SAMED
advancing patient care through MedTech

Member Forum

17 February 2022, 13:00 – 16:00

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SAMED

advancing patient care through MedTech

South African Medical Technology Industry Association

Overview of the Medical Device Code
of Ethical Marketing and Business Practice

Principles that underline The Code

The Principle of Image and Perception

The Principle of Separation

The Principle of Transparency

The Principle of Equivalence

The Principle of Documentation

Interaction with HCPs

- Indispensable to good patient care and progressive practice
- Possible risk of manipulation to be avoided at all times
- Clear rules and sanction are essential

Why the Code?

It's all about the patient

The Medical Device Code advances quality care

- Safeguard the patient and improve healthcare
  - Industry self-regulation through dedicated Code
  - Serious about eradicating perceived perverse practices
  - Support independent clinical decision making
  - It is essential that HCPs at all times apply CLINICAL JUDGEMENT when selecting products for their patients WITHOUT any untoward inducements!

The Code draws the ethical line

- Signatories may not offer inducement to HCP or other customer in order to sell, lease, recommend or arrange for the sale or lease of their products
- Gives effect to existing legislation and HPCSA rules: Essence is to draw the line between central value of key practices and distortion of practices for unethical gain
- Code gives clear guidance on where the line lies in each set of circumstances

Governed by the Code

SAMED members and medtech industry (signatories)

Impacted by the Code

Healthcare professionals and societies
Healthcare providers
Healthcare funders
Procurement personnel
Conference organisers
Patients

Progress in recognition of Code

- Project 18C in collaboration with Marketing Code Authority (Pharma & others)
- Meet with MoH – supported by Dr Crisp DDG NHI

Snapshot of The Code

Part 1: Interactions with healthcare professionals

- Company & third-party arranged educational events
- Promotional items, competitions & charitable donations
- Demo products, samples, loaned & placed devices
- Consultant fees & royalties
- Patient registries
- False claims to medical schemes
- Conduct of healthcare representatives
- Advertising of medical devices

Part 2: Dealing with infringements

- Complaint procedure
- Whistle-blowing hotline
- Formal complaint
- Independent chairperson
- Ethics committee
- Hearings
- Sanctions

Part 3: Questions and answers

Part 4: Complaint form

Part 5: Addendums

General Criteria for Events

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General Criteria for Events

General Criteria for Events

General Criteria for Events

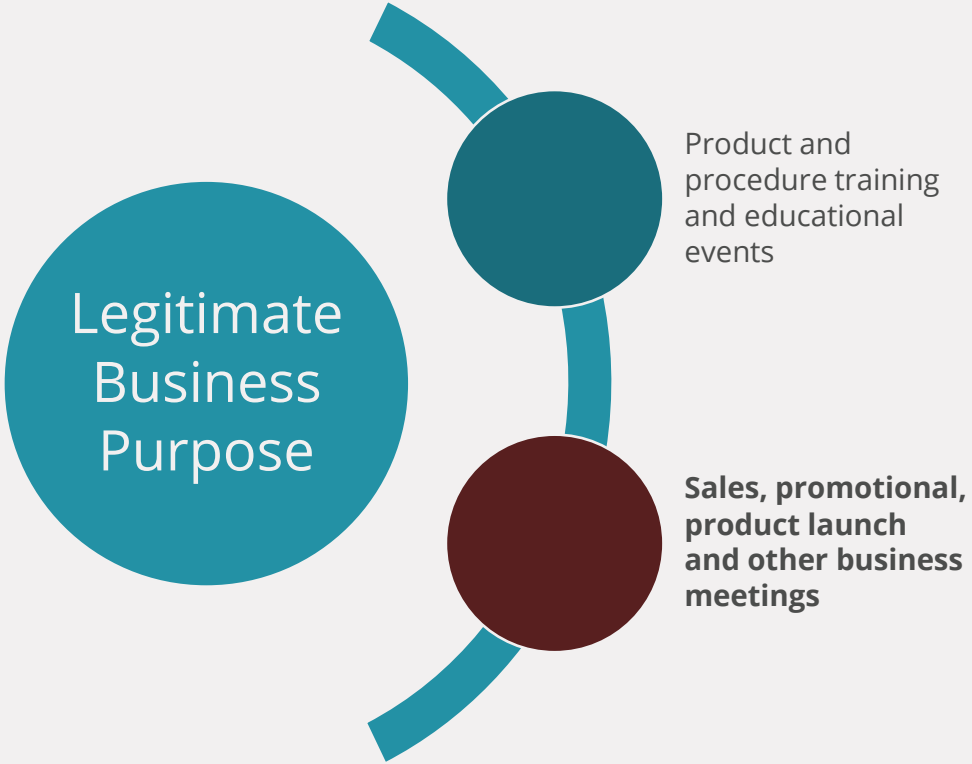
General Criteria for Events

CHAPTER 2: Company Events

Company events should comply with the principles mentioned in Chapter 1: General Criteria for Events

Types of Company Events

Types of Company Events



CHAPTER 3: Virtual Events

- Principles in Chapter 1 and Chapter 2 apply to virtual events

Virtual Events

- Event consists of virtual exhibitions, presentations, panel discussions or live clinical procedures (e.g., hands-on sessions, surgery simulations, live surgeries, etc.) and their broadcasting to an audience which is not physically in attendance.

Hybrid Events

- Event consists of exhibitions, presentations, panel discussions or live clinical procedures (e.g., hands-on sessions, surgery simulations, live surgeries, etc.) where the attendance is a mix of speakers and HCPs attending either physically and/or virtually.

