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REPUBLIC OF SOUTH AFRICA

# GOVERNMENT GAZETTE

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# STAATSKOERANT

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STATE PRESIDENT'S OFFICE

No. 1492.

3 July 1991

It is hereby notified that the State President has assented to the following Act which is hereby published for general information:—

No. 94 of 1991: Medicines and Related Substances Control Amendment Act, 1991

KANTOOR VAN DIE STAATSPRESIDENT

No. 1492.

3 Julie 1991

Hierby word bekend gemaak dat die Staatspresident sy goedkeuring geheg het aan die onderstaande Wet wat hierby ter algemene inligting gepubliseer word:—

No. 94 van 1991: Wysigingswet op die Beheer van Medisyne en Verwante Stowwe, 1991



- (ii) restoring, correcting or modifying any somatic or psychic or organic function; or
- (iii) the diagnosis or prevention of pregnancy, and which does not achieve its purpose through chemical, pharmacological, immunological or metabolic means in or on the human body but which may be assisted in its function by such means; or
- (b) declared by the Minister by notice in the *Gazette* to be a medical device, and includes any part or an accessory of a medical device;”;
- (d) by the substitution for the definition of “medical practitioner” of the following definition:  
 “‘medical practitioner’ means a person registered as such under the Medical Act, and includes an intern registered under that Act **[and, in relation to any medicine and any Schedule 1, Schedule 2, Schedule 3 and Schedule 4 substance, a student intern registered under that Act who prescribes or provides the medicine or any such substance, as contemplated in section 36 (2) (aA) of the said Act]**”;
- (e) by the deletion of the definition of “medicinal purpose”;
- (f) by the substitution for the definition of “Minister” of the following definition:  
 “‘Minister’ means the Minister of National Health [Welfare and Pensions]”;
- (g) by the insertion after the definition of “Minister” of the following definition:  
 “‘nurse’ means a person registered as such under the Nursing Act, 1978 (Act No. 50 of 1978)”;
- (h) by the substitution for the definition of “pharmacist” of the following definition:  
 “‘pharmacist’ means a person registered as such under the Pharmacy Act, 1974 **[and includes a trainee pharmacist, as defined in that Act, during the twelfth month of the period or periods of practical training referred to in section 20 (1) of that Act]**”;
- (i) by the deletion of the definition of “pharmacist’s assistant”;
- (j) by the substitution for the definition of “pharmacologist” of the following definition:  
 “‘pharmacologist’, except for the purposes of **[paragraph (c) of subsection (1) of] section [10] 24 (1) (c)**, means a pharmacologist to whom authority has been granted under section 27”;
- (k) by the deletion of the definition of “pharmacy Board”;
- (l) by the insertion before the definition of “prescribed” of the following definition:  
 “‘practitioner’ means a person registered as such under the Associated Health Service Professions Act, 1982 (Act No. 63 of 1982)”;
- (m) by the substitution for the definition of “Scheduled substance” of the following definition:  
 “‘Scheduled substance’ means any medicine or other substance **[included in any Schedule to this Act]** prescribed by the Minister under section 22A”;
- (n) by the deletion of the definitions of “Schedule 1 substance”, “Schedule 2 substance”, “Schedule 3 substance”, “Schedule 4 substance”, “Schedule 5 substance”, “Schedule 6 substance”, “Schedule 7 substance”, “Schedule 8 substance” and “Schedule 9 substance”;
- (o) by the deletion of the definitions of “the territory” and “trainee pharmacist”; and
- (p) by the substitution for the definition of “veterinarian” of the following definition:  
 “‘veterinarian’ means a person registered as such under the Veterinary and Para-Veterinary Professions Act, [1933] 1982 (Act No. [16] 19 of [1933] 1982)”.

## Amendment of section 2 of Act 101 of 1965

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2. Section 2 of the principal Act is hereby amended by the addition of the following subsection, the existing section becoming subsection (1):

Act No. 94, 1991

MEDICINES AND RELATED SUBSTANCES  
CONTROL AMENDMENT ACT, 1991

“(2) The Council may advise the Minister or furnish a report to the Minister on any matter referred to the council by the Minister for consideration and arising from the application of this Act.”.

