



GNR.1160 of 20 November 2000: Regulations relating to the registration of persons and the maintenance of registers

DEPARTMENT OF HEALTH

The Minister of Health has, in consultation with the South African Pharmacy Council, in terms of section 14 of the Pharmacy Act, 1974 (Act 53 of 1974), as amended, made the regulations in the Schedule.

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Minister of Health

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1. Definitions.—In these regulations, unless the context otherwise indicates—

“Act” means the Pharmacy Act, 1974, (Act 53 of 1974), as amended, and regulations;

“assessor” for purposes of these regulations means any pharmacist registered by council in accordance with criteria determined and published for this purpose by council to measure outcomes of pharmacy education and training;

“certificate of approval” means a certificate issued by council to a person or institution that complies with the criteria determined and published by council for the approval of providers;

“certificate of qualification” means documentary evidence of a qualification required for registration as a pharmacist’s assistant;

“Close Corporations Act” means the Close Corporations Act, 1984 (Act No 69 of 1984), as amended;

“community pharmacy” means a pharmacy wherein or from which some or all of the services as prescribed in regulation 18 of the Regulations Relating to the Practice of Pharmacy are provided to persons requiring pharmaceutical services, but excludes an institutional pharmacy;

“Companies Act” means the Companies Act, 1973 (Act No 61 of 1973), as amended;

“consultant pharmacy” means a pharmacy wherein or from which some or all of the services as prescribed in regulation 19 of the Regulations Relating to the Practice of Pharmacy are provided to persons requiring pharmaceutical services;

“continuing professional development” means the process by which pharmacists continuously enhance their knowledge, skills and personal qualities throughout their professional careers, and encompasses a range of activities including continuing education and supplementary training;

“in-service training” means the training undertaken by a pharmacist’s assistant (learner basic) or pharmacist’s assistant (learner post-basic) under the direct personal supervision of a tutor at a pharmacy approved by council for purposes of such training;

“institutional pharmacy” means a pharmacy situated in—

- (a) a public health facility, wherein or from which some or all of the services as prescribed in regulation 18 of the Regulations Relating to the Practice of Pharmacy are provided to persons requiring pharmaceutical services from or at that public health facility; or
- (b) a private health facility, wherein or from which some or all of the services as prescribed in regulation 18 of the Regulations Relating to the Practice of Pharmacy are provided to persons requiring pharmaceutical services from or at that private health facility,

but excludes a community pharmacy;

“internship” means the practical training undertaken by a pharmacist intern in terms of a contract under the direct personal supervision of a tutor in a pharmacy approved by council for purposes of such training or at an institution registered as a provider of a qualification in pharmacy;

“manager” means the pharmacist designated and registered as such by a close corporation entitled to carry on the business of a pharmacist in terms of the Act and who shall be responsible for performing the duties as prescribed in regulation 25 of the Regulations Relating to the Practice of Pharmacy;

“managing director” means the pharmacist designated and registered as such by a company entitled to carry on the business of a pharmacist in terms of the Act and who shall be responsible for performing the duties as prescribed in regulation 25 of the Regulations Relating to the Practice of Pharmacy;

“manufacturing pharmacy” means a pharmacy wherein or from which some or all of the services as prescribed in regulation 16 of the Regulations Relating to the Practice of Pharmacy are provided and which shall sell medicine only to a wholesale pharmacy or a community pharmacy or an institutional pharmacy or to persons who are authorised to purchase medicines in terms of the Medicines Act or to an organ of State;

“Medicine Act” means the Medicines and Related Substances Control Act, 1965 (Act No 101 of 1965), as amended;

“nominee” means the natural person appointed and registered as such by a company or a close corporation entitled to carry on the business of a pharmacist in terms of the Act and who shall be responsible for the duties as prescribed in regulation 24 of the Regulations Relating to the Practice of Pharmacy;

“pharmaceutical community service” means the provision of services or the performance of one or more or all of the acts forming part of the scope of practice of a pharmacist in a public health facility or a complex of health facilities in accordance with the Regulations Relating to the Performance of Pharmaceutical Community Service;

“pharmacist’s assistant” means a natural person registered in one of the following categories:

- (a) pharmacist’s assistant (learner basic);
- (b) pharmacists assistant (basic);
- (c) pharmacist’s assistant (learner past-basic);
- (d) pharmacist’s assistant (post basic); or
- (e) pharmacy student;

“pharmacy owner” means any person who owns a pharmacy and who is registered as such in terms of the Act;

“pharmacy student” means a natural person registered as such in terms of the Act;

“private health facility” means any hospital, institution or facility at which provision is made for diagnostic interventions, medical or surgical treatment, and nursing or other health care, which is not owned or controlled by an organ of State;

