

REPUBLIC OF SOUTH AFRICA

PHARMACY AMENDMENT BILL

(As introduced)

(MINISTER OF HEALTH)

[B 69—97]

REPUBLIEK VAN SUID-AFRIKA

WYSIGINGSWETSONTWERP OP APTEKERS

(Soos ingedien)

(MINISTER VAN GESONDHEID)

[W 69—97]

ISBN 0 621 27245 0

- “ ‘pharmacy practice’ means acts specially pertaining to the scope of practice of a pharmacist as prescribed in terms of section 35A of this Act; ‘pharmacy student’ means a person registered as such in terms of this Act; ‘pharmacy support personnel’ means the various categories of support personnel as prescribed and registered as such in terms of this Act”;
- (g) by the substitution for the definition of “registrar” of the following definition: “ ‘registrar’ means the registrar of the council appointed in terms of section 4(u) of this Act or a person lawfully acting in that capacity”;
- (h) by the insertion after the definition of “regulation” of the following definition: “ ‘responsible pharmacist’ means a natural person who is a pharmacist and who shall be responsible to the council for complying with all the provisions of this Act and other legislation applicable to services which specially pertain to the scope of practice of a pharmacist, and the legislation applicable to the pharmacy which is under his or her personal supervision;”;
- (i) by the substitution for the definition of “scheduled substance” of the following definition: “ ‘scheduled substance’ means a scheduled substance as referred to in the Medicines and Related Substances [Control] Act, 1965 (Act No. 101 of 1965);”;
- (j) by the deletion of the definition of “South African Pharmacy Council”;
- (k) by the deletion of the definition of “Transkeian Medical Council”; and
- (l) by the insertion after the definition of “Transkeian Medical Council” of the following definition: “ ‘unprofessional conduct’ means conduct which is regarded as improper or disgraceful by an inquiry conducted by the council in consultation with the Minister when regard is had to the registration of such person in terms of this Act.”.

Substitution of heading to Chapter 1 of Act 53 of 1974, as substituted by section 2 of Act 6 of 1995

2. The following heading is hereby substituted for the heading to Chapter 1 of the principal Act:

“ESTABLISHMENT OF THE SOUTH AFRICAN PHARMACY COUNCIL, ITS OBJECTS, GENERAL POWERS AND FUNCTIONS”.

Substitution of section 2 of Act 53 of 1974, as substituted by section 2 of Act 69 of 1985 and section 3 of Act 6 of 1995

3. The following section is hereby substituted for section 2 of the principal Act:

“Establishment of South African Pharmacy Council

2. (1) There is hereby established a juristic person to be known as the South African Pharmacy Council, which shall be deemed to be the successor-in-title of the Interim Pharmacy Council of South Africa, and the first meeting of the council shall be convened by the registrar.

(2) The head office of the council shall be situated in Pretoria.

(3) Any reference to the Interim Pharmacy Council of South Africa in any deed, document or Act shall be deemed to be a reference to the council established in terms of subsection (1) with effect from the date determined in accordance with section 51, and every registrar of deeds or the officer where an official record is kept shall on application by the registrar amend his or her records accordingly without it being necessary for the council to pay any transfer fees, duties or taxes.”.

Substitution of section 3 of Act 53 of 1974, as amended by section 4 of Act 6 of 1995

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

“Objects of council

3. The objects of the council shall be—

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| (a) | to assist in the promotion of the health of the population of the Republic; | 5 |
| (b) | to advise the Minister or any other person on any matter relating to pharmacy; | |
| (c) | to promote the provision of pharmaceutical care which complies with universal norms and values, in both the public and the private sector, with the goal of achieving definite therapeutic outcomes for the health and quality of life of a patient; | 10 |
| (d) | to uphold and safeguard the rights of the general public to universally acceptable standards of pharmacy practice in both the public and the private sector; | 15 |
| (e) | to establish, develop, maintain and control universally acceptable standards— | |
| | (i) in pharmaceutical education and training; | |
| | (ii) for the registration of a person who provides one or more or all of the services which form part of the scope of practice of the category in which such person is registered; | 20 |
| | (iii) of the practice of the various categories of persons required to be registered in terms of this Act; | |
| | (iv) of professional conduct required of persons to be registered in terms of this Act; and | 25 |
| | (v) of control over persons registered in terms of this Act by investigating in accordance with this Act, complaints or accusations relating to the conduct of registered persons; | |
| (f) | to be transparent to the profession and the general public in achieving its objects and in performing its functions and executing its powers; and | 30 |
| (g) | to maintain and enhance the prestige, status and dignity of the pharmacy profession and the integrity of persons practising that profession.”. | |

Amendment of section 4 of Act 53 of 1974, as amended by section 4 of Act 6 of 1995 35

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

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| (a) | by the substitution for the heading to section 4 of the following heading:
“ General powers of council ”; | |
| (b) | by the deletion of paragraphs (g) and (h); | |
| (c) | by the deletion of the word “and” at the end of paragraph (m); and | 40 |
| (d) | by the insertion of the following paragraphs after paragraph (m) and before the word “generally”:
“(n) to designate the office-bearers of the council and to determine the procedure for the election of office-bearers and members of the council; | 45 |
| (o) | to appoint any committee it may deem necessary and to delegate any of its powers to any such committee and to prescribe the conditions of such delegation, including the power to subdelegate any delegated power to any member of its staff or officer duly appointed in terms of this Act; | 50 |
| (p) | to co-opt a representative of a professional board established in terms of this Act on to the council: Provided that such a representative shall not have the right to vote; | |
| (q) | to co-opt any person on to any of its committees that it may deem necessary; | 55 |
| (r) | to determine the number of meetings to be held by the council and | |

