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## Competition law reminder and conflict of interest

The meeting is held with no intent to collude or engage in any matter that might contravene competition law. Conflicts of interest must be declared and if required, members recuse themselves, either before or during the meeting, as and when they become apparent.

## Disclaimer

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# SAMED Competition Law Guidelines: Do's and Don'ts

## Don't

**Don't** reach understandings or agreements or even hold discussions with a competitor (or even a potential competitor) on commercially sensitive topics such as selling or purchase prices, trading or credit terms (including delivery charges, minimum purchase quantities or interest rates) or billing practices, production, inventory, supply volumes, sales, costs, future business plans, budgets, upcoming tender or bids, or individual suppliers or customers.

**Don't** attend meetings with competitors or any industry body without written agenda or clear indication of the purpose.

**Don't** attend unscheduled gatherings with competitors or any industry body unless you know that they are for a bona fide purpose or that they are purely social gatherings.

**Don't** discuss business related topics at social functions.

**Don't** accept written non-public information or agree to the exchange of oral non-public information with Members who manufacture, market or sell (or could manufacture, market or sell) competing products.

**Don't** exchange any current or future information with your competitors (what your company intends to charge or do).

**Don't** participate in market surveys, or benchmarking exercises that allow access to any competitive information of any individual company. Any data published pursuant to a market survey must be aggregated and contain only aggregated/average data for at least 5 competitors.

**Don't** engage in joint negotiations, joint sales or joint buying without legal advice.

**Don't** agree to exclude competitors or engage in collective boycotts of suppliers or customers.

## Do

**Do** read the SAMED Competition Law Compliance Guidelines as contained in the [SAMED Committee SOPs](https://samed.org.za/about-samed/our-committees/) (<https://samed.org.za/about-samed/our-committees/>)

**Do** discuss public policy, education, scientific developments, regulatory matters of general interest, general industry trends, appropriately aggregated and non-individualized (statistical) market surveys or benchmarking projects, publicly available information and historical information, but be prepared to terminate the discussion and record your disagreement if anyone mentions any of the subjects listed in the "Don't" list above.

**Do** insist that your company's individual, commercial information is kept confidential by anyone conducting a survey.

**Do** inform SAMED if you disagree with any of its decisions and keep a copy for your files of any such correspondence.

**Do** return commercially sensitive information you receive from any competitor, without keeping copies, and explain in writing that you do not wish to obtain such information.

**Do** inform your company counsel of any approaches seeking to exchange non-public information or coordinate conduct on the market.

**Do** ask SAMED to have counsel attend SAMED meetings if you or your company has any doubts.

MEMBER FORUM

FORUM 4 OF 4 ON THE CODE UPDATES

## Medical Device Code Forum: Donations, intermediaries and enforcement

22 November 2023, 09:00 - 11:00, Virtual

In this forum we take a look at charitable donations, third party intermediaries and the enforcement process as we conclude the series covering the updated Medical Device Code of Ethical Market and Business Practice.

**SAMED**  
advancing patient care through MedTech

**Please make use of the chat function to send us your questions or raise your hand and the moderator will call on you to speak.**



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# Chapter 8: Charitable donations

The background features a series of overlapping, flowing, organic shapes in a palette of warm and cool colors. The colors include various shades of orange, from light peach to deep red-orange, and teal, ranging from light mint to a more saturated turquoise. The shapes have a soft, almost fabric-like texture and are set against a gradient background that transitions from a warm orange on the left to a cooler light blue on the right.



# A few important definitions

## “Charitable Donations”

means provision of cash, equipment, Member 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 to bona fide charities or other non-profit entities or bodies whose main objects are genuine charitable or philanthropic purposes.

## “In Kind”

means the provision of Grants, Charitable Donations and other types of support in the form of goods or services other than money, including the provision of labour, lent or donated goods, or lent or donated services (e.g. catering services for events, provision of venue space, company products and other services).

## “Financial Hardship”

means in relation to a Healthcare Organisation extreme and unavoidable financial distress resulting from matters outside the Healthcare Organisation’s control where the Healthcare Organisation is unable to operate and where patient care is consequently jeopardised. Financial distress resulting in whole or in part from mismanagement of the Healthcare Organisation’s funds or other matters within its control is not considered to be Financial Hardship. Financial Hardship must be documented and objectively substantiated.

