MCA Registered Office:
Unit 7 Boskruin Business Park
Bosbok Road
Randpark Ridge
2169
South Africa

THE EX-PARTE PANEL OF THE MARKETING CODE AUTHORITY OF SOUTH AFRICA

Ex Parte Case No: .....MCA Ex0003.....

Date: ...03 December 2015.....

In the matter requested by:

B. Brief summary of nature of complaint
- N/A
- Ex-parte review request: Advertising material of a S2 Medicine,

C. Relevant facts which are common cause (not in dispute).
Facts (and law) in dispute:-
- Advertising of a S2 medicine

Any other relevant documentary evidence tendered.
- Visual of the packaging material
- Visual of Advertisement

Any relevant oral evidence tendered (and cross-examination!?)
- N/A

D. Evaluation of the applicable Code (clauses)
- Regulation 45 of the Medicines and Related Substances Act, Act 101 of 1965 (as amended) and Clauses 7.9 & 9.7 of the Marketing Code.

MCA

ADVERTISING OF MEDICINES

45. (1) The under mentioned requirements shall apply to any advertisement of a medicine.

(2) (a) Medicines which do not contain a scheduled substance and medicines which contain a substance appearing in Schedule 0 or Schedule 1 may be advertised to the public; and (b) Medicines which contain a substance appearing in Schedule 2, Schedule 3, Schedule 4, Schedule 5 or Schedule 6 may be advertised only for the information of medical practitioners, dentists, veterinarians pharmacists and other persons authorised to prescribe or in a publication which is normally or only made available to persons referred to therein; (c) Paragraph (b) shall not be so construed as to prohibit informing the public of the prices, names, pack sizes and strengths of medicines which contain a substance appearing in Schedule 2, Schedule 3, Schedule 4, Schedule 5 or Schedule 6.

(3) No advertisement for a medicine may contain a statement which deviates from, is in conflict with or goes beyond the evidence submitted in the application for registration of such medicine with regard to its safety, quality or efficacy where such evidence has been accepted by the Council in respect of such medicine and incorporated into the approved package insert of such medicine.

(4) A 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 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.

(5) In the case of an advertisement for a medicine which contains more than one active ingredient, no specific reference shall be made to the specific properties of any individual active ingredient unless a reference of this nature has been approved by the Council for inclusion in the package insert of such medicine.

(6) When a medicine is advertised verbally for the first time to persons referred to in subregulation 2(b), written information, which shall include at least the information referred to in regulation 9 or regulation 40, shall simultaneously be given to the person to whom the oral advertisement is directed, and when the medicine is advertised orally on subsequent occasions such information shall be available on request.

- No product legal branding allowed however company general branding is not precluded
- Product redress in the advertisement however not expressly precluded in the Marketing Code

E. Finding on facts-balance of probabilities (evidence/credibility/material contradictions/inherent improbabilities etc).
Marketing Code:

> 7.9 **Artwork**
>
> All artwork, including illustrations, graphs, tables, logos and trade dress must conform to the letter and spirit of the Code. Graphs and tables must be presented in such a way as to give a clear, fair, balanced view of the matters with which they deal, and must not be included unless they are relevant to the claims or comparisons being made.

- 9.7 All material relating to health products and their uses, which is sponsored by a company, must clearly indicate the details of the company that sponsored it. The only exception to this clause is market research material that need not reveal the name of the company involved but must state that a company sponsors it.

- Company branding required by the Code. Ilustration and trade dress conform to the letter and spirit of the Code.

F. Case precedent in SA law
- N/A

G. Conclusion
- Acceptable: Advert is in line with provisions of the Marketing Code as well as the Medicines and Related Substances Act, Act 101 of 1965 (as amended).
- Sanction - N/A

H. This is a non-binding opinion.
- This analysis was performed as per the request of the Applicant specific to this particular advertisement (printed advert submitted to us) and does not serve as precedent i.e. similar advertisements must still be reviewed on a case by case basis.

I. Sign

- Signed at...Bryanston..... On this .....03rd...day of...December...2015

- Chairperson: .....

- Signed at...Bryanston..... On this .....03rd...day of...December...2015

.....

- Signed at..... On this .....day of.....2015

.....