarise themselves with the products and/or related services
- acquire experience in dealing with them safely and effectively in clinical use and to determine whether, or when, to use, order, purchase, prescribe or recommend the product and/or service in the future.

For single-use product samples:
The quantity provided for purposes of familiarisation must not exceed the amount reasonably necessary for the HCPs/HCOs to acquire adequate experience in dealing with the products.

For multiple-use product samples:
The specific length of time necessary for a HCP to familiarise him/herself with the product will depend on the frequency of anticipated use; the duration of required training; the number of HCPs who will need to acquire experience in dealing with the product; and similar considerations.

We should in all cases ensure that they retain title to multiple-use samples and that they have a process in place for promptly removing such multiple-use samples from the HCP's location at the conclusion of the familiarisation period.

Group Work: in your groups tabulate the differences and similarities between Demo, Evaluation and Sample products.

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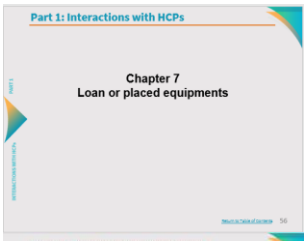

Chapter 7: Loan or placed equipment

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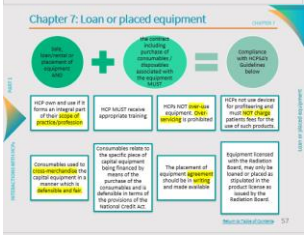
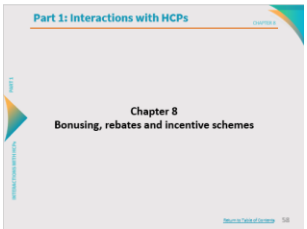


The sale, loan/rental or placement of equipment with a HCP, where the contract between the member and the HCP includes the purchase of consumables / disposables associated with the equipment, are subject to the following provisions:

- **HCPSA's Guidelines for Good Practice in the Healthcare Professions – Booklet 11, item 3.6 Technological Equipment:**
  - HCPs shall only own and use technological equipment if it forms an integral part of their scope of the profession and practice and on condition that the HCP concerned has received appropriate training in using and managing such equipment.
  - HCPs shall not over-use equipment for procedures, tests and other applications that are not indicated, scientific or based on evidence. This constitutes over-servicing and is prohibited.
  - HCPs shall not use technological equipment, healthcare products or devices for profiteering and must refrain from charging patients fees for the use of such products or devices that are not market related.

- The consumables are used to cross-merchandise the capital equipment in a manner which is defensible and fair.
- The consumables relate to the specific piece of capital equipment being financed by means of the purchase of the consumables and is defensible in terms of the provisions of the National Credit Act.
- The placement of equipment agreement should be in writing and, in cases of valid complaints, made available as per the complaints handling process in Part 2: Dealing with infringements of the Code.
- In the case of equipment licensed with the Radiation Board, such equipment may only be loaned or placed as stipulated in the product license as issued by the Radiation Board.



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Chapter 8: Bonusing, rebates and incentive schemes

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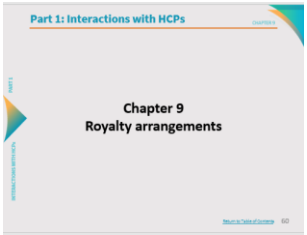
Members must provide accurate, transparent and responsible billing information to HCPs, reimbursement authorities and other payors. Such documentation should be in writing and in cases of valid complaints should be available as per the complaints handling process in Part 2, lodging a complaint.

Members are expected to follow the principles of acceptable invoicing procedures as detailed in the SAMED Policy on Transparent Invoicing. See addendum 2.

No member may offer a bonus, free goods or other incentive scheme deemed to be perverse, to an HCP in relation to the acquisition of goods and services in contravention of regulations issued in terms of the Medicines and Related Substances Act.



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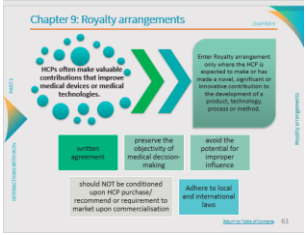
Chapter 9: Royalty arrangements



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HCPs, acting individually or as part of a group in which they are an active participant, often make valuable contributions that improve medical devices or medical technologies.

They may develop intellectual property, for example patents, trade secrets, or know-how, under a product or technology development or intellectual property licensing agreement.

A member should enter into a royalty arrangement with an HCP only where the HCP is expected to make or has made a novel, significant or innovative contribution to the development of a product, technology, process or method. A significant contribution by an individual or group, if it is the basis for compensation, should be appropriately documented.

Arrangements involving the payment of royalties to an HCP must be formalised in a written agreement, which may be subject to scrutiny by the SAMED Ethics Committee if such interaction forms part of a complaint lodged in terms of this Code.

The calculation of royalties payable to an HCP in exchange for intellectual property should be based on factors that preserve the objectivity of medical decision-making and avoid the potential for improper influence.

Royalties paid in exchange for intellectual property should not be conditioned upon:
(1) a requirement that the HCP purchase, order or recommend any product or medical device of the member or any product or technology produced as a result of the development project; or
(2) a requirement to market the product or medical device upon commercialisation. We should exclude from the calculation of royalties the number of units purchased, used or ordered by the HCP and / or member of the HCP's practice.

Local and international laws pertaining to royalties and intellectual property need to be adhered to.

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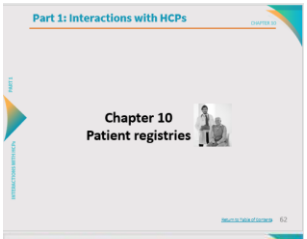

Chapter 10: Patient registries

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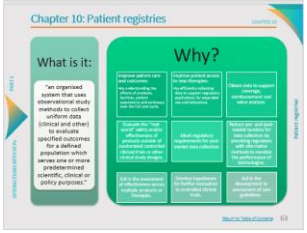

A patient registry is defined as "an organised system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population.

This population is defined by a particular disease, condition or exposure, and that serves one or more predetermined scientific, clinical or policy purposes."