“public health facility” means any hospital, institution or facility at which provision is made for diagnostic interventions, medical or surgical treatment, and nursing or other health care, which is owned or controlled by an organ of State;

“provider” means any person or institution approved by and registered with council to provide education and training for purposes of conferring a qualification in pharmacy or a certificate of qualification or for purposes of continuing professional development;

“qualification in pharmacy” means a qualification prescribed for purposes of registration as a pharmacist;

“registrar” means the registrar of the South African Pharmacy Council;

“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 the 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 and who is registered as such in terms of the Act;

"retail pharmacy" means a community pharmacy or an institutional pharmacy in a private health facility;

"specialist pharmacist" means a pharmacist who is registered as such in terms of the Act;

"speciality" means a specialist qualification in one of the fields of pharmacy approved and published in rules made by council;

"supplementary training" means training approved by council which empowers a registered person to perform acts or provide services, in terms of the Act or any other law, which fall outside the scope of practice of the category in which he or she is registered;

"tutor" means the pharmacist approved by council to supervise the internship of a pharmacist intern or the in-service training of a pharmacist's assistant;

"wholesale pharmacy" means a pharmacy wherein or from which some or all of the services as prescribed in regulation 17 of the Regulations Relating to the Practice of Pharmacy are provided and which shall sell medicine only to a wholesale pharmacy or a community pharmacy or an institutional pharmacy or to persons who are authorised to purchase medicines in terms of the Medicines Act or to an organ of State.

CHAPTER I

2. Categories of persons that may be registered.—For purposes of registration in terms of the Act, there shall be the following categories of persons—

- (1) Pharmacy student;
- (2) Pharmacist intern;
- (3) Pharmacist;
- (4) Specialist pharmacist;
- (5) Pharmacist's Assistant;
- (6) Company entitled to carry on the business of a pharmacist;
- (7) Close Corporation entitled to carry on the business of a pharmacist;
- (8) Pharmacy owner;
- (9) Responsible pharmacist;
- (10) Managing director;
- (11) Manager;
- (12) Nominee;
- (13) Provider; and
- (14) Assessor; who must be registered by council in registers kept for this purpose;

CHAPTER II

3. Requirements and conditions for registration as a pharmacy student.—Any person registered with a provider of a qualification in pharmacy must register with the council as a pharmacy student at the commencement of the second year of study: provided that no person shall be registered as a pharmacy student with the council unless he or she complies with the provisions of regulation 4.

4. Any person who applies for registration with the council as pharmacy student must—

- (1) submit to the registrar:
 - (a) a duly completed application on a form approved and provided by the council;
 - (b) a certified copy of his or her identity document or passport;
 - (c) acceptable documentary evidence from the provider concerned that he or she has been admitted to the second or subsequent year of study for a qualification in pharmacy; and
- (2) pay the registration fee as determined by the council.

5. Any person who complies with the requirements in regulation 4 must be registered as a pharmacy student and issued with a registration certificate by the registrar.

6. Removal from the register.—

- (1) Except as provided for in terms of sections 23, 24 and 39 of the Act, the registrar may remove from the register of pharmacy students the name of a student—
 - (a) who has complied with the requirements for a qualification in pharmacy;
 - (b) who no longer complies with the requirements and conditions for registration as a pharmacy student: provided that a student who interrupts his or her studies may, on making written application annually to the registrar, have his or her name retained on the register of pharmacy students for a period not exceeding two years from the end of the year in which he or she interrupted his or her studies; or
 - (c) who is deceased.
- (2) A person in respect of whose entry a removal as contemplated in sub-regulations (1) (a) and (b) has been made, must be notified thereof and any certificate issued in respect of the registration in question shall be deemed to be cancelled as from the date on which notice has so been given.

7. Restoration to the register.—A pharmacy student whose name was removed from the register in terms of regulation 6 may, if applicable, have his or her name restored to the register by—

- (1) submitting to the registrar:
 - (a) a duly completed application for restoration of his or her name to the relevant register on a form as approved and provided by the council; and

- (b) acceptable documentary evidence from the provider concerned to the effect that he or she has been re-admitted for the second or subsequent year of study for a qualification in pharmacy; and
- (2) paying the prescribed restoration fee; and

if the registrar is satisfied that he or she is a fit and proper person to be restored to the relevant register. If the registrar is not satisfied that he or she is a fit and proper person to be restored to the relevant register, the registrar must submit the application concerned to the council for a decision.

CHAPTER III

8. Requirements and conditions for registration as a pharmacist intern.—Any person who holds a qualification in pharmacy may register as a pharmacist intern with the council: provided that no person shall be registered as a pharmacist intern, unless he or she complies with regulation 9.

