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GENERAL NOTICE

NOTICE 763 OF 2002

DEPARTMENT OF HEALTH

MEDICINES AND RELATED SUBSTANCES AMENDMENT BILL, 2002

The Minister of Health intends to table the Medicines and Related Substances Amendment Bill, 2002, in Parliament this year, 2002.

Interested persons are invited to submit any substantiated comments or representations on the proposed Bill to the Director-General: Health, Private Bag X 828, Pretoria, 0001, within a period of one month from the date of publication of this Notice.

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 amend the Medicines and Related Substances Act, 1965, as amended, so as to provide for some definitions, to provide for the appointment of a Deputy Registrar, to provide for a term of office of members of the Pricing Committee, to provide for the delay of the coming into operation of provisions requiring a licence before a person can compound and dispense medicines or manufacture, act as a wholesaler or distributor; to provide that appeals against the decisions of the Director-General and the council shall be to the Minister; to provide for a Marketing Code for pharmaceutical companies, to provide that the powers of inspectors shall be exercised pursuant to a warrant issued by a magistrate or a judge of the High Court or without a warrant in certain instances; and to provide for matters connected therewith.

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

Amendment of section 1 of Act 101 of 1965 as amended by section 1 of Act 65 of 1974, section 1 of Act 17 of 1979, section 1 of Act 20 of 1981, section 1 of Act 94 of 1991 and section 1 of Act 90 of 1997

1. Section 1 of the Medicines and Related Substances Act, 1965 (hereinafter referred to as the principal Act), is hereby amended-
 - (a) by the insertion in subsection (1) after the definition of "dentist" of the following definition:
"Department" means the national Department of Health"
 - (b) by the substitution in subsection (1) for the definition of "medical Act" of the following definition:

"medical Act" means the Health Professions Act, 1974;

- (c) by the substitution in subsection (1) for the definition of "practitioner" of the following definition:

"practitioner" means a person registered as such under the **[Chiropractors, Homeopaths and] Allied Health [Service] Professions Act, 1982 (Act No.63 of 1982).**

Amendment of section 6 of Act 101 of 1965 as amended by section 5 of 65 of 1974, section 3 of Act 17 of 1979, section 46 of Act 97 of 1986, section 4 of Act 94 of 1991 and section 5 of Act 90 of 1997

2. Section 6 of the principal Act is hereby amended-

- (a) by the deletion of paragraph (b) of subsection (2); and
(b) by the substitution for subsection (3) of the following subsection:

"(3) If the office of any member becomes vacant before the expiration of the period for which he or she was appointed, the Minister may **[, subject to the provisions of section 3,]** appoint another person to hold office for the unexpired portion of the period for which his or her predecessor was appointed."

Substitution of section 12 of Act 101 of 1965 as substituted by section 10 of Act 65 of 1974 and amended by section 7 of Act 90 of 1997

3. The following section is hereby substituted for section 12 of the principal Act:

"12. (1) The Minister may, after consultation with the Council, appoint a Registrar and one or more Deputy Registrars.

(2) The Registrar shall perform the functions and carry out the duties assigned to or imposed upon the Registrar by or under this Act and such other functions and duties as may from time to time be assigned to or imposed upon him or her by the Minister, council or Director-General.

(3) A Deputy Registrar shall assist the Registrar in the performance of his or her functions and the carrying out of his or her duties and may, subject to the approval of the Registrar, exercise any power conferred upon the Registrar."

Amendment of section 18C of Act 101 of 1965 as inserted by section 12 of Act 90 of 1997

4. The following section is hereby substituted for Section 18C of the principal Act:

"18C. (1) The Minister shall, after consultation with the pharmaceutical industry and other stakeholders, make regulations relating to a Marketing Code relating to the marketing practices of pharmaceutical companies.

(2) The regulations referred to in subsection (1) shall also provide for-

- (a) the appointment of a body comprising representatives of trade associations, pharmaceutical industry, consumers and health care providers to enforce the Marketing Code together with the council;
- (b) the funding for the body referred to in paragraph (a); and
- (c) the enforcement of the Marketing Code referred to in paragraph (a)."