**Amendment of section 3 of Act 101 of 1965, as amended by section 3 of Act 65 of 1974, section 1 of Act 36 of 1977, section 2 of Act 17 of 1979 and section 46 of Act 97 of 1986** 5

3. Section 3 of the principal Act is hereby amended—

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

“(1) The council shall consist of so many members, but not more than 24, as the Minister may from time to time determine.”; and

(b) by the substitution for paragraphs (d), (dA), (e) and (f) of subsection (2) of the following paragraphs: 10

“(d) at least one person who shall be a pharmacist in private pharmaceutical practice;

(e) at least one person who shall be a veterinarian;

(f) one person who shall be an officer of the Department of National Health and Population Development; 15

(g) one person who shall be an officer of the Department of Agriculture and be designated by the Minister of Agriculture;

(h) at least one person who shall be a pharmacist who has a special knowledge of pharmacology or pharmaceutical chemistry; 20

(i) at least one person who shall have a special knowledge of pharmaceuticals; and

(j) not more than four other persons.”.

**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 and section 46 of Act 97 of 1986** 25

4. Section 6 of the principal Act is hereby amended—

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

“(b) who is disqualified under the Veterinary and Para-Veterinary Professions Act, [1933] 1982, the Medical Act or the Pharmacy Act, 1974, from carrying on his profession, while so disqualified; or”; 30

(b) by the deletion of paragraph (c) of subsection (1); and

(c) by the deletion of subsection (4).

**Repeal of section 10 of Act 101 of 1965, as substituted by section 8 of Act 65 of 1974 and amended by section 4 of Act 17 of 1979 and section 46 of Act 97 of 1986** 35

5. Section 10 of the principal Act is hereby repealed.

**Repeal of section 11 of Act 101 of 1965, as amended by section 9 of Act 65 of 1974, section 5 of Act 17 of 1979 and section 46 of Act 97 of 1986**

6. Section 11 of the principal Act is hereby repealed.

**Amendment of section 14 of Act 101 of 1965, as substituted by section 12 of Act 65 of 1974 and amended by section 6 of Act 17 of 1979** 40

7. Section 14 of the principal Act is hereby amended—

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

“(b) Any such resolution may also relate only to medicines which were available for sale in the Republic [or the territory] immediately prior to the date on which it comes into operation in terms of paragraph (c) or only to medicines which were not then so available.”; 45

(b) by the substitution in subsection (3) for the words preceding paragraph (a) of the following words: 50

“In the case of a medicine which was available for sale in the Republic **[or the territory]** immediately prior to the date of publication in the *Gazette* of the resolution by virtue of which it is subject to registration in terms of this Act, the provisions of subsection (1) shall come into operation—”; and

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

“(4) The provisions of subsection (1) shall not apply in respect of the sale of any medicine—

(a) compounded in the course of carrying on his professional activities by a medical practitioner, pharmacist, practitioner or **[a]** veterinarian for a particular **[person or animal, as the case may be]** patient in a quantity not greater than the quantity required for treatment as determined by the medical practitioner, pharmacist, practitioner or veterinarian; or

(b) compounded by a pharmacist **[for a particular person or animal]** in a quantity not greater than that **[normally required for the purpose for which it is sold]** prescribed by regulation for sale in the retail trade, subject to the conditions likewise prescribed or in a quantity for a particular person or animal as prescribed by a medical practitioner or a dentist or a veterinarian or a practitioner, as the case may be,

if such medicine does not contain any component the sale of which is prohibited by this Act or any component in respect of which an application for registration has been rejected, and is not and has not been advertised.”.

**Amendment of section 15 of Act 101 of 1965, as substituted by section 13 of Act 65 of 1974**

8. Section 15 of the principal Act is hereby amended by the substitution for paragraph (a) of subsection (10) of the following paragraph:

“(a) if no appeal is lodged against the rejection within the period **[prescribed]** referred to in section 24, as soon as possible after the expiration of that period; or”.