9. Any person who applies for registration as a pharmacist intern must—

- (1) submit to the registrar:
 - (a) a duly completed application on a form as approved and provided by the council;
 - (b) a certified copy of his or her identity document or passport;
 - (c) a duly completed and signed contract approved and provided by the council for the undertaking of an internship; and
 - (d) acceptable documentary evidence—
 - (i) of the approval by the council of the pharmacy or provider where the internship will be undertaken;
 - (ii) of the approval by council of the tutor under whom such internship will take place;
 - (iii) that he or she holds a qualification in pharmacy; and
 - (iv) where applicable, that he or she is registered with a provider approved by council as a provider of a course of study which will lead to the awarding of at least a master's degree; and
- (2) pay the registration fee as determined by council.

10. Every person who complies with the requirements in regulation 9 must be registered as a pharmacist intern and issued with a registration certificate by the registrar.

11. Removal from the register.—

- (1) Except as provided for in terms of sections 23, 24 and 39 of the Act, the registrar may remove from the register of pharmacist interns the name of a pharmacist intern—
 - (a) who has completed his or her internship to the satisfaction of the council;
 - (b) who has not completed his or her internship to the satisfaction of the council;

- (c) who has discontinued his or her internship with the consent of the council;
 - (d) who no longer complies with the requirements and conditions for registration as a pharmacist intern; or
 - (e) who is deceased.
- (2) A person in respect of whose entry a removal as contemplated in sub-regulations (1) (a) to (d) has been made, must be notified thereof and any certificate issued in respect of the registration in question shall be deemed to be cancelled as from the date on which notice has so been given.

12. Restoration to the register.—A pharmacist intern whose name was removed from the register in terms of regulation 11 may if applicable, have his or her name restored to the register by—

- (1) submitting to the registrar—
 - (a) a duly completed application for restoration of his or her name to the register on a form as approved and provided by the council;
 - (b) acceptable documentary evidence that he or she complies with the conditions under which he or she may be registered as a pharmacist intern; and
 - (c) acceptable documentary evidence from a tutor to the effect that he or she has resumed his or her internship; and
- (2) paying the prescribed restoration fee; and

if the registrar is satisfied that he or she is a fit and proper person to be restored to the relevant register. If the registrar is not satisfied that he or she is a fit and proper person to be restored to the relevant register, the registrar must submit the application concerned to the council for a decision.

CHAPTER IV

13. Requirements and conditions for registration as a pharmacist.—Any person who holds a qualification in pharmacy—

- (1) obtained in the Republic may apply to the registrar for registration as a pharmacist: provided that he or she shall not be so registered unless he or she complies with the provisions of regulation 14;
- (2) obtained outside the Republic may apply to the registrar for registration as a pharmacist: provided that he or she shall not be so registered unless he or she complies with the provisions of regulation 17.

14. Applicants with a qualification in pharmacy obtained in the Republic.—Any person with a qualification in pharmacy obtained in the Republic and who applies for registration as a pharmacist must—

- (1) submit to the registrar:
 - (a) a duly completed application on a form as approved and provided by council;
 - (b) a certified copy of his or her identity document or passport;
 - (c) acceptable documentary evidence that—

- (i) he or she holds a qualification in pharmacy;
 - (ii) completed his or her internship: provided that the council may exempt him or her partially or in full from this requirement on submission of documentary evidence to the satisfaction of council that he or she has undertaken practical training as part of his or her undergraduate studies under the supervision of a provider of a qualification in pharmacy; and
 - (iii) he or she has passed an examination(s) or other evaluation as approved by council, if applicable; and
- (d) acceptable documentary evidence of the name of the public health facility or complex of health facilities where he or she has been placed to perform pharmaceutical community service and the date on which he or she will assume duty at such facility; and
- (2) pay the registration fee as determined by the council.

15. Every person who complies with the requirements in regulation 14 must be registered as a pharmacist and issued with a registration certificate by the registrar: provided that any person registered as a pharmacist in terms of this regulation shall only be entitled to practise as such—

- (1) for purposes of performing pharmaceutical community service; and
- (2) for a period not exceeding two years.

16. The council may revoke the conditions imposed in regulation 15 upon the submission by the relevant health authority of a report to the council that such pharmacist has satisfactorily completed pharmaceutical community service in terms of the Act.