Meals at Virtual Events

Meal delivery is arranged for delivery at the invited HCP's place of business, i.e., hospital or clinic, only	Invited HCPs must confirm their attendance before the event and member companies must track attendance to ensure that only appropriate recipients of the Virtual training/education program are receiving the meals
The Virtual event, excluding any time reserved for meals, is a minimum of 2 hours in duration	Only meal delivery is permitted and providing cash or cash equivalents (e.g., restaurant or meal delivery service vouchers or gift cards) are prohibited
Providing meals are limited to a group of HCPs only and for the avoidance of doubt, a group should not be less than 3 HCPs	Providing meals and refreshments to HCPs in their homes whilst attending virtual events is considered inappropriate

CME during Virtual Events

- In respect of a Continuing Medical Education (CME), no commercial promotion of the product may be allowed during the CME accredited presentation portions of the event.
- Commercial promotion is allowed during non-CME slots earmarked for advertising purposes.

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

In this chapter the following will be covered:

1. General principles
2. Promotional item
3. Items of medical utility
4. Gifts
5. Other interactions with HCPs
6. Competitions

1. General principles

No personal enrichment of HCPs or other healthcare providers.

- Includes: Gifts, benefit in kind, rebate, discount, kickback or any other pecuniary advantage

2. Promotional item

- Item provided by or on behalf of a company to a HCP
- Intended as a promotional reminder / campaign relating to the Company and/or its products.

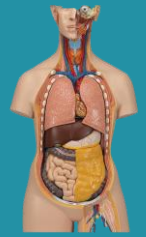
2. Promotional item

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.
- Not for personal use.
- Educational and/or of scientific value.
- Benefit the patient and/or be relevant to the practice.
- No cash or cash equivalents are allowed.
- Promotional items must be branded with Company name and/or Product and/or Logo .
- For values, please see Part 3: Questions and answers.

3. Items of medical utility

Permitted - genuine educational function



4. Gifts

Gifts are prohibited, including but not limited to those pertaining to cultural, religious or national events.

Do you understand the distinction between a Gift Vs a Promotional item Vs a Medical Utility? Can you give examples?

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.

Can you give examples of direct vs indirect payments that may be made? Can you give examples of other services that we may not pay for?

6. Competitions

Based on medical/product knowledge.

Individual prizes or educational items offered should benefit the patient and / or be relevant to the practice.

Prizes cannot comprise of cash or a cash equivalent.

Entry must not be dependent upon prescribing, ordering or recommending a product.

No cash or cash equivalents are allowed for completion of a survey or as a prize for a competition.

Part 1: Interactions with HCPs

Chapter 4: Charitable donations

Chapter 4: Charitable donations

Definition

- Provision of cash, equipment, company product or relevant third-party product
- Exclusive use/benefit for charitable or philanthropic

Bonafide

- charities or other non-profit entities with genuine charitable or philanthropic purposes

Permitted

- if made on an unrestricted basis
- not contingent on purchase, lease, recommendation, prescription, use, supply or procurement of products or services

Charitable donations to institutions, organisations or associations

- Permitted if **purpose is supporting healthcare or research**
- **documented** and on record by the donor/grantor.
- **not be paid directly** to HCPs or to healthcare administration staff

Chapter 4: Charitable donations

Recorded and approved

Recommend making info available publicly

implement an independent decision-making/review process to identify, prevent and mitigate against potential bribery and corruption risks.

Chapter 6: Arrangements with Consultants

In this chapter the following will be covered:

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

Chapter 6: Arrangements with Consultants

1. General Principles

Member Companies

May:

- **Engage HCPs as consultants and advisors to provide *bona fide* consulting and other services.**
- **Pay HCPs remuneration of fair market value for performing these services.**

May Not:

- **Make consulting arrangements contingent 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.**

Chapter 6: Arrangements with Consultants

2. Criteria for genuine consulting arrangements

Genuine: legitimate business need(s) for the services is/are identified

Number of consultants: not greater than reasonably necessary

Selection criteria: directly related to identified business need(s) & relevance of the consultant's qualifications, expertise/experience

Consulting arrangements documented in a **written agreement**, signed by the parties **in advance** of the commencement of the services

Not an inducement to purchase, lease, recommend, prescribe, use, supply or procure products or services

Remuneration must be reasonable and reflect **the fair market value** of the services provided

Maintain records of the services, and associated work products provided by the consultant HCPs

The **venue and other arrangements** for member company meetings with consultants shall follow the rules for such arrangements as set out in **Chapter 1**

Chapter 6: Arrangements with Consultants

3. Remuneration and fair market value

FMV: value of consultancy services

- Dealing at arm's length
- In an open and unrestricted market
- Neither party is under any compulsion to buy or sell
- Both parties have reasonable knowledge of the relevant facts

Commercial reasonableness

- Agreement should make commercial sense if entered into by reasonable parties
- Even if no potential for additional business
- 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 need relative to resource. 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.

Chapter 6: Arrangements with Consultants

3. Remuneration and fair market value

The Valuation Risk Assessment

A higher risk of potential non-compliance exists where:

- No formal valuation processes are established
- Payment rates based on anecdotal information
- **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

Chapter 6: Arrangements with Consultants

3. Remuneration and fair market value

Assessing FMV for HCPs and Key Opinion Leaders (KOL's)

Compensation earned in practice may not be **directly comparable** to the compensation for 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
- Specific services required
- HCP's experience and expertise
- Time requirements for the engagement
- HCP's clinical specialty
- HCPs versus KOLs

Chapter 6: Arrangements with Consultants

3. Remuneration and fair market value

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

- (i) greater than a typical international level HCP
- (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

Valuation is specific to the individual Consultant

Chapter 6: Arrangements with Consultants

4. Payments

Payments made for services must comply with all applicable tax and other legal requirements.

