South Africa

1. The Principal Legislation


Medicines and Related Substances Amendment Bill was introduced in the National Assembly and explanatory summary of Bill was published in Government Gazette No. 37361 of 20 February 2014.

2. Website Links

(1) Medicines and Related Substances Act, 1965 (Act No. 101 of 1965) (Lastly Amended by Medicines and Related Substances Control Amendment Act No. 90 of 1997)

2) Medicines and Related Substances Control Amendment Act No. 59 of 2002

3) Medicines and Related Substances Control Amendment Act No. 72 of 2008

4) Medicines and Related Substances Amendment Bill published in 2014

(2) General Regulations Made in terms of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965)
http://www.saflii.org/za/legis/consol_reg/marsa101o1965rangnr510723/

3. Extract from the legislation related to counterfeit medicines

(1) Medicines and Related Substances Act, 1965 (Act No.101 of 1965) (Lastly Amended by Medicines and Related Substances Control Amendment Act No. 72 of 2008)

Extract of Section 1(1)
Section 1
Definitions
(1) In this Act, unless the context otherwise indicates –

'advertisement', in relation to any 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 or other publication; or
(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 product, medical device or IVD; and 'advertise' has a corresponding meaning;
‘Authority’ means the South Africa Health Products Regulatory Authority established by section 2;

‘IVD (in vitro diagnostic medical device)’ means a medical device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnosis, monitoring or compatibility purposes;

‘magistrate’ means a magistrate as defined in section 1 of the Magistrates Act, 1993 (Act No. 90 of 1993), and includes an additional magistrate and an assistant magistrate;

'medical device' means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article—
(a) intended by the manufacturer to be used, along or in combination, for human beings for—
(i) diagnosis, prevention, monitoring, treatment or alleviation of disease;
(ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
(iii) investigation, replacement, modification or support of the anatomy of a physiological process;
(iv) supporting or sustaining life;
(v) control of conception;
(vi) disinfection of medical devices; or
(vii) providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body; and
(b) which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means;

'medicine' means any substance or mixture of substances used or purporting to be suitable for use or manufactured or sold for use in—
(a) the diagnosis, treatment, mitigation, modification or prevention of disease, abnormal physical or mental state or the symptoms thereof in humans; or
(b) restoring, correcting or modifying any somatic or psychic or organic function in humans, and includes any veterinary medicine;

'product' means a machine, a Scheduled substance or a cosmetic or foodstuff which contains a scheduled substance;

'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 dispose of to any person whether for a consideration or otherwise; and 'sale' and 'sold' have corresponding meanings;

'this Act' includes any regulation;

Section 20
20. Publication or distribution of false advertisements concerning products, medical devices or IVDs
(1) No person shall—
(a) publish or distribute or in any other manner whatsoever bring to the notice of the public or cause or permit to be published or distributed or to be so brought to the notice of the public any false or
misleading advertisement concerning any product, medical device or IVD; or
(b) in any advertisement make any claim to the effect that the therapeutic efficacy and effect of any
product is other than that stated by the Authority in terms of sub-paragraph (ii) of
Paragraph (a) of section twenty-two or state or suggest that any product, medical device
or IVD should be used for a purpose or under circumstances or manner other than that stated by the
Authority in terms of subparagraph (iii) of paragraph (a) of that section.
(2) It shall be a sufficient defence in any prosecution for an offence under paragraph (a) of sub-section (1)
if it is proved to the satisfaction of the court that the accused, not being a person selling the product,
medical device or IVD to which the false or misleading advertisement which is the subject of the
prosecution relates, did not know, and could not reasonably be expected to have known, that the
advertisement was in any respect false or misleading.

Section 29 (d), (h), (i)
29. Offences
Any person who-
(d) contravenes the provisions of section 20 (1); or
(h) makes any false or misleading statement in connection with any product, medical device or IVD-
   (i) in an application for the registration thereof; or
   (ii) in the course of the sale thereof; or
(i) sells any product, medical device or IVD upon the container of which a false or misleading statement in
connection with the contents is written;
shall be guilty of an offence.

Section 30
30. Penalties
(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.
(2) The court convicting any person of an offence under this Act may, upon the application of the
prosecutor, declare any product, medical device or IVD in respect of which the offence has been
committed to be forfeited to the State.
(3) Any product, medical device or IVD forfeited under this Act shall be destroyed or otherwise dealt with
as the Chief Executive Officer may direct.
(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.

Section 33
33. Act or omission by manager, agent or employee
(1) Whenever any manager, agent or employee of any person (hereinafter called the employer) does or
omits to do any act which it would be an offence under this Act for the employer to do or omit to do, then
unless it is proved that-
(a) in doing or omitting to do that act the manager, agent or employee was acting without the connivance
or the permission of the employer; and
(b) all reasonable steps were taken by the employer to prevent any act or omission of the kind in question; and
(c) it was not under any condition or in any circumstances within the scope of the authority or in the
course of the employment of the manager, agent or employee to do or omit to do acts, whether lawful or
unlawful, of the character of the act or omission charged,
the employer shall be presumed himself to have done or omitted to do that act and shall be liable to be convicted and sentenced in respect thereof; and the fact that he issued instructions forbidding any act or omission of the kind in question shall not, of itself, be accepted as sufficient proof that he took all reasonable steps to prevent the act or omission.

(2) Whenever any manager, agent or employee of any such employer does or omits to do an act which it would be an offence under this Act for the employer to do or omit to do, he shall be liable to be convicted and sentenced in respect thereof as if he were the employer.

(3) Any such manager, agent or employee may be so convicted and sentenced in addition to the employer.


Extract of Section 1

1. DEFINITIONS
In these Regulations any word or expression defined in the Act and not defined herein bears the same meaning as in the Act and unless the context otherwise indicates -

“counterfeit medicine” means a medicine in respect of which a false representation has been made with regard to its contents, identity or source by any means including its labelling and packaging;

Section 32(1) (b)

32. SEIZURE OF MEDICINES
(1) A medicine may be seized if it:
(b) is suspected counterfeit;