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The meeting is being recorded for record purposes, by participating you consent to the recording thereof.

## 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

The content i.e. presentations, views, opinions, advice expressed within the context of this event by invited speakers are theirs and not those of SAMED and as such does not imply an endorsement by SAMED of either the content or the speaker. The content is not a substitute for appropriate legal advice and is not binding on SAMED. SAMED, its board members, committees, employees and members, will not be responsible for any inaccuracies or omissions, or, liable for any damages or loss of whatsoever nature suffered by any person as a result of relying on or using the content provided.



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INTEGRITY



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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 1 OF 4 ON THE CODE UPDATES

# Medical Device Code Forum: Updated Medical Device Code - What's Coming

12 October 2023, 14:00 - 15:30, Virtual

Learn more about the purpose of this Code review, the influential materials used to strengthen the Code, what was updated, when the changes come into effect and how to remain compliant.

**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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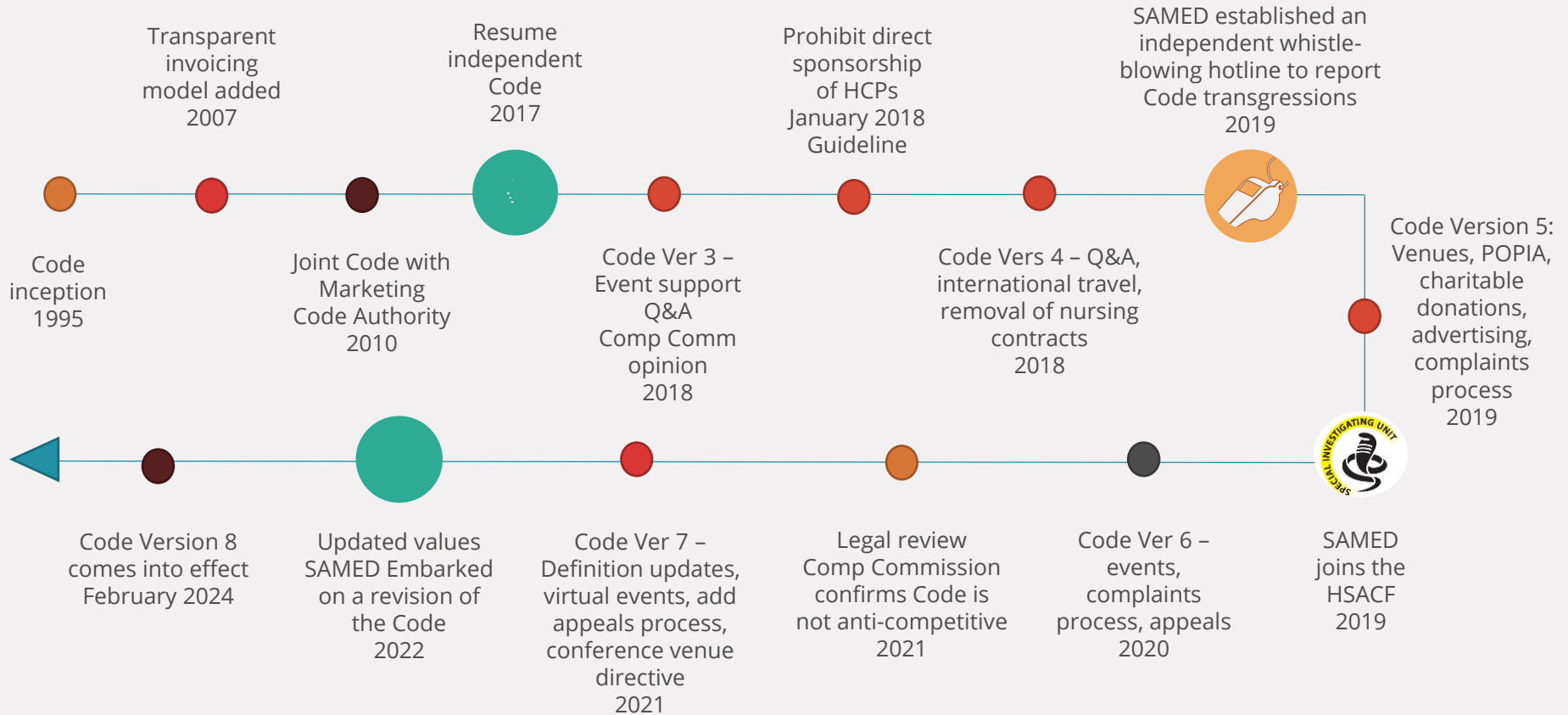