A patient registry may be designed to achieve one or more of the following objectives:

- Improve patient care and outcomes by understanding the effects of products, facilities, patient populations and pathways over the full care cycle.
- Improve patient access to new therapies by efficiently collecting data to support regulatory applications for expanded use and indications.
- Obtain data to support coverage, reimbursement and value analysis.
- Evaluate the "real-world" safety and/or effectiveness of products outside of randomised controlled clinical trials or other clinical study designs.
- Meet regulatory requirements for post-market data collection.
- Reduce pre- and post-market burdens for data collection by providing regulators with alternative methods to monitor the performance of technologies.
- Aid in the assessment of effectiveness across multiple products or therapies.
- Develop hypotheses for further evaluation in controlled clinical trials.
- Aid in the development or assessment of care guidelines.

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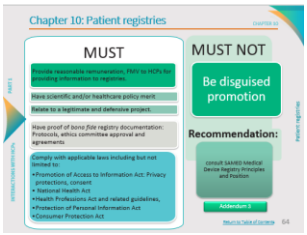

With regard to HCPs providing information to registries, remuneration provided must be reasonable, of fair market value and in relation to the work performed.

Registries may not be disguised as promotion, should be of scientific and/or healthcare policy merit, and relate to a legitimate and defensive project to obtain data/information. Proof of such *bona fide* registry data and documentation, including protocols, ethics committee approval and agreements, may be called for in the event of a complaint as per Part 2, lodging a compliant.

Registries should comply with all applicable laws, including but not limited to privacy protections, the consent of the person whose information it is, the Promotion of Access to Information Act, the National Health Act, the Health Professions Act and related guidelines, the Protection of Personal Information Act and the Consumer Protection Act.

When deciding on whether to conduct or participate in a registry, members are encouraged to consult and follow the SAMED Medical Device Registry Principles and Position Paper. See Addendum 3.

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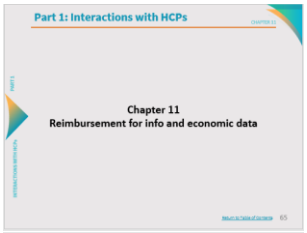

Chapter 11: Reimbursement for information and other economic data – marketing data, formulary, managed care and similar fees.

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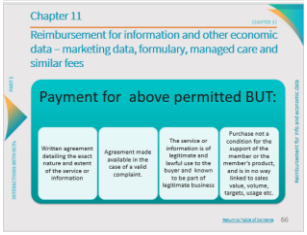

Members may pay for marketing data, formulary listings, managed care or any other similar information to persons or institutions offering such services or information, provided that such fees:

Are based on a written agreement detailing the exact nature and extent of the service or information for which the fees are paid, which agreement should be available on request or for evaluation in the case of a valid complaint.

The service or information is of legitimate and lawful use to the buyer and such service or information is known to form part of the legitimate business of the seller thereof. The purchase of the service or information is not a condition for the support of the member or the member's product, and is in no way linked to sales value and/or sales volume, targets and/or preferential usage or recommendation of any medical device.

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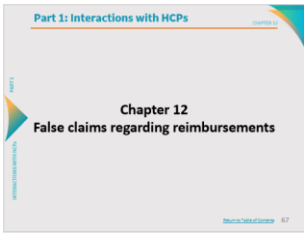

Chapter 12: False claims regarding reimbursement

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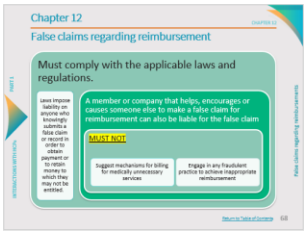

Since many healthcare programmes (medical schemes, etc) reimburse and pay for member products, each member must comply with the applicable laws and regulations.

These laws may impose liability on anyone who knowingly submits a false claim or record in order to obtain payment or to retain money to which they may not be entitled.

An example is invoicing for a cheaper product in supplying a more expensive version.

A member or company that helps, encourages or causes someone else to make a false claim for reimbursement can also be liable for the false claim. No member may suggest mechanisms for billing for services that are not medically necessary, or for engaging in any fraudulent practice to achieve inappropriate reimbursement.

Ie. Criminal law and Criminal Procedure Act, as well as Medical Schemes Act and regulations.

Chapter 13: Healthcare representatives

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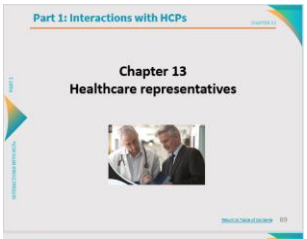

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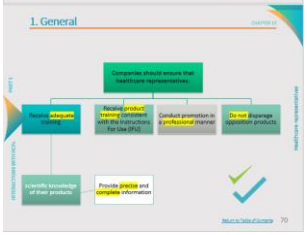

Companies should ensure that healthcare representatives have adequate training to ensure sufficient scientific knowledge of the medical devices which they promote to enable the provision of precise and complete information about such products.

Product training must be consistent with the instructions for use of a medical device.

Healthcare representatives are to conduct the promotion of a medical device in a professional manner, and are not permitted to disparage any opposition products.

In the event that the healthcare representative is attending the operating room / clinical environment in his/her capacity as a company representative and on company time he/she may not use and/or apply company product, deliver patient or medical care directly to a patient even if they hold appropriate certification/licences.

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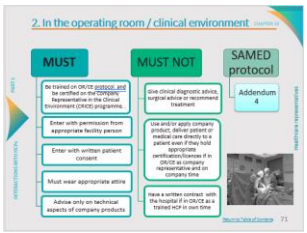

In the operating room / clinical environment

Healthcare representatives acting on behalf of the company in the operating room / clinical environment:

- Must be trained on operating room / clinical environment protocol, and be certified on the Clinical Representative in the Clinical Environment (CRICE) programme. Refer to www.crice.co.za.
- May only enter an operating room / clinical environment upon permission from appropriate members of the medical staff of the facility and with written consent from the patient concerned.

