Marketing Code Authority
Unit 7 Boskruin Business Park
Bosbok Road
Randpark Ridge
2169

25th August 2016

The Director-General: Health
Private Bag X828
Pretoria
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FOR THE ATTENTION OF THE REGISTRAR OF MEDICINES - DR. JOEY GOUWS

Dear Dr Gouws

MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT NO. 101 OF 1965)
GENERAL REGULATIONS MADE IN TERMS OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT NO. 101 OF 1965): AMENDMENT - MARKETING CODE AUTHORITY (MCA) COMMENT - REGULATION 45

Thank you for the opportunity to comment on the proposed amendments to Regulation 45.

Please find herewith The Marketing Code Authority's (MCA) comment in this regard.

BACKGROUND:

The Marketing Code Authority (MCA) is a self-regulatory body that governs the advertising and promotion of health products by our member companies in South Africa.

The MCA is unique globally, as it has been formed and agreed to by members from the innovative, generic and self-medication sectors of the pharmaceutical industry as well as the medical devices, in-vitro diagnostics and veterinary medicines. We are in addition in the process of incorporating the complementary medicines industry into our fold.

The MCA is a voluntary organisation built on a constitution that was signed in 2012. It is deemed a juristic body and is a Not for Profit company according to South African tax legislation.

The Board is vested with the power to manage and conduct all affairs of the MCA in order to achieve its objectives.

All members agree to abide by the Code of Marketing Practice in the South Africa ('The Code'). The Code ensures that the health industry advertises and promotes their products according to the high ethical standards of the Code and aligned with international best practice. This indicates the commitment of the local industry to fair and ethical business practices in dealings with patients, healthcare practitioners and other stakeholders in this sector.

The MCA encourages all persons in the health product industry and other stakeholders who are linked to

this industry, to understand and apply the Code in their day-to-day business. An individual can complete the on-line assessment and certification to demonstrate their understanding of the Code, the Guidelines and the relevant legislation.

The MCA is the body through which enforcement of the Code takes place, in line with the principles embodied in the Constitution. The MCA has eminent panelists for the adjudication, appeals and legal panels to deliberate on potential breaches of the Code.

The MCA is allied with international authorities and ensures that the principles of the Code remain current with the global evolution in transparency and compliance.

COMMENT:

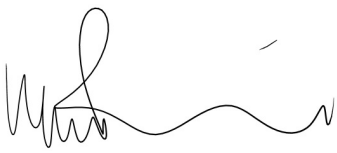
The MCA wishes to comment on the recent proposed amendment to Regulation 45.

AMENDMENTS TO REGULATION 45	
PROPOSED CHANGES	**COMMENT**
Removal of the word 'written' and inclusion of complementary medicine information	
(4) An ~~written~~ advertisement for a medicine shall contain- (a) the proprietary name of such medicine; (b) the approved name and quantity of each active ingredient of such medicine in lettering having minimum legibility: Provided that, in the case of a medicine containing only one active ingredient, such lettering shall be not less than one half the size of the largest lettering used for the said proprietary name; and (c) in the case - (i) of a registered medicine, the registration number allocated to it in terms of section 15 (6); (ii) of a medicine in respect of which an application for registration has been submitted in terms of section 14 of the Act, the reference number allocated to such application by the Registrar, followed by the words 'Act 101/1965)'; (iii) where a name other than the proprietary name	The MCA would appreciate clarity as to why the word 'written' has been removed from Regulation 45, and requests that the Medicines Control Council give due consideration to the fact that in the case of radio or other audio advertising for a schedule 0 or schedule 1 product by way of example, it would not be practically possible to provide " *the approved name and quantity of each active ingredient of such medicine in lettering having minimum legibility: Provided that, in the case of a medicine containing only one active ingredient, such lettering shall be not less than one half the size of the largest..'* as this relates directly to the written word and not to the spoken word as in the case of radio and other audio advertising. Removal of the word 'written' in front of the word 'advertising' suggests all forms of advertising including audio advertising are subject to conditions that can only relate to the written word. Should it be suggested that the information required be verbally listed this would be impractical to do so - particularly for multiple-active ingredient products.

is also used, such other name in lettering one half the size of the largest type size in which the proprietary name appears in such advertisement; (iv) of a veterinary medicine, an indication that the medicine is for veterinary use; and ~~(v) of a homeopathic medicine, an indication that the medicine must be used in accordance with homeopathic principles.~~ (v) of a complementary medicine - (aa) a statement identifying the discipline of the medicine~~s~~ where relevant; (bb) an indication that the medicine must be used in accordance with the applicable complementary discipline and principles where relevant; (cc) if the medicine has not received registration with the council the disclaimer: "This medicine~~s~~ has not been evaluated by the council. The medicine is not intended to diagnose, treat, cure or prevent any disease", and (dd) in the case of health supplements, upon registration, the disclaimer "Health supplements are intended only to complement health or supplement the diet".	

Many thanks

Yours sincerely



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