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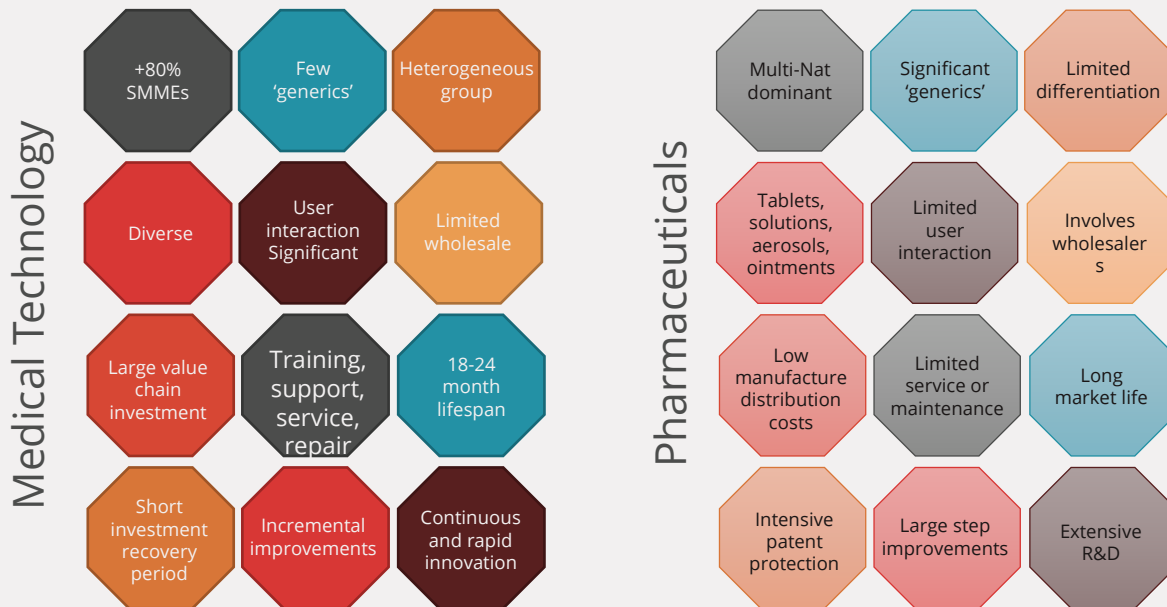
# Purpose of the review

# Background on the Code



# Why did SAMED choose independence from MCA in 2017?

- Medicines and medical technologies are inherently different



- MCA Code primarily deals with advertising, the Medical Device Code covers interactions with HCPs on numerous fronts as well as advertising

# Why a Code?

## Importance of Industry Codes



Safeguards industry and HCPs



Ensures independent clinical judgement of HCPs



Ensures patient's best interest at the heart of healthcare



Supports sector credibility



Creates an even playing field



Instils and fosters ethical behaviour



Fights corruption



Instils local and international best practices

# Changing local and international legislative landscapes

There has been a substantive global movement to stem corruption, fraud, money laundering and unethical business and marketing practices

- Anti-corruption Acts
  - SA: Prevention and Combating of Corrupt Activities Act
  - Foreign Corrupt Practices Act
  - Sunshine Act
  - UK anti-bribery Act
  - Dutch GMH code
- Anti-fraud and money laundering legislation
- Health Sector Anti-corruption Forum
- BHF fraud, waste and abuse report
- Transparency International

