In the Ex parte matter:

Case number: MCA Ex0001/2015

"Applicant"

Committee members:

Chairperson and member of the adjudication panel
Member of the adjudication panel
Member of the adjudication panel

Date of ruling: 18 September 2015

1. The matter at hand

1.1. The Adjudication Panel ("the Panel") was tasked to decide whether "the Applicant") is permitted to use information contained in a randomized trial, as marketing material and whether this is within the ambit and spirit of the South African Code of Marketing Practice ("the Code").

1.2. In this regard the Applicant requested a non-binding opinion from the Marketing Code Authority ("MCA").

2. Applicant's case

2.1. The Applicant aims to use the information of a randomized trial, *"Randomized controlled trial of three burns dressings for partial thickness burns in children*[1]*"* in its promotional material.

2.2. In support of its request the Applicant provided copies of the following supporting documentation for review by the Panel:

2.2.1. Burn study leave-behind;
2.2.2. How to use MepilexAg;
2.2.3. ISO certificate;
2.2.4. CE certificate;
2.2.5. Declaration of conformity EU;
2.2.6. Product data sheet; and
2.2.7. Randomized controlled trial of three burns dressings for partial thickness burns in children.

[1] Gee Kee, E.L. et al. Randomized controlled trial of three burns dressings for partial thickness burns in children. Burns. 2015. http//dx.doi.org/10.1016/j.burns.2014.11.005

3. The facts established by the Panel

3.1. The Panel subsequent to review and discussion of the supporting documentation as recorded above established that:

3.1.1. The information recorded in the Burn study leave-behind:

3.1.1.1. was based on the randomized trial, but only incorporated partial information. In this regard the Panel noticed that the trial compared the effects of the following three silver dressing combinations:

3.1.1.1.1. Acticoat;

3.1.1.1.2. Acticoat with Mepitel; and

3.1.1.1.3. Mepilex Ag.

However the Applicant chose to reference and compare only Mepilex Ag and Acticoat.

3.1.1.2. Recorded both the tradenames and trade marks of the compared products.

3.1.2. The Applicant is both ISO Certificate and EC Certificate accredited and on 13 March 2013 signed a Declaration of Conformity EU, confirming that medical devices will be manufactured in accordance with the provisions of the Council directive 93/42/EEC of 14 June 1993 as amended.

4. Evaluation of the applicable sections of the Code

4.1. During the evaluation the Panel agreed that the provisions of the following salient clauses of the Code was relevant for purposes of determining the Applicant's application:

4.2. ***Clause 7.5 Comparisons* state the following:**

"7.5.1 *A comparison in the marketing and promotion of health products is only permitted in promotional material if:*

7.5.2 It is not misleading or disparaging.

7.5.3 Health products or services for the same needs or intended for the same purpose are compared.

7.5.4 One or more material, relevant and representative feature(s) which is/ are capable of substantiation is/are compared.

7.5.5 No confusion is created between the health product advertised and that of a competitor or between the advertisers' trademarks, proprietary names, other distinguishing marks and those of a competitor.

7.5.6 The trademarks, proprietary names, other distinguishing marks, health products, services, activities or circumstances of a competitor are not discredited or denigrated.

7.5.7 Trademarks/trade names or company names of another company may only be mentioned with written permission from the other company.

7.5.8 No unfair advantage is taken of the reputation of a brand, trademark, proprietary name or other distinguishing marks of another company.

7.5.9 Health products or services are not presented as imitations or replicas of goods or services bearing another company trademark or trade name.

7.5.10 Hanging (open ended) comparisons are not allowed."

4.3. ***Clause 7.7 References* state the following:**

4.3.1. *"When promotional material refers to published studies, clear and complete references must be given."*

4.4. **Clause 26: INFORMATION, CLAIMS AND COMPARISONS IN ADVERTISING AND/OR PROMOTION state the following:**

4.4.1. *"26.1 All advertising and/or promotion must be consistent with the provisions of the Medicines Act i.e. all advertising and/or promotion must give the information necessary for the correct use of a product as approved by the medicines regulatory authority and may not deviate from, be in conflict with or go beyond the evidence submitted in the application for registration with regard to its safety, quality and efficacy in respect of what has been approved by the medicines regulatory authority and incorporated in the approved package insert.*

4.4.2. *26.2 In the case of an advertisement for a health product 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 medicines regulatory authority for inclusion in the package insert of the medicine.*

4.4.3. *26.3 A written advertisement for a medicine shall comply with Regulation 45 of the Medicines Act.*

4.4.4. *26.4 Advertising and/or promotion shall not unfairly disparage or discredit, either directly or by implication, a competitor product, ingredient or treatment type.*

4.4.5. *26.5 Advertising and/or promotion should not suggest that a health product's effects are better than or equal to another identifiable product or treatment.*

4.4.6. *26.6 Advertising and/or promotion shall not state that a product does not contain an active ingredient or ingredients used in competitor products other than as permitted by the medicines regulatory authority.*

4.4.7. *26.7 Proprietary or trade names of products of other companies shall not be used without permissions of the owner.*

4.4.8. *26.8 Hanging (open ended) comparisons are not allowed.*

4.4.9. *26.9 Comparisons are only permitted in advertising and/or promotion or promotional material if:*

