



Marketing Code Authority submission in respect of the “*Request for comment on the General Regulation Relating to Bonusing. GG 41287 GN 1321 of 1st December 2017*”.

Issued in terms of the Medicines and Related Substances Act, 1965 (Act 101 of 1965).

1 EXECUTIVE SUMMARY

The Marketing Code Authority (MCA) is a voluntary self-regulatory body promoting and enforcing compliance with a "Code of practice for the ethical marketing of Medicines, Medical Devices and IVD's (Health Products)". Sanctions imposed on members¹ in cases of a breach in the Code are however not enforceable under the current legislative frameworks for Health Products.

The independence of healthcare practitioners in making patient care choices is important in the public interest as is the attainment of affordable prices for health products. The MCA advocates for a regulatory environment with respect to marketing practices in which legislation complements formal MCA enforced self-regulation by the industry.

When structuring enforcement frameworks to ensure ethical practices, consideration must be given to ensuring that processes are in place to ensure that legitimate marketing practices can continue and are ethically implemented. There is also a need for practices which are generally considered as perverse incentives through the fact of undermining the transparent pricing system and the independence of HCPs, to be clearly defined and prohibited.

The MCA has previously submitted² comment supporting a regulated framework to enforce the ethical marketing of Health Products. The framework proposed by the MCA includes proposals for the recognition in regulations of one or more “Marketing Code Authorities” and guidelines for the development and enforcement of acceptable standards for marketing code/s. (Submission attached as Appendix 3).

The MCA submits that marketing codes should establish clear principles against which ethical marketing practices can be set up and compliance can be measured.

In conclusion, the MCA emphasises the need for regulations to support S18C of the Act and which should encompass all legitimate marketing activities. Also needed are regulations to clearly identify those practices which are not acceptable marketing activities (S18A of the Act) and which undermine the transparent pricing system and the independence of HCPs.

¹ Membership of the MCA is open to manufacturers of Medicines, Medical Devices and iVDs (Health Products).

² Submitted in response to the publication for comment of the General Regulations issued in terms of the Medicines and Related Substances Act, 1965 (Act 101 of 1965), GN 50, GG 40577, 27 January, 2017

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3 MCA SUBMISSION ON DRAFT REGULATIONS TO S18A OF THE ACT

Society has increasingly high expectations of ethical behaviour from the Health Products industry and pharmaceutical companies, expectations that go beyond what is just legally required. Patients and HCPs have the right to demand and expect the highest ethical behaviour from all stakeholders in the health industry in interactions between providers, funders and suppliers of healthcare. The MCA principles and Code define and provide for the enforcement of ethical marketing of all Health Products to the public and to HCPs in the human and veterinary fields.

The Marketing Code Authority (MCA) welcomes the move to give effect to the prohibition of activities which are not legitimate marketing activities and which undermine the transparent pricing system of medicines and detract from the independence of HCPs.

The MCA is of the view that regulation of both Section 18A(1) and 18C (compliance with an ethical code for the industry) **are both required** in order to achieve the stated objectives of the draft regulations on Bonusing. However, the MCA recommends that the principles put forward in the Draft Regulations could be more viably and effectively implemented by:

1. Regulating all legitimate marketing practices through S18C of the Act and self-regulatory codes, and

2. Regulating practices in respect of S18A which from an ethical viewpoint, inappropriately incentivise the sale of health products in exclusion of consideration for the needs of patients,

Determination of what constitutes acceptable marketing practices:

