

# PROJECT 18C

## Terms of Reference for the Establishment and Operation of Project 18C

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## Glossary

- DoH means the National Department of Health
- *Founding Associations* means SAMED and the MCA
- *IPASA* means the Innovative Pharmaceutical Association of South Africa.
- MCA means the Marketing Code Authority. MCA represents all members of IPASA, PHARMISA and the Self Care Association and a number of independent companies who are members of the MCA
- *Member Associations* means associations are involved in the Project 18C as recognised by the two founding associations and that have their own self-administered code and participate equally in the funding of the Project 18C
- *PHARMISA* means Pharmaceuticals Manufactured in South Africa.
- *SAHPRA* means the South African Health Products Regulatory Authority
- SAMED means the South African Medical Technology Industry Association. SAMED represents members of SAMED

## 1. Introduction

**Parties involved:** Initially, the South African Medical Technology Industry Association (SAMED) and the Marketing Code Authority (MCA), the *member associations*, both of which are self-regulatory bodies.

Scope of Project 18C: Advertising and promotion of Medical devices, IVDs and Medicines, to be collectively described as health products.

**Purpose:** To motivate for the publication of regulations for the enforcement of an ethical marketing code/s for health products. Engagement with stakeholders will potentially involve the National Department of Health (NDoH) and the South African Health Products Regulatory Authority (SAHPRA), members of *member associations*, Health care practitioners (HCPs), the broader health products industry and other representative bodies such associations and statutory bodies and consumers.

**Funding:** The project will be funded equally by all *member associations*, initially *founding members*, until such time as a framework has been developed and other member associations commit to the objectives of Project 18C.

## 2. Objectives

Advocating for the establishment of South African standards for ethical marketing practices in the health product industry in line with the Medicines Act and ethical principles that provide for:

- the recognition of self-regulatory industry bodies for industry self-regulation of ethical and legal marketing practices,
- the compulsory enforcement of these standards across the entire industry by SAHPRA/DoH in collaboration with the industry,
- ensuring transparency and accountability in marketing activities for health products,
- protecting the interests of consumers and patients,
- Protecting the independent clinical judgement of healthcare practitioners in relation to the use and prescription of health products,
- ensuring the availability of accurate and substantive information to HCPs and consumers, and
- enhancing the reputation of the health products industry.



### 3. Scope of Work

- *Member association* roles in providing input into the development of policy and regulations for ethical and legal advertising and promotion of health products in South Africa.
- *Member association* role in code development and implementation frameworks to national standards (to be developed).
- *Member association* role in monitoring and enforcement of the industry codes.
- Collaborative efforts to raise awareness and educate stakeholders on the importance of truthful, accurate, legal and ethical advertisements and promotional activities for health products.

### 4. Timeline

Immediate commencement of collaboration with DoH in the drafting of a policy document.

### 5. Funding and Budget

The *member associations* will jointly fund costs related to this project subject to the approval of the respective governance bodies/boards.

### 6. Reporting and Communication

The Executive Officers of both organisations will provide regular progress reports of the Project to the respective governance bodies.

### 7. Governance

Project 18C will operate as a committee constituted by the Executive Officers of both associations and technical expertise drawn from both organisations.

### 8. Management Structure

#### 8.1 Committee Composition

Executive Officers: Each *member association*, shall mandate their respective Executive Officers to serve on the committee. These Executive Officers will represent their organizations and provide strategic guidance and decision-making.

- Subject Matter Experts: The committee will also include subject matter experts selected from both associations. These experts will offer technical knowledge and insights related to the health product industry and marketing practices.
- Chairman: The Chairman of the committee will be elected by the committee members. The Chairman will preside over meetings, facilitate discussions, and ensure that the objectives are met. The Chairman's role is to maintain impartiality and foster collaboration between *member associations*.
- The Chairman shall have a fixed tenure of one year and shall serve no longer than 2 consecutive one year cycles (2 years) at one time.

#### 8.2 Voting

Member associations will have one vote each and the Chairman will have a casting vote where appropriate.

#### 8.3 Roles and Responsibilities

- Executive Officers: The Executive Officers from SAMED and MCA warrant that they have the authority to make decisions and provide direction on behalf of their respective organizations subject to reference to the associations governing bodies as required by that body. They will ensure that the agreement's objectives are met and oversee the Project 18C and the



development and implementation of self-regulatory bodies and sector codes within the project 18C community.

- Subject Matter Experts: Subject matter experts will contribute their expertise in crafting the marketing code, ensuring that it aligns with industry best practices and regulations. They will also provide insights on potential challenges and solutions.
- Chairman: The Chairman will be responsible for leading committee meetings, moderating discussions, and acting as a neutral party in conflict resolution. The Chairman will also coordinate with the Executive Officers for reporting back to SAMED and MCA.

#### 8.4 Reporting Mechanism

The committee will establish a regular reporting mechanism to keep both SAMED and MCA informed of progress and activities. Reporting will include:

- Periodic Updates: The committee will provide periodic updates to SAMED and MCA regarding progress in terms of the objectives of the Project (see Clause 2. Objectives)
- Issue Resolution: In case of issues or challenges, the committee will promptly report these to the respective organisations governing bodies and propose solutions for consideration.
- Ad-hoc Reporting: Additional reporting may be required as deemed necessary by either SAMED or MCA governing bodies.

### 9. Additional Members

Additional stakeholder representative bodies may be co-opted where they are not represented by either association and on agreement of both parties.

### 10. Confidentiality and Data Protection

The need for confidentiality and data protection in relation to any activities or documentation pertaining to the project will be identified where appropriate and advised. Typically, the committee will not be dealing with confidential or sensitive data however if this is the case then the committee will ensure compliance with POPIA.

### 11. Termination and Dispute Resolution

Project 18C can be terminated with immediate effect upon agreement of all parties.

Where the committee representation grows beyond the founding members then members may resign subject to advising the committee in writing.

### 12. Signatories

This agreement will be signed jointly by the Executive Officers of each association (SAMED and MCA) in conjunction with the Chairperson of Project 18C, and the Chairpersons of the respective associations.

### 13. Appendices

- Medical Devices Code of Marketing and Ethical Business Practices.
- Marketing Code Authority Code of Ethical Marketing Practice.

### 14. Revision of ToR

Revision of the ToR can be recommended by the Project 18C Committee from time to time and will be subject to approval of the Governance Structures of committed organisations.

### 15. Signatories

**Project 18C Chairman**

DocuSigned by:  
*Rob Millar*  
04B219563C204E8...

Date 1/31/2024



**For SAMED:**

SAMED Chairman  
Peter Mehlappe

DocuSigned by:  
*Peter Mehlappe*  
BBBAE2FE900A457...

Date 1/31/2024

SAMED Executive Officer

T Vogt

DocuSigned by:  
*Tanya Vogt*  
DDC14EB3C7CB424...

Date 2/5/2024

**For MCA**

MCA Chairman  
E Hay

DocuSigned by:  
*Elzette Hay*  
80C3441FAB04423...

Date 1/25/2024

MCA Executive Officer  
VJ Beaumont

DocuSigned by:  
*Val Beaumont*  
9496486C88C24F5...

Date 1/24/2024