17. Applicants with a qualification in pharmacy obtained outside the Republic.—Any person with a qualification in pharmacy obtained outside the Republic and who applies for registration as a pharmacist must—

- (1) submit to the registrar:
 - (a) a duly completed application on a form as approved and provided by council;
 - (b) a certified copy of his or her identity document or passport;
 - (c) acceptable documentary evidence of—
 - (i) the qualification in pharmacy obtained outside the Republic which entitles him or her to practise as a pharmacist in the country in which the institution or examining body that awarded such qualification is situated;
 - (ii) the fact that he or she is registered as a pharmacist in the country in which the institution or examining body that awarded such qualification is situated;
 - (iii) the fact that he or she is a fit and proper person and in good standing as a pharmacist with the relevant registration authority;

- (iv) the practical training which he or she has undertaken and completed, if any; and
 - (v) the fact that he or she has passed an examination(s) or other evaluation as approved by council, if applicable; and
- (2) pay the registration fee as determined by the council.

18. The registrar must submit an application that complies with the requirements of regulation 17 to the council for evaluation, and the council may—

- (1) register the applicant as a pharmacist's assistant in the category pharmacist's assistant (post basic) under such conditions as the council may determine from time to time; or
- (2) register the applicant as a pharmacist intern until he or she has completed practical training to the satisfaction of the council; or
- (3) register the applicant as a pharmacist if he or she submits prior to such registration acceptable documentary evidence to the registrar of the name of the public health facility or complex of health facilities where he or she has been placed to perform pharmaceutical community service and the date on which he or she will assume duty at such facility: provided that any person registered as a pharmacist in terms of this regulation shall only be entitled to practise as such—
 - (a) for purposes of performing pharmaceutical community service;
 - (b) for a period not exceeding two years; and
 - (c) subject to such further restrictions in respect of his or her professional activities as the council may determine.

19. Every person registered in terms of regulation 18 must be issued with a registration certificate by the registrar.

20. The council may—

- (1) revoke the conditions imposed in sub-regulations 18 (3) (a) and (b) upon the submission by the relevant health authority of a report to the council that such pharmacist has satisfactorily completed pharmaceutical community service in terms of the Act; and
- (2) prior to revoking the restrictions in sub-regulation 18 (3) (c) require that the applicant passes an examination(s) or other evaluation(s) as determined by the council.

21. Removal from the register.—

- (1) Except as provided for in terms of sections 23, 24 and 39 of the Act, the registrar may remove from the register of pharmacists the name of a pharmacist—
 - (a) who no longer complies with the requirements and conditions for registration as a pharmacist; or
 - (b) who is deceased.
- (2) A person in respect of whose entry a removal as contemplated in sub-regulation (1) (a) has been made, must be notified thereof and any certificate issued in respect of the registration in question shall be deemed to be cancelled as from the date on which notice has so been given.

22. Restoration to the register.—A pharmacist whose name was removed from the register in terms of regulation 21 may, if applicable, have his or her name restored to the register by—

- (1) submitting to the registrar:
 - (a) a duly completed application for restoration of his or her name to the register on a form as approved and provided by the council;
 - (b) acceptable documentary evidence that he or she complies with the conditions under which he or she was registered as a pharmacist; and
- (2) paying the prescribed restoration fee; and

if the registrar is satisfied that he or she is a fit and proper person to be restored to the relevant register. If the registrar is not satisfied that he or she is a fit and proper person to be restored to the relevant register, the registrar must submit the application concerned to the council for a decision.

CHAPTER V

23. Requirements and conditions for registration as a specialist pharmacist.—A pharmacist who applies for registration as a specialist pharmacist must—

- (1) submit to the registrar:
 - (a) a duly completed application on a form approved and provided by council;
 - (b) a certified copy of his or her identity document or passport;
 - (c) acceptable documentary evidence that he or she has obtained a speciality or has complied with the requirements for registration in terms of the Act; and
- (2) submit acceptable documentary evidence to the registrar that he or she has obtained practical experience published in rules made by council in the field of pharmacy for which registration as a specialist pharmacist is being applied for;
- (3) give notice to the registrar of the speciality in which he or she intends to practise; and
- (4) pay the registration fee as determined by the council.

24. A pharmacist who complies with the requirements of regulation 23 must be registered as a specialist pharmacist and be issued with a registration certificate by the registrar, indicating his or her speciality.

25. Removal from the register.—

- (1) Except as provided for in terms of sections 23, 24 and 39 of the Act, the registrar may remove from the register of specialist pharmacists the name of a specialist pharmacist who—
 - (a) no longer complies with the requirements and conditions for registration as a specialist pharmacist; or
 - (b) who is deceased.

- (2) A person in respect of whose entry a removal as contemplated in sub-regulation (1) (a) has been made, must be notified thereof and any certificate issued in respect of the registration in question shall be deemed to be cancelled as from the date on which notice has so been given.

