COMMENT ON THE DRAFT GENERAL REGULATIONS MADE IN TERMS OF

THE MEDICINES AND RELATED SUBSTANCES ACT, 1965 (Act 101 of 1965) GN50 GG 40577 27 January, 2017

This document is supported by an Executive Summary and more detailed motivation. See separate document.

Name of Organisation / Individual:	**Marketing Code Authority (MCA), an industry self-regulating body implementing and enforcing a code of practice for the ethical marketing of health products**

The MCA has commented below on the matter of implementing and enforcing the ethical marketing of medicines.
The comments are supported by a separate document with more detail to substantiate the recommendations below. This is necessary as some of the principles are proposed for the first time.

The MCA proposal has 3 parts which require to be addressed in order to achieve the implementation and enforcement of a code/s of practice as referred to in draft Regulation 43(3):

- Comment 1: Proposal for a new Regulation for S18C in respect of the designation of agency/ies to establish and enforce a code/s
- Comment 2: Proposed amendment to Regulation 43 (3)
- Comment 3: Addition of Conditions of Licensing in terms of S22C(1)(b) to enforce membership of Designated Agencies implementing and enforcing a code.

Terms used in this Submission

Authority means the Regulatory Authority responsible for the administration of the Medicines and Related Substances Act (*The Medicines Control Council or its successor in name, the South African Health Products Regulatory Authority).*

Designated Agency means a self-regulatory agency which implements a code of marketing practice and administers enforcement frameworks on behalf of its members and is recognised by the Authority.

Code means an ethical code and supporting documents such as guidelines which describes requirements for the ethical marketing if health products. It should ensure the independence of Healthcare Practitioners and that information provided on health products is accurate and substantiated.

Date of submission:	**10/04/2017**
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Comment no.	Regulation, sub-regulation or paragraph			Comment and Rationale	Proposed Revised Text **Bold underlined** – additions **[square brackets bold]** – deletions
	Reg	Subreg	Par.		
Comment 1: Proposed new Regulation to address S18C on a code and the enforceability of a code					
1	S 18C calls for a new Regulation	n/a	n/a new wording	We propose a new regulation to address S18C of the Act which is currently not addressed. S18C provides for the Minister to make regulations relating to the marketing of medicines which shall be enforced through an applicable and enforceable code of practice. Principle proposed: In line with the operation of section 18C of the Medicines Act, the Authority shall be empowered to recognise, against published standards, certain designated, self-regulatory enforcement agencies. It is envisaged that a code of practice shall be enforceable at an initial level by the designated agency (eg the MCA) as an entry level avenue of recourse for affected persons, followed by the Authority as may be appropriate. Once a matter is referred to the Authority from either the designated agency (due to non-compliance with an order it issues) or by an affected party (not satisfied with the decision reached by a designated agency), the Authority should be empowered to resolve such a matter itself. This could take the form of providing the breaching party with an additional time period within which to comply with an order or, in more serious circumstances, order that product registration be revoked, through a process which the Authority at its discretion must determine.	**Wording in new regulation to address the requirement for a Code** **1. Pursuant to the provisions of section 18C of the Act, the Authority shall be empowered by the Minister, following due process, to bring into force an industry applicable Code of Practice (the "Code") relating to the marketing of medicines.** **2. In order to give effect to the provisions of the Code, which provisions will be endorsed by the Authority, the Authority shall identify and empower certain established self-regulatory enforcement agencies (the "Designated Agency(ies)"), as the case may be.** **3. A Designated Agency must:** **3.1 Be independent;** **3.2 Hold a Code of Practice endorsed by or capable of endorsement by the Authority;** **3.3 Be clearly mandated by the Authority to render its function;** **3.4 At all times be able to demonstrate to the Authority the implementation of an effective Code of Practice and enforcement frameworks.**