# Chapter 8: Charitable donations

- For charitable or other philanthropic purposes
- Support programmes for valid reasons
  - advancing HCP medical education and training
  - patient and public awareness campaigns
  - helping underserved or indigent populations (bona fide charitable programs)
  - funding independent scientific or clinical research
- Support charitable programmes can be
  - Monetary
  - in-kind
  - other contributions (equipment, company product or relevant third-party product)
- **Note:** Only charitable organisations or other non-profit entities which have charitable and/or philanthropic purposes as their main purposes, and which are objectively engaged in charitable or philanthropic activities.


# Chapter 8: Charitable donations

- Not be contingent on
  - Purchase
  - Lease
  - Recommendation
  - Prescription
  - Use
  - Supply
  - Procurement
- Must not be viewed as a price concession, reward to favoured customers or as an inducement
- Mindful that perception and contractual risks may arise for repeat donations to same charity.
- Non-profit hospitals permissible in case of demonstrated Financial Hardship, provided the Charitable Donation benefits patients, is limited to specific needs identified in advance, or is explicitly permitted by applicable national laws.



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

- **A:** Yes
- **B:** No



Take the  
Poll in the  
Chat

# Chapter 8: Charitable donations

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

**Answer:** No, a member company cannot make available a charitable donation to support the general running of a hospital or other HCO. A charitable donation shall only be given to a legal entity or body which has charitable and/or philanthropic purposes as its main purposes. For the purpose of the Code and irrespective of their legal status, hospitals and HCOs are considered to generally have health functions as their main purposes and accordingly, are not generally considered to have charitable and/or philanthropic functions as their main purposes. It is not therefore appropriate to provide charitable donations to support their general running.

**Question: What is an example of an “independent decision-making/review process”?**


**Answer:** Such a process could be led by a Member Company's legal, finance or compliance functions, operating within a robust governance framework and according to clear, consistent and transparent criteria for review and decision-making.

# Chapter 8: Charitable donations

- **Use of Funds.** A Company must require that any donation is used only towards charitable or philanthropic purposes.
- **Indigent Care Donations.** A Company may make charitable donations of product for indigent patients, provided that these donations serve exclusively to benefit patients and are permitted under applicable laws. Companies should consider making product donations for indigent cases contingent upon a hospital's agreement that no third parties will be billed for the donated product.
- **Charitable Events.** A Company may not pay for or provide tickets to Healthcare Professionals or their spouses or guests to attend charitable events, such as galas and golf outings.

Quick Poll: 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?

- **A:** Yes
- **B:** No



Take the  
Poll in the  
Chat

# FAQ:

**Question: 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?**

**Answer:** Yes, charitable donations made by member companies may take the form of dinner invitations for a fundraising dinner or participating in other recreational events such as a fundraising golf tournament, if arranged by a charitable or other non-profit philanthropic organisation. The member company may use some or all of its ticket allotment for its own employees and return any unused portion to the sponsoring charitable or non-profit philanthropic organisation for use as the sponsoring organisation sees fit. However, the member company should not invite HCPs to attend such an event at the member company's expense. Furthermore, the member company is not permitted to suggest to the sponsoring organisation, the names of HCPs who could be invited to attend the event, irrespective of whether or not the specified HCPs will be seated at the member company's table.

**Question: My Company has been asked to sponsor a local hospital's heart walk to raise money for heart disease research. In exchange for a fee, my Company will receive exhibit space at a health care expo the hospital is holding in connection with the walk. My Company will also receive prominent placement in the relevant advertising. Is this OK?**

**Answer:** Yes. A Company may provide a Commercial Sponsorship in support of a fundraising event, separate from a charitable donation. As with Commercial Sponsorship of a Third-Party Arranged event:

- The level of Commercial Sponsorship should reflect a commercially reasonable fee in exchange for the marketing and promotional benefits received by the Company, such as advertising, signage, display/exhibit space, or other promotional opportunities; and
- The Commercial Sponsorship must comply with applicable laws governing the marketing and promotion of its products.

