South African Health Products
Regulatory Authority
Building A
Loftus Park
Arcadia
Pretoria

GUIDELINES FOR ADVERTISEMENT OF MEDICNES AND HEALTH PRODUCTS

This document has been prepared to serve as a guidance document regarding SAHPRA requirements for advertisement of medicines and health products- Regulatory Compliance Unit.

DR BOITUMELO SEMETE – MAKOKOTLELA
CEO of SAHPRA

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1. BACKGROUND

The South African Health Products Regulatory Authority (hereinafter referred to as the ("SAHPRA or Authority") is a statutory body, established to provide for the monitoring, evaluation, regulation, investigation, inspection, registration and control of medicines, Scheduled substances, clinical trials and medical devices, IVDs and related matters in the public interest according to section 2A of the Medicines and Related Substances Act, Act 101 of 1965, as amended ("the Medicines Act"). The Authority must ensure health products and medicines registered or authorised by the Authority, during the entire life cycle, comply with the information that has been evaluated and approved by the Authority through section 2B(1)(c) of the Act.

The Regulatory Compliance Unit is responsible to ensure that advertising and marketing of medicines shall be in compliance with the medicines Act and its general regulations. Inappropriate promotion and advertisement of medicines may contribute to the irrational or incorrect use of medicinal products. The impact of accurate and science-based promotional activities is related to the existence of trustworthy and accessible information sources and the level of medical knowledge of the population. Hence, the control of promotion and advertisement of medical products is necessary and should be consistent with the Medicines Act and the general regulations.

2. DEFINITIONS

4.1 **'Advertisement'** 'advertisement' in relation to any medicine, Scheduled substance product; medical device or IVD, means any written, pictorial, visual or other descriptive matter or verbal statement or reference—

(a) appearing in any newspaper, magazine, pamphlet, electronic media (including radio television or other publication;
(b) distributed to members of the public; or
(c) brought to the notice of members of the public in any manner whatsoever, which is intended to promote the sale of that medicine, Scheduled substance, medical device or IVD, and 'advertise' has a corresponding meaning;
(d) also includes sampling

4.2 **'Authority or SAHPRA'** means South African Health Products Regulatory Authority.

4.3 **'Claims'** means any representation which states, suggests or implies that a product has particular qualities relating to its origin, properties, nature, processing, composition or any other quality. Justification in respect of any claim shall be in the light of current scientific knowledge.

4.4 **'Health product'** means Medicines (including orthodox, complementary products (herbal and homoeopathic), medical devices.

4.5 **'Label'** when used as a verb, means brand, mark or otherwise designate or describe, and when used as a noun, means any brand or mark or any written, pictorial or other descriptive matter appearing on or attached to or packed with and referring to any article or the package containing any article.

4.6 **'Medicines'** includes

(a) means any substance or mixture of substances used or purporting to be suitable for use or manufactured or sold for use in—

(i) the diagnosis, treatment, mitigation, modification or prevention of disease, abnormal physical or mental state or the symptoms thereof in humans; or

(ii) restoring, correcting or modifying any somatic or psychic or organic function in humans, and

(b) includes any veterinary medicine,

4.7 **'Medical device** or **IVD establishment**' means a facility used by a manufacturer, wholesaler, distributor retailer, service provider or an importer of medical devices or IVDs for conducting business;

4.8 **'Package'** means anything in or by which any medicine or Scheduled substance is enclosed, covered, contained or packed;

4.9 **'Scheduled substance'** means any medicine or other substance prescribed by the Minister under section 22A

4.10 **'Sell'** means sell by wholesale or retail and includes import, offer, **advertise**, keep, expose, transmit, consign, convey or deliver for sale or authorize, direct or allow a sale or prepare or possess for purposes of sale, and barter or exchange or supply or otherwise dispose of to any person whether for a consideration or; and **'sale' a**nd **'sold'** have corresponding meanings

3. PURPOSE

This guideline is intended to assist with requirements for advertisement of medicines and health products in South Africa. All advertising claims shall comply with prescribed conditions and be reliable, accurate, truthful, informative, balanced, up-to-date, capable of substantiation and appropriate. They shall not contain misleading or unverifiable statements or omissions likely to induce medically unjustifiable medicine use or to give rise to undue risks. To ensure guidance that the Applicants avoid communication of false or misleading information to health professionals, the public, or any other stakeholders.

