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GUIDELINES FOR ADVERTISEMENT OF MEDICINES AND HEALTH PRODUCTS

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

Document History

Version	Date	Reason for amendment
Version 1	30 10 2021	New Guideline - Incorporation of Industry Comments – alignment to Act and Regulations
Version 2	06 06 2022	Update to new template Change from document number 5.16 to SAHPGL-INSP-RC-07

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Contents

List of abbreviations and definitions

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;
Authority or SAHPRA	means South African Health Products Regulatory Authority
Claims	means any representation which states, suggests or implies that a product has particular qualities relating to its origin, properties, nature, processing, composition, safety or efficacy or any other quality as well as health-related claims. Justification in respect of any claim shall be in the light of current scientific knowledge
Complementary medicine	means any substance or mixture of substances that – (a) originates from plants, fungi, algae, seaweeds, lichens, minerals, animals or other substance as determined by the Authority; (b) is used or purporting to be suitable for use or manufactured or sold for use – (i) in maintaining, complementing or assisting the physical or mental state; or (ii) to diagnose, treat, mitigate, modify, alleviate or prevent disease or illness or the symptoms

	or signs thereof or abnormal physical or mental state of a human being or animal; and (c) is used- (i) as a health supplement; or (ii) in accordance with those disciplines as determined by the Authority;
Health product	means Medicines (including orthodox, all complementary products including herbal and homoeopathic), veterinary medicines.
Health supplement	means any substance, extract or mixture of substances as determined by the Authority, sold in dosage forms used or purported for use in restoring, correcting or modifying any physical or mental state by- (a) complementing health; (b) supplementing the diet; or (c) a nutritional effect, and excludes injectable preparations, medicines or substances listed as Schedule 1 or higher in the Act;
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;
Medicine	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;

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;
Package	means anything in or by which any medicine or Scheduled substance is enclosed, covered, contained or packed
Scheduled substance	means any medicine or other substance prescribed by the Minister under section 22A;
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 otherwise; and 'sale' and 'sold' have corresponding meanings.
Veterinary medicine	means any substance or mixture of substances, other than a stock remedy or farm feed to be registered in terms of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947), used or purporting to be suitable for use or manufactured or sold for use in connection with vertebrates, for the treatment, diagnosis, prevention or cure of any disease, infection or other unhealthy condition, or for the maintenance or improvement of health, growth, production or working capacity, or for curing, correcting or modifying any somatic or organic function, or for correcting or modifying behaviour.

1. Introduction

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 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. Background

Advertising is important to inform the public of medicine available to treat different ailments. This marketing tool that business especially medicine manufacture and their agent should utilised. However, there is need of guideline in terms of Medicine act in which medicines can advertise directly to public which should not, furthermore, how to advertise different scheduled medicines.

3. 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:

3.2.3 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.

3.2.4 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.

3.2.5 Section 18 of the Medicines Act provides that:

3.2.5.1 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; and

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

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

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

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

3.2.5.5 *The Minister may prescribe additional requirements for the labeling of medicines, medical devices or IVDs.* Therefore, any person who contravenes provisions of these section shall be guilty of an offence.

3.3 Section 22E of the Medicines Act describes reasons for the suspension and cancellation of a licence issued under Section 22C,

3.4 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.

3.5 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 accepted by the Authority in respect of such medicine and incorporated into the approved professional information of such medicine.*

3.6 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.

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

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

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

3.7.3 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.

4. Purpose

The Guideline outline requirements that are key principles for any advertisement of any scheduled medicines. The Advertisement content cannot deviate from the evidence submitted in the application for registration of medicines

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.

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

5.1.3 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.

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

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

5.1.6 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 and / or health practitioners..

5.1.7 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.

5.2 For Scheduled Medicines

5.2.1 Medicines which contain a Schedule 0 substance or a substance listed as Schedule 1 may be advertised to the public.

5.2.2 Medicines which contain a substance listed as Schedule 2, Schedule 3, Schedule 4, Schedule 5 or Schedule 6 may be advertised:

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

5.2.2.2 in a publication which is normally or only made available to persons referred to in paragraph (1).

5.2.2.3 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 provided that no inference is made to the registered indication.

5.2.3 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 Authority in respect of such medicine and incorporated into the approved professional information of such medicine.

5.2.4 An advertisement for a medicine shall contain –

a) the proprietary name of such medicine;

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 must be in accordance with approval

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

a. 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*. ";

5.2.5 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.

5.2.6 When a medicine is advertised verbally for the first time to persons contemplated to in point 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.