REPUBLIC OF SOUTH AFRICA

MEDICINES AND RELATED SUBSTANCES AMENDMENT BILL

(As amended by the Portfolio Committee on Health (National Assembly))
(The English text is the official text of the Bill)

(MINISTER OF HEALTH)

[B 40B—2002]

ISBN 0 621 33092 2

No. of copies printed 1 800

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, so as to provide for some definitions; to provide for the appointment of one or more Deputy Registrars; 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 or manufacture medicines, or act as a wholesaler or distributor; to provide for appeals against the decisions of the Director-General and the council; to provide for regulations relating to the marketing of medicines; 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 amended by—

(a) the insertion in subsection (1) after the definition of ''label'' of the following definition:

'' '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;''; and

(b) 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 Act 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 amended by—

(a) the deletion of paragraph *(b)* of subsection (2); and

(b) the substitution for subsection (3) of the following subsection:

''(3) If the office of any member of the council 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 substituted for section 12 of the principal Act:

"Appointment of Registrar and Deputy Registrar of Medicines

12. (1) The Minister may, after consultation with the council, appoint a Registrar and one or more Deputy Registrars or revoke such an appointment.

(2) The Registrar shall exercise the powers and perform the duties assigned to, or imposed upon, him or her in terms of this Act and such other powers and duties as may from time to time be assigned to or imposed upon him or her by the council, Minister or Director-General.

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

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

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

"Marketing of medicines

18C. The Minister shall, after consultation with the pharmaceutical industry and other stakeholders, make regulations relating to the marketing of medicines, and such regulations shall also provide for an enforceable Code of Practice.''.

Amendment of section 22A of Act 101 of 1965, as inserted by section 21 of Act 65 of 1974, 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 amended by—

(a) the substitution for paragraph *(p)* of subsection (6) of the following paragraph:

''*(p)* the sale of a specified Schedule 5 or Schedule 6 substance by a manufacturer of or wholesale dealer in pharmaceutical products shall be recorded in a register which shall be kept in the prescribed manner, and shall be balanced so as to show clearly the quantity of every specified Schedule 5 or Schedule 6 substance remaining in stock as on the last day of March, June, September and December of each year, and such balancing shall be completed within the 14 days following each of the said dates;'';

(b) the substitution for subsection (8) of the following subsection:

''(8) Subject to subsection (9), a **[Schedule 7]** 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 recommendation of the council, may determine.'';

(c) the substitution for subparagraph (i) of paragraph *(a)* of subsection (9) of the following subparagraph:

"(i) acquire, use, possess, manufacture or supply any Schedule 7 or Schedule 8 substance, or manufacture any specified Schedule 5 or Schedule 6 substance unless he or she has been issued with a permit by the Director-General for such acquisition, use, possession, manufacture, or supply: Provided that the Director-General may, subject to such conditions as he or she may determine, acquire or authorise the use of any Schedule 7 or Schedule 8 substance in order to provide a medical practitioner, analyst, researcher or veterinarian therewith on the prescribed conditions for the treatment or prevention of a medical condition in a particular patient, or for the purposes of education, analysis or research;";

(d) the substitution for paragraph *(a)* of subsection (11) of the following paragraph:

"*(a)* No person shall import or export any specified Schedule 5, Schedule 6 **[or]**, 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 **[the prescribed]** such conditions as may be determined by the Director-General;";

(e) the substitution for subparagraph (i) of paragraph *(a)* of subsection (12) of the following subparagraph:

"(i) any specified Schedule 5, Schedule 6 **[or]**, Schedule 7 or Schedule 8 substance;";

(f) the substitution for paragraph *(b)* of subsection 12 of the following paragraph:

"*(b)* The obtaining of import or export permits as required in terms of subsection (11) shall not apply to any preparation which contains a substance as prescribed which is specifically exempted from all control measures for the obtaining of such import or export permits by the 1961 Single Convention on Narcotic Drugs referred to in paragraph *(a)*.";

(g) the substitution for paragraph *(c)* of subsection (12) of the following paragraph:

"*(c)* Notwithstanding paragraph *(b)*, no such importation or exportation shall take place unless authorised by the Director-General.";

(h) the substitution for paragraph *(a)* of subsection (14) of the following paragraph:

"*(a)* a pharmacist's assistant shall not handle any specified Schedule 5 or Schedule 6 substance except as contemplated in subsection (5)*(a)* and *(b)*; and"; and

(i) 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 amended by—

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

"*(b)* the council may, on application in the prescribed manner and on payment of the prescribed fee, issue to a manufacturer, wholesaler or distributor of a medicine or medical device a licence to manufacture, import or export, act as a wholesaler of or distribute, as the case may be, such medicine or medical device, upon such conditions as to the application of such acceptable quality assurance principles and good manufacturing and distribution practices as the council may determine.";

(b) 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]** determined by the South African Pharmacy Council after consultation with the Health Professions Council of South Africa, the Allied Health Professions Council of South Africa and the South African Nursing Council.";

(c) the substitution for subsection (5) of the following subsection:

"(5) No person shall compound or 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)*.";

(d) the substitution for subsection (6) of the following subsection:

"(6) No manufacturer, wholesaler or distributor referred to in subsection (1)*(b)* shall manufacture, import, export, act as a wholesaler of or distribute, as the case may be, any medicine **[or medical device]** unless he or she is the holder of a licence contemplated in the said subsection."; and

(e) 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 22F of Act 101 of 1965, as inserted by section 14 of Act 90 of 1997

7. Section 22F is amended by—

(a) the substitution in subsection (1) for the words preceding paragraph *(a)* of the following words:

"(1) Subject to subsections (2), (3) and (4), a pharmacist or a person licensed in terms of section 22C(1)*(a)* shall—"; and

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

"*(a)* inform all members of the public who visit **[his or her]** the pharmacy or any other place where dispensing takes place, as the case may be, with a prescription for dispensing, of the benefits of the substitution for a branded medicine **[of]** by an interchangeable multi-source medicine, and shall, in the case of a substitution, take reasonable steps to inform the person who prescribed the medicine of such substitution; and".

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

8. Section 22G of the principal Act is amended by—

(a) 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.";

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

"*(c)* on an appropriate fee to be charged by wholesalers or distributors or any other person selling Schedule O medicines."; and

(c) the substitution for paragraph *(b)* of subsection (3) of the following paragraph:

"*(b)* No pharmacist or person licensed in terms of section 22C(1)*(a)* or wholesaler or distributor shall sell a medicine at a price **[greater]** higher than the price contemplated in paragraph *(a)*.".

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

9. Section 24 of the principal Act is amended by—

(a) the substitution for the existing heading of the following heading:

"**Appeal against decision of council or Director-General**";

(b) the substitution for subsection (1) of the following subsection:

''(1) Any person aggrieved by a decision of the **[Director-General 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) the substitution for paragraph *(a)* of subsection (2) of the following paragraph:

''*(a)* the chairperson shall be **[a person]** appointed on account of his or her knowledge of the law **[with at least 10 years experience thereof]**;'';

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

''(3) The appeal committee may after hearing the appeal—

(a) confirm, set aside or vary the decision of the **[Director-General or]** the council; and

(b) direct the **[Director-General or the]** council**[, as the case may be,]** to execute the decision of the appeal committee.'';

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

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

(f) the substitution for subsection (6) of the following subsection:

''(6) Any person aggrieved by the decision of the Director-General may within the prescribed period and in the prescribed manner, make written representations with regard to such decision to the Minister.''; and

(g) the addition of the following subsection:

''(7) The Minister shall, after considering representations made in terms of subsection (6), confirm, set aside or vary the decision of the Director-General.''.

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

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

"Privileges of council and committees

25. The council or a committee appointed under **[subsection (1) of section 9]** section 9(1), 22G(1) or 24(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 28 of Act 101 of 1965, as amended by section 26 of Act 65 of 1974, section 12 of Act 17 of 1979 and section 16 of Act 90 of 1997

11. Section 28 of the principal Act is amended by—

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

''(1) An inspector may, at all reasonable times—

(a) enter upon—

(i) any place or premises from which—

(aa) a person authorized under this Act to compound or dispense medicines or scheduled substances;

(bb) the holder of a licence as contemplated in section 22C(1)*(b)*;

(cc) the holder of a certificate of registration of a medicine, conducts business;

(ii) any place, premises, vessel or aircraft if he or she suspects on reasonable grounds that an offence in terms of this Act has been or is being committed thereon or therein or that an attempt has been made or is being made to commit such an offence thereon or therein; or

(iii) any private dwelling, with the consent of the occupier or under the authority of a warrant issued in terms of subsection (5) or without a warrant in terms of subsection (6);

(b) inspect any medicine or scheduled substance, any book, record or documents that the inspector believes on reasonable grounds contains any information relevant to the administration or enforcement of this Act;

(c) seize any book, record or documents or take so many samples of any such medicine or scheduled substance as he or she may consider necessary for the purpose of testing, examination or analysis in terms of this Act.'';

(b) the addition of the following subsections:

''(5) Where on application to a magistrate it appears to such magistrate from information on oath that there are reasonable grounds to believe that—

(a) the conditions for entry described in subsection (1)*(a)* exist in relation to a private dwelling;

(b) entry to that private dwelling is necessary for any purpose relating to the administration or enforcement of this Act; and

(c) entry to the private dwelling has been refused or that entry thereto will be refused,

a magistrate may issue a warrant authorizing the inspector named therein to enter that private dwelling subject to such conditions as may be specified in the warrant.

(6) If an inspector believes on reasonable grounds that—

(a) a warrant would be issued to him or her under subsection (5) if he or she applies for such a warrant; and

(b) a delay in obtaining such warrant would defeat the object of the entry, search and seizure,

he or she may without a warrant enter and search any premises for any medicines, scheduled substance, book, record or document relevant to the administration or enforcement of this Act and seize or take samples as contemplated in subsection (1)*(c)*.''.