The consulting agreement must detail which expenses can be claimed by the consultant.

Chapter 6: Arrangements with Consultants

5. Disclosure & transparency

Member companies:

- shall 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.
- shall include appropriate obligations on the consultant.

Chapter 7: Demonstration products and samples

Definitions:

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, e.g. as part of an agreed discount arrangement, or as substitute products provided pursuant to a warranty agreement

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, e.g. as part of an agreed discount arrangement, or as substitute products provided pursuant to a warranty agreement.

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, e.g. as part of an agreed discount arrangement, or as substitute products provided pursuant to a warranty agreement

General principles

- May provide examples of products in the form of mock-ups
- May provide a reasonable number of samples
- Company shall in all cases maintain appropriate records
- 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

Chapter 8: Loan or placed equipment

Contract between the member and the HCP subject to the following provisions:

Consumables cross-merchandise capital equipment in a manner which is defensible and fair.

Consumables linked to capital equipment being financed by means of the purchase of the consumables. National Credit Act provisions.

Equipment agreement should be in writing

In line with HPCSA Booklet 11

HPCSA Booklet 11:
Guidelines on over servicing, perverse incentives and related matters

3.6 TECHNOLOGICAL EQUIPMENT

3.6.1 [HCP] **shall only own and use technological equipment if it forms an integral part of their scope of the profession and practice…has received appropriate training in using and managing such equipment.**

3.6.2 [HCP] **shall not over-use equipment** for procedures, tests and other applications that are not indicated, scientific or based on evidence. **This constitutes overservicing…is prohibited.**

3.6.3 [HCP] **shall not use technological equipment, health care 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.

Chapter 9: Bonusing, rebates and incentive schemes

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.

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.

Chapter 10: Royalty arrangements

- 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.**
- Must be formalised in a **written agreement**,
- Calculation of royalties should be based on factors that preserve the objectivity of medical decision-making and avoid the potential for improper influence.
- 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.

Chapter 11: Patient Registries

What is it?

An organised system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a defined population which serves one or more predetermined scientific, clinical or policy purposes

Why Set Up A Registry?

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.	Reduce pre- and post-market burdens for data collection by providing regulators with alternative methods to monitor the performance of technologies.	Meet regulatory requirements for post-market data collection.
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.

Chapter 11: Patient Registries

MUST

Provide reasonable remuneration, FMV to HCPs for providing information to registries.

Have scientific and/or healthcare policy merit

Relate to a legitimate and defensive project.

Have proof of *bona fide* registry documentation: Protocols, ethics committee approval and agreements

Comply with applicable laws including but not limited to:

- Promotion of Access to Information Act: Privacy protections, consent
- National Health Act
- Health Professions Act and related Guidelines,
- Protection of Personal Information Act
- Consumer Protection Act

MUST NOT

Be disguised promotion

Recommendation:

Consult the SAMED Medical Device Registry Principles and Position

Addendum 3

Chapter 12: Reimbursement for information and economic data

Reimbursement for information and other economic data, marketing data, formulary, managed care and similar fees

Payment for above permitted BUT:

- Written agreement detailing the exact nature and extent of the service or information
- Agreement made available in the case of a valid complaint.
- The service or information is of legitimate and lawful use to the buyer and known to be part of legitimate business
- Purchase not a condition for the support of the member or the member's product, and is in no way linked to sales value, volume, targets, usage etc.

Chapter 13: False claims regarding reimbursement

Must comply with the applicable laws and regulations

Laws 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.

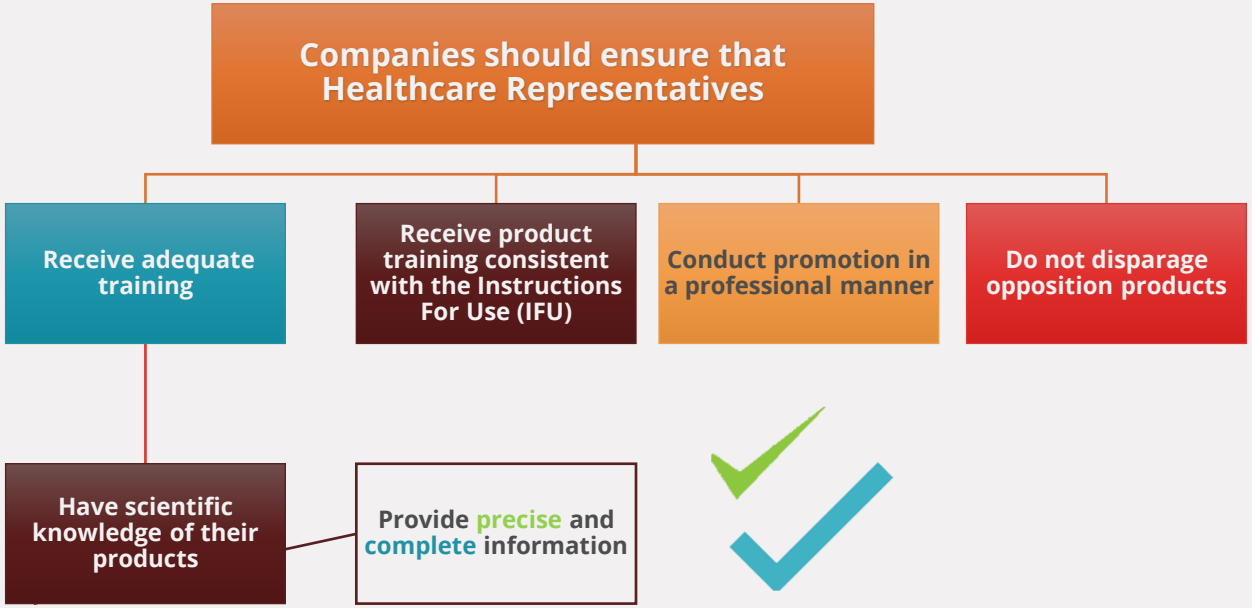
A member or company that helps, encourages or causes someone else to make a false claim for reimbursement can also be liable for the false claim