1. Marketing and advertising are commercially accepted practices in a free market economy and in accepted legal opinion, the premise that marketing and advertising is necessary for commercial success, is uncontroversial.
2. In order to determine whether a payment for services can be considered a breach of the Medicines Act or an unethical marketing practice, the doctrine of *in fraudem legis* can be applied. This means that in attempting to determine whether payments for services are intended to circumvent the provisions of the law, the court will strip away the form (what appears at face value) and reveal the substance (intent) of the transaction.
3. Application of ethical principles that should inform ethical marketing practices:
 - a. Not all marketing and advertising payments are necessarily an incentive, discount or are inappropriate. Pharmacies today are no longer traditional apothecaries selling only medicines but are in fact fully functional retail business with a small portion of the income generated from the dispensary and OTC sections, as opposed to the front shop.
 - b. The draft regulations make reference to “...acceptable practices of any marketing code approved and or endorsed by the regulator...”. The MCA is encouraged by this reference to regulation.
 - c. However, the lack of a Marketing Code (s) approved and endorsed by the regulator contributes to the current problem with respect to enforcing ethical marketing and advertising. Such a Code has been implemented amongst our members and makes provision for the ethical marketing and advertising of all all Health Products. The gap however is the lack of code regulation and endorsement by the regulator.
 - d. The MCA advocates that the draft regulations in their present form not be implemented without recognition of marketing practices which would be legitimate in terms of the Marketing Code. A clear distinction needs to be made between regulations to S18C to govern ethical marketing practices and between the subjects of the new draft regulations to S18A to prohibit certain activities that negatively impact patient care. In order to achieve this, the standards of Codes and provisions for self-regulatory enforcement need to be given formal legal recognition including but not limited to:
 - i. Defining acceptable marketing and advertising practices;
 - ii. Fees or payments related to sales or prescriptions are not acceptable
 - iii. No offset of payments for “services” against invoice,

- iv. Clear, objective and transparent methodology documented in compliance procedures and records for determining an acceptable Fair Market Value for services rendered by HCPs. Transactions must be recorded.
- v. Clear processes and parameters to ensure Transfer of Value or proof of service delivery;
- vi. Self-regulation by industry code enforcement bod/ies via audits / reviews of documentation and internal processes;
- vii. Implementation of pathways of cooperation between the regulator and the industry self-regulatory body/es for reporting breaches and implementation of legally enforceable sanctions in the event of non-compliance with sanctions imposed.

4 CONCLUSION

Clear and unambiguous regulations with substantial penalties are essential for the full implementation of the envisaged transparent pricing system and to ensure the independence of healthcare practitioners in making patient care choices:

1. Regulate S18A(1) to provide clarity for the prohibition of activities which have the effect of undermining the transparent pricing system of medicines and the independence of HCPs.
2. Regulate S18C including compulsory requirements for companies to subscribe to a code of ethical marketing practice and self-regulatory enforcement through an effective self-regulatory authority and codes of sufficient standard.
3. It is our opinion that the intents of S18A and S18C in principle, are not mutually exclusive. Whether upstream or downstream, the unethical marketing and advertising of health products will place undue pressure on the entire value chain to continue to find loopholes. These unregulated loopholes will ultimately compromise the consumer who will be confronted with medicines and health products that are unaffordable and compromised independence of HCPs.

5 FOR FURTHER INFORMATION

For further information contact Val Beaumont (Executive Officer)

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6 APPENDIX 1: SUPPLEMENTARY NOTES ON EDITING

The following comments are made to highlight mainly editorial problems in the text. Our comment does not imply support for any of the principles.

Comm ent no.	Comment and Rationale			Proposed Revised Text
	Page and section	Par.	Rationale	Proposed revision
1	Pg 161, Preamble, line 3.		S22G pertains to medicines and scheduled substances.	Is the preamble correct in stating that the transparent pricing system applies to medicines and medical devices? Should state: ... <i>the prohibition of activities which have the effect of undermining the transparent pricing system for medicines and scheduled substances and the activities envisaged.....</i>
2	Pg 161, Preamble, line 5.		Editorial error	Replace " Regulation " with " Section "
3	Pg 162, "customer", (i)		All practitioner and professional associations should be included including veterinary practices which are not covered by the definition of health establishments.	Add: <i>comma</i> after hospital Delete: and Add: <i>veterinary practice</i>
4	Pg 162, "customer", (ii)		Editorial oversight An important part of the chain.	Insert " <i>suppliers of</i> " before "Health Insurance Products" Add: <i>brokers of medical scheme and health insurance products.</i>
5	Pg 162, "customer", (iv)		Courier pharmacies and medical aid administrators work through call centres.	Add: <i>Call centres</i>
6	Pg 162, "customer", additional points after point v		On line ordering systems and dispensing software are used to promote products over others. Customer to include front shop pharmacy staff and practice administrators.	Add new point: Pharmacy software vendors and electronic ordering systems. Add new point: <i>All persons employed by "customers".</i>
7	Pg 162, "discounts", (ii), after IVDs,		Consumer products are also used in bonusing	Add; <i>or other products such as consumer products.</i>