**Substitution 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**

9. The following section is hereby substituted for section 22A of the principal Act:

**“Control of medicines, categories of medicines and substances**

**22A. (1)** The Minister may, on the recommendation of the council, by regulation prescribe a medicine or substance or category of medicine or substance which shall not be sold by any person other than—

(a) a pharmacist;

(b) a pharmacist upon a written prescription or oral instructions of a medical practitioner, dentist, veterinarian or practitioner;

(c) the Director-General for providing a medical practitioner therewith;

(d) a medical practitioner, dentist, veterinarian or practitioner in the course of lawfully carrying on his professional activities as such to or for any patient under his care or treatment;

(e) a person employed by a manufacturer or wholesale dealer in pharmaceutical products, and authorized thereto in writing by that manufacturer or dealer, to any medical practitioner, dentist, pharmacist or veterinarian on the prescribed conditions; or

(f) a veterinary assistant and veterinary nurse referred to in the Veterinary and Para-Veterinary Professions Act, 1982 (Act No. 19 of 1982), upon a written prescription issued by a veterinarian for the treatment of a particular patient.

(2) The Minister may, on the recommendation of the council, by regulation prescribe a medicine or substance or category of medicine or substance which no person shall acquire, use, have in his possession, manufacture or import unless a permit for such acquisition, use, posses-

sion, manufacture or import has been issued to him by the Director-General subject to prescribed conditions and any other conditions specified in the permit.

(3) A regulation referred to in subsection (2) may prohibit or prescribe measures to control the acquisition, import, collection, cultivation, keeping or export of any plant or substance from which any substance or medicine referred to in subsection (2) can be extracted, derived, produced or manufactured.

(4) The Minister may—

- (a) by notice in the *Gazette* after consultation with the council and the South African Pharmacy Council referred to in section 2 of the Pharmacy Act, 1974, grant a person or organization or group or category of persons or organizations exemption to the extent and subject to the conditions as prescribed by regulation or specified in the notice, from the provisions of subsection (1); and
- (b) in like manner amend or withdraw any such notice.

#### Insertion of section 22B in Act 101 of 1965

10. The following section is hereby inserted in the principal Act after section 22A:

**“Publication of information relating to medicine, Scheduled substance or medical device**

**22B.** (1) Notwithstanding the provisions of section 34 the council may, if it deems it expedient and in the public interest, disclose information in respect of the prescribing, dispensing, administration and use of a medicine, Scheduled substance or medical device.

(2) The Director-General may publish the information referred to in subsection (1) or release it to the public in a manner which he thinks fit.

#### Substitution of section 24 of Act 101 of 1965, as amended by section 23 of Act 65 of 1974

11. The following section is hereby substituted for section 24 of the principal Act:

**“Appeal against decisions of council**

**24.** (1) Any person aggrieved by a decision of the council may within the prescribed period and in the prescribed manner appeal against such decision to an appeal committee appointed by the Minister for the purposes of the appeal concerned.

(2) An appeal committee shall consist of—

- (a) a retired judge or an advocate of the Supreme Court of South Africa who has practised as such for a period of at least five years, and who shall be the chairman of the committee;
- (b) a pharmacologist; and
- (c) if the appeal relates to—
- (i) a veterinary medicine, a veterinarian and a pharmacist;
- (ii) a homoeopathic medicine, a practitioner;
- (iii) a medicine, other than a veterinary and homoeopathic medicine, a medical practitioner who has a speciality in medicine entered in the appropriate register contemplated in section 18 of the Medical Act and a pharmacist;
- (iv) a medical device, a specialist or a technician who has expert or special knowledge or experience of such a device, who has no direct or indirect interest in the affairs of the appellant.

(3) An appeal under subsection (1) shall be heard on the date and at the place and time fixed by the appeal committee, which shall previously in writing notify the appellant as well as the council thereof.