# Advisory opinions: Donation of medtech to a patient who cannot afford it

**Query:** A customer of the company requested the donation of a medical device for a patient who could not afford the device as they did not have private medical cover. The company received several such requests annually.



What do you think? Compliant?

## Advisory opinions: Donation of medtech to a patient who cannot afford it

### **Taking the Chapter on Charitable Donations into account the Code Committee arrived at the following opinion:**

If the patient approaches the company directly to request the donation, with no HCP or hospital involvement, it would be considered a purely CSR/philanthropic action guided by the company's internal policies and procedures. Charitable donations can only be made to a registered charity/NPO and not to customers.

# Advisory opinions: Donations to and participation in a charity providing after hour surgeries

**Query:** A company was introduced to a charity project which raises funds for patients to get female cancer surgery after hours to assist with clearing patient backlogs at government facilities. Similar backlogs existed for male cancer patients.

The company was approached to work with the charity project to expand the charity's scope into offering male cancer surgery after hours as well.

The company was keen to be involved and wanted to pilot the programme, where the company would provide the equipment, a trained company representative to ensure understanding of the use of the equipment and disposable items required for the procedure.

Further to this, the company wanted to provide donations toward the after-hour rates for staff. The donation would be offered twice, after which the programme would need to raise funds to continue support of the programme. The company would, through the charity, provide this at the first two facilities. Various HCPs would offer their time in support of the charitable initiative.



What do you think? Compliant?



# Advisory opinions: Donations toward a hospital awards evening

**Taking the Chapter on Charitable Donations (as well as Chapter on Events) into account the Code Committee arrived at the following opinion:**

The charity was deemed a bone fide charity, with a genuine charitable or philanthropic purpose and it was deemed appropriate for the company to participate in and make contributions to the project.

# Advisory opinions: Donations toward a hospital awards evening

**Query:** A hospital hosting an awards ceremony for their staff at the hospital invited the company to make a financial contribution (donations) towards the event. The company wanted to know if participation was acceptable.



What do you think? Compliant?

# Advisory opinions: Donations to and participation in a charity providing after hour surgeries

## **Taking the Chapter on Charitable Donations into account the Code Committee arrived at the following opinion:**

Such a donation would in all likely hood not be deemed appropriate as an annual award ceremony is not an educational event (which may be deemed to be of a mainly entertainment, social and/or leisure nature).

In addition, the entity asking for the donation does not appear to be a bone fide charitable organisation and such donation may well be used to fund the entertainment / social aspect of the event and not for the purposes of supporting healthcare and research.

Below are a few points to consider:

- If it is a Government Hospital, then the Public Finance Management Acts applies, and it is very easy to violate this Act with a “Charitable Contribution”.
- Additionally, a Charitable Contribution request should be approved by the Accounting Officer of that Institution.
- It is only Charitable if a Tax Certificate 18A can be provided.

# Advisory opinions: Donation of a television

**Query:** A company received a request from a public healthcare institution for the donation of a television for the nuclear medicine division. The HCP who sent the request motivated that the television was to provide a diversion to patients who had to wait for several long hours for scans. Majority of the patients were illiterate and as such reading materials were not suitable. The company wanted to know if it would be acceptable to contribute to making patients' experience more pleasant when visiting the public hospital.




What do you think? Compliant?

# Advisory opinions: Donation of a television

**Taking the Chapter on Charitable Donations (as well as Chapter on promotional items and items of medical utility and gifts) into account the Code Committee arrived at the following opinion:**

A television used to provide entertainment to patients whilst they wait to be treated would not be considered an appropriate donation as a television does not align with the definitions in the code of a promotional item or an item of medical utility.

The Code committee understood the aim is to give patients a more pleasant waiting room experience, however, determined the hospital should incur this expense as an overhead/running cost of providing a service to their patients. It would be impossible to monitor whether staff share the use of the television during their breaks and so indirectly this would provide entertainment, which companies are prohibited from providing to HCPs.



