



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

Case number: MCA Ex0005/2016  
9 September 2016

In the matter requested by:

**NOVARTIS**

*"Applicant"*

**1. Committee members:**

Lizel Jacobs	Chairperson and member of the adjudication panel
Nicole Edelstein	Member of the adjudication panel
Lynette Terblanche	Member of the adjudication panel

**2. The matter at hand**

- 2.1. The Adjudication Panel ("the Panel") was tasked to decide whether Novartis ("the Applicant") is permitted to perform certain promotional activities in terms of Clause 31 of the SA Code of Marketing Practice ("Marketing Code") pertaining to the Applicant's interaction with patients and testimonials they provide to the Applicant.
- 2.2. In this regard the Applicant provided four specific questions and requested a non-binding opinion from the Marketing Code Authority ("MCA").

**3. Relevant sections of the Marketing Code**

- 3.1. Clause 31 of the Marketing Code relating to Testimonials is located in Part B of the Marketing Code and regulates marketing and promotion to the consumer/public. Clause 31 states the following:

**"31. TESTIMONIALS**

- 31.1 *Testimonials shall comply with the approved package insert / instructions for use and with the other principles of this Code.*
- 31.2 *Testimonials should be less than three years old and be the genuine views of the user.*
- 31.3 *The use of Healthcare Professionals for marketing, promotion, endorsements or testimonials has to take place within the scope set by the professional Codes applicable to such professionals."*

- 3.2. Clause 20 of the Marketing Code relating to *Items for Patients and Patient Organizations* is located in Part A of the Marketing Code and regulates marketing and promotion to healthcare professionals ("HCPs"). For purposes of this Non-binding Opinion, the salient provisions of this clause states the following:

**"20.4 Written agreements**

*When companies provide financial support, significant indirect support and/or significant non-financial support to patient organisations, they must have in place a written agreement which states the amount of funding and also the purpose.*

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**20.6 Editorial control**

*Companies must not seek to influence the text of patient organisation material they sponsor in a manner favourable to their own commercial interests. This does not preclude companies from correcting factual inaccuracies.*

**20.7 Contracted services**

*Contracts between companies and patient organisations under which they provide any type of services to companies are only allowed if such services are provided for the purpose of supporting healthcare or research.*

**20.9 Relations with the general public and the media.**

*Medicines must not be advertised to the general public if they are Schedule 2 - 6 products.*

*20.11 Information that is made available to the general public either directly or indirectly about health products must be factual and presented in a balanced way. It must not raise unfounded hopes of successful treatment or be misleading or disparaging with respect to the safety of the product and may not refer to a medicine's safety, quality or efficacy. Statements, representations or tie-off lines must not be made for the purpose of encouraging members of the public to ask their doctors to prescribe/recommend a specific health product. Clause 20.9 does not prohibit education or information relating to substitution of a health product or information on safe use, and/or storage of health products in general.*

**4. Non-binding Opinion to the Applicant's specific Questions**

**4.1. Question 1:**

- 4.1.1. In the instance where a known and established Patient Organisation is active in South Africa, may the Applicant request the Patient Organisation to identify a patient to share their testimonial with the Applicant?
- 4.1.2. May the Company utilize this testimonial and share with the relevant HCP's?
- 4.1.3. Further to this, may the patient share their story with the Company employees at a Townhall?

**Non-binding Opinion 1:**

- 4.1.4. The Marketing Code governs interactions between the industry and healthcare professionals in Part A and the industry and the general public in Part B. In this regard it states that there should be no direct interaction and/or contact between a company and a patient, except for the purposes of product quality complaints or other Medical Scientific Liaison ("MSL") matters where appropriate.
- 4.1.5. Subsequently, in accordance with the above and the provisions of sections 20.6 and 20.7 of the Marketing Code, i.e. stating that companies should not seek to influence or use patients in a manner favourable to their own commercial interests, the Applicant may not:
  - 4.1.5.1. ask a Patient Organisation to identify a patient to share their testimonial;
  - 4.1.5.2. share a patient's testimonial with a HCP;
  - 4.1.5.3. ask a patient to share his/her testimonial at the Applicant's Townhall
  - 4.1.5.4. use a patient's testimonial in any way to advertise and/or support the Applicant's interests.

**4.2. Question 2:**

- 4.2.1. In the instance where there is no known Patient organization, how does the Applicant go about selecting and engaging with a patient?
- 4.2.2. Would we be allowed to contact a Key Opinion Leader (KOL) and request that they identify a suitable patient whom is willing to share their story?

