

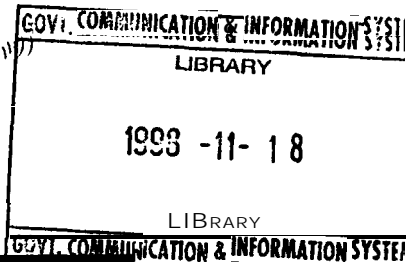
REPUBLIC OF SOUTH AFRICA

**PORTFOLIO COMMITTEE AMENDMENTS
TO
SOUTH AFRICAN MEDICINES
AND MEDICAL DEVICES
REGULATORY AUTHORITY BILL**

[B 114-98]

(As agreed to by the Portfolio Committee on Health (National Assembly))

[B 114A—98]



REPUBLIEK VAN SUID-AFRIKA

**PORTEFEULJE KOMITEE-AMENDEMENTE
OP
WETSONTWERP OP DIE SUID-
AFRIKAANSE MEDISYNE EN
MEDIESE TOESTELLE
REGULERENDE OWERHEID**

[W 114—98]

(Soos goedgekeur deur die Portefeuljekomitee oor Gesondheid (Nasionale Vergadering))

[W 114A—98]

ISBN O 621289418

AMENDMENTS AGREED TO

SOUTH AFRICAN MEDICINES AND MEDICAL DEVICES REGULATORY AUTHORITY AMENDMENT BILL [B 114–98]

CLAUSE 1

1. On page 6, in line 43, to omit “ 1“.
2. On page 6, in line 38, to omit the definition of “adverse drug event” and substitute:

“adverse event or adverse drug event” means an unintended deleterious effect of a medicine when used in usual dosage;
3. On page 8, from line 6, to omit the definition of “complementary medicine” and to substitute:

“complementary medicine” means any substance or mixture of substances, which—

 - (a) originates from a plant, mineral, or animal, and which may be, but is not limited to, being classified as herbal, homeopathic, ayurvedic or nutritional; and
 - (b) is used or intended to be used for, or manufactured or sold for use in, or purported to be useful in, complementing the healing power of a human or animal body in the treatment, modification or alleviation or prevention of disease, abnormal physical or mental state or the symptoms thereof in a human being or animal; and
 - (c) is used in, but not limited to, the disciplines of Western herbal, African traditional, traditional Chinese, Homeopathy, Ayurveda, Unani, Antroposophy, Acupuncture and Nutritional supplementation; or
 - (d) because of its origin, intended use in a discipline, is determined by the Authority, by notice in the *Gazette*, to be a complementary medicine;

4. On page 8, after line 19, to insert:

“day” means calendar day;

5.

On page 8, after line 21, to insert:

“Department” means the Department of Health, or in relation to a matter concerning veterinary medicines, means the Department of Health and the Department of Agriculture;

6. On page 8, after line 24, to insert:

“dispensing” means the interpretation and evaluation of a prescription, the selection, manipulation, of the medicine, the labelling and supply of medicines in an appropriate container and the provision of information and instructions to ensure the safe and effective use of medicines by a patient, and “dispense” has a corresponding meaning;

7. On page 8, after line 43, to insert:

“manufacture” means all operations including purchasing of material, processing, production, packaging, quality control, release and storage of medicinal products and related control.

8. On page 10, in line 4, to omit “the Minister must be deemed to refer to”.

9. On page 10, after line 5, to insert:

“nurse” means a person registered as a nurse under the Nursing Act, 1978 (Act No. 50 of 1978).

10.

On page 10, from line 6, to omit the definition of “orthodox medicine” and to substitute:

orthodox medicine: “Orthodox medicine” or “medicine” means any substance or mixture of substances intended to be used by, or administered to, human beings for any of the following therapeutic purposes:

- (a) Treating, preventing or alleviating symptoms of disease, abnormal physical or mental state or the symptoms thereof;
- (b) Diagnosing disease or ascertaining the existence, degree or extent of a physiological condition;
- (c) Otherwise preventing or interfering with the normal operation of physiological function, whether permanently or temporarily and whether by way of terminating, reducing, postponing or increasing or accelerating the operation of that function.

11. On page 10, in line 23, after “Act” to insert “ 1974 and includes a pharmacist’s assistant registered under the Act” .