MEMBER COMPANIES MUST NOT

- Suggest mechanisms for billing for medically unnecessary services
- Engage in any fraudulent practice to achieve inappropriate reimbursement

Chapter 14: Healthcare representatives

General



Chapter 14: Healthcare representatives

In the operating room / clinical environment

MUST

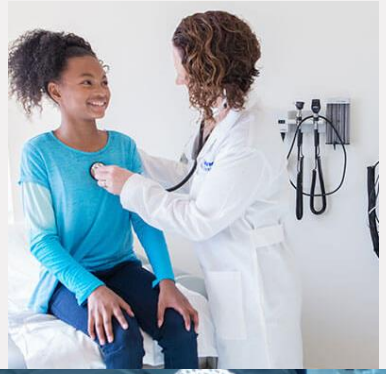
- Be trained on OR/CE protocol, and be certified on the Company Representative in the Clinical Environment (CRICE) programme
- Enter with permission from appropriate facility person
- Enter with written patient consent
- Must wear appropriate attire
- Advise only on technical aspects of company products

MUST NOT

- Give clinical diagnostic advice, surgical advice or recommend treatment
- Use and/or apply company product, deliver patient or medical care directly to a patient even if they hold appropriate certification/licences if in OR/CE as company representative and on company time
- Have a written contract with the hospital if in OR/CE as a trained HCP in own time

SAMED Protocol

- **Addendum 4**



Chapter 15
Advertising of and promoting medical devices

General Principles

Do's	Dont's
• Advertise in accordance with Laws and Regulations • Portray Technology in accordance with approved uses and attributes of technology	• Suggest that a medical consultation or surgical operation is unnecessary • Discourage consumers from seeking medical advice
• 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	• 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	• 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

Public Risk

The use of words such as safe, new and other claims should be within the relevant legal and regulatory frameworks

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 contain correct and balanced statements only and claims which the supplier has already verified.

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.

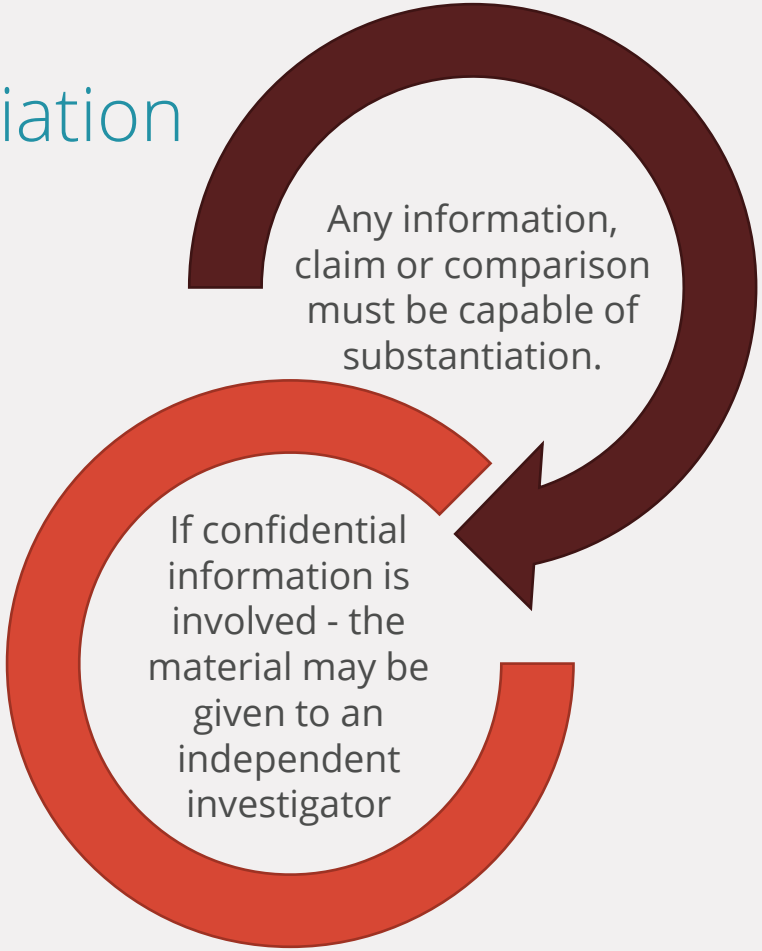
Must not mislead, or be likely to mislead, directly or by implication or through emphasis, comparisons, contrasts or omissions: that they are suffering from a serious ailment or there will be any consequences for failure to use the technology.

Advertising 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.

Claim Substantiation



Legality

- Where the alleged contravention of a law forms the only, or one of, the bases for a complaint, and the Independent Chairperson is unable to decide the complaint without resolving the question of whether or not a law has been contravened, the Independent Chairperson shall refer the complaint to the Ethics Panel, from which an appeal to the Final Appeal Committee will lie.
- The Ethics Panel may call on the party or parties to such dispute to submit legal representations on the question of the alleged contravention to the Ethics Panel before the decision as to whether or not the law in question has been contravened is made.
- Nothing in this clause must be read as implying that the Ethics Panel may seek to enforce regulations or laws. This task falls on the relevant regulator. The Ethics Panel may only enforce the Code.