26. Restoration to the register.—A specialist pharmacist whose name was removed from the register of specialist pharmacists in terms of regulation 25 may, if applicable, have his or her name restored to the register by—

- (1) submitting to the registrar:
- (a) a duly completed application for restoration of his or her name to the register of specialist pharmacists on a form as approved and provided by the council; and
 - (b) acceptable documentary evidence that he or she complies with the conditions under which he or she may be registered as a specialist pharmacist; and
- (2) paying the prescribed restoration fee; and

if the registrar is satisfied that he or she is a fit and proper person to be restored to the relevant register. If the registrar is not satisfied that he or she is a fit and proper person to be restored to the relevant register, the registrar must submit the application concerned to council for a decision.

27. Practising more than one speciality.—A pharmacist may register more than one speciality: provided that he or she may only practise in one speciality.

CHAPTER VI

28. Requirements and conditions for registration as a pharmacist's assistant in the category pharmacists' assistant (learner basic) or pharmacists' assistant (learner post-basic).—Any person registered for a learning programme with a provider of a certificate of qualification must register with the council at the commencement of such learning programme: provided that no person will be registered with council as a pharmacist's assistant in the category pharmacist's assistant (learner basic) or pharmacist's assistant (learner post-basic), as the case may be, unless he or she complies with the provisions of regulation 29.

29. Any person who applies for registration as a pharmacist's assistant in the category pharmacist's assistant (learner basic) or pharmacist's assistant (learner post-basic), as the case may be, must—

- (1) submit to the registrar:
- (a) a duly completed application on a form approved and provided by council;
 - (b) a certified copy of his or her identity document or passport;
 - (c) acceptable documentary evidence—
 - (i) from the provider concerned that he or she has been registered for a learning programme for a certificate of qualification in the category pharmacist's assistant (basic) or pharmacist's assistant (post-basic), as the case may be;
 - (ii) of the approval by council of the pharmacy where the in-service training of the pharmacist's assistant will be undertaken; and

- (iii) of the approval by council of the tutor under whom such training will take place; and
- (2) pay the registration fee as determined by the council.

30. Every person who complies with the requirements of regulation 29 must be registered in the category pharmacist's assistant (learner basic) or pharmacist's assistant (learner post-basic), as the case may be, and issued with a registration certificate by the registrar.

31. Transitional arrangements.—A pharmacist's assistant who is undertaking training in the Republic in terms of the Act, for purposes of registration as a pharmacist's assistant prior to the commencement of these regulations shall be deemed to be registered as a pharmacist's assistant in the category pharmacist's assistant (learner post-basic): provided that such pharmacist's assistant will have the choice of either:

- (1) completing such training; or
- (2) applying to a provider to be admitted to a learning programme for a certificate of qualification and informing the registrar in writing of such application.

32. Removal from the register.—

- (1) Except as provided for in terms of sections 23, 24 and 39 of the Act, the registrar may remove from the register of pharmacist's assistants (learner basic) or pharmacist's assistants (learner post-basic), as the case may be, the name of a pharmacist's assistant—
 - (a) who has complied with the requirements for a certificate of qualification as a pharmacist's assistant (basic) or pharmacist's assistant (post-basic) as the case may be;
 - (b) who no longer complies with the requirements and conditions for registration as a pharmacist's assistant (learner basic) or pharmacist's assistant (learner post-basic), as the case may be; or
 - (c) who is deceased.
- (2) A person in respect of whose entry a removal as contemplated in sub-regulations (1) (a) and (b) has been made, must be notified thereof and any certificate issued in respect of the registration in question shall be deemed to be cancelled as from the date on which notice has so been given.

33. Restoration to the register.—A pharmacist's assistant (learner basic) or pharmacist's assistant (learner post-basic), as the case may be, whose name was removed from the register in terms of regulations 32 may, if applicable, have his or her name restored to the register by—

- (1) submitting to the registrar:
 - (a) a duly completed application for restoration of his or her name to the register on a form as approved and provided by the council; and
 - (b) acceptable documentary evidence from the provider concerned to the effect that he or she has been re-admitted to a learning programme for a certificate of qualification; and

- (2) paying the prescribed restoration fee; and

if the registrar is satisfied that he or she is a fit and proper person to be restored to the relevant register. If the registrar is not satisfied that he or she is a fit and proper person to be restored to the relevant register, the registrar must submit the application concerned to the council for a decision.