12. On page 10, from line 24, to omit the definition of “pharmacist’s assistant”

13. On page 10, after line 25, to insert:

“Pharmaco-vigilance” means the active collection, detection, assessment, and prevention of adverse drug events;

14. On page 10, after line 28, to insert:

“register” when used as a noun, means to register referred to in section 25 and when used as a verb, means to enter in the register;

15. On page 10, in line 33, to omit “cosign” and to substitute “consign”.

16. On page 10 in line 33, to omit “expose,”.

17. On page 10, in line 34, to omit “and barter”.

18. On page 10, after line 43, to insert:

“Veterinarian” means a person registered or deemed to be registered under the Veterinary and Para-Veterinary Professions Act, 1982 (Act No. 39 of 1982),

19. On page 10, in line 49, to omit “foodstuffs” and to substitute “feedstuffs”.

CLAUSE 5

1. On page 12, in line 47, to omit “ensure that the best practices are adopted so as to”.

CLAUSE 6

1. On page 14, in line 9, to omit “three months” and to substitute “60 days.”
2. On page 14, in line 23, to omit “Expert” and to substitute “Standing”.

CLAUSE 8

1. On page 14, in line 45, after the last “1974” to insert “the Nursing Act, 1978 (Act No. 50 of 1978)”.
2. On page 16, in line 9, to omit (3) and to substitute (2).
3. On page 16, in line 9, after “person” to insert “who was”.

CLAUSE 12

1. On page 18, in line 14, to omit the words “present up to and including the words “at that meeting.”
In line 15 to substitute subsection (4) “The quorum for any meeting of the Board is the majority of the voting members.”
2. On page 18, in line 19, to omit “chairman’s” and to substitute “chairperson’s.”.

CLAUSE 14

1. On page 18, from line 32, to omit subsection (1) and to substitute:

A member of the Board or of the staff or of any committee of the Authority, may not vote at, attend or in any other manner participate in the proceedings of any meeting or hearing of the Board or any committee of the Authority if—

2. On page 18, from line 49, to omit “if” up to and including “Member” and to substitute in line 51:

If at any stage during the course of any proceedings of the Board or committee of the Authority there is reason to believe that a member of

the Board or Committee of the Authority has an interest contemplated in subsection (1) that member—

3. On page 18, in line 54, to omit the first “Authority”.
4. On page 18, in line 58, to omit the first “Auth ority”.

CLAUSE 15

1. On page 20, from line 9, to omit paragraph (c) and to substitute:

(c) the fact that any person who is disqualified from being a member of the Board or who was removed from that office sat as such in the Board at the time when such decision was taken, if such decision was taken by a majority of the members of the Board lawfully entitled to vote and present at the time, and the said members of the Board at the time constituted a quorum.

CLAUSE 16

17. On page 20, in line 17, to omit “assist the Authority in the performance of” and to substitute “perform”.

CLAUSE 17

1. On page 24, from line 12, to omit subsection 3) and to substitute:

(3) The Authority may in the prescribed manner receive donations or contributions from any person, and must use any donations or contributions so acquired for such purposes as it may determine in connection with the performance of its functions in terms of this Act, provided that all such contributions are published in the annual report of the Authority:

2. On page 24, after line 18, add:

(5) The funds contemplated in subsection (2) do not form part of the National Revenue Fund.

CLAUSE 19

1. On page 24, in line 41, to omit “accountant or”

CLAUSE 21

Clause rejected.

CLAUSE 21

1. On page 26, from line 13, to omit “appoint” and to substitute “establish”.
2. On page 26, in line 14, after Committees to insert “and appoint”.

Establish standing committees, and appoint their chairpersons and deputy chairpersons for, but not limited to—
2. On page 26, in line 24, to omit “Despite” and to substitute “Subject to”.
3. On page 26, from line 29, to omit subclause (1) and to substitute:
- (4) The Board may appoint any appropriately qualified person who is fit and proper to the committees established in terms of this section.

CLAUSE 22

1. On page, in line 32, to omit subsection (1) and to substitute:

A member of any committee of the Board who is not a member of the Board or on the staff of the Authority or in the full-time employ of the State must be paid such remuneration and allowances as the Board may from time to time in consultation with the Minister and the concurrence of the Minister of Finance, determine.