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).

Market & Scientific Research

Market Research

- Must be conducted specifically for market research purposes and should clearly specify who it is sponsored by, if it is sponsored
- Must not be disguised promotions
- Must not contain or lead to disparaging comments about competitors or their products

Clinical Trials

- Must have a legitimate scientific purpose
- Must comply with SA legal requirements and guidelines

Comparative Advertising

- 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.

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.

Non-Promotional Material

WHAT IS IT

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.

Artwork & Visual Representations

Artwork must conform to the principles of the Code. Postcards, other exposed mailings must not carry matter which may be regarded as advertising and/or promotion to the general public.	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.
Graphs and tables must present 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.	Advertisements should not be flippant or use inappropriate imagery or imagery out of context.
Advertising shall not use misleading, alarming or improper visuals to represent changes in the human body.	Promotional material must include either the date or a code identifying the version on which the promotional material was drawn up or last revised.

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.

Electronic/Digital Media

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

- **Use of electronic/digital communications**
- **Internet links**
- **Audio visual material**

Snapshot of The Code

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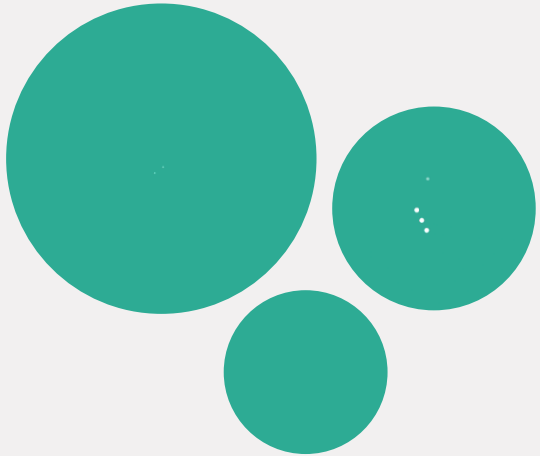


PART 2: Dealing with infringements of the Code

Overall goal:

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

Independent Chairperson

- The SAMED Board will appoint an independent chairperson for a period as determined by the Board. The Independent chairperson will be a legally qualified expert.
- Responsible to ensure complaints and hearings dealt with speedily and fairly
- Custodian of the process, ensuring that both the principles of administrative justice, as well as the substance of this Code, are preserved and promoted.
- Current Independent Chairperson: Michael Judin

Formal written complaints

A formal complaint may be lodged on completion of the prescribed forms.

- No lodging fee required. Anyone can submit a complaint.
- The prescribed complaint form is available on the code page of SAMED's website, which is https://samed.org.za/medical-device-code/
- The following information must be provided on the form:
  - Signature, name and contact details of complainant (including a named person who will represent the complainant and who could provide further information, if requested). No anonymous complaints will be entertained when putting a formal complaint to SAMED.
  - The company that employs the complainant
  - The complainant's field of business (manufacturer, distributor, doctor, private hospital etc).
  - The name of the alleged infringing company ("the respondent").
  - The facts of the alleged infringement (what, when, where, how).
  - The clauses of the Code that the respondent has allegedly infringed.
  - Any supporting evidence in the possession of the complainant, which substantiates his or her allegations regarding the alleged infringement.
- The complaint form must be sent directly to the Independent Chairperson at the following e-mail address: michael@elawnet.co.za and copy michellet@elawnet.co.za; codecomplaint@samed.org.za

Medical Device Code Hotline

Totally anonymous

The caller doesn't disclose any personal information to the call centre agent. The caller can use the unique reference number to follow up on the case or to provide additional information.

Partially anonymous

The caller discloses his/her details to Deloitte only.