- Must wear appropriate attire as provided or permitted by the facility.
- May only advise on technical aspects of company products consistent with the approved package insert / instructions for use.
- May not give clinical diagnostic advice, surgical advice or recommend treatment, even as the result of a direct request from the surgeon, operating room staff or any other healthcare professional.
- In the event that the healthcare representative is attending the operating room / clinical environment in his/her capacity as a trained HCP, he/she must have a written contract with the hospital and should be in a position to produce the contract, within a reasonable time, upon request.
- Also see addendum 4: SAMED protocol on member company employees' attendance in operating room / clinical environment.

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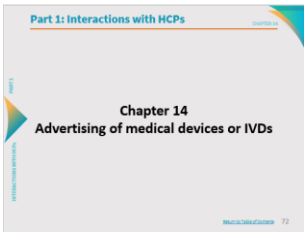

Chapter 14: Advertising and promoting medical devices

1. General principles
2. Public risk
3 Advertising and promotional materials to healthcare professionals
4. Claim substantiation
5. Scientific information
6. Market and scientific research

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7. Comparative advertising
8. Endorsements and testimonials by healthcare professionals
9. The use of non-promotional material
10. Artwork and visual representation
11. Journal advertising
12. Electronic/digital media.

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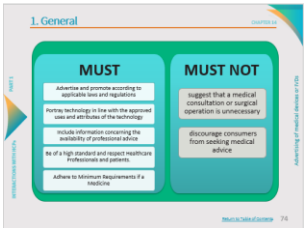

1. General Principles

All medical devices must be advertised and promoted according to any applicable laws and regulations which exist or may be set for the promotion and advertisements of medical devices in South Africa.

- Advertisements and promotions must portray the technology in line with the approved uses and attributes of the technology.
- Advertising and/or promotion shall not suggest that a medical consultation or surgical operation is unnecessary nor shall it discourage consumers from seeking medical advice. Consideration should be given to the inclusion of information concerning the availability of professional advice.
- All promotions and advertisements should be of a high standard and respect Healthcare Professionals and patients.

Minimum requirements must conform to the Medicines Act including the Regulations and MCC/SAHPRA Guidelines.

In other words, they must:

- be provided in a clear and legible manner,
- be consistent with the most recently approved instructions for use, and
- an advertisement which contains two or more pages must not be false or misleading when each page is read in isolation.

- The conformity of an advertisement with this section should be assessed in terms of its probable impact upon the reasonable person to whom the advertisement is directed.
- No company shall be involved in promotional schemes which are hazardous to the public or which bring the industry into disrepute.
- Information, claims and comparisons used in promotional materials and activities, must be accurate, balanced, fair, objective and unambiguous and must be based on an up-to-date evaluation of all the evidence, and must reflect that evidence.
- Such information or the manner in which it is portrayed, must not mislead either directly or by implication or by distortion or undue emphasis. Material must be sufficiently complete to enable the recipients to form their own opinion of the therapeutic value of the medical device.
- Promotional material must not be misleading as to the nature of the product, its ingredients or indications and must encourage the rational use of a medical device by presenting it objectively and without exaggerating its properties

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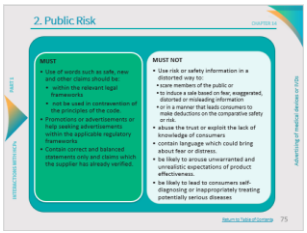

2. Public Risk

MUST

The use of words such as safe, new and other claims should be within the relevant legal frameworks, and should not be used in contravention of the principles of the code.

- Promotions or advertisements to the public must take place within the applicable regulatory frameworks, and where such advertisement or promotion relates to help-seeking behaviour amongst the public.
- Must contain correct and balanced statements only and claims which the supplier has already verified.

MUST NOT

- Must not use risk or safety information in a distorted way to scare members of the public or to induce a sale based on fear, exaggerated, distorted or misleading information or in a manner that leads consumers to make deductions on the comparative safety or risk.
- Must not abuse the trust or exploit the lack of knowledge of consumers or contain language which could bring about fear or distress.
- Must not be likely to arouse unwarranted and unrealistic expectations of product effectiveness.
- Must not be likely to lead to consumers self-diagnosing or inappropriately treating potentially serious diseases.
- Must not mislead, or be likely to mislead, directly or by implication or through emphasis, comparisons, contrasts or omissions:
    - that they are suffering from a serious ailment; or
    - that harmful consequences may result from the technology not being used.
    - that encourages, or be likely to encourage, inappropriate or excessive use;
    - that contain any claims, statement or implication that it is infallible, unfailing, magical, miraculous, or that it is a certain, guaranteed or sure cure;
    - that contains any claim, statement or implication that it is effective in all cases of a condition;
    - that contains any claim, statement or implication that the goods are safe or that their use cannot cause harm or that they have no side-effects.

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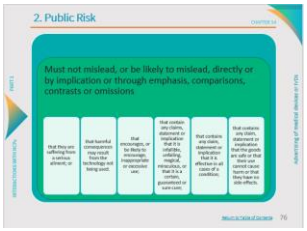


Must not mislead, or be likely to mislead, directly or by implication or through emphasis, comparisons, contrasts or omissions:

- that they are suffering from a serious ailment; or
- that harmful consequences may result from the technology not being used.
- that encourages, or be likely to encourage, inappropriate or excessive use;
- that contain any claims, statement or implication that it is infallible, unfailing, magical, miraculous, or that it is a certain, guaranteed or sure cure;
- that contains any claim, statement or implication that it is effective in all cases of a condition;

that contains any claim, statement or implication that the goods are safe or that their use cannot cause harm or that they have no side-effects

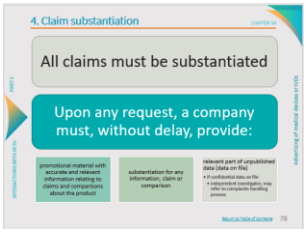
Slide 77

3. Advertising and promotional materials to healthcare professionals

When Company Representatives introduce a medical device to a healthcare professional for the first time, they should provide a copy of the latest instructions for use. On subsequent occasions, such information should be available on request.

An advertisement or promotional material must not offer any personal incentive to a pharmacy assistant, clinic nurses or other non-healthcare professional sales person at retail level, to recommend or supply medical devices.