- its committees, the procedure applicable to such meetings, the manner in which special meetings shall be convened and the procedures applicable to such special meetings;
- (s) to determine the quorum requirements for a meeting of the council and any of its committees; 5
 - (t) to determine the manner in which decisions shall be taken at a meeting of the council or any of its committees;
 - (u) to appoint or dismiss a registrar or such other staff members as it may deem necessary and to determine their conditions of service: Provided that the appointment or dismissal of the registrar shall be subject to the approval of the Minister; 10
 - (v) to appoint any officer or inspector to perform any duty or act on behalf of the council in terms of this Act and to prescribe and determine their powers and duties;
 - (w) to delegate any of its powers to any officer or inspector and in general to regulate the duties of any officer or inspector; 15
 - (x) to delegate to any organisation such powers as it may deem necessary from time to time;
 - (y) to determine the manner in which the business of the council shall be conducted and the manner in which the accounts of the council shall be kept; 20
 - (z) to purchase or in any other manner acquire property, which shall include but not be limited to the acceptance of donations, or to sell, let, mortgage or in any other manner dispose of any property of the council; 25
 - (zA) to administer the assets of the council or any assets to be held in trust for the benefit of the council;
 - (zB) to settle the liabilities of the council;
 - (zC) to establish and administer a pension or a provident fund for the employees of the council; 30
 - (zD) to institute, defend and proceed with any legal action in its own name;
 - (zE) to borrow money on such terms and conditions as the council may determine and to encumber any of the assets of the council as security therefor; 35
 - (zF) to pay to any members of the council, office-bearers, committee members, officers appointed in terms of this Act, or any other person or any witness *subpoenaed*, including persons employed by the State, such allowances as it may determine from time to time;
 - (zG) to determine the fees payable to the council for services performed by the council in terms of this Act or for any other reason the council may decide on; 40
 - (zH) to require any person or institution registered in terms of this Act, or involved in pharmacy practice or offering pharmaceutical education or training, to furnish the council with the information the council requires; 45
 - (zI) to establish professional boards for pharmacy support personnel registered in terms of this Act, when the council, in consultation with the Minister, deems it necessary; and
 - (zJ) to prescribe the scope of practice of the various categories of persons registered in terms of this Act, and” 50

Substitution of section 5 of Act 53 of 1974, as amended by section 2 of Act 20 of 1979, section 3 of Act 69 of 1985 and substituted by section 6 of Act 6 of 1995

6. The following section is hereby substituted for section 5 of the principal Act:

“Constitution of council

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5. (1) The council shall consist of 25 persons elected or appointed as follows:

- (a) nine pharmacists registered with the council, resident in the Republic of South Africa and elected by pharmacists;

- (b) nine pharmacists nominated by the Members of the Executive Council responsible for health matters in the provinces of the Republic and appointed by the Minister;
- (c) an officer of the Department appointed by the Minister;
- (d) two pharmacists who are members of the staff of a university at which provision is made for the education and training of pharmacists, nominated by such a university and appointed by the Minister: Provided that such pharmacists shall not be from the same university;
- (e) four other persons appointed by the Minister, one of whom shall be a person appointed on account of his or her legal knowledge.
- (2) The council shall have a president and vice-president, and all members of the council shall be entitled to vote during the election of the president and the vice-president and other office-bearers of the council.
- (3) Whenever the persons entitled in terms of subsection (1)(a) to elect any member of the council, fail, before the expiry of the prescribed period, to elect any person to fill any vacancy in respect of the office of such a member, the Minister may, after consultation with the executive committee of the council, appoint a pharmacist who shall thereafter be deemed to have been duly elected.
- (4) Subject to the provisions of section 7, the members of the council shall hold office for a period of five years, but shall be eligible for reappointment or re-election, as the case may be.
- (5) The procedure to be followed at the election of the nine members referred to in subsection (1)(a) shall be prescribed.
- (6) If anything required to be done in terms of this Act in connection with the appointment or election or nomination of any member is omitted or not done within the time or in the manner required by this Act, the Minister may order all such steps to be taken as may be necessary to rectify the omission or error, or may validate anything done in any irregular manner, in order to give effect to the objects of this Act.
- (7) The registrar shall give notice in the *Gazette* of the appointment or election of any member of the council, the date of such appointment or election and the period for which such member has been appointed or elected.
- (8) Any person who makes or causes to be made a false declaration in connection with the election contemplated in subsection (1)(a), shall be guilty of an offence and liable on conviction to a fine not exceeding the amount determined by the Minister from time to time by notice in the *Gazette*.
- (9) The Minister may, in the public interest, and after consultation with a person or body responsible for the appointment or election of a member, terminate the membership of any member of the council after giving written notice to the member and affording the member an opportunity to furnish reasons to the Minister why his or her membership should not be terminated.
- (10) The Minister shall notify the registrar in writing of the names of the members appointed in terms of subsection (1) of this Act.