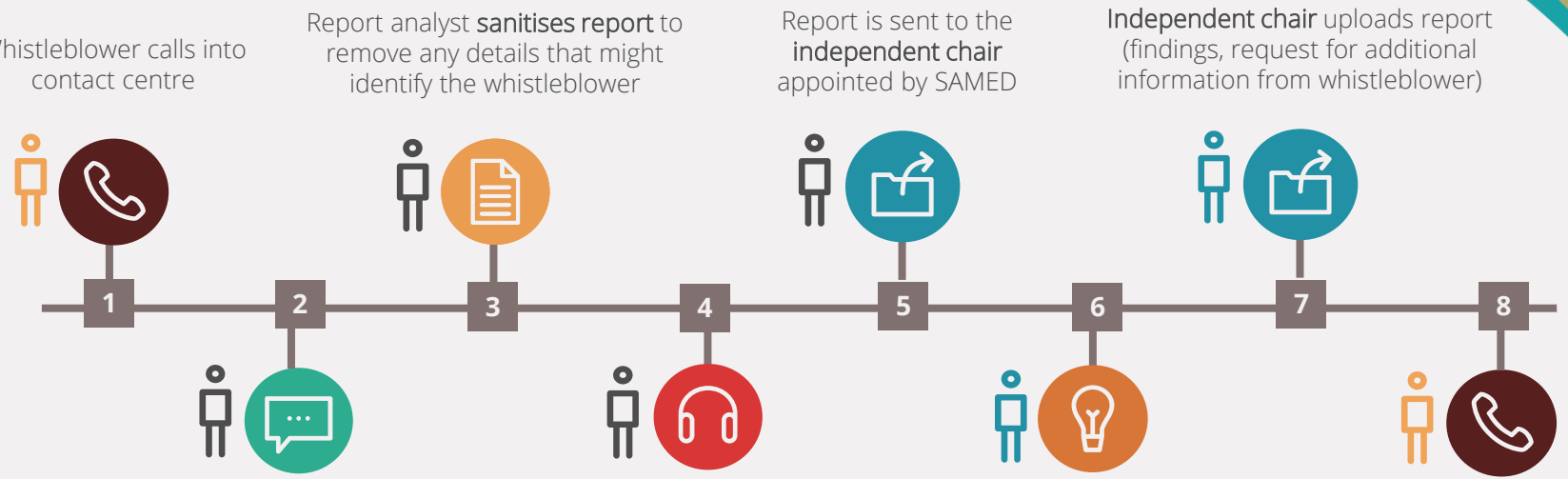
Full disclosure

The caller discloses his/her details to be included in the report.

What can be reported?

- Contraventions of the Medical Device Code of Ethical Marketing and Business Practice.
- Other matters may be referred to relevant agencies or authorities

Anonymous reporting



DON'T SUPPORT IT. REPORT IT.

Whistleblower responsibility | Deloitte responsibility | SAMED responsibility

Anonymous whistleblowing hotline

Whistleblowing is recognised as the most effective measure to guard against fraudulent or unethical activity within organisations. **The Medical Device Code whistleblowing hotline is an anonymous tip-off mechanism available to any member of the public wishing to report contraventions of the Code.** The hotline is independently managed and available 24/7.

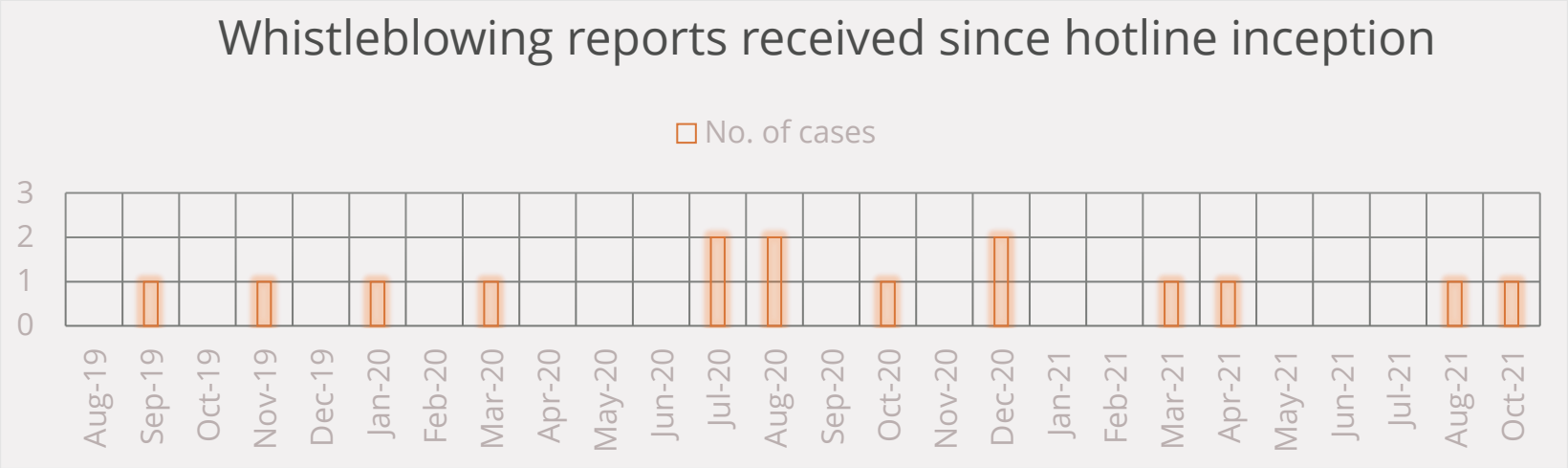
Contact the medical device code hotline:

- Free call: 0800 00 04 68
- E-mail: samed@tip-offs.com accompanied by completed complaint form

Download complaint form

Cases and outcomes

15 cases received



9 cases referred to the relevant authorities

6 cases closed

0 active cases

Cases and outcomes

Complaint	Summary of the complaint	Complaint outcome
1	The complaint was regarding a company trading without a medical device quality management system.	The matter was referred to the relevant authorities - South African Health Products Regulatory Authority (SAHPRA).
2	The complaint was regarding tender irregularities.	The matter was referred to the relevant authority i.e. the HAWKS/SAPS.
3	The complaint was regarding unethical marketing and sales practices by the sale staff of the Respondent. The complainant indicated the respondent is not transparent in their marketing ventures, provide false information to promote their product and interrupt training sessions for sales calls. The Respondent denied the allegations made by the complainant. The complainant was requested to contact the Independent Chair to provide further information or evidence which they failed to do.	No further investigation due to a lack of further information provided. The matter was closed.
4	The complaint was regarding altering of manufactured products as supplied by the complainant. The Respondent is not a SAMED member therefore SAMED has no jurisdiction over the Respondent.	The complainant was advised to report the matter to Minister of Health and/or the South African Police Service. Complainant indicated they would not be supplying the Respondent products going forward and would report them to the relevant authority should they become aware that the Respondent continues this activity.