Increase in and recognition of health sector ethical rules and codes

- Health professions ethical rules
- International codes (self regulation vs hybrid vs govt led)
- Ethical research rules: clinical trials, registries





## The review process

# Influential materials consulted

- International Codes of Practice
  - Advamed
  - Mecomed
  - Medtech Europe
- Health Professions (HPCSA): Booklet 11 on Ethics
- Competition law

# The process of review

- Time taken
  - Review process started in 2022
- Who participated
  - SAMED Code Committee members
  - Competition Law expert
  - Independent Ethics Chair
- Steps followed
  - Reviewed and identified potential gaps in the current Code
  - Reviewed influential materials
  - Aligned with best practice
  - Considered the local context
  - Formatting and usability review
  - Resource inclusions
- Still to come
  - Design and final layout
  - Resource updates – training and other resources
  - Code Certification Test update
  - Compliance officer declaration

Coming changes



# What to expect

## Content Page






- Red flag is new
- Yellow is updated / significant changes
- Blue is unchanged

## Inclusions

- Definitions / Glossary (Context)
- Q&A with the section that it applies to
- Templates
- Position papers
- Guidelines

# Principles and Values

## Principles

-  The Principle of Image and Perception
-  The Principle of Separation (patient best interest)
-  The Principle of Transparency
-  The Principle of Equivalence
-  The Principle of Documentation

## Values

-  Education
-  Integrity
-  Respect
-  Cooperation and responsibility



Interpretation of provisions of the Code

# Scope



Legal Principles



Geographic reach



Applicability of the Code



Multiple business lines





# Date of Effect

1 February 2024

## Mandatory Code certification

- New platform underway (with additional functionality)
  - Limited to 200 users per month
  - New test roll out 1 February 2024
  - 6 Month for all existing members (compliance officers and customer facing staff) to complete the test (end July 2024)
  - Valid for 3 years (pending any significant updates to the Code)
  - Additional / New staff to take test as soon as possible
- New members
  - 4 Weeks for compliance officer to take the test (membership certificate)
  - 3 months for all customer facing staff to take the test

# Compliance officer annual declaration

- Any time after all compliance officers and customer staff have completed the certification
- Deadline: 31 August 2024

## Company Compliance programmes

- Adopt an effective ethics and compliance programme



# SAMED Code Committee

- Composition



SAMED Board Member  
(chair or vice chair)



Member representatives  
(max one per company)



Legal experts  
(as need)