Slide 78



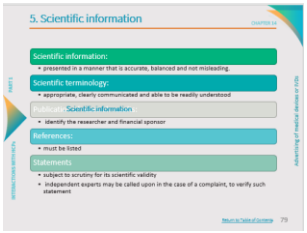
4. Claim substantiation

All claims must be substantiated. Any information, claim or comparison must be capable of substantiation. No substantiation is required for claims in the instructions for use which have been approved by the medical devices regulatory authority.

Upon any request, a company must, without delay, provide promotional material with accurate and relevant information relating to claims and comparisons about the products which the company markets. Substantiation for any information, claim or comparison must be provided without delay.

When promotional material refers to (unpublished) data on file, the relevant part of this data must be provided without delay on request.

Slide 79



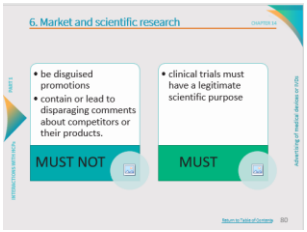
5. Scientific information

Any scientific information in an advertisement should be presented in a manner that is accurate, balanced and not misleading.

- Scientific terminology must be appropriate, clearly communicated and able to be readily understood by the audience to whom it is directed.
- Publication of research results must identify the researcher and financial sponsor of the research.
- All references must be listed.

- Any statement made may be subject to scrutiny for its scientific validity, and independent experts may be called upon in the case of a complaint, to verify such statement(s).

Slide 80



6. Market and scientific research

Market research activities, and the like must not be disguised promotions, nor contain or lead to disparaging comments about competitors or their products.

- Such market research must be conducted with a primarily market research scientific or educational purpose.
- Material relating to medical devices and their uses, whether promotional in nature or not, which is sponsored by a company should clearly indicate by whom it has been sponsored.
- All clinical trials must have a legitimate scientific purpose. Post-marketing surveillance studies, post authorisation studies, observational/non-interventional studies and the like must not be disguised promotions. All clinical trials must comply with SA legal requirements, South African Good Clinical Practice Guidelines (GCP) and research ethics approvals as required

Slide 81

7. Comparative advertising

Comparative advertisements must be in alignment with South African law, be balanced and must not be misleading or likely to be misleading, either about the technology or classes of technology, with which it is compared.

Points of comparison should be factual and reflect the body of scientific evidence. Comparisons should not imply that the technology, or classes of technology, with which comparison is made, are harmful or ineffectual.

A comparison in promotion of a medical device is only permitted if:

- it is not misleading or disparaging,
- medical devices for the same needs or intended for the same purpose are compared,
- one or more material, relevant and representative feature(s) which is/are capable of substantiation is/are compared. Points of comparison should be factual and reflect the body of scientific evidence. Comparisons should not imply that the medical devices with which comparison is made, are harmful or ineffectual,
- no confusion is created between the medical device advertised and that of a competitor or between the advertisers' trademarks, proprietary names, other distinguishing marks and those of a competitor,
- the trademarks, proprietary names, other distinguishing marks, medical devices, services, activities or circumstances of a competitor are not discredited or denigrated. No unfair advantage must be taken of the reputation of a brand, trademark, proprietary name or other distinguishing marks of another company,
- trademarks/trade names or company names of another company may only be mentioned with written permission from the other company, unless doing so is permitted by intellectual property law and / or common law, as amended and developed from time to time, medical devices are not presented as imitations or replicas of goods bearing another company trademark or trade name, and hanging (open ended) comparisons are not allowed.

Slide 82

8. Endorsements and testimonials by healthcare professionals

Advertising and/or promotion shall not contain recommendation of a medical device by scientists or healthcare professionals unless substantiated.

The Health Professions Council South Africa does not allow endorsement for financial gain.

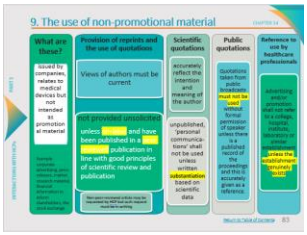
The name or photograph or film / video, television advertisement, radio advertisement or any other reproduction of a member of a healthcare professional must not be used in any way that is contrary to the applicable professional code(s) for that profession and all endorsements, where permitted by professional codes, must be done within the scope of such codes.

The use of healthcare professionals for marketing, promotion, endorsements or testimonial must take place within the scope set by the professional codes applicable to such professionals.

Testimonials should be less than three years old and be the genuine views of the user.

Testimonials must not breach the Code. They must be documented, genuine, not misleading and illustrate typical cases only.

Slide 83



9. The use of non-promotional material

Material issued by companies that relates to medical devices but which is not intended as promotional material for those medical devices per se, for example corporate advertising, press releases, market research material, financial information to inform shareholders, the stock exchange, should be examined to ensure that it does not contravene the relevant statutory requirements.

Provision of reprints and the use of quotations

Utmost care must be taken to avoid ascribing claims or views to authors when these no longer represent the current views of the authors concerned.

Reprints of journal articles

Reprints of articles in journals must not be provided unsolicited to any healthcare professional unless the articles are on-label and have been published in a peer reviewed publication in line with good principles of scientific review and publication. If a non-peer-reviewed article is requested by a healthcare professional, a copy may be provided on written request or as per requirements for scientific or medical information.

Scientific quotations

Quotations from medical and scientific literature must accurately reflect the intention and meaning of the author(s). If unpublished, 'personal communications' shall not be used unless the company, organisation or individual is able to supply written substantiation based on scientific data upon request.

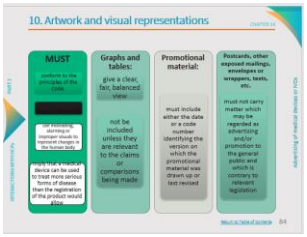
Public quotations

Quotations taken from public broadcasts, for example radio, television or the Internet, and from private occasions, such as medical conferences or symposia relating to medical devices, must not be used without

the formal permission of the speaker unless there is a published record of the proceedings and this is accurately given as a reference.

Reference to use by healthcare professionals
Advertising and/or promotion shall not refer to a 'college', 'hospital', 'institute', 'laboratory' or similar establishment, unless the establishment genuinely exists.