# Chapter 9: Arrangements with Consultants

# A few important definitions

## “Consulting Arrangement”

means any provision of service by a Healthcare Organisations (HCO) or Healthcare Professionals (HCP) for or on behalf of a Member Company. Consulting arrangements include, but are not limited to marketing and Clinical Research activities, providing technical expertise for the development, testing, etc. of Medical Technology, providing feedback in post- market evaluations and market research, providing speaking services at events, teaching other Healthcare Professionals, providing training on how to use the Member Company’s Medical Technology, participating in research-related meetings, etc.

## “Fair Market Value (FMV)”

means the value of the specified services (or products, if applicable) which would be paid by the member company to the other party (for example a HCP or a HCO), each dealing at an 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.

## “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 provided by the seller, or which is not in existence; and which is bought solely, or mostly 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.

# Chapter 9: Arrangements with Consultants

## 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 9: Arrangements with Consultants

## 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 9: Arrangements with Consultants

## Remuneration and fair market value

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

**FMV: value of consultancy services**

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?

**Commercial reasonableness**

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.

**Valuation elements**

# Chapter 9: Arrangements with Consultants

## 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 9: Arrangements with Consultants

## 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 9: Arrangements with Consultants

## 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**

## Quick Poll: How should member companies determine FMV for a service?

- **A:** Use the SAMED set values for FMV
- **B:** Ask the HCP to determine FMV
- **C:** Use internal methodology to determine FMV
- **D:** Apply international equivalents to determine FMV
- **E:** A combination of the above

A red, multi-pointed starburst shape with a white border, containing the text 'Take the Poll in the Chat'.

Take the  
Poll in the  
Chat

# FAQ:

## Question: How should member companies determine FMV for a service?

**Answer:** A member company must be able to demonstrate internal methodology to determine fair market value. Amongst other matters this shall take account of the consultant's qualifications, expertise and experience as well as the actual services to be provided to the member company.

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

**Answer:** 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.

# Chapter 9: Arrangements with Consultants

## 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.**




## 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.






PART 2:  
Dealing with  
transgressions  
of the Code

# Quick Poll: Who can lodge / report a Code complaint?

1: Any SAMED member  
3: Member of the Public  
5: Healthcare Organisation

2: Signatory to the Code  
4: Healthcare Professional  
6: Regulatory Body

- **A:** 1, 2, 3 & 4
- **B:** 1, 2, 4 & 5
- **C:** 3, 4, 5 & 6
- **D:** 1-6



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Poll in the  
Chat

# Who can complain?



Any SAMED  
member



Signatory to the  
Code



Member of the  
Public



Healthcare  
Professional



Healthcare  
Organisation



Regulatory  
Body

- Encouraged to first attempt a genuine direct conciliation, or mutual settlement between members.
- If such is unsuccessful then lodge a complaint either via the formal written process or via the whistleblowing mechanism.
- Members must inform SAMED of the outcome of complaints resolved directly between members.



# 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

# Complaint form

## Addendum 4: Code Transgression Report Form

### Medical Technology Code of Ethical Marketing and Business Practice

#### Transgression Report Form

Any person, including but not limited to, a SAMED member, signatory to the Code, member of the public, healthcare professional, healthcare organisation, or regulatory body may report a transgression.

Reports by a SAMED Member and/or signatory to the Code, should where possible be initiated and administrated by the Compliance Officer and / or CEO of the Company.

For hotline reports, send the form to: [samed@tip-offs.com](mailto:samed@tip-offs.com)

Alternatively, a report may also be submitted directly to SAMED: [info@samed.org.za](mailto:info@samed.org.za)

Date: \_\_\_\_\_

#### 1. Complainant (do not complete if you wish to remain anonymous):

- a. Name and surname: \_\_\_\_\_
- b. Job title: \_\_\_\_\_
- c. E-mail address: \_\_\_\_\_
- d. Mobile Number: \_\_\_\_\_ Work Number: \_\_\_\_\_
- e. Name of Company / organisation: \_\_\_\_\_
- f. Name of Company CEO: \_\_\_\_\_
- g. Field of business of the complainant (manufacturer, distributor, doctor, private hospital, member of the public etc)  
\_\_\_\_\_

#### 2. Details of the individual / Company who is the subject of the alleged transgression, i.e. 'the respondent'

- a. Name and surname: \_\_\_\_\_
- b. Job title: \_\_\_\_\_
- c. Name of Company / organisation: \_\_\_\_\_
- d. Contact details of this person (if you have them):  
E-mail address: \_\_\_\_\_  
Mobile Number: \_\_\_\_\_ Work Number: \_\_\_\_\_

3. Field in which transgression has occurred (e.g., insulin pumps, orthopaedic implants, wound care, etc)

\_\_\_\_\_

4. Clause(s) within the Medical Technology Code, detail and circumstances relating to the alleged transgression. Succinctly describe the essence of the transgression in the table below. Use one line for each transgression. Where available list and attach any proof/evidence substantiating the reported transgression.