4. SCOPE

3.1 This guideline applies to requirements for advertisement of medicines and health products.

3.2 This guideline is informed by the provisions of the Medicines Act and its regulations as follows:

3.2.1 Section 19 (1) of the Medicines Act states that *No person shall sell any medicine unless it complies with the prescribed requirements*. Therefore, any

person who contravenes provision of this sub-section shall be guilty of an offence.

3.2.2 In terms of section 14 of the Medicines Act the sale of medicines, medical devices or IVDs which are subject to registration and are not registered is prohibited.

3.2.3 Section 18 of the Medicines Act provides that:

(1) *No person shall sell any*

a) Medicine or Scheduled substance unless the immediate container or the package in which that medicine or Scheduled substance is sold bears a label stating the prescribed particulars.

b) medical device or IVD unless the medical device or IVD, or its packaging, bears a label, where practical stating the prescribed particulars

(2) No person shall advertise any medicine or Scheduled substance, medical device or IVD for sale unless such advertisement complies with the prescribed requirements

(3) The label referred to in subsection (1) shall be approved by the Authority.

(4) The Authority may authorize a deviation from the prescribed format and contents of any label.

(5) The Minister may prescribe additional requirements for the labeling of medicines, Scheduled substances, medical devices or IVDs.

Therefore, any person who contravenes provisions of these section shall be guilty of an offence.

3.2.4 Section 29 of the Medicines Act describes Offences for failure to comply with the provisions of the Act, and Section 30 of the Medicines Act provides for penalties when an offence has been committed.

3.2.5 In terms of Regulation 42 (4) of the General Regulations, *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 the Authority in respect of such medicine and incorporated into the approved professional information of such medicine.*

3.2.6 Regulation 52 of the General Regulations provides that Any person who fails to comply with, contravenes the provisions of or furnishes incorrect information, as the case may be, in respect of-regulations 42 with regard to the advertising of medicines.

3.3 Section 18B of the Medicines Act relates to Sampling of medicines, medical devices or IVDs, and provides that

3.3.1 No person shall sample any medicine, medical device or IVD

3.3.2 Use of medicine, medical devices or IVDs for exhibition or appraisal purposes shall be as prescribed.

3.3.3 For the purposes of this section 'sample' means the free supply of medicine, medical devices or IVDs by a device or IVD establishment, manufacturer or wholesaler or its agent to a pharmacist, medical practitioner, dentist, veterinarian, practitioner, nurse or other person registered under the Health Professions Act, 1974 (Act No. 56 of 1974), or any professional or person authorized to use the device.

5. REQUIREMENTS

5.1 **General Requirements**

5.1.1 No person or media shall advertise any scheduled medicines unless the product is registered with the Authority.

5.2 No person or media shall advertise any registered product that has undergone some variation and the amendment has not been approved by the Authority.

5.2.1 An advertisement shall be accurate, complete, clear and designed to promote credibility and trust by the general public and health practitioners. Statements or illustrations must not mislead directly or by implication.

5.2.2 No advertisement shall bring the respective industry into disrepute, undermine confidence in advertising or prejudice public confidence in the product.

5.2.3 No advertisement shall disparage any product of a competitor, either directly or by implication.

5.2.4 No advertisement shall imitate the general layout, text, slogans or visual presentation or devices of other advertisements from other companies in a way likely to mislead, deceive or confuse the consumer.

5.2.5 No advertisement shall be framed in such a manner as to exploit the superstitious belief and/or induce fear in the consumer to purchase the product. No advertisement shall contain words such as magic, miracle or mystical; exotic descriptions, such as "super potency" or such other words as to induce the daily and continuous use of the product.

5.3 **For Scheduled Medicines**

5.3.1 medicines or substances listed in Schedule 0 Schedule 1 may be advertised to the public.

5.3.2 Medicines or substances listed in Schedule 2, Schedule 3, Schedule 4, Schedule 5 or Schedule 6 may be advertised:

a) only for the information of pharmacists, medical practitioners, dentists, veterinarians, practitioners, and other authorised prescribers;

b) in a publication which is normally or only made available to persons referred to in paragraph (a).

5.3.1 and 5.3.2 shall not be so construed as to prohibit informing the public of names, pack sizes and strengths of medicines which contain a substance Schedule 2, Schedule 3, Schedule 4, Schedule 5 or Schedule 6 provided that no inference is made to the registered indication.