CHAPTER VII

34. Requirements and conditions for registration as a pharmacist's assistant in the category pharmacist's assistant (basic) or pharmacist's assistant (post-basic).—Any person who holds a certificate of qualification:

- (1) obtained in the Republic may apply to the registrar for registration as a pharmacist's assistant in the category pharmacist's assistant (basic) or pharmacist's assistant (post basic), as the case may be: provided that he or she shall not be so registered unless he or she complies with the provisions of regulation 35;
- (2) obtained outside the Republic may apply to the registrar for registration as a pharmacist's assistant in the category pharmacist's assistant (basic) or pharmacist's assistant (post-basic), as the case may be: provided that he or she shall not be so registered unless he or she complies with the provisions of regulation 37.

35. Applicants with a certificate of qualification obtained in the Republic.—Any person with a certificate of qualification obtained in the Republic and who applies for registration as a pharmacist's assistant in the category pharmacist's assistant (basic) or pharmacist's assistant (post-basic), as the case may be, must—

- (1) submit to the registrar:
 - (a) a duly completed application on a form approved and provided by council;
 - (b) a certified copy of his or her identity document or passport;
 - (c) acceptable documentary evidence that he or she holds a certificate of qualification that entitles him or her to be registered as a pharmacist's assistant in the category pharmacist's assistant (basic) or pharmacist's assistant (post-basic), as the case may be, and has completed the in-service training in terms of the Act;
 - (d) acceptable documentary evidence that he or she has passed an examination(s) or other evaluation(s) as determined by council, if applicable; and
- (2) pay the registration fee as determined by the council.

36. Every person who complies with the requirements of regulation 35 must be registered as a pharmacist's assistant in the category pharmacist's assistant (basic) or pharmacist's assistant (post-basic), as the case may be, and issued with a registration certificate by the registrar.

37. Applicants with a certificate of qualification obtained outside the Republic.—Any person with a certificate of qualification obtained outside the Republic who applies for registration as a

pharmacist's assistant in the category pharmacist's assistant (basic level) or pharmacist's assistant (post-basic), as the case may be, must—

- (1) submit to the registrar:
 - (a) a duly completed application on a form as approved and provided by council;
 - (b) a certified copy of his or her identity document or passport;
 - (c) acceptable documentary evidence of-
 - (i) the certificate of qualification obtained outside the Republic which entitles him or her to practise as a pharmacist's assistant in the country in which the examining body that awarded such qualification is situated;
 - (ii) the fact that he or she is registered as a pharmacist's assistant in the country in which the examining body that awarded such qualification is situated;
 - (iii) the fact that he or she is a fit and proper person and in good standing as a pharmacist's assistant with the relevant registration authority; and
 - (iv) the in-service training which he or she has undertaken and completed, if any; and
- (2) pay the registration fee as determined by the council.

38. The registrar must submit an application that complies with the requirements of regulation 37 to the council for evaluation, and the council may—

- (1) refuse to register the applicant as a pharmacist's assistant in the category pharmacist's assistant (basic level) or pharmacist's assistant (post basic);
- (2) register the applicant as a pharmacist's assistant in the category pharmacist's assistant (learner basic) or pharmacist's assistant (learner post-basic), as the case may be; or
- (3) register the applicant as a pharmacist's assistant in the category pharmacist's assistant (basic) or pharmacist's assistant (post basic), as the case may be,

Provided that prior to approving an application for registration in terms of sub-regulations 38 (2) or (3), the council may require that the applicant passes an examination(s) or other evaluation(s) determined by the council.

39. A person registered in terms of regulation 38 (2) must prior to registration as a pharmacist's assistant in the category pharmacist's assistant (basic) or pharmacist's assistant (post-basic), as the case may be, comply with the requirements relating to in-service training in terms of the Act.

40. Every person registered in terms of regulation 38 must be issued with a registration certificate by the registrar.

41. Removal from the register.—

- (1) Except as provided for in terms of sections 23, 24 and 39 of the Act, the registrar may remove from the register of pharmacist's assistants (basic) or pharmacist's assistants (post-basic) the name of a pharmacist's assistant—
 - (a) who no longer complies with the requirements and conditions for registration as a pharmacist's assistant (basic) or a pharmacist's assistant (post-basic), as the case may be; or
 - (b) who is deceased.
- (2) A person in respect of whose entry a removal as contemplated in sub-regulation (1) (a) has been made, must be notified thereof and any certificate issued in respect of the registration in question shall be deemed to be cancelled as from the date on which notice has so been given.

42. Restoration to the register.—A pharmacist's assistant (basic) or pharmacist's assistants (post-basic) whose name was removed from the register in terms of regulation 41 may, if applicable, have his or her name restored to the register by—

- (1) submitting to the registrar:
 - (a) a duly completed application for restoration of his or her name to the register on a form as approved and provided by the council;
 - (b) acceptable documentary evidence that he or she complies with the conditions under which he or she may be registered as a pharmacist's assistants (basic) or pharmacist's assistant (post basic); and
- (2) paying the prescribed restoration fee; and

if the registrar is satisfied that he or she is a fit and proper person to be restored to the relevant register. If the registrar is not satisfied that he or she is a fit and proper person to be restored to the relevant register, the registrar must submit the application concerned to the council for a decision.

