REPUBLIC OF SOUTH AFRICA

SOUTH AFRICAN MEDICINES AND MEDICAL DEVICES REGULATORY AUTHORITY BILL

(As introduced)

(MINISTER OF HEALTH)

[B 114-981

REPUBLIEK VAN SUID-AFRIKA

WETSONTWERP OP DIE SUID-AFRIKAANSE MEDISYNE EN MEDIESE TOESTELLE REGULERENDE OWERHEID

(Soos ingedien)

(MINISTER VAN GESONDHEID)

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GENERAL EXPLANATORY NOTE:

[ ] Words in bold type in square brackets indicate omissions from existing enactments.

Words underlined with a solid line indicate insertions in existing enactments.

BILL

To provide for the regulation and registration of medicines intended for human and for animal use; for the regulation and registration of medical devices; for the establishment of the South African Medicines and Medical Devices Regulatory Authority; for the control of orthodox medicines, complementary medicines, veterinary medicines, scheduled substances and medical devices; for the control of persons who may compound and dispense orthodox medicines, complementary medicines and veterinary medicines; for the repeal of the Medicines and Related Substances Control Act, 1965; the amendment of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947; and for matters incidental thereto.

BE IT ENACTED by the Parliament of the Republic of South Africa, as follows:—

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CHAPTER I

INTRODUCTORY PROVISIONS

Definitions

1. In this Act, unless the context indicates otherwise—

"advertisement", in relation to any orthodox medicine, complementary medicine, veterinary medicine, medical device or Scheduled substance, 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 orthodox medicine, complementary medicine, veterinary medicine, medical device or Scheduled substance; and "advertise" has a corresponding meaning;

"adverse drug events" includes adverse effects of orthodox, complementary and veterinary medicines and medical devices. The adverse drug events scheme will encompass, amongst other things, risk assessment, pharmaco-vigilance, drug utilisation studies and international monitoring;

"analyst" means an analyst to whom authority has been granted under section 38;

"approved name" in relation to a medicine, means 1 the international nonproprietary name (INN) of such medicine or, where no such name exists such other name as the Board may determine, not being a brand or trade name registered in terms of the Trade Marks Act, 1993 (Act No. 194 of 1993);

"Appeal Board" means the Appeal Board appointed in terms of section 27(1);

"audit committee" means the audit committee appointed in terms of section 19(3);

"Auditor-General" means the person who in terms of item 20 of Schedule 6 to the Constitution continues to function and to hold office under the Auditor-General Act, 1995 (Act No 12 of 1995) or is appointed as such in terms of section 193 of the Constitution;

"Authority" means the South African Medicines and Medical Devices Regulatory Authority established by section 2;

"Board" means the Board appointed in terms of section 6(1);

"Chief Executive Officer" means the Chief Executive Officer appointed in terms of section 16(2);

"complementary medicine" means any substance or mixture of substances, originating from a plant, mineral or animal, which may be, but is not limited to being, classified as herbal, homeopathic, ayurvedic or nutritional, used or intended to be used for or manufactured or sold for use in complementing the healing power of a human or animal body or for which there is a claim regarding its effect in complementing the healing power of an animal or human body in the treatment, modification, alleviation or prevention of disease, abnormal physical or mental state or the symptoms thereof in a human being and may encompass substances or mixture of substances used in the disciplines generally referred to as Western herbal medicine, African traditional medicine, traditional Chinese medicine, traditional Dutch medicine, homeopathy, ayurveda, aromatherapy and food supplementation;

"Constitution" means the Constitution of the Republic of South Africa, 1996 (Act No 108 of 1996);

"dentist" means a person registered as such under the Medical, Dental and Supplementary Health Service Professions Act, 1974 (Act No. 56 of 1974);

"Director-General" means the Director-General of Health or, in relation to a matter concerning veterinary medicines, means the Director-General: Health acting in consultation with the Director-General of Agriculture;

"export" includes deliver or supply within the Republic for dispatch to any destination outside the Republic;

"hospital" means any institution established as a hospital or a nursing home or registered as such in terms of any law;

"immediate container", in relation to an orthodox medicine, complementary medicine, veterinary medicine, or scheduled substance, means a container which is in direct contact with the medicine, complementary medicine, veterinary medicine or substance;

"immediate family member", in relation to any person, means that person's spouse, parent, child, brother or sister;

"inspector" means a person designated as such under section 41;

"interchangeable multi-source medicines". means medicines that contain the same active substances which are identical in strength or concentration, dosage form and route of administration and meet the same or comparable standards, which comply with the requirements for therapeutic equivalence as prescribed;

"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;

"medical device" or "device" means any instrument, appliance, material, machine, apparatus, implant or diagnostic reagent or any other article, whether used alone or in combination, including software necessary for its proper application used for or purporting to be suitable for use or manufactured or sold for use in or on a human or animal body—

(i) in the diagnosis, prevention, monitoring, treatment or alleviation of disease; or

(ii) in diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap; or

(iii) in investigation, replacement or modification of the anatomy or of a physiological process; or

(iv) in the diagnosis of pregnancy, or the control of conception or termination of pregnancy;

and which does not achieve its principal intended action in or on the human body by chemical, pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;

"medical practitioner" means a person registered as such under the Medical, Dental and Supplementary Health Service Professions Act, 1974 and includes an intern registered under that Act;