5.3.3 No advertisement for a medicine may contain a statement which deviates from, 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 Authority in respect of such medicine and incorporated into the approved information of such medicine.

5.3.4 An advertisement for a medicine shall contain -

a) the proprietary name of such medicine;

b) (b) in the case of a written advertisement-

i. 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;

ii. of a registered medicine, the registration number allocated to it in terms of section 15(5) of the Act;

iii. 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 Authority, followed by the words "Act 101 /1965 ";and

iv. where a name other than the proprietary name is also used, such other name shall be in lettering one half the size of the largest type size in which the proprietary name appears in such advertisement; and

(c) in the case of a

i. veterinary medicine, an indication that the medicine is for veterinary use;

ii. And in the case of a complementary medicine -

- a statement identifying the discipline of the medicine where relevant;
- an indication that the medicine must be used in accordance with the applicable complementary discipline and principles where relevant; and
- if the medicine has not received registration with the Authority the following disclaimer:

"*This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use*. ";

5.3.5 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 Authority for inclusion in the professional information of such medicine.

5.3.6 When a medicine is advertised verbally for the first time to persons contemplated to in subregulation 5.3.2(a), written information, which shall include at least the information referred to in regulation 11(professional information for medicines for human use) or regulation 14 (professional information for veterinary medicines) of the general regulations of the Medicines Act, 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.

6. OFFENCES

- Anyone who contravenes or fails to comply with the provisions of section 14 (1), 18, 18A or 18B; or
- contravenes the provisions of section 19 (1) or fails to comply with a notice issued under section 19 (2); or
- contravenes the provisions of section 20 (1); or
- contravenes or fails to comply with any condition imposed under section 15 (6); or
- fails to comply with any direction given under section 23 or contravenes the provisions of section 23 (3); or
- with fraudulent intent tampers with any sample taken in terms of this Act; or
- makes any false or misleading statement in connection with any medicine Scheduled substance, medical device or IVD; and
- in an application for the registration thereof; or
- in the course of the sale thereof; or
- sells any medicine, Scheduled substance, medical device or IVD upon the container of which a false or misleading statement in connection with the contents is written

7. SANCTIONS

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7.1 Suspension and cancellation of licence

7.1.1 If the holder of a licence under section 22C-

(a) has in or in connection with an application for a licence or renewal of a licence furnished the Director-General or the Authority, as the case may be, with any information which to the knowledge of such holder is untrue or misleading in any material respect;

(b) has contravened or failed to comply with a condition upon which the licence was issued;

(c) has contravened or failed to comply with a provision of this Act;

(d) has, in the case of a licence issued in terms of section 22C (1) (a), at any time been convicted of an offence which is of such a nature that, in the opinion of the Director-General, it renders him or her unsuitable to compound or dispense medicines,

the Director-General or the Authority, as the case may be, may by way of a notice in writing call upon

him or her to show cause within the period specified in the notice, which period shall not be less than 20 days as from the date of the notice, why the licence in question should not be suspended or revoked.

7.1.2 The Director-General or the Authority, as the case may be, may after considering the reasons furnished in terms of subsection (1)—

(a) suspend the licence in question for such period the Director-General or the Authority may determine; or

(b) revoke the licence in question.

7.1.3 No person shall be entitled to the repayment of any prescribed fee in respect of any application for the granting or renewal of a licence if such application has been refused or if the licence has been suspended or revoked.

7.2 Penalties

7.2.1 Any person who is convicted of an offence referred to in section 29 shall be liable to a fine, or to imprisonment for a period not exceeding 10 years.

7.2.2 The court convicting any person of an offence under this Act may, upon the application of the prosecutor, declare any medicine, Scheduled substance, medical device or IVD in respect of which the offence has been committed to be forfeited to the State.

7.2.3 Any medicine, Scheduled substance, medical device or IVD forfeited under this Act shall be destroyed or otherwise dealt with as the Chief Executive Officer may direct.

7.2.4 Notwithstanding anything to the contrary in any law contained, a magistrate's court shall be competent to impose any penalty provided for in this section.

8. UPDATE HISTORY

Date	Reason for update	Version & Publication
23 September 2021	First publication	Version 1, 23 September 2021