(4) The appeal committee may for the purposes of an appeal lodged with it—

- (a) summon any person who, in its opinion, may be able to give material information concerning the subject of the appeal or who it believes has in his possession or custody or under his control any document which has any bearing upon the subject of the appeal, to appear before it at a time and place specified in the summons, to be interrogated or to produce that document, and retain for examination any document so produced; 5
- (b) administer an oath to or accept an affirmation from any person called as a witness at the appeal; and
- (c) call any person present at the hearing of the appeal as a witness and interrogate him and require him to produce any document in his possession or custody or under his control. 10
- (5) The procedure at the hearing of an appeal shall be determined by the chairman of the appeal committee.
- (6) The appeal committee may after hearing the appeal— 15
- (a) confirm, set aside or vary the relevant decision of the council; and
- (b) direct the council to execute the decision of the appeal committee in connection therewith.
- (7) 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 council. 20
- (8) The members of the appeal committee who are not in the full-time employment of the State may be paid such remuneration and allowances as the Minister determines with the concurrence of the Minister of Finance.”.

**Amendment of section 29 of Act 101 of 1965, as amended by section 27 of Act 65 of 1974** 25

12. Section 29 of the principal Act is hereby amended by the addition of the following paragraphs:

- “(l) contravenes or fails to comply with the provisions of section 34;
- (m) manufactures, sells or uses a veterinary medicine in contravention of a prohibition referred to in section 36A, or contravenes, or fails to comply with, a condition imposed in terms of the said section,”. 30

**Amendment of section 30 of Act 101 of 1965, as amended by section 28 of Act 65 of 1974**

13. Section 30 of the principal Act is hereby amended by the substitution for subsection (1) of the following subsection: 35

- “(1) Any person who is convicted of an offence referred to in section 29 shall be liable to a fine not exceeding R40 000 or to imprisonment for a period not exceeding 10 years or to both such fine and such imprisonment.”. 40

**Substitution of section 34 of Act 101 of 1965** 40

14. The following section is hereby substituted for section 34 of the principal Act:

**“Preservation of secrecy**

34. No person shall, except for the purpose of the exercise of his powers or the performance of his functions under this Act, or for the purpose of legal proceedings under this Act, or when required to do so by any competent court or under any law, or with the written authority of the Director-General, disclose to any other person any information acquired by him in the exercise of his powers or the performance of his functions under this Act and relating to the business or affairs of any person, or use such information for self-gain or for the benefit of his employer.”. 45 50

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MEDICINES AND RELATED SUBSTANCES  
CONTROL AMENDMENT ACT, 1991**Substitution of section 34A of Act 101 of 1965, as inserted by section 2 of Act 19 of 1976**

15. The following section is hereby substituted for section 34A of the principal Act:

**“Delegation of powers**

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34A. (1) The Minister may in writing authorize the Director-General or any officer of the Department of National Health and Population Development to exercise any of the powers conferred upon him by this Act other than the powers referred to in sections 3, 24 (1) and 35, or to exercise or perform any of the duties or functions conferred or imposed on the Minister in terms of this Act. 10

(2) The Director-General may in writing authorize any officer of the Department of National Health **[Welfare]** and **[Pensions]** Population Development to exercise or perform in general or in a particular case or in cases of a particular nature, any power, duty or function, excluding any power, duty or function referred to in subsection (1), conferred or imposed on the Director-General by or in terms of this Act.” 15

**Amendment of section 35 of Act 101 of 1965, as substituted by section 31 of Act 65 of 1974 and amended by section 3 of Act 19 of 1976, section 14 of Act 17 of 1979 and section 7 of Act 20 of 1981**

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16. Section 35 of the principal Act is hereby amended—

(a) by the insertion in subsection (1) after paragraph (vi) of the following paragraph:

“(viA) prescribing the circumstances in which, the conditions on which and the persons or classes of persons to whom any medicine or Scheduled substance may be sold;” 25

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

“(xii) prescribing the procedure at meetings of the council **[and of the appeal board]** and of any committee appointed under section 9 (including the quorum in the case of committees) and the manner in which meetings of **[the appeal board and of]** any such committee shall be called;” 30

(c) by the deletion of paragraph (xiii) of subsection (1);

(d) by the deletion of paragraphs (xv) and (xvi) of subsection (1);

(e) by the substitution for paragraphs (xviii), (xix), (xx) and (xxi) of subsection (1) of the following paragraphs, respectively: 35

“(xviii) requiring the furnishing of returns and reports and information in respect of **[Schedule 6 and Schedule 7 substances and specified Schedule 5]** Scheduled substances, and plants from which any such substance can be extracted, derived, produced or manufactured, and in respect of any medicine or other substance of which any such Scheduled substance is a component; 40