Repeal of section 8 of Act 53 of 1974

7. Section 8 of the principal Act is hereby repealed.

Repeal of section 9 of Act 53 of 1974, as amended by section 3 of Act 20 of 1979 and section 9 of Act 6 of 1995

8. Section 9 of the principal Act is hereby repealed.

Repeal of section 10 of Act 53 of 1974, as amended by section 4 of Act 20 of 1979

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

Repeal of section 11 of Act 53 of 1974

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

Amendment of section 12 of Act 53 of 1974

11. Section 12 of the principal Act is hereby amended—

(a) by the substitution for subsection (1) of the following subsection: 5

“Fees of council

(1) All fees payable in terms of this Act shall be paid to the council and shall be utilised as its funds for defraying expenses incurred in connection with the performance of its functions.; and

(b) by the deletion of subsection (2).” 10

Substitution of section 13 of Act 53 of 1974

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

“Registration

13. (1) No person shall be entitled to provide the services which form part of the services specially pertaining to the scope of practice of a pharmacist or assist therewith, unless he or she is duly registered in one of the categories prescribed in terms of this Act. 15

(2) No person shall practise as a specialist pharmacist or shall conduct himself or herself as such a specialist, or shall in any other manner profess to be a person in respect of whom any such speciality has been registered, unless the speciality in question has been registered in terms of this Act in respect of such person. 20

(3) Every person who has been suspended from practising in terms of this Act or whose name has been removed from a register, shall be disqualified from providing any of the services or performing any act specially pertaining to the scope of practice of pharmacy as determined in the practice rules made by the council, and his or her registration certificate shall be deemed to be withdrawn until the period of suspension has expired or until his or her name has been restored to the register by the council. 25

(4) Any person who has been suspended from practising in terms of this Act or whose name has been removed from a register in terms of subsection 45(1)(c) and whose name has not been restored to such register shall not be entitled to remain, or be registered as the owner of a pharmacy, or hold any beneficial interest in a pharmacy.” 30

Substitution of section 14 of Act 53 of 1974, as amended by section 5 of Act 20 of 1974 and section 6 of Act 69 of 1985 35

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

“Registration of persons, recording of licensed premises and maintenance of registers

14. With regard to the registration of persons and the recording of licensed pharmacy premises in terms of this Act: 40

(a) the various categories of persons who may be registered and pharmacies which may be recorded in terms of this Act shall be prescribed;

(b) the requirements and conditions for registration, removal, restoration or reinstatement of the various categories of persons shall be prescribed; 45

(c) the council shall require any person who is entitled and intends to

- provide one or more or all of the services which are deemed to be services specially pertaining to the scope of practice of a pharmacist, and pharmacy support personnel, or any person who assists in the provision thereof, to register with the council;
- (d) the council shall keep, amend, correct and maintain such registers in the format as the council deems necessary and cause copies of such registers to be printed at the discretion of the council; 5
- (e) the council may remove, in the prescribed manner, the name of any person from the relevant register;
- (f) the council may restore, in the prescribed manner, the name of any person to the relevant register on such conditions as the council may deem fit; 10
- (g) the council may issue, in the prescribed manner, any certificate the council may deem necessary, on such conditions as it may deem fit, and may cancel any certificate in the prescribed manner; 15
- (h) the council may refuse, in the prescribed manner, to record any person who or a pharmacy which does not comply with the prescribed conditions; and
- (i) the council may require, in the prescribed manner, all persons authorised in terms of section 22A to record the prescribed information with the council.”. 20

Repeal of section 15 of Act 53 of 1974

14. Section 15 of the principal Act is hereby repealed.

Repeal of section 16 of Act 53 of 1974

15. Section 16 of the principal Act is hereby repealed. 25

Repeal of section 17 of Act 53 of 1974, as amended by section 2 of Act 20 of 1983

16. Section 17 of the principal Act is hereby repealed.

Repeal of section 18 of Act 53 of 1974

17. Section 18 of the principal Act is hereby repealed.

Repeal of section 19 of Act 53 of 1974, as substituted by section 6 of Act 20 of 1979 30

18. Section 19 of the principal Act is hereby repealed.

Repeal of section 20 of Act 53 of 1974, as amended by section 7 of Act 20 of 1979 and section 3 of Act 20 of 1983

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

Repeal of section 21 of Act 53 of 1974, as amended by section 8 of Act 20 of 1979, section 1 of Act 39 of 1982 and section 7 of Act 69 of 1985 35

20. Section 21 of the principal Act is hereby repealed.

Substitution of section 22 of Act 53 of 1974, as amended by section 9 of Act 36 of 1977, section 9 of Act 20 of 1979, section 2 of Act 39 of 1982 and section 8 of Act 69 of 1985 40

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

“Licensing of pharmacies

22. (1) A person authorised in terms of section 22A to own a pharmacy shall in the prescribed manner, specifying the prescribed particulars, apply to the Director-General for a licence for the premises wherein or from which such business shall be carried on and the Director-General may be entitled to issue or refuse such licence on such conditions as he or she may deem fit. 5

(2) A person issued with a licence in terms of subsection (1) shall notify the council thereof in writing and on production of the said licence the council shall record the name, address, date of licence, licence number and any other particulars as prescribed. 10

(3) A licence issued in terms of subsection (1) may be subject to conditions as determined by the Director-General.