CLAUSE 24

1. on page 28, in line 4, to omit subsection (1) and to substitute:

“An application for the registration of medicine, complementary medicine, veterinary medicine or device must be submitted to the Authority in the prescribed form, and must be accompanied by the prescribed particulars and samples, where appropriate, and by the prescribed fees.
2. On page 28, in line 11, to omit “medicine”.
3. On page 28, in line 26, to omit “one month” and to substitute “60 days”.
4. On page 28, in line 30, to omit “one month” and to substitute “60 days”.
5. On page 28, in line 34, to omit “of Health”
6. On page 28, in line 36, to omit “must” and to substitute “may”.
7. On page 28, in line 46, to omit the words “the Health” up to and including other body and to substitute “any body”.
8. On page 30, in line 6, to omit “stock remedy” .
9. On page 30, in line 16, to omit “stock reined!”
10. On page 30 in line 29, to omit or “stock remedy”.
11. On page 30 in line 31, to omit “stock remedy” and to substitute “device”.
12. on page 30 in line 60, to omit “Interim National Medical and Dental Council” and to substitute “Health Professionals Council”.

13. On page 32, in line 1 to omit “Interim Pharmacy Council of South Africa” and to substitute “South African Pharmacy Council”.
14. On page 32, in line 6, to omit “must be” and to substitute “is”.

CLAUSE 25

1. On page 32, in line 44 after “pharmacist” to insert pharmacist, pharmacist intern, pharmacy support personnel in accordance with the scope of practice of such personnel as prescribed under the Pharmacy Act, 1974.

CLAUSE 26

1. On page 34, in line 7, after the second “of” to insert “a maximum of”.
2. On page 34, in line 15, after “device” to insert “or”.

CLAUSE 28

1. On page 34, in line 4 I, after “medicine” to insert “medical devices”.
2. On page 34, in line 5 I, to omit “after” and to substitute “in”.

CLAUSE 29

1. On page 36, in line 3, to insert “(1)” before “(a)”.

CLAUSE 30

1. On page 36, in line 32, after “may” to insert “only”.

CLAUSE 31

1. On page 36, in line 43, to omit subsection (2) and to substitute:

(2) The Minister may on the recommendation of the Authority:
(a) prescribe the Scheduled substances referred to in this section;
and
(b) prescribe such Schedules as the Minister deems necessary.
2. On page 36, in line 48, to omit subparagraph (i) and to substitute:

(i) a pharmacist intern, or pharmacy support personnel in accordance with the scope of practice of such personnel as prescribed under the Pharmacy Act, 1974.
3. On page 36, in line 53, to omit “or” and to substitute “and”.
4. On page 38, in line 5, to omit “or” and to substitute “and”.

- S. On page 38, in line 11, to omit “pharmacist’s assistant” and to substitute “pharmacy support personnel in accordance with the scope of practice of such personnel as prescribed under the Pharmacy Act, 1974”.
6. On page 38, in line 21, to omit paragraph (a) and to substitute:
- (a) a pharmacist, a pharmacist intern or pharmacy support personnel in accordance with the scope of practice of such personnel as prescribed under the Pharmacy Act 1974, who may sell only Schedule 2 substances without a prescription;
7. On page 38, from line 24, to omit all the words after the second “or” up to and including “pharmacist” in line 25, and to substitute:
- pharmacy support personnel in accordance with the scope of practice of such personnel as prescribed under the Pharmacy Act, 1974, who may sell only Schedule 2 substances without a prescription;
8. On page 38, in line 38, to omit “or” and to substitute “and”.
9. On page 38 in line 40, after (i) to insert “only”.
10. On page 38, in line 56, to omit “pharmacist’s assistant” and to substitute “pharmacy support personnel in accordance with the scope of practice of such personnel as prescribed under the Pharmacy Act, 1974”.
11. On page 40, in line 41, to omit “concerning” and to substitute “confirming”.
12. On page 42, in line 14, to omit “pharmacist intern, or pharmacist’s assistance acting under the personal supervision of a pharmacist” and to substitute “or a pharmacist intern or pharmacy support personnel in accordance with the scope of practice of such personnel as prescribed under the Pharmacy Act, 1974”.
13. On page 42, in line 26, after “practitioner” to insert “or veterinarian”.
14. On page 42, in line 29, after “possess”, to insert “cultivate,”.
15. On page 42, in line 59, to omit “or complementary medicine”.
16. On page 44, in line 5, to omit. “complementary medicine”.
17. On page 44, in line 10, to omit “complementary medicine.”.
18. On page 44, in line 14, to omit “(e)” and to substitute “(d)”.
19. On page 44, in line 15, to omit “(f)” and to substitute “(e)”.
20. On page 44, in line 37, to omit “complementary medicine”.

21. On page 44 in line 49, to omit “complementary medicine.”.
22. On page 46, in line 2, to omit “is in possession of” and to substitute “has obtained”.
23. On page 46 in line 25 to omit subsection (16) and to substitute:

(18)(u) The Minister may, on the recommendation of the Authority, prescribe conditions for the manufacture, sale and possession of a medical device; and

(b) no person may manufacture, sell or have in his or her possession a medical device contemplated in paragraph (a) except in accordance with the prescribed conditions.