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				It may also perceivably refer the matter back to the designated agency for re-evaluation where it is satisfied that the adjudication and appeal committees have erred.	**4. Once appointed by the Authority, the Authority shall publish the names of each Designated Agency via a Government Gazette notice.** **5. Each Designated Agency must publish in the public domain in a manner acceptable to the Authority, a detailed register of member companies.** **Wording in new regulation to address the requirement for "enforceability" of a code.** **1. Member companies of a Designated Agency, may refer a matter considered to be in breach of a particular Code to such Designated Agency for adjudication and determination.** **2. A Designated Agency must make a determination of the matter before it in accordance with the provisions and processes of its Code.** **3. The Authority shall at all times maintain oversight of the decisions reached by a Designated Agency.** **4. Pursuant to Regulation 3 above, should a member company/affected party not be satisfied with the outcome of a matter adjudicated upon by a Designated Agency, it may upon the meeting of**

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					certain pre-determined criteria, refer the matter to the Authority for final resolution. **5.** **A matter may also be referred to the Authority for final resolution by the complainant member company or by the Designated Agency where the defaulting member company has failed and/or refused to comply with a decision made by a Designated Agency.** **6.** **In circumstance contemplated by Regulation 5 above, the Authority may at its discretion order the defaulting member company to comply with the decision reached by the Designated Agency or in more serious circumstances, order that product registration be revoked.** 7. **Notwithstanding the provisions of Regulations 6 and 7 above, the Authority may order that the matter be referred back to the Designated Agency in the case where it is found that the Designated Agency has erred in its findings.**

Comment 2: Proposed amendment to Regulation 43(3) on requirements for code enforcement provisions					
2	Regulation 43	(3)	Addition to existing	In addressing the content of Regulation 43(3), the accepted code of practice must be one which meets minimum standards specified by the Authority and administered by a Designated Agency. For the avoidance of doubt, such a code must be clear on the scope of products covered, who may complain, the processes to be followed as well as mechanisms for enforcement. Designated agencies may have the right to publish their own codes and enforcement frameworks. However, should this be accepted by the Authority, the designated agencies must demonstrate to the Authority the implementation of an effective and independent code enforcement framework. The Authority must also at all times have the ability to review and input into the codes of Designated Agencies. Once appointed, the Authority shall publish the names of the Designated Agencies via a Government Gazette. Designated Agencies must publish in the public domain, detailed registers of member companies committed to code compliance. Designated Agencies must submit reports of complaints and findings to the Authority on an annual basis. (Could consider making them publicly available?)	**Proposed amendment to Regulation 43 (3)** 1. Any marketing of a medicine, medical device or IVD must comply with the Code**(s)** of Practice for the relevant industries. 2. **The abovementioned Code(s) of Practice shall be enforced by a Designated Agency authorised in its mandate by the Authority, which shall be empowered to render Ex Parte Applications (as a form of pre-publication control), adjudicate on competitor and consumer complaints as well as hold the ability to implement sanctions on defaulting member companies.**

Comment 3 on the proposed addition of a condition of licensing in terms of S22C(1)(b) of the Act					
3	S 22C (1) (b) Addition of conditions of registration in terms of this section.			The MCA proposes that compliance to an enforceable industry code be established as a condition of licensing of manufacturers and/or importers/exporters of health products in terms of S 22C (1) (b). Identical requirements should apply to medicine, medical device and IVD license holders. In our view, this would create an effective and efficient entry-point level of control in respect of the ethical promotion of health products. It would also provide the designated agencies with the enforcement ability to effectively carry out their respective mandates. Mechanism proposed; The MCA proposes the implementation of a condition of licensing in accordance with section 22C (1) (b) for manufacturers and/or importers/exporters of medicines, IVD and medical device establishments to the effect that compliance to an enforceable industry code be established as a condition of licensing. In our view, this would create an effective and efficient entry-point level of control in respect of the ethical promotion of health products. It would also provide the Designated Agencies with the enforcement ability to effectively carry out their respective mandates.	**Addition of Conditions of Licensing in terms of S22C(1)(b)** **1. In relation to section 22C (1)(b), subscription to a Code of a Designated Agency must be shown as a specific condition of registration before a license may be granted by the Authority to a manufacturer, wholesaler or distributor of a medicine or medical device to import or export, act as a wholesaler of or distribute, as the case may be such medicine or medical device.** **2. No manufacturer, wholesaler or distributer referred to in section 22C (1)(b) shall manufacture, import or export, act as a wholesaler of or distribute, as the case may be, any medicine unless he or she is the holder of a licence contemplated in the said subsection, incorporating the requirement as stipulated in Regulation 1 above.**

Please refer to separate substantiating document for more detail.