Cases and outcomes

Complaint	Summary of the complaint	Complaint outcome
5	The complaint was regarding an adverse event following a procedure done at a hospital. A member of SAMED was not mentioned in the complaint. No mention of the hospital or the doctor involved was made in the complaint.	The complainant was requested to report the matter to the relevant authorities; hospital management and the HPCSA.
6	The complaint was regarding the reuse of single-use devices.	The matter was referred to the relevant authority i.e. the South African Health Products Regulatory Authority (SAHPRA)
7	The complaint was regarding a company trading without a medical device establishment licence.	The matter was referred to the relevant authority i.e. the - South African Health Products Regulatory Authority (SAHPRA).
8	A medical device rep from a non-SAMED member was moonlighting at a hospital and promoting her company products with surgeons at the same time.	The complaint has been forwarded to the Hospital mentioned in the complaint as well as the medical device company.
9	The complaint is regarding provision of a recreational lunch for healthcare professionals.	The respondent addressed the matter with the rep involved and implemented measures to prevent a similar future incident. The Independent Chair was satisfied and closed the matter.
10	The complaint is regarding comparative advertising.	Ethics Panel applies a ruling and in subsequent appeal the original verdict was upheld. The transgressor was told to remove all of the offending advertising from the market and fined R20 000.

Cases and outcomes

Complaint	Summary of the complaint	Complaint outcome
11	The complaint is regarding provision of a recreational lunch for healthcare professionals.	The respondent provided a detailed response to the complaint and documentation as proof of legitimacy of the exchange of scientific and academic information at a venue they deemed fit for purpose. The Independent Chair was satisfied and closed the matter.
12	The complaint is regarding the untrained use of and incorrect reporting on a competitor device.	The respondent provided a response as to the opinion he provided the HCP upon the HCPs requests with the limitations on the information the respondent had access to. No evidence could be provided to indicate that the respondent has given an opinion on the efficacy of the complainant's device. The Independent Chair was satisfied and closed the matter.
13	The complaint is regarding unpaid company taxes and the general unethical and irregular practices within the company	The company is not a SAMED member. The complainant also referred the matter to the HAWKS, SAPS, the Commercial Crime Unit and the HPCSA. As this falls within their jurisdiction, the matter was closed.
14	A company used the hotline to vet a SAMED member company.	The query was answered, and the matter closed.
15	The complaint was on false advertising by a treatment centre based on claims of assured outcomes.	The company is not a SAMED member. The matter was referred to Consumer Ombud and the matter closed.

Complaints that are reported through the hotline

- Any person wishing to lodge a complaint anonymously must provide all relevant details in order to adequately deal with the complaint.
- Must follow up on the progress of the complaint within 10 days of lodging incase further information is required to be provided to the Independent Chairperson.
- If further information is required to be furnished by the complainant, the complainant is required to furnish such information within 5 days.
- Should no further information be provided, as requested, the complaint will be dismissed without investigation.
- 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 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 their identity, the Independent Chairperson will decide on the further steps that are to be taken, including appointing an independent investigator and/or referring the complaint or the independent investigator's report to another authority, including SAHPRA, HPCSA, 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 National Department of Health, the South African Police Service (SAPS), the National Prosecuting Authority (NPA) etc.

Powers of Independent Chair

The Independent Chairperson

- Upon receipt of a complaint, the Independent Chairperson will, within 7 days, issue directions for the further resolution of the complaint.
- His powers for resolving complaints are as follows. To direct:
  - the respondent to file a written answer to the complaint and the complainant to reply within a specified timeframe.
  - that the matter be submitted to conciliation or mediation by a recognised organisation.
  - the parties to attempt to settle the matter within a specified time-period.
  - that a hearing is to be held before him in order to hear and determine the complaint. To give directions for the manner in which the hearing is to be conducted.
  - that a hearing be held before an Ethics Panel constituted by him. To appoint two other persons from SAMED's list of suitably qualified experts, to an Ethics Panel over which he will preside to hear and determine the complaint with him. To give directions for the manner in which the hearing is to be conducted.

Ruling

Within 30 days of the conclusions of proceedings the Independent Chairperson must issue written findings in relation to the complaint and his reasons for such findings.

Sanctions

- The Independent Chairperson, or an Ethics Panel has the power to issue a sanction that is appropriate in the circumstances and in accordance with sanctioning guidelines in terms of paragraph 28.

  The following factors are relevant to determining an appropriate sanction:

  - The nature and extent of the breach, including its impact on the market and the reputation of the industry.
  - Whether the breach should have been evident to the company.
  - The length of time over which the breach took place.
  - The number and type of alleged breach/es.
  - Previous and/or similar breaches of the Code.
  - The impact of the breach on competitors, patients, health care providers and/or the provision of healthcare services.
  - The respondent's failure to implement previously imposed sanctions and/or undertakings.
  - The circumstances in which the breach occurred; and
  - The potential costs to be incurred by a company in order take corrective action – the Independent Chairperson/panel will consider the overall cost of the sanctions, for example, the cost of issuing a corrective letter in combination with a fine.
  - The Independent Chairperson will set out his reasons for imposing a sanction in the Ruling.