(4) A pharmacy shall, subject to such conditions as may be prescribed, be conducted under the continuous personal supervision of a pharmacist, in accordance with good pharmacy practice as determined in the rules made by the council. 15

(5) The pharmacist referred to in subsection (4) shall be responsible to the council for any act performed by or on behalf of the body corporate in question, including any omission to perform an act required to be performed by or on behalf of the body corporate, which may involve disciplinary action by the council, unless he or she satisfies the council that the responsibility for such act rests upon a pharmacist other than himself or herself employed by the body corporate. 20

(6) The council shall have the right to inspect premises in which the business of a pharmacy is carried on in terms of this Act, and the registrar shall provide the Director-General and the person who made the application in terms of subsection (1) with a written report of the findings of its inspection if it has been found that the inspected premises are not suitable for the business of a pharmacy. 25

(7) The Director-General may cancel or suspend any licence contemplated in subsection (1) which does not comply with the licensing conditions as determined in terms of subsection (3), after giving notice in writing to the owner of the pharmacy or the responsible pharmacist, and affording the owner or the responsible pharmacist an opportunity to furnish reasons why the licence should not be cancelled or suspended. 30

(8) If a licence is suspended or cancelled, the premises shall from the date of the suspension or the cancellation be considered to be unsuitable for the carrying on of the business of a pharmacy. 35

(9) A person registered to carry on the business of a pharmacy at the commencement of this Act shall be deemed to be licensed in terms of subsection (1). 40

(10) The Director-General in consultation with the council may close a pharmacy which is being conducted in contravention of this Act and the Medicines and Related Substances [Control] Act, 1965, or which does not comply with the licensing conditions, after giving notice to the owner or the responsible pharmacist, and affording the owner or the responsible pharmacist an opportunity to furnish reasons to the Director-General why the pharmacy should not be closed. 45

(11) 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 appeal against such decision to an appeal committee appointed by the Minister: Provided that the chairperson of such appeal committee shall be a person appointed on account of his or her knowledge of the law.”. 50 55

Substitution of section 22A of Act 53 of 1974, as amended by section 10 of Act 36 of 1977 and section 9 of Act 69 of 1985

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

“Ownership of pharmacies

22A. The Minister may prescribe who may own a pharmacy, the conditions under which such person may own such pharmacy, and the conditions upon which such authority may be withdrawn.”.

Repeal of section 22B of Act 53 of 1974 5

23. Section 22B of the principal Act is hereby repealed.

Amendment of section 29 of Act 53 of 1974, as amended by section 10 of Act 20 of 1979

24. Section 29 of the principal Act is hereby amended—

(a) by the substitution for the words following paragraph (b) of subsection (1) of the following words: 10

“shall be guilty of an offence and on conviction liable to a fine not exceeding **[five hundred rand or to imprisonment for a period not exceeding twelve months or to both such fine and such imprisonment]** the amount determined by the Minister from time to time by notice in the *Gazette*.”. 15

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

“(2) The acts prescribed in terms of section 35A(a)(i) shall for purposes of subsection (1) be deemed to be acts specially pertaining to the profession of a pharmacist.” 20

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

“(a) the keeping of medicines or the supply of medicines to his or her own patients by any medical practitioner, dentist **[or veterinary surgeon]**, practitioner or nurse in accordance with the provisions of the Medicine and Related Substances **[Control]** Act, 1965.”. 25

(d) by the substitution for subparagraph (ii) of paragraph (b) subsection (3) of the following paragraph:

“(ii) of a pharmacist’s assistant, pharmaceutical technician or other pharmaceutical **[auxiliary]** support personnel;” 30

(e) by the substitution for paragraph (f) of subsection (3) of the following paragraph:

“(f) the keeping of medicine and its supply by any person or organization performing a health service and authorized in writing by the **[Secretary for Health]** Director-General acting after consultation with the council, to acquire medicines for the performance of such service.”; 35

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

“(4) The Minister may in consultation with the council grant any person not registered in term of this Act authority to perform a service specially pertaining to the scope of practice of a pharmacist, or in writing exempt any person from the provision of this Act, on such conditions as he or she may determine.” 40

(g) by the substitution for subsection (5) of the following subsection:

“(5) If he or she is of the opinion that it is in the public interest to do so, the **[Secretary for Health]** Director-General may, pending the Ministers’ decision in respect of an application for a **[permit] authorisation** referred to in subsection (4), grant a provisional **[permit] authorisation** to the applicant concerned, authorising him or her to manufacture, pawn or sell any medicine or medicinal or chemical substance specified in such provisional **[permit] authorisation**, subject to such conditions to be determined by the said **[Secretary]** Director-General and set out in the provisional **[permit] authorisation**.”. 45 50

Amendment of section 30 of Act 53 of 1974

25. Section 30 of the principal Act is hereby amended by the substitution for the words following paragraph (e) of the following words: 55

“shall be guilty of an offence and on conviction liable to a fine not exceeding [one thousand rand] the amount determined by the Minister from time to time by notice in the *Gazette*.”

Repeal of section 31 of Act 53 of 1974

26. Section 31 of the principal Act is hereby repealed. 5

Substitution of section 33 of Act 53 of 1974, as amended by section 3 of Act 39 of 1982 and sections 46 and 47 of Act 97 of 1986

27. The following section is hereby substituted for section 33 of the principal Act:

“Pharmacy education and training

33. (1) The Minister may in consultation with the council make regulations to— 10

(a) develop, establish, maintain and control standards of pharmacy education and training;

(b) require any institution or person intending to provide education and training to apply for the approval of such institution or person; 15

(c) evaluate and authorise any institution or person to offer education and training to qualify a person for registration in terms of this Act, lay down the conditions upon which such education and training may be provided and amend such conditions from time to time, or cancel or withdraw such authority; 20

(d) make rules regarding the evaluation of a person applying for registration in terms of this Act to ensure competence;

(e) prescribe the unit standards for pharmaceutical education and training required from a person entitled to be registered in terms of this Act;