Slide 84

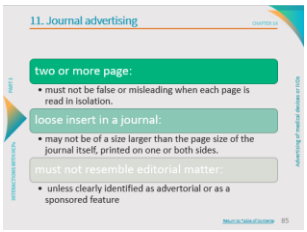


10. Artwork and visual representations

All artwork, including illustrations, graphs, tables, logos and trade dress must conform to the principles of the Code.

- Graphs and tables must be presented in such a way as to give a clear, fair, balanced view of the matters with which they deal, and must not be included unless they are relevant to the claims or comparisons being made.
- Advertising shall not use misleading, alarming or improper visuals to represent changes in the human body.
- Visuals may not imply that a medical device can be used to treat more serious forms of disease than the registration of the product would allow.
- Advertisements should not be flippant or use inappropriate imagery or imagery out of context. Advertisers are encouraged to convey the message that medical devices should be treated with respect and may not be suitable for some people.
- Promotional material must include either the date or a code number identifying the version on which the promotional material was drawn up or last revised.
    - Postcards, other exposed mailings, envelopes or wrappers, texts, etc. must not carry matter which may be regarded as advertising and/or promotion to the general public and which is contrary to relevant legislation.

Slide 85

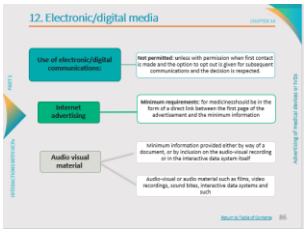


11. Journal advertising

An advertisement which contains two or more pages must not be false or misleading when each page is read in isolation.

An advertisement taking the form of a loose insert in a journal may not be of a size larger than the page size of the journal itself, printed on one or both sides.
Advertisements in journals must not resemble editorial matter unless clearly identified as advertorial or as a sponsored feature.

Slide 86



Promotion of Medical Devices and IVDs via digital or electronic media must comply with all aspects of the Code.

Use of electronic/digital communications

- The telephone, mobile phone, SMS, e-mail, mobile messaging, social media, facsimile machines, or any form of electronic communications as defined in the Electronic Communications and Transactions

Act, No 25 of 2002, as amended from time to time, must not be used for promotional purposes, except where, when first contact is made, the option to opt out is given and the decision is subsequently respected.

- The option to opt out should also be provided on all subsequent communications, even if the addressee has not opted out after the first contact. This provision shall be subject to all national legislation in force from time to time, to the extent applicable.

Internet links

In the case of an advertisement included as part of independently produced information on the internet, the statement should be in the form of a direct link between the first page of the advertisement and the minimum information.

Audio visual material

Audio-visual or audio material such as films, video recordings, sound bites, interactive data systems and such like:

The minimum information required by the South African legislative frameworks must be provided either by way of a document that is made available to all persons to whom the material is shown or sent, or by inclusion on the audio-visual recording or in the interactive data system itself.

When the minimum information is included in an interactive data system, instructions for accessing it must be clearly displayed, and if the material consists of sound only, the minimum information may be provided by the way of a document that is made available to all persons to whom the material is played or sent

12. Electronic/digital media

Promotion of Medical Devices and IVDs via digital or electronic media must comply with all aspects of the Code.

Notes

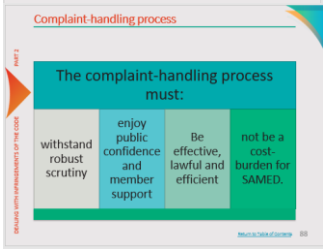
This concludes Part 1: Interaction with Health Care Professionals.

Part 2: Dealing with infringements of the Code

Slide 87

PART 2: Dealing with infringements of the Code

Slide 88



The overall goal of this procedure is to ensure a complaint-handling process that withstands robust scrutiny, enjoys public confidence and member support, and which is effective, lawful and efficient and not a cost-burden for SAMED.

Slide 89

Lodging a complaint

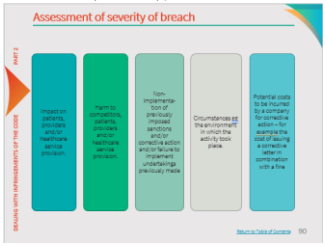
Any person may lodge a complaint against a SAMED member or a signatory to the Code via the whistleblowing mechanism as indicated on the code page of SAMED's website. Such complaints may be lodged anonymously.

Alternatively, a formal complaint may be lodged on completion of the prescribed forms. There is no lodging fee required.
The Independent Chairperson has the powers to deal with such complaint as are set out under paragraph 5 above subject to the complainant remaining anonymous.

If, at any stage of the proceedings, it is no longer possible or fair to continue to conduct the proceedings whilst the complainant remains anonymous, the Independent Chairperson will communicate this to the whistle blower and request him or her whether he or she consents to his identity being revealed so that the complaint may be dealt with to completion.

If the complainant elects not to disclose his her identity, the Independent Chairperson will decide on the further steps that are to be taken, including appointing an independent investigator, from SAMED's panel of independent investigators and/or referring the complaint or the independent investigator's report to another authority, including the Regulatory Authority that is responsible for IVD regulation and device or IVD establishment registration, the Health Professions Council of South Africa, the Nursing Council, Pharmacy Council or other professional body, the Hospital Association of South Africa, the Council for Medical Schemes, the Consumer Commissioner or the Department of Health, the South African Police Service (SAPS), the National Prosecuting Authority (NPA).

Slide 90

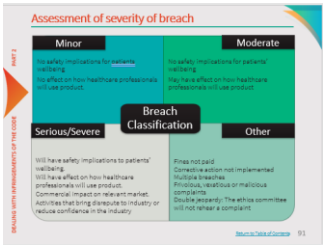


The severity of the breach is assessed based on the following:

- Impact on patients, providers and/or healthcare service provision.
- Harm to competitors, patients, providers and/or healthcare service provision.

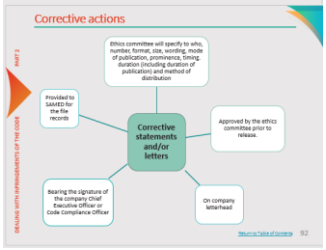
- The non-implementation of previously imposed sanctions and/or corrective action and/or failure to implement undertakings previously made.
- Circumstances eg. the environment in which the activity took place.