Amendment of section 35 of Act 101 of 1965, as substituted by section 31 of Act 65 of 1974, 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 and section 16 of Act 94 of 1991 and substituted by section 23 of Act 90 of 1997

12. Section 35 of the principal Act is amended by—

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

''(xxiv) as to the importation, exportation, conveyance, keeping, storage, processing and packing of medicines and Scheduled substances, and the manner in which medicines and Scheduled substances shall be kept and controlled in different categories of hospitals;'' and

(b) the substitution in subsection (1) for paragraph (xxvii) of the following paragraph:

''(xxvii) authorizing, regulating, controlling, restricting or prohibiting the registration, manufacture, modification, importation, exportation, storage, transportation, sale or use of any medical device or class of medical devices or medicines in respect of its safety, quality and efficacy;''.

Substitution of 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

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

"ACT

To provide for the registration of medicines and related substances intended for human and for animal use; to provide 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 is subject to the approval of the Minister; to provide for the control of medicines and Scheduled substances and 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 provide that labels be approved by the council; to prohibit sampling and bonusing of medicines; to provide for the licensing of certain persons to compound, dispense or manufacture medicines and medical devices and also to act as wholesalers or distributors; to provide for the generic substitution of medicines; to provide for the establishment of a pricing committee; to regulate the purchase and sale of medicines by manufacturers, distributors, wholesalers, pharmacists and persons licensed to dispense medicines; to make new provisions for appeals against decisions of the Director-General or the council; to provide that the council may acquire and appropriate funds; to regulate the Minister's power to make regulations; to provide for the rationalization 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 to the Constitution of the Republic of South Africa, 1996; and to provide for matters connected therewith.''.

Repeal of Act 132 of 1998

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

Short title and commencement

15. 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*.

MEMORANDUM ON THE OBJECTS OF THE MEDICINES AND RELATED SUBSTANCES AMENDMENT BILL, 2002

1. OBJECTS OF BILL

The Bill amends the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965) (''principal Act''), and repeals the South African Medicines and Medical Devices Regulatory Authority Act, 1998 (Act No. 132 of 1998).

2. DISCUSSION

Clause 1 of the Bill provides for amendments relating to definitions, specifically to ensure consistency with regard to name changes that have occurred to certain Acts referred to in the principal Act. It also inserts the definitions of a magistrate and a justice in relation to the powers of inspectors.

Clause 2 deletes reference to a section that is no longer relevant to the provision.

Clause 3 provides for the appointment of a Deputy Registrar and his or her functions.

Clause 4 provides for regulations relating to the marketing of medicines.

Clause 5 introduces Schedule 8 substances i.e. banned substances, and how these can be obtained. It further provides for the so-called specified Schedule 5 substances. These are substances which despite being Schedule 5 substances are subject to more stringent control measures as required by international treaties on the control of medicines to which South Africa is a signatory.

Clause 6 provides for the issuing by the council of licences to compound and dispense medicines and, in particular, that a course that must be completed by medical practitioners, practitioners and nurses before they can compound and dispense medicines must be determined by the South African Pharmacy Council after consultation with the relevant professional councils.

Clause 7 provides that not only pharmacists, but also persons who dispense medicines must inform patients of the availability of generic substitutes.

Clause 8 provides for the term of office of members of the pricing committee. It further provides for a recommendation on a fee to be charged by wholesalers.

Clause 9 provides for appeals against the decisions of the Director-General and the council, that appeals against the decisions of the Director-General shall lie to the Minister and that those against the decisions of council shall lie to an appeal committee appointed by the Minister.

Clause 10 provides indemnity to members of the council and committees established in terms of the Act against liability for acts committed in good faith.

Clause 11 provides for the powers of inspectors to search and seize. The section of the principal Act dealing with the powers of inspectors was declared unconstitutional and these provisions seek to fill the gap created by the Constitutional Court ruling.

Clause 12 provides for regulations relating to the exportation of medicines.

Clause 13 provides for the revised long title of the Act.

Clause 14 repeals the South African Medicines and Medical Devices Regulatory Authority Act, 1998 (Act No. 132 of 1998). Act No. 132 of 1998 is repealed for the following reason: All the matters that Act 132 of 1998 provided for are provided for in both Act 90 of 1997 and this Bill. Therefore, Act 132 of 1998 has become redundant.

Clause 15 provides for the short title and commencement of the Act.

3. CONSTITUTIONAL IMPLICATIONS

The Department is satisfied that the Bill is not unconstitutional.

4. IMPLICATIONS FOR PROVINCES

The Bill has no direct implications for provinces.

5. COMMUNICATION IMPLICATIONS

The Bill was published for public comment and was also published in accordance with the Rules of Parliament.

6. FINANCIAL IMPLICATIONS FOR STATE

The Bill on its own has no direct financial implications for the State.

7. PERSONS OR BODIES CONSULTED

The pharmaceutical industry has been widely consulted. There were also consultations with the Department of Trade and Industry, in particular on the provisions relating to the marketing of medicines.

8. PARLIAMENTARY PROCEDURE

The State Law Advisers and the Department of Health are of the opinion that the Bill must be dealt with in accordance with the parliamentary procedure established by section 75 of the Constitution since it contains no provision to which section 74 or 76 of the Constitution applies.

Printed by Creda Communications

ISBN 0 621 33092 2