(xix) as to the transshipment or the exportation from or importation to the Republic **[or the territory]** of any **[Schedule 5, Schedule 6, Schedule 7, Schedule 8 or Schedule 9]** Scheduled substance, and specifying the ports or places at which such substance may be brought into the Republic **[or the territory]**; 45

(xx) authorizing and regulating or restricting the transmission through the Republic **[and the territory]** of **[such]** Scheduled substances;

(xxi) prescribing the manner in which packages containing **[Schedule 5, Schedule 6, Schedule 7 or Schedule 8]** Scheduled substances shall be labelled when imported into or manufactured in the Republic **[or the territory]** and the persons by whom and the manner in which they shall be kept;” 50

(f) by the deletion of paragraph (xxiv) of subsection (1); 55

(g) by the substitution for paragraphs (xxv) and (xxvA) of subsection (1) of the following paragraphs, respectively:

- “(xxv) authorizing and regulating the possession by persons entering or departing from the Republic **[or the territory]** of specified quantities of **[Schedule 5, Schedule 6, Schedule 7 and Schedule 9] Scheduled** substances for personal medicinal use;
- (xxvA) as to the disposal or destruction of a medicine or Scheduled substance, **[included in Schedule 8 in terms of section 37A]** and the records which shall be kept in respect thereof;”;
- (h) by the substitution for paragraph (xxx) of subsection (1) of the following paragraph:
- “(xxx) prescribing the fee to be paid to the registrar in respect of the application for the registration, and in respect of the registration, of a medicine or medical device, the fee to be paid annually to the registrar in respect of the retention of the registration of a medicine or medical device and by a person who may in terms of section 14 (3) sell unregistered medicine, and the date on which the **[last-mentioned]** said annual fee shall be so paid;”;
- (i) by the insertion in subsection (1) after paragraph (xxx) of the following paragraphs:
- “(xxxA) as to the safekeeping of medicine and Scheduled substances;
- (xxxB) authorizing, regulating, controlling, restricting or prohibiting the registration, manufacture, modification, importation, storage, transportation, sale, use or destruction of any medical device or class of medical devices;”;
- (j) by the substitution for subsection (7) of the following subsection:
- “(7) Any regulations made under this section may prescribe penalties for any contravention thereof or failure to comply therewith, not exceeding a fine of **[five hundred rand] R4 000** or imprisonment for a period of **[six] 12** months.”.

**Insertion of section 36A in Act 101 of 1965**

17. The following section is hereby inserted in the principal Act after section 36:

**“Minister may prohibit the manufacture, sale or use of certain veterinary medicines**

**36A.** Notwithstanding anything to the contrary in this Act or in any other law contained, the Minister may by notice in the *Gazette* for any reason other than the safety, quality or therapeutic efficacy of a veterinary medicine—

- (a) prohibit the manufacture, sale or use of any veterinary medicine containing a substance mentioned in the notice; or
- (b) prohibit such manufacture, sale or use, except in accordance with such conditions as may be specified in the notice, and may in like manner repeal or amend such notice.”.

**Substitution of section 37 of Act 101 of 1965, as substituted by section 33 of Act 65 of 1974**

18. The following section is hereby substituted for section 37 of the principal Act:

**“Medicines manufactured for export**

**37.** Notwithstanding anything to the contrary in this Act contained, the provisions of this Act relating to the registration of medicines shall not apply in respect of any medicine or any quantity of any medicine which is manufactured in or imported into the Republic **[or the territory]** solely for the purpose of export from the Republic **[or the territory]** and is not used or disposed of for use in the Republic **[or the territory]** and in respect of which the council has granted a certificate that it is satisfied in regard to its quality, purity and safety.”.