Amendment of section 22A of Act 101 of 1965, as inserted by section 21 of Act 65 of 1974 and amended by section 9 of Act 17 of 1979 and substituted by section 13 of Act 90 of 1997

5. Section 22A of the principal Act is hereby amended-

(a) by the substitution for subsection (8) of the following subsection:

"(8) Subject to subsection (9) [a Schedule 7] or Schedule 8 substance shall not be acquired by any person other than the Director-General for the purpose of providing a medical practitioner therewith, on the prescribed conditions for the treatment of a particular patient of that medical practitioner upon such conditions as the Director-General, on the recommendations of the council, may determine."

(b) by the substitution for paragraph (a) of subsection (11) of the following paragraph:

"(a) No person shall import or export a Schedule 6, Schedule 7 or Schedule 8 substance or other substance or medicine prescribed for that purpose unless a permit has been issued to him or her by the Director-General in the prescribed manner and subject to **[prescribed]** conditions as may be determined by the Director-General.";

(c) by the substitution in subsection (12) of subparagraph (i) of paragraph (a) of the following subparagraph:

"(i) any Schedule 6, Schedule 7 or Schedule 8 substance; and

(d) by the substitution for paragraph (b) of subsection (16) of the following paragraph:

"(b) any person may possess a Schedule 3, Schedule 4, Schedule 5~~[.]~~ or Schedule 6 **[or Schedule 7]** substance if he or she is in possession of a prescription issued by an authorised prescriber."

Amendment of section 22C of Act 101 of 1965 as inserted by section 14 of Act 90 of 1997

6. Section 22C of the principal Act is hereby amended-

(a) by the substitution for paragraph (a) of subsection (1) of the following paragraph:

"(a) The **[Director-General] Department** may on application in the prescribed manner and on payment of the prescribed fee issue to a medical practitioner, dentist, nurse or other person registered under the Health Professions Act, 1974, a licence to compound and dispense medicines on the prescribed conditions;

(b) by the substitution for subsection (2) of the following subsection:

"(2) A licence referred to in subsection (1)(a) shall not be issued unless the applicant has successfully completed a supplementary course prescribed under the Pharmacy Act, 1974 **[(Act No. 53 of 1974)]** by the **[Interim Pharmacy Council of South Africa]** South African Pharmacy Council;
and

(c) by the substitution for subsection (3) of the following subsection:

"(3) The **[Director-General]** Department or the council, as the case may be, may require an applicant contemplated in subsection (1) to furnish such information, in addition to any information furnished by the applicant in terms of the said subsection, as the **[Director-General]** Department or the council may deem necessary".

(c) by the substitution in subsection (4) for the words preceding paragraph (a) of the following words:

"(4) When the **[Director-General]** Department or the council, as the case may be, grants or refuses an application for a licence-

(d) by the substitution for subsection (5) of the following subsection

"(5) No person shall compound and dispense a medicine unless he or she is authorised thereto in terms of the Pharmacy Act, 1974, is a veterinarian or is the holder of a licence as contemplated in subsection (1)(a)." and

(e) by the substitution for subsection (7) of the following subsection:

"(7) Subsections (5) and (6) shall come into operation **[six months after the]** twelve months from the date of commencement of this section."

Amendment of section 22D of Act 101 of 1965 as inserted by section 14 of Act 90 of 1997

7. The following section is hereby substituted for section 22D of the principal Act:

"22D. A licence issued under section 22C shall be valid for the prescribed period but may be renewed on application in the prescribed manner and before the prescribed time or such later time as the **[Director-General]** Department or the council, as the case may be, may allow and on payment of the prescribed fee.

Amendment of section 22E of Act 101 of 1965 as inserted by section 14 of Act 90 of 1997

8. Section 22E of the principal Act is hereby amended-

(a) by the substitution for paragraph (a) of subsection (1) of the following paragraph:

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

(b) by the substitution for paragraph (d) of subsection (1) of the following paragraph"

"(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] Department**, it renders him or her unsuitable to compound and dispense medicines," and

(c) by the substitution for the words following upon paragraph (d) of the following words:

"the **[Director-General] Department** or the council, 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."