Indicate Code Clause (s)	Describe each alleged transgression i.e., what, how, where	Date/period of the alleged transgression	Indicate proof/evidence substantiating the reported transgression
	What  How  Where		
	What  How  Where		
	What  How  Where		

5. Statement of the relief sought.

\_\_\_\_\_



## 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](mailto:samed@tip-offs.com) accompanied by completed complaint form

[Download complaint form](#)

# Quick Poll: If you lodge a totally anonymous complaint, the next step is to...

- **A:** There is no next step, your whistleblowing responsibilities are met
- **B:** Call back daily for an update on your case
- **C:** Call back within 10 Days to hear if any additional information is required
- **D:** Send an email to SAMED to confirm that the report has been received



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# Anonymous reporting

Whistleblower calls into contact centre

Report analyst **sanitises report** to remove any details that might identify the whistleblower

Report is sent to the **independent chair** appointed by SAMED

**Independent chair** uploads report (findings, request for additional information from whistleblower)



**DON'T SUPPORT IT. REPORT IT.**

 Whistleblower responsibility

 Deloitte responsibility

 SAMED responsibility



# Independent Chairperson

The Independent chairperson will be responsible to ensure that all complaints and hearings are dealt with speedily and fairly and will be the custodian of the process, ensuring that both the principles of administrative justice, as well as the substance of this Code, are preserved and promoted.



Michael Judin

# His powers for resolving complaints are:

- To direct written responses from respondents and complainants
- To direct that the matter be submitted to conciliation or mediation
- To direct the parties to attempt to settle the matter within a specified time-period
- To direct (when and how) hearings held to hear and determine the complaint
- To appoint and direct (when and how) Compliance panel constituted by him
- To decide on sanctions

# Examples of sanctions



A written reprimand



Internal corrective action



Fines



Recover non-compliant promotional materials



Offender publishes / disseminates corrective or clarificatory statements



Audit of offender's compliance systems



Prohibition to stand for SAMED elected office



Publication of decisions or sanctions imposed



Suspension



Expulsion

# Costs

- Each party will pay its own costs – may be claimed as directed by Independent Chairperson/a compliance panel
- Member companies to cover costs (time off, travel, etc.) of employees required to participate in complaint proceedings (witness, compliance panel, etc.)
- The Independent Chairperson and compliance panel (provided they are not SAMED member company employees) will be paid a fee by SAMED
- Independent investigator will be paid a fee by SAMED
- Offender may be liable for all legal costs and disbursements
- 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, it may still appoint an independent investigator or report to another authority

## Criminal conduct

- If the complaint raises conduct that may constitute, involve, or give rise to a crime, then will also refer the matter to SAPS and/or the NPA

# Appeal

- Should either party wish to lodge an appeal they would need to lodge an appeal fee
  - Fee to lodge an appeal R40 000.00 of which R10 000.00 is a non-refundable






## 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

# Some resources

- <https://samed.org.za/library-accessed/library-compliance/non-binding-medical-device-code-advisory-opinions/>
- <https://samed.org.za/library-accessed/library-compliance/samed-medical-device-code-hotline-complaints/>

# Reminder of important dates

-  1 February 2024 Code Version 8 comes into effect
-  1 February 2024 Code certification period opens (existing members)
-  20 February 2024 Forum: Your questions answered
-  31 July 2024 Code certification period closed (existing members) – valid for 3 years unless updated – CPD accredited – Open to everyone
-  31 August 2024 Deadline for Annual Declarations



Questions?



# Thank you for joining us.

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Email additional questions to: [communication@samed.org.za](mailto:communication@samed.org.za)