Slide 91



Breaches may be classified as Minor, Moderate or Severe as indicated here

Slide 92

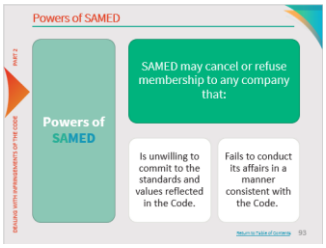


Guidelines in relation to specific sanctions

In the case of a corrective letter, the ethics committee will specify to whom the letter must be sent. This will reflect the audience that may have been involved / received the material found in breach of the Code. A copy of the distributed corrective letter (on company letterhead bearing the signature of the company Chief Executive Officer or Code Compliance Officer) should be provided to SAMED for the file records.

The number, format, size, wording, mode of publication, prominence, timing (including duration of publication) and method of distribution of corrective statements / letters must be approved by the ethics committee prior to release

Slide 93



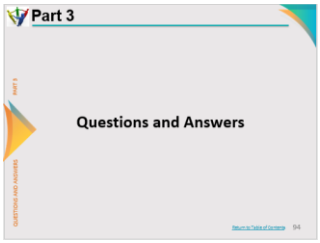
Ultimately, SAMED may cancel or refuse membership to any company that is unwilling to commit to the values reflected in the Code.

Notes

This now concludes Part 2.

PART 3: Questions and Answers

Slide 94



PART 3: Questions and Answers

Group Work

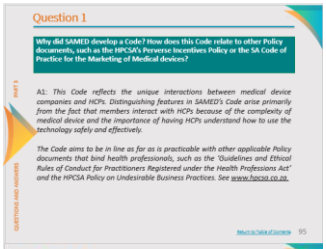
Recommend covering this section using the game Double Jeopardy as outlined below. Please incorporate the 5 principles as part of answers where possible.

Double Jeopardy

- Create a grid scorecard on flipchart paper that reflects the different groups as vertical columns and the number of questions as horizontal columns.
- In a round robin allow each group to answer a question.
- Allocate 1 point for complete and accurate answer
- For every wrong answer, deduct half a point.
- If any other group adds a valid and additional point to the answer given, give that group 1 point as well. However, if the other group gave a wrong answer, deduct one point.

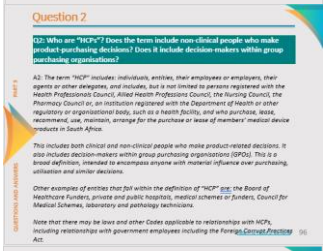
Part 3: General questions

Slide 95



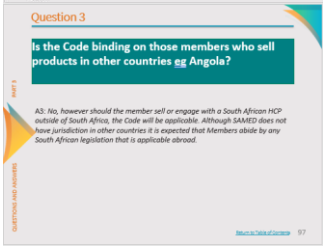
Q1: Why did SAMED develop a Code? How does this Code relate to other Policy documents, such as the HPCSA's Perverse Incentives Policy or the SA Code of Practice for the Marketing of Medical devices?

Slide 96



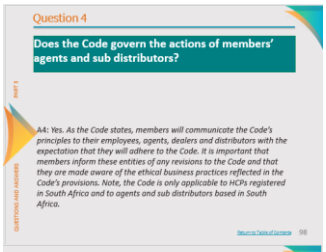
Q2: Who are "HCPs"? Does the term include non-clinical people who make product-purchasing decisions? Does it include decision-makers within group purchasing organisations?

Slide 97



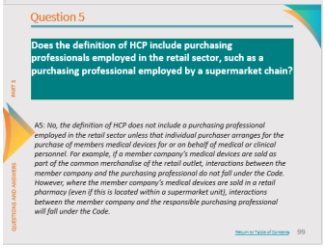
Q3: Is the Code binding on those members who sell products in other countries eg. Angola?

Slide 98



Q4: Does the Code govern the actions of members' agents and sub distributors?

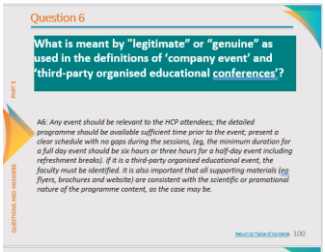
Slide 99



Q5: Does the definition of HCP include purchasing professionals employed in the retail sector, such as a purchasing professional employed by a supermarket chain?

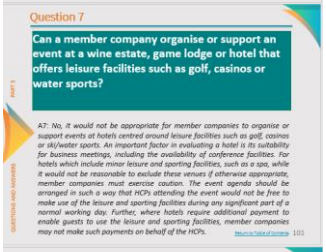
Part 3: Chapter 1 -General criteria for events

Slide 100



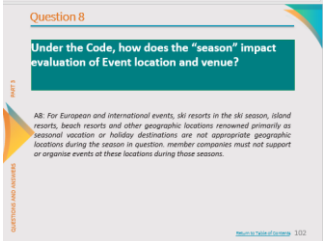
Q6: What is meant by "legitimate" or "genuine" as used in the definitions of 'company event' and 'third-party organised educational conferences'?

Slide 101



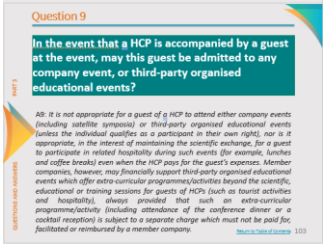
Q7: Can a member company organise or support an event at a wine estate, game lodge or hotel that offers leisure facilities such as golf, casinos or water sports?

Slide 102



Q8: Under the Code, how does the "season" impact evaluation of Event location and venue?

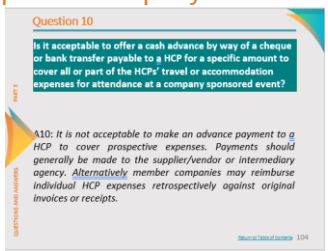
Slide 103



Q9: In the event that a HCP is accompanied by a guest at the event, may this guest be admitted to any company event, or third-party organised educational events?