(f) conduct a pre-registration examination or evaluation to ensure competence of a person applying for registration in terms of this Act; 25

(g) conduct, recognise and control supplementary training of a person registered in terms of this Act;

(h) recognise qualifications, competencies and skills for purposes of registration in terms of this Act; 30

(i) determine the number of pharmacy support personnel or pharmacist interns who may be trained under the supervision of a pharmacist;

(j) investigate or cause to be investigated any institution or premises recognised by the council for purposes of education and training in terms of this Act, or request such information as may be deemed necessary from such institution to enable the council to establish compliance with the requirements prescribed by the council relating to such education and training; 35

(k) conduct examinations or evaluations for purposes of registration or continued registration in terms of this Act; 40

(l) appoint or accredit examiners or moderators needed for purposes of conducting any examination or evaluation prescribed by the council;

(m) award, cancel or withdraw certificates or documents issued in respect of any examination or training provided or recognised by the council;

(n) upon notice to the institution and pharmacy students who may be affected thereby, and after furnishing reasons, withdraw further recognition of any qualification for purposes of registration in terms of this Act on such conditions as the council may deem fit; 45

(o) require any person registered in terms of this Act to remain competent in the manner prescribed; 50

(p) make rules as to the additional qualifications, specialities or titles that may be registered in terms of this Act.”.

Substitution of section 34 of Act 53 of 1974

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

“Pharmacy education and training institutions

34. (1) No person shall be entitled to offer education and training for purposes of registration in terms of this Act, unless such institution or person and the education and training concerned have been approved by the council. 5

(2) Any person intending to offer education and training referred to in subsection (1) shall, before offering such education and training, apply to the council in the prescribed manner for the approval of such education and training, and of such institution or person. 10

(3) Any person who prevents a person authorised in terms of this Act to perform a function for or to act on behalf of the council from entering, at a reasonable time, an institution or premises offering education and training or who hinders such person in making therein or therefrom any investigation required to be done by the council, shall be guilty of an offence: Provided that the person carrying out the investigation shall produce proof of his or her identity and such authority, on request.”. 15

Substitution of section 35 of Act 53 of 1974

29. The following section is substituted for section 35 of the principal Act; 20

“Authorisation for provision and levies for services

35. (1) Except with the prior approval of the council, or authorised in terms of this Act, no person shall provide a service which pertains specially to the scope of practice of the various categories of persons, as laid down in terms of this Act. 25

(2) No person registered in terms of this Act, shall pay any person directly or indirectly or in any other manner reward him or her or it in connection with a prescription, issued by an authorised prescriber, in terms of the Medicines and Related Substances [**Control**] Act, 1965.

Insertion of section 35A of Act 53 of 1974

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30. The following section is hereby inserted after section 35 of the principal Act:

“Pharmacy practice**35A.** With regard to the control of pharmacy practice—

- (a) the following shall be prescribed: 35
- (i) the scope of practice of persons registered in terms of this Act, or the services or acts which shall for purposes of this Act be deemed to be services or acts specially pertaining to pharmacists or pharmacy support personnel, and the conditions under which those services may be provided or the acts which may be performed; 40
 - (ii) the services which may be provided in the various categories of pharmacies, and the conditions under which these services shall be provided;
- (b) the council shall be entitled to make rules as to: 45
- (i) a code of conduct for pharmacists and other persons registered in terms of this Act;
 - (ii) what constitutes good pharmacy practice;
 - (iii) the services for which a pharmacist may levy a fee and guidelines for levying such a fee or fees;

- (c) the council may approve the title or name under which a pharmacy may be conducted;
- (d) the council shall be entitled to investigate and inspect the practice and the conduct of the business of a pharmacy.”.

Amendment of section 36 of Act 53 of 1974, as amended by section 13 of Act 69 of 1985 5

31. Section 36 of the principal Act is hereby amended—

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

“(a) the inclusion in the name, title or description of any pharmacy business of the surname of an owner thereof **[or, in the case of such a business wholly owned by a body corporate referred to in section 22 or 22B, of the surname of any director thereof or of a member of the corporation, as the case may be, who is a pharmacist]**”; and 10
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- (b) by substitution for subsection (4) of the following subsection:

“(4) Any person who contravenes any of the provisions of this section shall be guilty of an offence and liable on conviction to a fine not exceeding **[five hundred rand or to imprisonment not exceeding twelve months or to both such fine and such imprisonment]** the amount determined by the Minister from time to time by notice in the Gazette.” 20

Substitution of section 37 of Act 53 of 1974, as amended by section 12 of Act 20 of 1979 and section 4 of Act 39 of 1982

32. The following section is hereby substituted for section 37 of the principal Act: 25

“Continuation of pharmacy business of person registered in terms of this Act by executor, trustee, liquidator, curator, or judgment creditor

37. Notwithstanding anything to the contrary in this Act contained—

- (a) the person responsible for reporting the estate of a person who owns a pharmacy and registered in terms of this Act to the Master, or the executor of the deceased estate of such person who owns a pharmacy may, subject to the laws relating to the administration of estates, for a period not exceeding 12 months after the death of such person who owns a pharmacy, and for an additional period not exceeding 12 months, continue the pharmacy business of the deceased, and such pharmacy business shall be conducted under the continuous personal supervision of a pharmacist; 30
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- (b) the executor shall, within 30 days of his or her appointment, inform the council by registered mail of his or her appointment and of the name and registration number of the pharmacist who shall be responsible to the council in respect of the pharmacy business referred to in paragraph (a); 40
- (c) the trustee in the insolvent estate of a pharmacist registered in terms of this Act or the liquidator of a body corporate entitled to carry on business as a pharmacist may, subject to applicable laws, for a period not exceeding 12 months after such a final sequestration order or final liquidation order, and for such additional period as the council may allow, continue the business of such a pharmacist or body corporate, and such business shall be conducted under the continuous personal supervision of a pharmacist; 45
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- (d) the trustee or liquidator shall, within 30 days of his or her appointment, deliver, by hand or registered mail, to the council the sequestration or liquidation order, as the case may be, referred to in paragraph (c), and the trustee or the liquidator shall inform the council, in writing, of the name and registration number of the pharmacist who shall be 55