Comm ent no.	Comment and Rationale			Proposed Revised Text
	Page and section	Par.	Rationale	Proposed revision
8	Pg 162, "discounts", (iii), add new point		Competitions are used as inducements to buy product.	<i>Add: other disguised inducements such as competition prizes other than provided for in the Marketing Code</i>
9	Pg 164, 5. Incentive Scheme, d), line 4		Clinical trials are approved by the Authority rather than registered.	Change: Registered to authority- approved
10	Pg 163, "formulary" definition.		Purpose of the formulary intended in this context should be clear. eg to restrict use of medicines to a limited few - not an inclusive evidence- based formulary.	
11	Pg 163, Inducement, 2 nd line		Meaning not clear – editorial. Is price-reduction intended?	Add: <i>Price</i> reduction,
12	Pg 163, Supplier 1st line		Meaning not clear – editorial	Add: Dealing in medicines etc
14	Schedule 0 medicines		In line with current practice	S0 medicines should be excluded from this regulation.
	Pg 165 (h)		Statement must be broad.	Add: ... which includes but is not limited to , salaries etc

7 APPENDIX 2: BACKGROUND INFORMATION ON THE MCA

The Marketing Code Authority (MCA) and its Code provide for the ethical marketing of medicines, IVDs and medical devices, as envisaged within the Medicines and Related Substances Control Act, 101 of 1965 (the "Medicines Act"). It is a self-regulating body, formally established in 2012, to ensure the ethical and scientific promotion of health products. It was established by the trade



associations representing those industries and membership is open to any companies marketing products subject to the “Medicines Act”.

MCA authority to enforce the Code in the absence of legislative or regulatory support is limited to voluntary compliance. There are members who abide by the Code and non-members who ignore the prescripts of the Code, resulting in a non-level playing field which ultimately impacts on the patient’s right to receive the most appropriate medicine from an HCP, free of any undue influence.

The MCA Code does not however have any bearing on the issue of bonussing beyond issues relating to the independence of practitioners in patient care.

The MCA Code is benchmarked against international codes with a fully constituted and functional Board already in place and operational. This self-regulatory enforcement framework removes a significant burden off the shoulders of nDoH / Authority.

The MCA website provides for the certification of sales representatives and other stakeholders in the implementation of the Marketing Code www.marketingcode.co.za

The MCA currently represents over 150 member companies marketing medicines, IVDS and devices in South Africa. (The trade associations themselves are not members).

The MCA has engaged with the National Consumer Commission (NCC) (with the support of the ASA – Advertising Standards Authority) with a request for medicines not to be included in the ASA code but rather to have health product promotion regulated under the Medicines Act in the MCA Code. In terms of the Consumer Protection Act (CPA), our understanding is that this can only occur if regulations to the Medicines Act that cover promotional practices of medicines, IVDs and devices regulated by the Medicines Act are published.

The MCA is based on a Constitution and managed by a Board which publishes a Code, Code guidelines and applicable sanctions. Expert panelists constitute committees to adjudicate on complaints and appeals. The MCA relies on Code Compliance Officers within each member company to set and implement appropriate standards.

The MCA is administered by an Executive Officer (EO), charged with promoting and enforcing ethical marketing practices. The EO remains independent of complaint resolution and decision making processes. Provision is made for the code certification of customer-facing company personnel through its website at www.marketingcode.co.za.



8 APPENDIX 3: MCA COMMENT ON THE DRAFT GENERAL REGULATIONS TO S18C MADE IN TERMS OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT 101 OF 1965) GN50 GG 40577 27 JANUARY, 2017

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
<p>The MCA has commented below on the matter of implementing and enforcing the ethical marketing of medicines.</p> <p>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.</p> <p>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):</p> <ul style="list-style-type: none"> • 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. <p><u>Terms used in this Submission</u></p> <p>Authority means the Regulatory Authority responsible for the administration of the Medicines and Related Substances Act (<i>The Medicines Control Council or its successor in name, the South African Health Products Regulatory Authority</i>).</p> <p>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.</p> <p>Code means an ethical code and supporting documents such as guidelines which describes requirements for the ethical marketing of health products. It should ensure the independence of Healthcare Practitioners and that information provided on health products is accurate and substantiated.</p>	
Date of submission:	10/04/2017
For Further Information	Val Beaumont, Executive Officer. val@marketingcode.co.za. 063-008-5150