4.4.10. *26.9.1 they are not misleading or disparaging;*

4.4.11. *26.9.2 health products or services for the same needs or intended for the same purpose are compared;*

4.4.12. *26.9.3 one or more materials, relevant and representative features, capable of substantiation, are compared;*

4.4.13. *26.9.4 no confusion is created between the health product advertised and that of a competitor or between the advertiser's trademarks, proprietary names, other distinguishing marks and those of a competitor;*

4.4.14. *26.9.5 the trademarks, proprietary names, other distinguishing marks, health product, services, activities or circumstances of a competitor are not discredited or denigrated. Trademarks/proprietary name of a competitor may only be mentioned with written permission from the competitor;*

4.4.15. *26.9.6 no unfair advantage is taken of the reputation of a trademark, proprietary name or other distinguishing marks of a competitor;*

4.4.16. *26.9.7 health products or services are not presented as imitations or replicas of goods or services bearing a competitor's trademark or trade name.*

4.4.17. *26.9.8 Points of comparison should be factual and reflect the body of scientific evidence. Comparisons should not imply that the technology, or classes of technology, with which comparison is made, are harmful or ineffectual.*

4.4.18. *26.10 Substantiation for any information, claim or comparison must be provided at the request of the MCA. It need not be provided, however, in relation to the validity of indications approved in the product registration.*

4.4.19. *26.11 When a written advertisement refers to the medicines regulatory authority approved package insert as well as scientific, published studies clear and complete references must be listed on the advertisement.*

4.4.20. *26.12 When a written advertisement refers to unpublished data on file, the relevant part of this data must be provided at the request of the MCA.*

4.4.21. *26.13 All artwork including illustrations, graphs, tables, logos and trade dress must conform to the letter and spirit of the Code.*

4.4.22. *26.13.1 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.*

4.4.23. *26.13.2 Information and claims about side effects must reflect available evidence or be capable of substantiation by clinical experience. It must not be stated that a health product has no side effects, toxic hazards or risks of addiction. It is acceptable to highlight the absence of a specific side effect, e.g. 'no drowsiness'. The word 'safe' or phrases containing reference to safety must not be used without adequate scientific substantiation.*

4.4.24. *26.13.3 Exaggerated, all-embracing claims or superiority claims must not be made and superlatives must not be used except for those limited circumstances where they relate to a clear fact about a health product. In this instance full substantiation must be provided. Claims should not imply that a health product or an active ingredient has some special merit, quality or property unless this can be substantiated.*

4.4.25. *26.13.4 The word 'new' must not be used to describe any product or presentation, which has been generally available or any therapeutic indication, which has been available on the market for more than 12 months in South Africa.*

4.4.26. *26.13.10 Advertising and/or promotion claims relating to speed of absorption, dissolution, distribution or other pharmacokinetic particulars are acceptable if supported by evidence and if in line with the product's registration dossier. Such evidence may however not be extrapolated to claims that a product offers improved efficacy or speed of efficacy, without supporting evidence to substantiate such claims."*

5. Interpretation of the applicable provisions of the Code to the matter

5.1. Based on the Panel's discussion, interpretation of the Code and review of the information, the Panel found that in the event that the Applicant proceeds to release the proposed promotional material *i.e.* leave-behind, distribution of such promotional material will contravene the following sections of the Code:

5.1.1. Clause 7.5.6;

5.1.2. Clause 7.5.7;

5.1.3. Clause 26.4;

5.1.4. Clause 26.5;

5.1.5. Clause 26.7; and

5.1.6. Clause 26.9.5.

6. Reasons for the findings determined in paragraph 5 *supra*

6.1. The Panel subsequent to review of the information and based on the abovementioned, bearing in mind the spirit of the Code, and upon careful consideration conclude the following pertaining to the Applicant's Ex parte application:

6.1.1. Clause 7.5.6 – the comparison of the two trade names, discredit the competitor product, *i.e. Acticoat;*

6.1.2. Clause 7.5.7 – the Panel assumes that the Applicant did not obtain written permission from the competitor company as same was not attached to the Ex parte application;

6.1.3. Clause 26.4 – the comparison by the Applicant of the competitor product, using the trade name *Acticoat*, unfairly disparages the competitor product;

6.1.4. Clause 26.5 – the leave behind suggest that the Applicant's product's effects are better than the competitor's product's, which is in contravention of this clause; and

6.1.5. Clause 26.7 and Clause 26.9.5 – the Panel assumes that the Applicant did not obtain written permission from the competitor company as same was not attached to the Ex parte application and further finds that the comparison denigrates the competitor's product, *i.e. Acticoat*.

7. **Conclusion / Recommendation**

7.1. In order to ensure compliance with the Code and in particular fair, balanced and accurate advertisements, the Applicant is recommended to change the proposed marketing material as follows:

7.1.1. The Applicant should reference and use all three dressings as compared and recorded in the study, and as such not only refer to two of the three products; and

7.1.2. The Applicant should genericize the tradenames when recording the other companies' tradenames in order to avoid contravention of the provisions of the Code.

Signed at.... .... on this 18th day of September 2015

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"a member and chairperson of the adjudication panel of the MCA"

Signed at.. ..... on this 18th day of September 2015

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