**Repeal of section 37A of Act 101 of 1965, as inserted by section 34 of Act 65 of 1974**

19. Section 37A of the principal Act is hereby repealed.

**Repeal of section 39 of Act 101 of 1965**

20. Section 39 of the principal Act is hereby repealed.

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**Repeal of Schedules to Act 101 of 1965**

21. Schedules 1 up to and including 9 to the principal Act are hereby repealed.

**Substitution of long title of Act 101 of 1965, as substituted by section 15 of Act 17 of 1979**

22. The following long title is hereby substituted for the long title of the principal Act: 5

“ACT

To provide for the registration of medicines intended for human and for animal use, for the registration of medical devices, for the establishment of a Medicines Control Council, for the control of medicines, **[and]** Scheduled substances and medical devices and for matters incidental thereto.” 10

**Amendment of section 1 of Act 53 of 1974, as amended by section 1 of Act 20 of 1979, section 1 of Act 20 of 1983 and section 1 of Act 69 of 1985**

23. Section 1 of the Pharmacy Act, 1974, is hereby amended by the substitution for the definition of “scheduled substance” of the following definition: 15

“‘scheduled substance’ means a scheduled substance as defined in section 1 of the Medicines and Related Substances Control Act, 1965 (Act No. 101 of 1965);”.

**Amendment of section 1 of Act 56 of 1974, as amended by section 1 of Act 33 of 1976, section 12 of Act 36 of 1977, section 1 of Act 52 of 1978, section 1 of Act 38 of 1982 and section 1 of Act 58 of 1984**

24. Section 1 of the Medical, Dental and Supplementary Health Service Professions Act, 1974, is hereby amended by the substitution for the definition of “scheduled substance” of the following definition:

“‘scheduled substance’ means a scheduled substance as defined in section 1 of the Medicines and Related Substances Control Act, 1965 (Act No. 101 of 1965);”.

**Substitution of section 52A of Act 56 of 1974, as inserted by section 17 of Act 36 of 1977 and substituted by section 7 of Act 58 of 1984**

25. The following section is hereby substituted for section 52A of the Medical, Dental and Supplementary Health Service Professions Act, 1974: 30

**“Authority for supply in certain circumstances of certain medicines by certain registered persons in accordance with directions of medical practitioner**

52A. The council may, if it is of the opinion that the consulting rooms of a medical practitioner contemplated in section 52 (1) (a) are not situated within a reasonable distance of a retail pharmacy, grant authority, subject to such conditions as it may deem fit to impose, for the supply by any person who is in the employment of such medical practitioner and who is registered as a nurse under the Nursing Act, 1978 (Act No. 50 of 1978), of any **[medicine mentioned in Schedule 1, 2, 3 or 4 to the Medicines and Related Substances Control Act, 1965 (Act No. 101 of 1965)]** scheduled substance to any person under the treatment of such medical practitioner: Provided that such supply shall take place in accordance with the directions of such medical practitioner.”. 45

**Amendment of section 1 of Act 50 of 1978**

26. Section 1 of the Nursing Act, 1978, is hereby amended by the substitution for the definition of “medicinal purpose” of the following definition:

“‘medicinal purpose’, in relation to a scheduled substance, means the treatment or prevention of a disease or some other definite curative or therapeutic purpose, but does not include the satisfaction or relief of a habit or craving for the substance used or for any other such substance except where the

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substance is administered or used in a hospital or similar institution maintained wholly or partly by the Government or a provincial administration, or approved for this purpose by the Minister;”.

**Amendment of section 38 of Act 63 of 1982, as amended by section 22 of Act 108 of 1985**

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27. Section 38 of the Associated Health Service Professions Act, 1982, is hereby amended by the substitution for subsection (3) of the following subsection:

“(3) The provisions of subsection (1) (l) and (m) shall not be applicable to a remedy which is a Scheduled substance as defined in section 1 of the Medicines and Related Substances Control Act, 1965.”.

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**Transitional provision**

28. Any reference in any law or document to any medicine or other substance included in any Schedule to the principal Act prior to the date of commencement of section 21 of this Act, and which is still in force on the said date of commencement, shall be construed from that date as a reference to an appropriate medicine or other substance prescribed by the Minister under section 22A of the principal Act, as amended by section 9 of this Act.

**Short title and commencement**

29. (1) This Act shall be called the Medicines and Related Substances Control Amendment Act, 1991, and shall come into operation on a date fixed by the State President by proclamation in the *Gazette*.

(2) Different dates may be fixed under subsection (1) in respect of different provisions of this Act.