Sanctioning Guidelines

Breach Classification	Expanded definition	Possible Corrective Action/Public Disclosure	Fine	Timelines
Minor	No safety implications for patients' wellbeing. No effect on how healthcare professionals will use product.	Immediate suspension of activity. Company to issue a corrective statement, as determined by ethics panel, including target audience. Written reprimand to company by SAMED. Notify HCP of breach, if relevant.	R10000-R50000	30 working days
Moderate	No safety implications to patients' wellbeing. May have effect on how healthcare professionals will use product.	Immediate suspension of activity. Company to issue a corrective statement, as determined by ethics panel, including target audience. Written reprimand to company by SAMED. Notify HCP of breach, if relevant.	R100000-R200000	30 working days

Sanctioning Guidelines

Serious/severe	**Will have safety implications to patients' wellbeing. Will have effect on how healthcare professionals will use product. Commercial impact on relevant market. Activities that bring disrepute to industry or reduce confidence in the industry**	**Immediate suspension of activity. Written reprimand to company by SAMED. Company to issue a corrective letter to healthcare professionals/public, as determined by ethics panel.**	**R200000 – R300000**	**30 working Days**
Additional sanctions/fines				
Fines not paid	When a monetary fine is not paid within the required time period from receipt of the decisions and the reasons for the decisions of the ethics panel		Further fine of R50000	60 working days
Corrective action not implemented	Where corrective action has not been actioned within required timelines. Any other sanction including orders as to cost and fees.	The matter will be raised by SAMED with the subject company and may be taken to the ethics panel for consideration.	Further fine of R100000	60 working days

Sanctioning Guidelines

Multiple breaches	**Where SAMED, through monitoring, finds a number of breaches of the Code by a company, SAMED will usually consider the aggregate of the breaches to determine whether a sanction should be imposed.**	**SAMED may publish the decision in a newspaper with national circulation along with the name of the offending company. Publication of the infraction on SAMED website. Inform the SAHPRA of infringement and recommend cancellation of registration of product/s involved. SAMED may impose a sanction in respect of each breach of the Code but may choose to impose an additional financial sanction.**	**First: R10000 + original fine Second: R15000 + original fine Third: R25000 + original fine R200000 max**	**60 working days**
Frivolous, vexatious or malicious complaints	Does not comply with requirement of complaint as defined in Code.	SAMED informs complainant in writing.	Complaint lodging fee forfeited plus R10000	60 working days

Appeal

Both parties have the right to appeal the ruling within 21 days of it being issued.

The SAMED Board will appoint an Independent Chairperson to hear the appeal.

Fee to lodge an appeal R40 000.00 of which R10 000 is a non-refundable payment for administrative costs. In the event that they are successful in the appeal, SAMED will refund R30 000 to the appellant.

Costs

Each party will pay its own costs. However, such costs may be claimed from the other party subject to any costs order as directed by the Independent Chairperson/a panel constituted to hear complaint.

Member companies whose employees are required to participate in complaint proceedings, for example, as witnesses or as members of a panel, will pay the costs of such, for example time off work and to travel to the hearing.

If a party has been found to have contravened the Code, such party shall be liable for all legal costs and disbursements including but not limited to the costs of obtaining expert opinion.

Payment shall be made within 30 days of demand.

Complaints in relation to which SAMED does not have jurisdiction

If SAMED receives a complaint, over which it does not have jurisdiction because the respondent is **not a member of SAMED**, it may nonetheless appoint an independent investigator to investigate it further and/or refer the complaint or the report of the independent investigator to another authority, including SAHPRA, HPCSA etc

Powers of SAMED

SAMED may cancel or refuse membership to any company that:

- Is unwilling to commit to the standards and values reflected in the Code.
- Fails to conduct its affairs in a manner consistent with the Code.

Snapshot of The Code

Part 1: Interactions with healthcare professionals

- Company & third-party arranged educational events
- Promotional items, competitions & charitable donations
- Demo products, samples, loaned & placed devices
- Consultant fees & royalties
- Patient registries
- False claims to medical schemes
- Conduct of healthcare representatives
- Advertising of medical devices

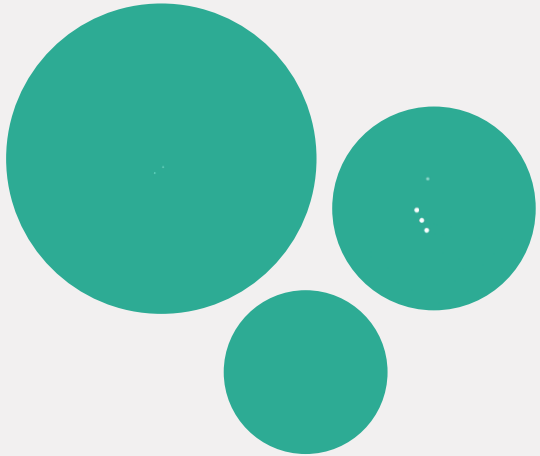
Part 2: Dealing with infringements

- Complaint procedure
- Whistle-blowing hotline
- Formal complaint
- Independent chairperson
- Ethics committee
- Hearings
- Sanctions

Part 3: Questions and answers

Part 4: Complaint form

Part 5: Addendums



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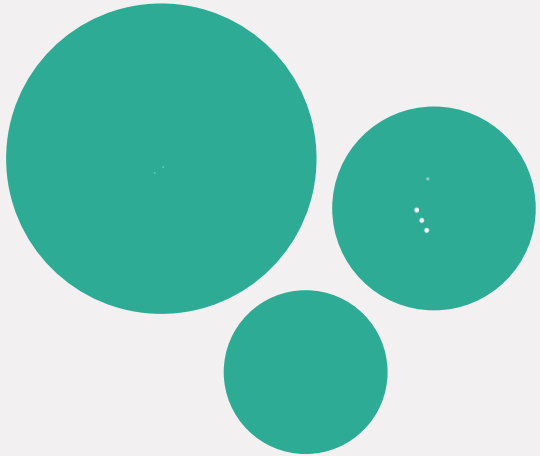

Questions?

SAMED
advancing patient care through MedTech

Thank you for joining us, please complete the poll.

Email additional questions to: communication@samed.org.za

Upcoming Events – Register on our Events page