- responsible to the council in respect of the business referred to in paragraph (c);
- (e) the curator of the estate of a person who is carrying on business as a pharmacist but who has been declared incapable of managing his or her affairs by an order of court, may, subject to applicable laws, for a period not exceeding 12 months after the order has been given and for such additional period as the council may allow, continue such pharmacy business, and such pharmacy business shall be conducted under the continuous personal supervision of a pharmacist;
- (f) the curator referred to in paragraph (e) shall, within 30 days from the date on which the order was made, deliver, by hand or registered mail, such order to the council, and the curator shall inform the council, in writing, of the name and registration number of the pharmacist who shall be responsible to the council in respect of the business referred to in paragraph (e);
- (g) the judicial manager or a judgment creditor of a body corporate carrying on business as a pharmacist may, subject to applicable laws, for a period not exceeding the period of judicial management or six months from the date on which the attachment order was made in the case of a judgment creditor, subject to conditions determined by the council, continue such pharmacy business, and such pharmacy business shall be conducted under the continuous personal supervision of a pharmacist;
- (h) the judicial manager or judgment creditor referred to in paragraph (g) shall, within 30 days of the granting or discharge of the order, deliver, by hand or registered mail, such order to the council, and such judicial manager or judgment creditor shall inform the council, in writing, of the name and registration number of the pharmacist who shall be responsible to the council in respect of the pharmacy business referred to in paragraph (e).”.

Amendment of section 39 of Act 53 of 1974

33. Section 39 of the principal Act is hereby amended by the substitution for subsection (1) of the following subsection:

“(1) The council shall have the power to enquire into any matter which is brought to the attention of the council or any complaint, charge or allegation of improper or disgraceful conduct against any person registered [under] in terms of this Act and, on finding such person guilty of such conduct, to impose any of the penalties prescribed in section 45(1).”.

Amendment of section 40 of Act 53 of 1974

34. Section 40 of the principal Act is hereby amended—

- (a) by the substitution for the words following upon subparagraph (iv) of paragraph (c) of subsection (1) of the following words:
 “shall be guilty of an offence and liable on conviction to a fine not exceeding **[one hundred rand]** the amount to be determined by the Minister from time to time by notice in the *Gazette*: Provided that every person so summoned shall be entitled to all the privileges to which a witness *subpoenaed* to give evidence before a provincial division of the Supreme Court is entitled.”; and
- (b) by the addition of subsection 3:
 “(3) The council shall be entitled to make an order as regards the costs incurred in an inquiry or investigation relating to the conduct of a registered person, of an amount not exceeding the amount determined by the Minister from time to time by notice in the *Gazette*.”.

Amendment of section 44 of Act 53 of 1974, as amended by section 15 of Act 20 of 1979

35. Section 44 of the principal Act is hereby amended by the insertion of the following subsection:

- “(4) When it appears—
- (a) from any disciplinary proceedings held by an employer into the conduct of a person registered in terms of this Act or any institution at which education and training in pharmacy is offered, that there is *prima facie* evidence of unprofessional conduct on the part of such employee or a student being trained as a pharmacist;
- (b) that the registration of a pharmacy student with an education and training institution has been suspended or cancelled,
- then the employer or the institution shall furnish the council with a copy of the record of such proceedings, or such portion thereof that is material to the issue, or notify in writing the council of such suspension or cancellation.”.

Amendment of Section 45 of Act 53 of 1974, as amended by section 16 of Act 20 of 1979

36. Section 45 of the principal Act is hereby amended—

- (a) by the substitution for paragraph (b) of subsection (1) of the following paragraph:
- “(b) Suspension for a specified period from practising or performing any acts forming part of his or her [profession or if he is a pharmacist intern or pharmacist assistant, from performing such acts as he may perform] scope of practice as prescribed in terms of this Act;”;
- (b) by the insertion of the following paragraph after paragraph (c) of subsection (1):
- “(d) A fine not exceeding the amount determined by the Minister from time to time by notice in the *Gazette*.”.

Insertion of section 45B to Act 53 of 1974

37. The principal Act is amended by the insertion of the following section after section 45A:

“Recovery of fines and cost orders

- 45B.** (1) Any fine imposed in terms of this Act shall, unless an appeal has been noted against such penalty, be paid to the council within 14 days after the imposition thereof, or within such extended period and in such instalments as the council may in its discretion determine.
- (2) Any cost order made in terms of this Act shall—
- (a) in the event of such order being made against the *pro forma* complainant or against the council be paid by the council within 14 days after the amount thereof has been fixed;
- (b) in the event of such order being made against any other person be paid to the council within 14 days after the amount thereof has been fixed, or within such extended period and in such instalments as the council may in its discretion determine.
- (3) The imposition of a fine or the making of a cost order in terms of this Act shall have the effect of a judgment in civil proceedings in the magistrate’s court of the district in which the person liable to pay such fine resides or has his or her registered address or main place of business.”.