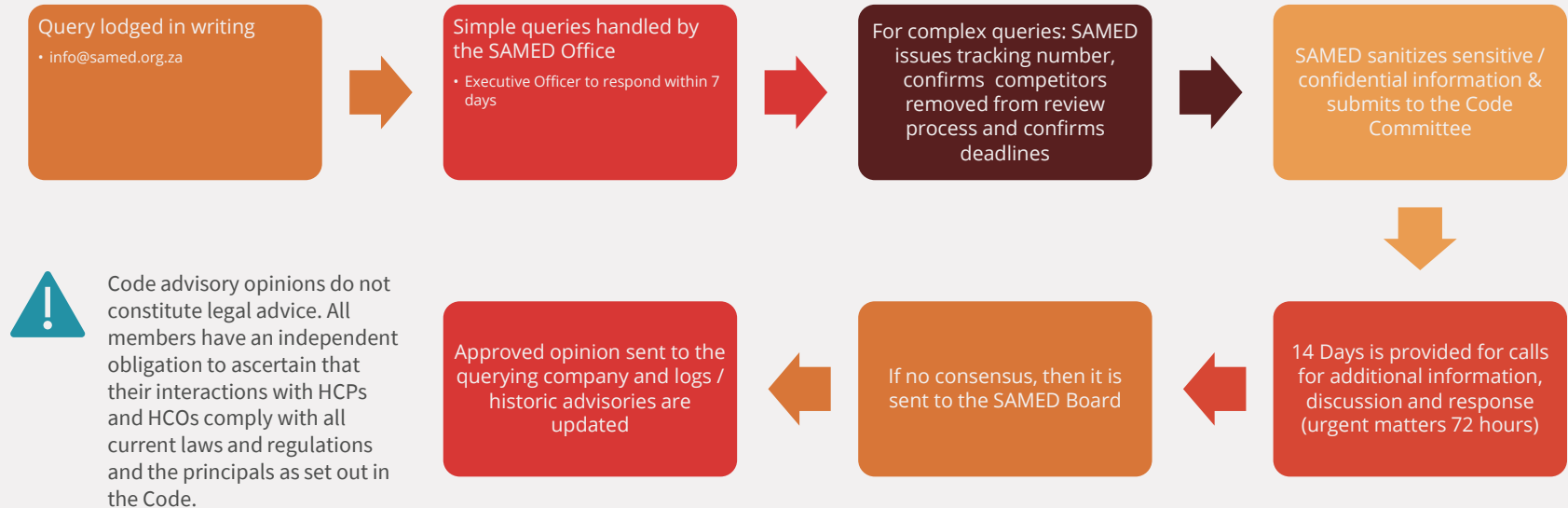
- Responsibilities:

- Advisory Opinions
- Code Reviews
- Training material development
- Forum participation

- JOIN the SAMED Code Committee: <https://samed.org.za/about-samed/our-committees/>

# Code Advisory Opinions

- Update process











Historical Code Advisory Opinions are located on the SAMED website (<https://samed.org.za/library-accessed/library-compliance/non-binding-medical-device-code-advisory-opinions/>)

# Enforcement of the Code

- SAMED has robust complaint reporting and investigation mechanisms
- SAMED does not investigate matters not within the scope or ambit of the Code; however, these will be referred to the appropriate entity as needed
- The full process will be covered in more detail at future forum

# Recap of important dates

-  25 October 2023 Forum: HCP interactions & event support
-  8 November 2023 Forum: Educational grant
-  17 November 2023 Forum: Charitable donations, intermediaries & the enforcement process
-  1 February 2024 Code Version 8 comes into effect
-  1 February 2024 Code certification period opens (existing members)
-  TBC February 2024 Forum: Your questions answered
-  31 July 2024 Code certification period closed (existing members)
-  31 August 2024 Deadline for Annual Declarations



# Questions and comments

**SAMED**   
advancing patient care through MedTech

# Thank you for joining us.

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



SAVE THE DATE

## October

F	<b>12</b>	Regulatory Forum
V	09:00 – 11:00 Draft Medical Device Regulations and Draft Fees – SAMED submission and impact analysis	
F	<b>24</b>	Transformation Forum
V	09:00 – 10:00 Sector targets and tacking metrics	
M	<b>25</b>	CEO Pulse Forum
I	13:00 – 17:00 Renewed format and focus Captains of Industry Forum covering burning medtech challenges, anti-money laundering, College of Medicine Journal and SAMED activities.	

F	<b>12</b>	Code Forum
V	14:00 – 15:30 Updated Medical Device Code of Ethical Marketing and Business Practice: What's coming	
F	<b>25</b>	Code Forum
V	09:00 – 10:00 Revise Code: Addressing HCP interactions and event support and requirements	

<https://samed.org.za/events/>

## November

F	<b>7</b>	Regulatory Forum
V	09:00 – 10:00 Programme TBC	
F	<b>8</b>	Code Forum
V	14:00 – 16:00 Revised Code: Educational grants & support of HCP participation in events	

F	<b>8</b>	Market Access Forum
V	09:00 – 10:00 Programme TBC	
F	<b>17</b>	Code Forum
V	09:00 – 11:00 Revised Code: Charitable donations, intermediaries, and enforcement process	