PROJECT 18C

Project 18 C Vision – Ethical marketing of health products

1. Introduction

- Parties involved in Project 18C: South African Medical Technology Industry Association (SAMED) and the Marketing Code Authority (MCA).
- Purpose: To motivate for the publication of regulations for the mandatory enforcement of an ethical marketing code/s for health products (medicines, medical devices and IVDs).

2. Objectives

- Promote ethical marketing practices in the health product industry.
- Promote transparency and accountability in marketing activities.
- Protect the interests of consumers, healthcare professionals (HCPs), healthcare organisations (HCOs), procurement personnel and patients.
- Enhance the reputation of the health product industry.

3. Why an enforceable Code/s

- Ethical marketing is in the public interest and for the protection of patients.
- Requirement for independence of HCPs in making patient care decisions.
- Requirement for independence of procurement personnel in making health product procurement decisions.
- Need for availability of accurate scientific information on health products.
- Requirement for enforcement of ethical standards.
- Dependency on voluntary codes renders the playing fields uneven and ultimately the patient suffers. Important role for a regulator in enforcement framework and powers.

4. Why should an ethics code/s be considered to be a valuable compliance tool:

- It is based on law, ethics principles and health product registration requirements.
- MCA Code of Marketing Practice and the Medical Device Code of Ethical Marketing and Business Practice applies the above to;
    - Ethical engagement with HCPs, healthcare organisations (HCOs), procurement personnel, the public, the media, patient organisations & CPD.
    - Ethical Promotion of health products.
- A self-regulatory enforcement framework.

5. What are the benefits of statutory vs self-regulation for health products

- Statutory regulation may recognise and, through regulations, give legal effect to self-administered codes. Such laws may create enforcement levels, e.g. appeals to a statutory body.
- Precedent exists under the POPIA, and the Consumer Protection Act, where regulators recognize self-regulated Industry Codes.
- Self-regulation therefore is recognized by such legislation.
- Self-regulation to work within and to complement statutory controls producing a result that neither system of control could achieve on its own.

6. Why can the industry be considered as an effective self-regulator?

- Industry experience in self-regulation and code enforcement (MCA since 2012, SAMED since 1995).
- Advantage of recognising industry lead on ethical marketing enforcement.
- Global collaboration and alignment.
- Formal governance (constitution and board) and independent administration (EO/ED), knowledgeable panels (from which adjudication and appeals-committees are appointed) and enforcement via independent enforcement frameworks.
- Industry funded through membership fees.
- Arm's length through the governance structures.
- Efficient, quick and mature system for receiving and managing complaints.
- Adjudication of code breaches by independent subject matter experts.

- Training & online certification in application of the code.
- Advocacy within industry and healthcare community.
- Broad recognition of MCA and SAMED as South African code self-regulatory bodies.

7. What is the industry position on enforcement of compliance in health product Marketing?

- There is a legislative mandate in terms of s18C of the Medicines Act to make regulations on the marketing of health products, and to provide for Codes of Practice.
    - These regulations could:
    - Include code standards.
    - Recognise self-regulating industry funded entities for managing enforcement of codes of practice, similar to what is being done under the Consumer Protection Act and POPIA.
    - Provide for unresolved / appealed issues to be escalated to the regulator for resolution in cases where;
        - by the Code entity for non-compliance with an order.
        - by an affected party not satisfied with the decision of an agency, or
        - referred by an agency.
- In the absence of specific codes for medicines, medical devices and IVDs, general consumer goods codes, published in terms of the Consumer Protection Act apply to health products. This is problematic, as health products have a different, strict regulatory (registration and licensing) regime (advertisements are regulated in regulations under the Medicines Act), and, are for a large part, dependent on healthcare professional input or prescription.

8. How can code compliance be enforced across the industry?

- Compulsory compliance to an industry code/s as a condition of product registration, and/or
- the implementation of a condition of licensing in accordance with section 22C (1) (b) for manufacturers, distributors, importers/exporters and wholesalers of medicines and medical devices, all of which are possible under the existing legislative regime.

9. Code standards and best practice must be;

- Incorporated into enforceable industry code/s through regulations and as licensing / registration conditions
- Apply similarly to medicines, medical device/IVD license holders.

10. A self-regulatory framework – key principles for enforcement

- Recognition and empowerment of self-regulatory bodies/agencies.
- Oversight by regulator.
- Licensed manufacturers, distributors, wholesalers etc. obliged to be a member of a recognised self-regulatory body and comply with a self-regulatory published code, as is the case under the Consumer Protection Act and PAIA.
- “Breach of Code” complaints in respect of members to be referred to the relevant entity to make and enforce a ruling on the matter.
- Complaint process must have rapid turnaround to eliminate the contravention and protect patients.
- Follow rules of natural justice.
- No significant barriers to entry.
- Regulations to empower establishment of frameworks and empower self-regulatory entities.
- Designated entities (industry driven) publish their own codes and enforcement frameworks for regulatory approval and publication in terms of regulations.
- Information on member companies, codes and complaint processes in public domain for directing complaints and information purposes.

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