(d) by the substitution in subsection (2) for the words preceding paragraph (a) of the following words:

"(2) The **[Director-General] Department** or the council, as the case may be, may after considering the reasons furnished to **[him or her]** it, in terms of subsection (1)-"

Amendment of section 22F of Act 101 of 1965 as inserted by section 14 of Act 90 of 1997

9. Section 22F of the principal Act is hereby amended by the substitution for paragraph (a) of subsection (1) of the following paragraph:

"(a) inform all members of the public who visits [his or her] the pharmacy or any other place where dispensing takes place with a prescription for dispensing, of the benefits of the substitution for a branded medicine of an interchangeable multi-source medicine; and"

Amendment of section 22G of Act 101 of 1965 as inserted by section 14 of Act 90 of 1997

10. Section 22G of the principal Act is hereby amended –

(a) by the substitution for subsection (1) of the following subsection:

"(1) The Minister shall appoint, for a period not exceeding five years, such persons as he or she may deem fit to be members of a committee to be known as the pricing committee; and

(b) by the addition in subsection (2) of the following paragraph:

"(c) on an appropriate fee to be charged by wholesalers or distributors."

Amendment of section 22H of Act 101 of 1965, as inserted by section 14 of Act 90 of 1997

11. Section 22H of the principal Act is hereby amended by the substitution for subsection (3) of the following subsection:

"(3) Any wholesaler may in the prescribed manner and on the prescribed conditions be exempted by the **[Director-General] Department** from the provisions of subsection (1)."

Amendment of section 24 of Act 101 of 1965, as substituted by section 11 of Act 94 of 1991 and section 15 of Act 90 of 1997

12. Section 24 of the principal Act is hereby amended-

- (a) by the substitution for the existing heading of the following heading:
"Appeal against decision of council, the Department or Director-General";
- (b) by the substitution for subsection (1) of the following subsection:

"(1) Any person aggrieved by the decision of the Director-General, the Department or the council, as the case may be, may, within the prescribed period, in the prescribed manner and upon payment of the prescribed fee, appeal against such decision to **[an appeal committee appointed by]** the Minister for the purposes of the appeal concerned.";

(c) by the deletion of subsection (2);

(d) by the substitution for subsection (3) of the following subsection:

"(3) The **[appeal committee]** Minister may, after hearing the appeal-

- (a) confirm, set aside or vary the relevant decision of the Director-General, the Department or the council; and
- (b) direct the Director-General, the Department or the council, as the case may be, to execute the decision of the **[appeal committee]** Minister."

(e) by the substitution for subsection (4) of the following subsection:

"(4) The decision of the **[appeal committee]** Minister shall be in writing and a copy thereof shall be furnished to the appellant as well as to the Director-General, the Department or the council, as the case may be."

(e) by the deletion of subsections (5) and (6);

Amendment of section 25 of Act 101 of 1965 as substituted by section 32 of Act 88 of 1996

13. The following section is hereby substituted for section 25 of the principal Act:

25. The council or committee appointed under **[subsection (1) of section 9]** sections 9(1) or 22G(1) or any member of the council or of any such committee shall not be liable in respect of anything done in good faith under this Act.

**Amendment of section 25 of Act 101 of 1965 as substituted by section 32 of Act 88 of 1996
section 12 of Act 17 of 1979 and section 16 of Act 90 of 1997**

14. The following section is hereby substituted for section 28 of the principal Act:

"Search and seizure

28. (1) For the purposes of the administration of this Act, a magistrate or a judge of the High Court may, on application by an inspector contemplated in section 26, issue a warrant, authorising the inspector named therein to, without prior notice and at any time –

(a) (i) enter and search any premises; and

(ii) search any person present on the premises, provided that such search is conducted by an officer of the same gender as the person being searched,

for any medicine, documents or things, that may afford evidence as to the non-compliance by any person with this Act;

(b) seize any such medicine, documents or things; and

(c) in carrying out any such search, open or cause to be opened or removed and opened, anything in which such officer suspects any medicine, documents or things to be contained.

(2) An application under subsection (1) shall be supported by information supplied under oath or solemn declaration, establishing the facts on which the application is based.

(3) A judge may issue the warrant referred to in subsection (1) if he or she is satisfied that there are reasonable grounds to believe that-

(a) (i) there has been non-compliance by any person with this Act, or

(ii) an offence in terms of this Act has been committed by any person;

(b) medicines, documents or things are likely to be found which may afford evidence of-

(i) such non-compliance; or

(ii) the committing of such offence; and

(c) the premises specified in the application are likely to contain such medicines, documents or things.