CLAUSE 32

1. On page 46, in line 35, after “medicine” to insert “or medical device”.
2. On page 46, in line 42, before “dispense” to omit “compound or”.
3. On page 46, in line 53, to omit “Interim Pharmacy Council or its succession in title of South Africa” and to substitute “South African Pharmacy Council”.
4. On page 48, in line 8, to omit “must”.

CLAUSE 36

1. On page 48, in line 54, to omit “pursuant of a direction other” and to substitute “pursuance of a direction under”.
2. On page 50, in line 5, to omit the first “a” and to substitute “the”.
3. On page 50, in line 13, to omit “and 22” and to insert “28(4)” and “30”.
4. On page 50, in line 16, to omit “(hereinafter called the employer)”
5. On page 50, in line 34, to omit “must shall” and to substitute “may”.

CLAUSE 40

1. On page 50, in line 42, to omit “members of its staff” and to substitute “persons”.
2. On page 54 in line 30, to omit “tempered” and to substitute “tampered”.
3. On page 56, after line 13, to add:

(14) Despite subsection (2) an inspector may without a warrant, during business hours conduct routine inspections of any place or premises from which a person authorised under this Act to manufacture, compound, dispense, distribute, advertise, or sell, any orthodox medicine, complementary medicine, veterinary medicine, medical device or Scheduled substance, conducts business, in order to ensure compliance with any prescribed requirements.

CLAUSE 41

On page 56, in line 29, after “veterinary medicine” to insert “medical device”.

CLAUSE 42

1. On page 56, in line 46, after “medicine” to insert “complementary medicine, veterinary medicine, medical device”.
2. On page 56, in line 48 after “medicine” to insert “complementary medicine, veterinary medicine, medical device”.

CLAUSE 43

1. On page 58, in line 11, after “medicine” to insert “complementary medicine, veterinary medicine, medical device”.

CLAUSE 45

1. On page 58, in line 43, to omit paragraph (d).

On page 58, in line 48, after “Minister” to insert “in the interest of public health”.

CLAUSE 48

1. On page 60, to omit subsection (1).
2. On page 60, in line 28, to omit the words “Without limiting the generality of subsection (1)”, and to substitute:

(1) “The Minister may, in consultation with the Authority, make regulations not inconsistent with this Act”.

3. On page 64, in line 51, after “complementary medicine” to insert “medical device”.
4. On page 64, in line 54, to omit “and”.
5. On page 64, in line 55, after “trials” to insert “ and”.
6. On page 64, after line 55, to insert:
(2L) any other matter not inconsistent with this Act.

CLAUSE 50

1. On page 66, in line 33, to omit subclause (1) and to substitute:

(1) Subject to subsection (2)—

- (a) the laws mentioned in Schedule 1 are hereby repealed to the extent set out in that Schedule; and
- (b) the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947) specified in Schedule 2 is hereby amended to the extent set out in that Schedule.

2. On page 66, in line 55, after “registration” to insert “in respect of veterinary medicine”.

3. On page 66, after line 56, to add:

(3) Subject to this Act, the Registrar appointed in terms of the Medicines Act must act as the Chief Executive Officer until a day immediately preceding the day on which a Chief Executive Officer is appointed in terms of section 16.

(4) Subject to this Act, the Medicines Control Council established by section 2 of the Medicines Act must perform the functions of the Board until a day immediately preceding the day on which the Minister appoints the Board in terms of section 6.

(5) Any officer or employee of—

- (a) the Department of Health’s Directorate: Medicines Administration, which provides support to the said Medicines Control Council, may act as a staff member of the Authority until a date determined by the Director-General of Health; and
- (b) the Department of Agriculture performing on a full-time basis functions regarding stock remedies may act as a staff member of the Authority until a date determined by the Director-General: Agriculture.

SCHEDULE 1
REPEAL OF LAWS
(Section 50)

No. and year of law	Short title	Extent of repeal
Act No. 101 of 1965	Medicines and Related Substances Control Act, 1965	The whole, except sections 1, 15B, 18, 229, 24, 34A and 40.
Act No. 90 of 1997	Medicines and Related Substances Control Amendment Act, 1997	The whole, except sections 1, 10, 12, 14, 15, 22, 26, 28, 31 and 33.
Transkei Act No. 27 of 1978	Medicines and Related Substances Control Amendment Act, 1978	The whole.