Substitution of section 48 of Act 53 of 1974, as substituted by section 52 of Act 88 of 1996

38. The following section is hereby substituted for section 48 of the principal Act:

“**Limitation of liability**

48. Subject to the provisions of this Act the council or any member or officer of the council shall not be liable in respect of any act done in good faith or duty performed in accordance with this Act.”.

Amendment of section 49 of Act 53 of 1974, as amended by section 11 of Act 36 of 1977, section 18 of Act 20 of 1979, section 5 of Act 39 of 1982, section 5 of Act 20 of 1983 and section 14 of Act 69 of 1985 5

39. Section 49 of the principal Act, is hereby amended—

(a) by the substitution for paragraph (d) of subsection (1) of the following paragraph: 10

“(d) any fees payable under this Act [**(including annual fees in respect of any pharmacy or fees in respect of the registration of any pharmacy or any person as a pharmacist intern, pharmacy student, pharmaceutical technician, pharmacist assistant, or pharmaceutical auxiliary personnel member or, of a body corporate carrying on business as a pharmacist or of a managing director of any such body corporate or of a manager of a corporation) and exemption from the payment of any such fees**];”;

(b) by the substitution for subparagraph (i) of paragraph (k) of subsection (1) of the following subparagraph: 20

(i) the syllabuses for the various subjects included in the curriculum for the diploma in pharmacy [**awarded by the council in terms of section 33(2)**];”;

(c) by the substitution for subparagraph (i) of paragraph (n) of subsection (1) of the following subparagraph: 25

(i) the election of members of the council required to be elected in terms of section [**5(1)(b) or 7(2)**] 5(1);”.

(d) by the insertion of the following subsections after subsection (3):

“(4) The council shall, not less than two months before any rule is made in terms of this Act, cause the text of such rule to be published in the *Gazette* together with a notice declaring the council’s intention to make such a rule and inviting interested persons to furnish the council with comments thereon or any representations they may wish to make in regard thereto. 35

(5) The Minister shall, not less than three months before any regulation is made in terms of this Act, cause the text of such draft regulation to be published in the *Gazette* together with a notice declaring the Minister’s intention to make such a regulation and inviting interested persons to furnish the Minister with comments thereon or any representations they may wish to make in regard thereto: Provided that if the Minister thereafter decides to alter the draft regulations as a result of any objections or representations so submitted, it shall not be necessary to publish such alterations before making the regulations.”. 40

Insertion of section 49A in Act 53 of 1974 45

40. The following section is hereby inserted after section 49 of the principal Act:

“**Delegation of powers**

49A. (1) The Minister may delegate or authorise in writing the Director-General or any officer of the Department or the council to exercise any of the powers conferred upon him or her by this Act, other than the powers referred to in section 49. 50

(2) The Director-General may delegate or authorise in writing any officer of the Department or the council to exercise any of the powers conferred upon him or her by this Act.”.

Substitution of section 50 of Act 53 of 1974

41. The following section is hereby substituted for section 50 of the principal Act:

“Penalty where not expressly provided

50. Any person who contravenes any provision of this Act in respect of the contravention of which no penalty is expressly provided shall on conviction be liable to a fine not exceeding **[five hundred rand]** the amount determined by the Minister from time to time by notice in the *Gazette*.”.

Substitution of section 51 of Act 53 of 1974, as amended by section 11 of Act 6 of 1995

42. The following section is hereby substituted for section 51 of the principal Act:

“Abolition of Interim Pharmacy Council of South Africa, and transitional provisions

51. The **[South African]** Interim Pharmacy Council of South Africa shall cease to exist on the day immediately preceding the date of the first meeting of the council, and all rights, obligations, assets and liabilities acquired or incurred, as the case may be, by the **[South African]** Interim Pharmacy Council of South Africa, shall immediately vest in the council and the council shall be deemed to have acquired or incurred such rights, obligations, assets and liabilities in terms of this Act.”.

Substitution of section 52 of Act 53 of 1974

43. The following section is hereby substituted for section 52 of the principal Act:

“Savings

52. (1) Any proclamation, notice, regulation, authorisation or order issued, made or granted or any registration, removal from a register, appointment or any other thing done in terms of a provision of any law repealed, shall, except in so far as may be otherwise required by this Act, be deemed to have been issued, made, granted or done under the provisions of this Act.

(2) The members of the council as constituted immediately prior to the commencement of this Act shall continue to be members, and the council shall be deemed to be validly constituted in terms of this Act, until a date determined by the Minister and published in the *Gazette*.

(3) If any of the members referred to in subsection (2) vacates his or her office, the council shall, until the date referred to in that subsection, consist of the remaining members.”.

Insertion of section 52A in Act 53 of 1974

44. The following section is hereby inserted in the principal Act, after section 52:

“Act binding on State

52A. This Act is binding on the State.”.

Substitution of long title of Act 53 of 1974

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

“Act

To provide for the establishment of the South African Pharmacy Council and for its objects and general powers; to extend the control of the council to the

public sector; and to provide for pharmacy education and training, requirements for registration, the practice of pharmacy, the ownership of pharmacies and the investigative and disciplinary powers of the council; and to provide for matters connected therewith.”.

Short title and commencement

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46. (1) This Act shall be called the Pharmacy Amendment Act, 1997, and shall come into operation on a date fixed by the President by proclamation in the *Gazette*.