43. Transitional arrangements.—Any person registered as a pharmacist's assistant with the council at the commencement of these regulations and who is designated in such register as an unqualified assistant or qualified assistant shall be deemed to be registered as a pharmacist's assistant in the category pharmacist's assistant (post-basic) in the same category of pharmacy as registered previously, for purposes of the Act.

CHAPTER VIII

44. Requirements and conditions for the registration of additional qualifications or supplementary training.—A person shall be entitled to register only the additional qualifications or supplementary training approved by the council and published in rules.

45. A person registered in terms of the Act who has obtained an additional qualification or supplementary training referred to in regulation 44 and who wants to register such additional qualification or supplementary training with council must—

- (1) submit to the registrar:

- (a) a duly completed application on a form as approved and provided by the council; and
 - (b) acceptable documentary evidence that he or she is entitled to register the additional qualification or supplementary training referred to in regulation 44; and
- (2) pay the registration fee as determined by council.

46. The additional qualification or supplementary training of every person who complies with the requirements of regulation 45 must be registered and such person be issued with a registration certificate by the registrar, indicating such additional qualification or supplementary training.

CHAPTER IX

47. Requirements and conditions for the registration of a company entitled to carry on the business of a pharmacist.—A company duly registered in terms of the Companies Act, 1973, which wants to carry on the business of a pharmacist in terms of the Act, must—

- (1) appoint and designate a pharmacist as managing director of such company;
- (2) designate a natural person to act as nominee for such company: provided that such person:
 - (a) resides in the Republic;
 - (b) is a director of the company; and
 - (c) is a pharmacist and a shareholder in the case of a company who wants to carry on the business of a retail pharmacy; and
- (3) apply to the council, for the registration of the company, the nominee, and the managing director: provided that such company shall not be so registered unless it complies with the provisions of regulation 48.

48. A company that complies with the requirements of regulation 47 must—

- (1) submit to the registrar:
 - (a) a duly completed application on a form approved and provided by the council for the registration of:
 - (i) the company as a company entitled to carry on the business of a pharmacist;
 - (ii) the managing director; and
 - (iii) the nominee; and
 - (b) a certified copy of its certificate of incorporation, memorandum and articles of association in terms of the Companies Act, 1973, which complies with regulation 49, if applicable;
 - (c) the latest CM22 and CM29 forms submitted to the Registrar of Companies, an acknowledgement of receipt thereof by the Registrar of Companies and an extract from the register of members kept in terms of section 105 of the Companies Act, 1973;

- (d) an undertaking in writing that the company will comply with good pharmacy practice as published by council in rules;
 - (e) the name of the category of pharmacy in which the company wishes to carry on the business of a pharmacist; and
 - (f) such other information as may be required by the registrar; and
- (2) pay the registration fees as determined by the council.

49. An applicant in terms of regulation 48, who wishes to carry on the business of a retail pharmacy or at any time after its registration carries on the business of a retail pharmacy, must include a clause in its Articles of Association which prohibits the alienation or disposal or transfer of its shares or any direct or indirect beneficial interest in such company to any person not entitled to conduct a retail pharmacy or derive a direct or indirect financial benefit from conducting such pharmacy business.

50. Every company that complies with the requirements of these regulations and the provisions of sections 22 and 22A of the Act must be registered as a company entitled to carry on the business of a pharmacist and issued with a registration certificate by the registrar, indicating the category of pharmacy in which it may carry on the business of a pharmacist.

51. A shareholder of a company registered in terms of the Act who carries on the business of a retail pharmacy must not in any manner whatsoever, dispose of his, her or its shares or the direct or indirect beneficial interest therein in contravention of the provisions of the Act or the clause contemplated in regulation 49.

52. Removal from the register.—Except as provided for in sections 23, 24 and 39 of the Act, the council may direct the registrar to remove from the register of companies entitled to carry on the business of a pharmacist or the register of pharmacy owners, if applicable, the name of a company—

- (1) which does not comply with any of the provisions of sections 22 or 22A of the Act;
- (2) which contravenes the provisions of regulations 49 and 51;
- (3) if the managing director fails to accept responsibility for the duties of the managing director as prescribed in regulation 25 of the Regulations Relating to the Practice of Pharmacy;
- (4) if the company fails to comply with good pharmacy practice as published by council in rules; or
- (5) if after an inquiry held in terms of the Act, the council finds that any director, shareholder, the managing director or the nominee of such company, as the case may be, has contravened any provision of the Act,

if, after the company has been given notice in the manner prescribed in regulation 103 of the intention to remove the name of the company from the relevant register and to close such pharmacy business, if applicable, and which has been afforded an opportunity to furnish the council with written reasons within 14 days after the date upon which the notice is deemed to have been received in terms of sub-regulation 102 (2) fails to furnish acceptable reasons why its name should not be removed from the relevant register.

