MCA
Marketing Code Authority
ethical marketing leadership for health products

Minimum Requirements for Advertisements for Health Products as legislated in the Medicines and Related Substances Act, 101 of 1965 (The Act).

(Author: Val Beaumont, EO Marketing Code Authority, June 2019)

The Act prescribes minimum requirements for advertisements of medicines, medical devices and IVDs (Health Products). This summary is intended to assist with the approval of promotional material against requirements of The Act. You are nonetheless advised to refer to the actual legislation when planning or approving promotional material to ensure correct context and interpretation.

References that pertain to this article:

- *Medicines and Related Substances Act 101 of 1965 (The Act), as amended.*
- *General Regulations, GN 859 in GG 41064 of 25 August 2017, issued in terms of the Medicines and Related Substances Act 101 of 1965 (General Regulation).*
- *Regulations relating to medical devices and In-Vitro Diagnostic Medical Devices (IVDs), GN 1515 in GG 40480 of 9 December 2016, issued in terms of the Medicines and Related Substances Act 101 of 1965 (Device Regulation).*

Definition of Advertisement

'advertisement', in relation to any medicine or scheduled substance, 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 and 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[1];*
Note for clarity: the term medicine embraces all allopathic medicines, complementary medicines and health supplements.

Requirements for Medicines Advertisements

Medicines schedule status	**May be advertised to:**
Medicines in Schedules 0 to 1	May be advertised directly to the public[2].
Medicines in Schedules 2 to 6	May be advertised only to healthcare professionals and authorised prescribers[3].
Medicines above Schedule 6	May not be advertised.
Information to the public regarding prices, names, pack sizes and strength of Schedule 2 to Schedule 6 medicines	Not restricted provided the rest of advertisement complies and no claims are made[4].
No person shall advertise any medicine or scheduled substance for sale unless su advertisement complies with the prescribed requirements[5].	
No advertisement may go beyond the information contained in the approved professional information for a medicine or instructions for use of a medical device or IVD[6].	
Misleading advertising of any health products included in the Act is prohibited[7].	
Where more than one active ingredient is present, reference may only be made to the individual ingredients **if a statement to this effect is included in the professional information**.	

If no such statement is included, an advertisement must comply with the professional information or instructions for use[8].
When a medicine is advertised verbally for the first time, its printed Professional Information must be offered and must be available on subsequent occasions[9].

A written advertisement for a medicine must contain the following information:[10]
• the proprietary name;
• in the case of a written advertisement;
  • the approved name and quantity of each active ingredient in a font at least half the size of the largest proprietary name;
  • the registration number of registered medicines;
  • in the case of 'old medicines', the reference number allocated to such application followed by the words 'Act 101/1965'; and
  • a name used, other than the proprietary name, must not exceed half the size of the proprietary name.

Special requirements: Advertisements for **veterinary medicines** must state; "for veterinary use only"[11]. Advertisements for **complementary medicines**[1]: • a statement identifying the discipline of the medicine where relevant; • an indication that the medicine must be used in accordance with the applicable complimentary discipline and principles where relevant; and • if the medicine has not received registration with the Authority the following disclaimer must be included: ***'This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use***'.

Requirements for Medical Device and IVD Advertisements[12]

Only Class A and B medical devices may be advertised to the public or a lay person. Exception: male and female condoms may be advertised to the public. A written advertisement for a medical device or IVD must contain: • the name of the medical device or IVD; and • in the case of a registered medical device or IVD, the registration number. When a Class C or D medical device or IVD is advertised for the first time to a prospective user, the instructions for use must simultaneously be given to the person to whom the *oral, electronic or printed advertisement is directed*. On subsequent occasions, the information must be available on request.

[1] The Act, Definition of Advertisement
[2] General Regulation 42(1)
[3] General Regulation 42 (2)
[4] General Regulation 42 (3)
[5] The Act, s 18 (2)
[6] The Act s 20(1)*(b)*
[7] The Act, s 20(1)*(a)*
[8].General Regulation 42 (6)
[9] General Regulation 42 (7)
[10] General Regulation 42(5) 5
[11] General Regulation 42 (5)(c)(i) and (ii)
[12] Device Regulation 21 (1)