(4) A warrant issued under subsection (1) shall-

(a) refer to the alleged non-compliance or offence in relation to which it is issued;

(b) identify the premises to be searched;

(c) identify the person alleged to have failed to comply with the provisions of the Act or to have committed the offence; and

(d) be reasonably specific as to any medicines, documents or things to be searched for and seized.

(5) Where the inspector named in the warrant has reasonable grounds to believe that-

(a) such medicines, documents or things are-

(i) at any premises not identified in such warrant; and

(ii) about to be removed or destroyed; and

(b) a warrant cannot be obtained timeously to prevent such removal or destruction, such inspector may search any premises and further exercise all the powers granted by this section, as if such premises had been identified in a warrant.

(6) Any inspector who executes a warrant may seize, in addition to the medicines, documents or things referred to in the warrant, any other information, documents or things that such officer believes on reasonable grounds afford evidence of the non-compliance with the this Act.

(7) The inspector exercising any power under this section shall on demand produce the relevant warrant (if any).

(8) The inspector, who shall take reasonable care to ensure that the medicines, documents or

things are preserved, may retain them until the conclusion of any investigation into the non-compliance or offence in relation to which the information, documents or things were seized or until they are required to be used for the purposes of any legal proceedings under this Act, whichever event occurs last.

(9) (a) Any person may apply to the relevant division of the High Court for the return of any medicines, documents or things seized under this section.

(b) The court hearing such application may, on good cause shown, make such order as it deems fit.

(10) The person to whose affairs any medicine, documents or things seized under this section relate, may examine and make extracts therefrom and obtain one copy thereof at the expense of the State during normal business hours under such supervision as the inspector may determine.

Amendment of section 35 of Act 101 of 1965 as substituted by section 31 of Act 65 of 1974, as amended by section 3 of Act 19 of 1976, section 14 of Act 17 of 1979, section 7 of Act 20 of 1981, section 7 of Act 71 of 1991, section 16 of Act 94 of 1991 and section 23 of Act 90 of 1997

15. Section 35 of the principal Act is hereby amended by the substitution for subparagraph (xxxiii) of subsection (1) of the following subparagraph:

“(xxxiii) relating to appeals against decisions of the Director-General, the Department or the council;”

Substitution of the long title of Act 101 of 1965 as substituted by section 22 of Act 94 of 1991 and section 29 of Act 90 of 1997

16. The following long title is hereby substituted for the long title of the principal Act:

“Act

To provide for the registration of medicines intended for human and for animal use, for the registration of complementary medicines, for the registration of certain medical devices, for the establishment of a Medicines Control Council; to provide that such Council shall be a juristic person, to make other provision for the constitution of the Council, to provide

that a member of the Council or committee shall declare his or her commercial interest related to the pharmaceutical or health care industry, to provide that the appointment of members of the executive committee shall be subject of the approval of the Minister; to provide for the control of medicines, complementary medicines, Scheduled substances and certain medical devices; to make further provision for the prohibition on the sale of medicines which are subject to registration and are not registered; to provide for procedures that will expedite the registration of essential medicines, and for the re-evaluation of all medicines after five years, to provide for measures for the supply of more affordable medicines in certain circumstances, to require labels to be approved by the Council; to prohibit sampling and bonusing of medicines; to provide for the licencing of certain persons to compound, dispense or manufacture medicines; and also to act as wholesalers or distributors; to provide for the generic substitution of medicines, for the establishment of a pricing committee; to regulate the purchase and sale of medicines by wholesalers; to make new provisions for appeals against decisions of the Director-General or the Council, to further regulate the powers of inspectors; to increase the jurisdiction of magistrates courts in respect of penalties in terms of this Act; to provide that the Council may acquire and appropriate funds; to regulate anew the Minister's power to make regulations; and to provide for the rationalisation of certain laws relating to medicines and related substances that have remained in force in various territories on the national territory of the Republic by virtue of item 2 of Schedule 6 of the Constitution of the Republic of South Africa, 1996; and to provide for matters connected therewith."

Repeal of Act 132 of 1998

17. The South African Medicines and Medical Devices Regulatory Authority Act, 1998, (Act No.132 of 1998) is hereby repealed.

Short title and commencement

18. This Act is called the Medicines and Related Substances Amendment Act, 2002 and shall come into operation on a date to be determined by the President by proclamation in the Gazette.

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