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**Non-binding Opinion 2:**

- 4.2.3. The Applicant is not permitted to interact with a patient directly and as stated above there should be no direct interaction and/or contact of any nature between a company and a patient.
- 4.2.4. In accordance with the content of provisions of *paragraphs 4.1.4 and 4.1.5 supra*, the Applicant is further not permitted to engage with a patient via a known KOL.

**4.3. Question 3:**

- 4.3.1. In terms of patient consent, is the patient consent applicable if the patient is not from South Africa? *i.e.* Our Principal Company based outside of South Africa shares patient testimonial videos which will be allowed in the country of origin. The testimonial is in line with the local PI; however the video clearly identifies the patient. As per internal Company guidelines, an agreement should be in place between the patient and the Company. However, is it allowed to share the patient testimonial locally without obtaining the direct written consent of the patient in question? Would the patient agreement between the Principal Company and the patient be sufficient in this instance?

**Non-binding Opinion 3:**

- 4.3.2. The Marketing Code governs activities within South Africa and therefore whether the patient is a South African or not, is irrelevant for purposes of this answer. In terms of the content of *paragraphs 4.1.4 and 4.1.5 supra*, the Applicant is prohibited from engaging in any direct interaction and/or contact with a patient, irrespective of the patient's nationality.

**4.4. Question 4:**

- 4.4.1. Our global Company sponsors an independent blog with multiple bloggers across the globe with the same disease. The aim of this blog is to create awareness of the disease and for the bloggers to share their personal stories with the audience. The South African Patient Organization for Multiple Sclerosis asked if Novartis SA can sponsor a local patient who participates in the blogging. The sponsorship will only include the payment of IT services rendered to upload the blog onto the relevant platforms.

**Non-binding Opinion 4:**

- 4.4.2. In terms of clause 20 of the Marketing Code the Applicant may *inter alia* sponsor a Patient Organisation, but the Applicant may not sponsor an individual patient. The Marketing Code further specifically states that sponsorships should not be provided to individuals for their personal use and/or benefit.

**5. Non-Binding opinion**

- 5.1. For purposes of this opinion it is important to distinguish between interactions with HCPs regulated in Part A of the Marketing Code and interactions with the public as regulated in Part B of the Marketing Code.
- 5.2. The Applicant's questions relate to Clause 31, pertaining to the use of *Testimonials*, and Part B, which governs marketing and promotional activities directed to the consumer, *i.e.* general public.
- 5.3. In accordance with the provision of the Medicines and Related Substances Control Act, 101 of 65 ("the Act"), the Marketing Code restricts such marketing and promotional activities to only Schedule 0 and Schedule 1 medicines.
- 5.4. Permitted "*testimonials*" in this instance would therefore only apply to self-medication products which may be advertised directly to the consumer in compliance with the Act, *i.e.* Schedule 0 and Schedule 1 products only.
- 5.5. Clause 31 also makes reference to a "*user*" as opposed to a "*patient*" which further supports the content of *paragraphs 4.1.4 and 4.1.5 supra*, as a patient by definition is a person receiving medical care or treatment.
- 5.6. Considering the limited information provided by the Applicant, it appears that the disease awareness campaign to be advertised/promoted via testimonials would most likely not be for a self-diagnosable condition for which an over-the-counter (OTC) medicine would be suitable. In such case Clause 31 which is limited to Schedule 0 and 1, would not apply and subsequently testimonials would not be permitted.

- 5.7. The Panel, subsequent to review of the information and based on the abovementioned provisions, assumed that the intended testimonials would relate to a disease or diseases requiring treatment with Scheduled medicines, *inter alia* including Schedule 2 and above. Therefore, bearing in mind the spirit of the Marketing Code and in particular the ethical promotion of medicines, we concluded, upon careful consideration, that the Applicant cannot use testimonials to interact with patients directly at any time.
- 5.8. The Committee is of the view that it would be inappropriate for the Applicant to interact directly with patients in such a manner and that such behaviour would constitute a transgression of the Marketing Code.

Signed at Johannesburg on this 9<sup>th</sup> day of September 2016

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

Signed at Johannesburg on this 9<sup>th</sup> day of September 2016

Nicole Edelstein  
Nicole Edelstein "a member of the adjudication panel of the MCA"

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Lynette Terblanche  
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