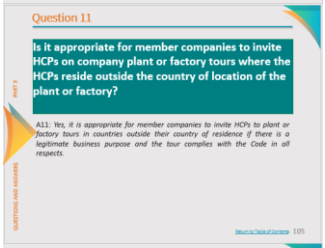
PART 3 Chapter 2: Company events

Slide 104



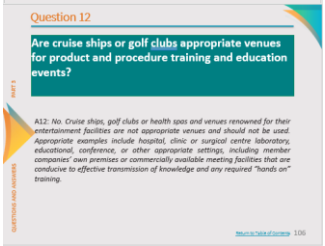
Q10: Is it acceptable to offer a cash advance by way of a cheque or bank transfer payable to a HCP for a specific amount to cover all or part of the HCPs travel or accommodation expenses for attendance at the event?

Slide 105



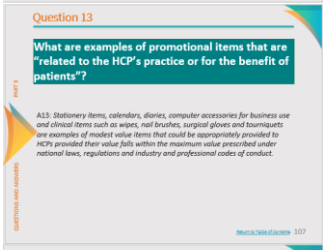
Q11: Is it appropriate for member companies to invite HCPs on company plant or factory tours where the HCPs reside outside the country of location of the plant or factory?

Slide 106



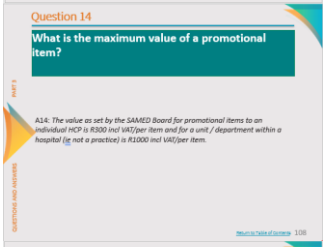
Q12: Are cruise ships or golf clubs appropriate venues for product and procedure training and education events?

Slide 107



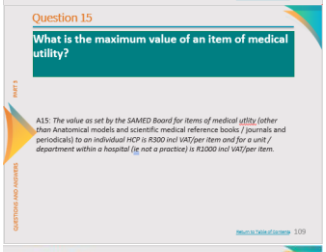
Q13: What are examples of promotional items that are "related to the HCP's practice or for the benefit of patients"?

Slide 108



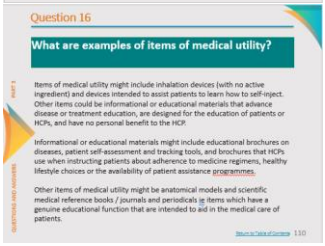
Q14: What is the maximum value of a promotional item?

Slide 109



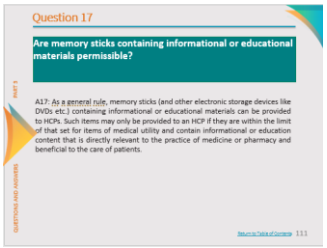
Q15: What is the maximum value of items of medical utility?

Slide 110



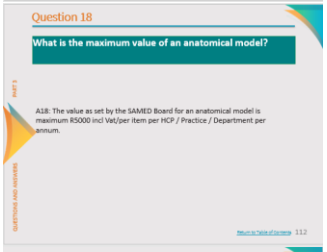
Q16: What are examples of items of medical utility?

Slide 111



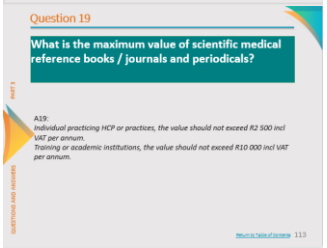
Q17: Are memory sticks containing informational or educational materials permissible?

Slide 112



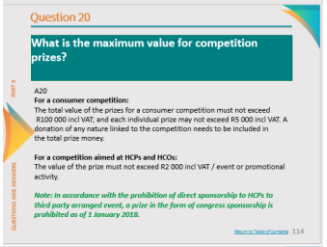
Q18: What is the maximum value of an anatomical model?

Slide 113



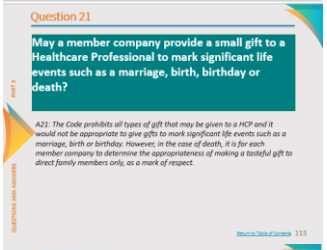
Q19: What is the maximum value of scientific medical reference books / journals and periodicals?

Slide 114



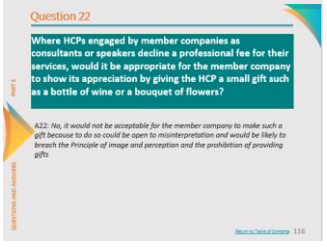
Q20:
What is the maximum value for competition prizes?

Slide 115



Q21: May a member company provide a small gift to a Healthcare Professional to mark significant life events such as a marriage, birth, birthday or death?

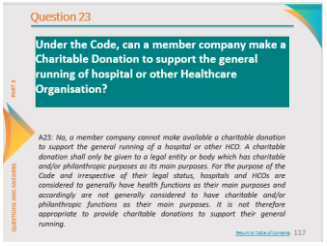
Slide 116



Q22: Where HCPs engaged by member companies as consultants or speakers decline a professional fee for their services, would it be appropriate for the member company to show its appreciation by giving the HCP a small gift such as a bottle of wine or a bouquet of flowers?

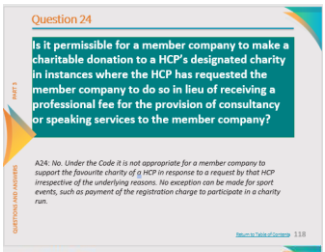
Part 3 Chapter 4: Charitable donations

Slide 117



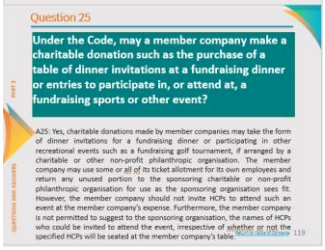
Q23: Under the Code, can a member company make a Charitable Donation to support the general running of hospital or other Healthcare Organisation?

Slide 118



Q24: Is it permissible for a member company to make a charitable donation to a HCP's designated charity in instances where the HCP has requested the member company to do so in lieu of receiving a professional fee for the provision of consultancy or speaking services to the member company?

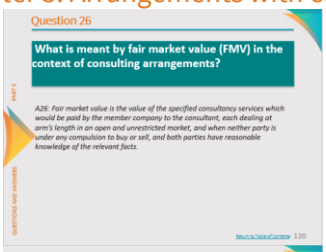
Slide 119



Q25: Under the Code, may a member company make a charitable donation such as the purchase of a table of dinner invitations at a fundraising dinner or entries to participate in, or attend at, a fundraising sports or other event?