Comm ent no.	Regulation, regulation paragraph		sub- or	Comment and Rationale	Proposed Revised Text
	Reg	Subr eg	Par.		<u>Bold</u> <u>underlined</u> – additions [square brackets bold] – deletions
Comment 1: Proposed new Regulation to address S18C on a code and the enforceability of a code					
1	S 18C calls for a new Regulat ion	n/a	n/a new wor ding	<p>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.</p> <p>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.</p> <p>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.</p> <p>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</p>	<p><u>Wording in new regulation to address the requirement for a Code</u></p> <p><u>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.</u></p> <p><u>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.</u></p> <p><u>3. A Designated Agency must:</u></p> <p><u>3.1 Be independent;</u></p> <p><u>3.2 Hold a Code of Practice endorsed by or capable of endorsement by the Authority;</u></p> <p><u>3.3 Be clearly mandated by the Authority to render its function;</u></p>

Comm ent no.	Regulation, sub- regulation or paragraph			Comment and Rationale	Proposed Revised Text <u>underlined</u> – additions [square brackets bold] – deletions
	Reg	Subr eg	Par.		
				<p>revoked, through a process which the Authority at its discretion must determine.</p> <p>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.</p>	<p>3.4 <u>At all times be able to demonstrate to the Authority the implementation of an effective Code of Practice and enforcement frameworks.</u></p> <ul style="list-style-type: none"> • <u>4. Once appointed by the Authority, the Authority shall publish the names of each Designated Agency via a Government Gazette notice.</u> • 5. <u>Each Designated Agency must publish in the public domain in a manner acceptable to the Authority, a detailed register of member companies.</u> <p><u>Wording in new regulation to address the requirement for “enforceability” of a code.</u></p> <ol style="list-style-type: none"> 1. <u>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.</u> 2. <u>A Designated Agency must make a determination of the matter before it in accordance</u>

Comm ent no.	Regulation, sub- or regulation paragraph			Comment and Rationale	Proposed Revised Text <u>underlined</u> – additions [square brackets bold] – deletions
	Reg	Subr eg	Par.		
					<p><u>with the provisions and processes of its Code.</u></p> <p>3. <u>The Authority shall at all times maintain oversight of the decisions reached by a Designated Agency.</u></p> <p>•</p> <p>4. <u>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 certain pre-determined criteria, refer the matter to the Authority for final resolution.</u></p> <p>5. <u>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.</u></p> <p>6. <u>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</u></p>

Comm ent no.	Regulation, sub- regulation or paragraph			Comment and Rationale	Proposed Revised Text <u>underlined</u> – additions [square brackets bold] – deletions
	Reg	Sub reg	Par.		
					<p><u>serious circumstances, order that product registration be revoked.</u></p> <p>7. <u>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.</u></p>

Comment 2: Proposed amendment to Regulation 43(3) on requirements for code enforcement provisions

2	Regulation 43	(3)	Addition to existing	<p>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.</p> <p>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.</p> <p>The Authority must also at all times have the ability to review and input into the codes of Designated Agencies.</p> <p>Once appointed, the Authority shall publish the names of the Designated Agencies via a Government Gazette.</p> <p>Designated Agencies must publish in the public domain, detailed registers of member companies committed to code compliance.</p> <p>Designated Agencies must submit reports of complaints and findings to the Authority on an annual basis.</p>	<p><u>Proposed amendment to Regulation 43 (3)</u></p> <ol style="list-style-type: none"> 1. Any marketing of a medicine, medical device or IVD must comply with the Code(s) of Practice for the relevant industries. 2. <u>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.</u>
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				(Could consider making them publicly available?)	

Comment 3 on the proposed addition of a condition of licensing in terms of S22C(1)(b) of the Act

<p>3</p>	<p>S 22C (1) (b) Addition of conditions of registration in terms of this section.</p>		<p>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).</p> <p>Identical requirements should apply to medicine, medical device and IVD license holders.</p> <p>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.</p> <p>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.</p>	<p><u>Addition of Conditions of Licensing in terms of S22C(1)(b)</u></p> <ol style="list-style-type: none"> <u>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.</u> <u>2. No manufacturer, wholesaler or distributor 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.</u>
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