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

MEMORANDUM ON THE OBJECTS OF THE PHARMACY AMENDMENT BILL, 1997

Clause 1 amends section 1 of the Pharmacy Act, 1974, firstly by deleting *inter alia* the definitions of “Ciskeian Medical Council”, “Transkeian Medical Council” and “South African Pharmacy Council” as these bodies no longer exist and secondly, by the insertion of the definitions of “pharmacy practice”, “pharmacy student”, “pharmacy support personnel”, “responsible pharmacist” and “unprofessional conduct”.

Clause 2 substitutes the heading of Chapter 1 as follows: “Establishment of the South African Pharmacy Council, its objects, general powers and functions” and clause 3 makes provision for the establishment of the South African Pharmacy Council, thereby doing away with the Interim Council and all reference to it.

Clause 4, which deals with the objects of the council, amends section 3 of the Act to emphasise compliance with universal norms and values, the protection of the rights of the public in general and transparency to the profession and members of the public.

Clause 5 amends section 4 of the Act and serves to add more powers to the already existing powers of the council. The added powers include *inter alia* the following: procedural matters on the election of the council, the appointment of committees and the delegation of powers to such committees, co-option of persons to the council or its committees, procedural matters on the conduct of the council’s meetings, appointment and dismissal of the registrar, delegation of some of its powers in general, the determination of fees payable to the council and the establishment of professional boards.

Clause 6 deals with the constitution of the council and ensures that there is provincial representation in the council. It also ensures that non-pharmacists may become members of the council.

Clauses 7 to 10 repeal sections 8 to 11 of the Act, whilst clause 11 amends the finances of the council to read that all fees payable in terms of this Act shall be paid to the council and may be utilised as its funds for defraying expenses incurred in connection with the performance of its functions.

Clause 12 deals with the registration of a person providing services in connection with the scope of practice of a pharmacist and Clause 13 provides for the registration of persons and the recording of premises licensed by the Minister as well as the maintenance of such registers.

Clauses 14 to 20 repeal sections 15 to 21 of the Act and Clause 21 deals with the licensing of a pharmacy, whilst a new section 22A has been inserted by clause 22 to provide that the Minister may prescribe who may own a pharmacy, the conditions under which such persons may own a pharmacy and the conditions upon which such authority may be withdrawn.

Clause 23 repeals clause 22B of the Act which made provision for a corporation to carry on business as a pharmacist under certain conditions.

Clause 24 amends section 29 of the Act to provide *inter alia* that the Minister may in consultation with the council grant to any person not registered in terms of this Act authority to perform a service specially pertaining to the scope of a practice of a pharmacist, or in writing exempt any person from the provisions of this Act, on such conditions as he or she may determine.

Clause 26 repeals section 31 of the Act, whilst clause 27 substitutes section 33 to provide for pharmaceutical education and training. Clause 28 deals with pharmaceutical training institutions and clause 29 substitutes section 35 which refers to authorisation for provision of and levies for services.

Clause 30 inserts section 35A which deals with pharmacy practice and clause 31 amends section 36 of the Act in respect of business names.

Clause 32 substitutes section 37 of the Act which deals with the continuation of the pharmacy business of a person registered in terms of this Act by an executor, trustee, liquidator, curator, or judgement creditor. Clause 33 makes provision for the council to enquire *inter alia* into any matter brought to the attention of the council and clause 34 amends section 40 of the Act regarding the procedure for the conduct of an inquiry by the council.

Clause 35 amends section 44 of the Act by adding a subsection with regard to proceedings of unprofessional conduct whilst clause 36 deals with the penalties which the council may impose.

Clause 37 inserts section 45B to the Act regarding the recovery of fines and cost orders and clause 38 deals with the limitation of liability.

Clause 39 amends section 49 of the Act which deals with regulations, whilst clause 40 inserts section 49A regarding the delegation of powers by the Minister.

Clause 41 substitutes section 50 of the Act to make provision for a penalty where not expressly provided and clause 42 deals with transitional provisions.

Clause 43 makes provision for savings, clause 44 makes the Act binding on the State, clause 45 changes the long title of the Act, whilst clause 46 provides for the short title and the commencement of the Act.

Interested parties consulted

1. The Interim South African Pharmacy Council
2. Chamber of Mines
3. MASA (Manufacturers Association of South Africa)
4. Family Practitioners Association
5. Free Market Foundation
6. Judasa
7. Medunsa (Medical University of South Africa)
8. United South African Pharmacies
9. Managed Health Care Coalition
10. Routledges Attorneys
11. PMA (Pharmaceutical Manufacturers Association)
12. Pharmaceutical Society
13. SA Association of Hospitals and Institutional Pharmacists
14. D M Kisch Inc
15. National Convention on Dispensing
16. Gaia Research Institute Stuart Thomson
17. Wholesalers
18. South African Association of Pharmacists in Industry
19. RAMS (Representatives Association of Medical Schemes)
20. NPPHCN
21. Sekunjalo Health Care
22. Pharmaceutical Society of South Africa
23. Township Pharmacy Group
24. SA Association of Community Pharmacists
25. Alpha Pharm
26. Hospice Association of SA
27. Dr NC Kamdar (MDSHS)
28. Sonnenberg, Hoffman & Galombik
29. National General Practitioners Group
30. Ms Dena Elias (HHD)
31. Cliffe, Dekker, & Todd Inc.

In the opinion of the Department and the State Law Advisers this Bill should be dealt with in terms of section 75 of the Constitution of the Republic of South Africa, 1996.