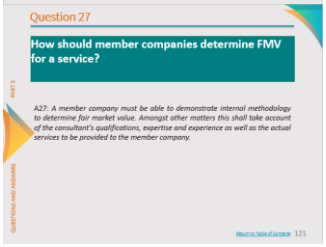
Part 3 Chapter 5: Arrangements with consultants

Slide 120



Q26: What is meant by fair market value (FMV) in the context of consulting arrangements?

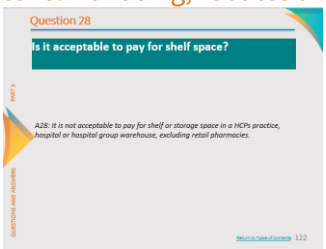
Slide 121



Q27: How should member companies determine FMV for a service?

Part 3 Chapter 8: Bonusing, rebates and incentive schemes

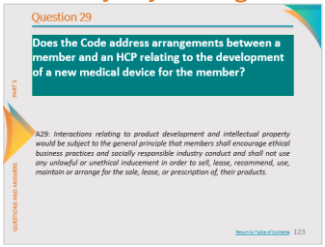
Slide 122



Q28: Is it acceptable to pay for shelf space?

Part 3 Chapter 9: Royalty arrangements

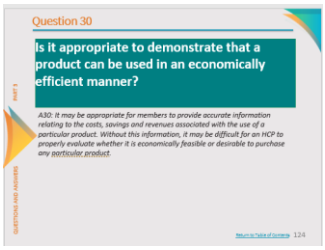
Slide 123



Q29: Does the Code address arrangements between a member and an HCP relating to the development of a new medical device for the member?

Part 3 Chapter 11: Reimbursement for information and other economic data – marketing data, formulary, managed care and similar fees

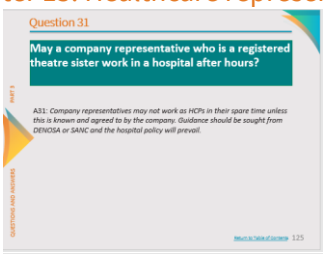
Slide 124



Q30: Is it appropriate to demonstrate that a product can be used in an economically efficient manner?

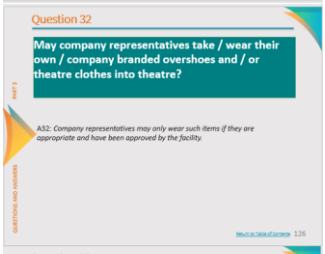
Part 3 Chapter 13: Healthcare representatives

Slide 125



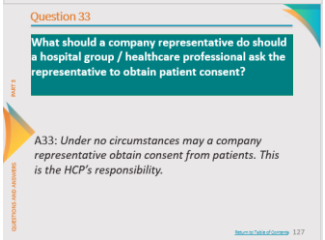
Q31: May a company representative who is a registered theatre sister work in a hospital after hours?

Slide 126



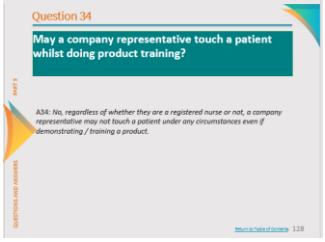
Q32: May company representatives take / wear their own / company branded overshoes and / or theatre clothes into theatre?

Slide 127



Q33: What should a company representative do should a hospital group / healthcare professional ask the representative to obtain patient consent?

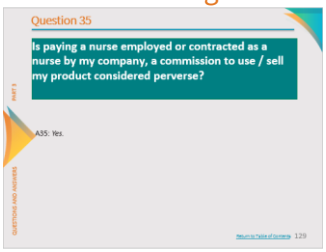
Slide 128



Q34: May a company representative touch a patient whilst doing product training?

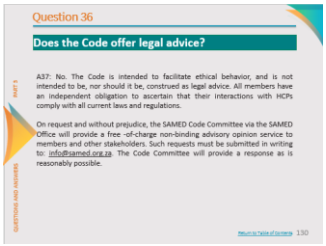
Questions on PART 2: Dealing with infringements of the Code

Slide 129



Q35: Can a HCP be reimbursed by a member for cleaning and packing a loan set at the place of their employ ie. a theatre nursing sister?

Slide 130

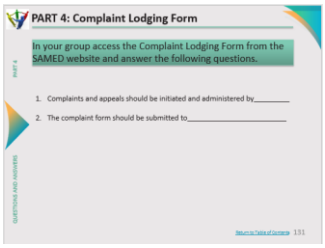


Q36: Does the Code offer legal advice?

Notes

PART 4: Complaint Lodging Form

Slide 131



PART 4: Complaint Lodging Form

Complaint in terms of the Medical Device Code of Ethical Marketing and Business Practice.

In your group access and review the Complaint Lodging Form. Anwser the following questions:

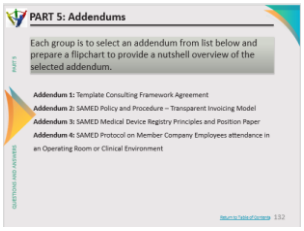
Group Work

1. Complaints and appeals should be initiated and administrated by_____.
2. The complaint form should be submitted to _____.

Answers:
Complaints and appeals should where possible be initiated and administrated by the Compliance Officer and / or CEO of the Company.
Complaint form should be submitted to info@samed.org.za

Notes

PART 5: Addendums



Slide 132

PART 5: Addendums

Addendum 1: Template Consulting Framework Agreement

Addendum 2: SAMED Policy and Procedure - Transparent Invoicing Model

Addendum 3: SAMED Medical Device Registry Principles and Position Paper

Addendum 4: SAMED Protocol on Member Company Employees' attendance in an Operating Room or Clinical Environment

Group Work

Each group select an addendum and prepare a flipchart to provide a nutshell overview of the selected addendum.

Notes

Conclusion

Slide 132

This now brings us to the end of the presentation.

Please remember that staff need to be complete the official SAMED Assessment.