53. Any company in respect of whose entry a removal as contemplated in regulation 52 has been made must be notified thereof and any certificate issued in respect of the registration in question shall be deemed to be cancelled from the date on which notice has so been given.

54. The company, as from the date on which notice of cancellation or withdrawal is deemed to have been received is not entitled to carry on the business of a pharmacist or allow any services or acts pertaining to the scope of practice of a pharmacist to be performed in its business, if applicable.

55. Restoration to the register.—Any company whose registration certificate has been cancelled or withdrawn and whose name has been removed from the register(s) in terms of regulation 52 may be restored to the register by—

- (1) submitting to the registrar:
 - (a) a duly completed application for restoration of its name on a form as approved and provided by council; and
 - (b) acceptable documentary evidence that it again complies with the conditions for registration in terms of these regulations; and
- (2) paying the prescribed restoration fee; and
- (3) furnishing proof to the registrar that the director(s), shareholder(s), managing director or nominee, as the case may be, are fit and proper person(s) to own or carry on the business of a pharmacist: provided that if the registrar is not satisfied that the company should be restored to the relevant register, the registrar must submit the application to the council for a decision.

56. In the event of a company registered in terms of the Act carrying on the business of a pharmacist at any time whilst so registered without a managing director, then the nominee or failing him or her, then the person who signed the application form in sub-regulation 48 (1) (a), shall be accountable to council for any act performed by or on behalf of the company in question, including any omission to perform any act required to be performed by or on behalf of the company, which may involve disciplinary action by the council.

CHAPTER X

57. Requirements and conditions for the registration of a close corporation entitled to carry on the business of a pharmacist.—A close corporation duly registered in terms of the Close Corporations Act, 1984, who wants to carry on the business of a pharmacist in terms of the Act, must—

- (1) appoint and designate a pharmacist as manager of such close corporation;
- (2) designate a natural person to act as nominee for such close corporation: provided that such person:
 - (a) resides in the Republic;
 - (b) is a member of the close corporation; and

- (c) is a pharmacist in the case of a close corporation who wants to carry on the business of a retail pharmacy; and
- (3) apply to council for the registration of the close corporation, the nominee and the manager: provided that such close corporation shall not be so registered unless it complies with the provisions of regulation 58.

58. A close corporation that complies with the requirements of regulation 57 must—

- (1) submit to the registrar:
 - (a) a duly completed application on a form approved and provided by the council for the registration of:
 - (i) the close corporation as a close corporation entitled to carry on the business of a pharmacist;
 - (ii) the manager; and
 - (iii) the nominee; and
 - (b) a certified copy of its founding statement with the registration number endorsed thereon in terms of the Close Corporations Act, 1984, and an acknowledgement of receipt thereof by the Registrar of Close Corporations, as well as any amendments thereof in terms of section 15 of the Close Corporations Act, 1984, which complies with regulation 59;
 - (c) a certified copy of an association agreement entered into in terms of section 44 of the Close Corporations Act, 1984, or a statement if the close corporation has more than one member or alternatively a statement by members and confirmed by the accounting officer of the corporation that section 46 of the Close Corporations Act, 1984, applies and that the prohibition in regulation 59 and 61 and the consequences in terms of regulation 62 (*d*) have been noted;
 - (d) an undertaking in writing that the close corporation will comply with good pharmacy practice as published by council in rules;
 - (e) the name of the category of pharmacy in which the close corporation wishes to carry on the business of a pharmacist; and
 - (f) such other information as may be required by the registrar; and
- (2) pay the registration fees as determined by the council.

59. An applicant in terms of regulation 58, who wishes to carry on the business of a retail pharmacy or any time after its registration carries on the business of a retail pharmacy must include a clause in its association agreement which prohibits the alienation or disposal or transfer in terms of sections 34, 35, 36, 37 or 39 of the Close Corporations Act, 1984, of any member's interest or any direct or indirect beneficial interest in the close corporation to any person not entitled to carry on the business of a retail pharmacy or derive a direct or indirect financial benefit from conducting such pharmacy business.

60. Every close corporation that complies with the requirements of these regulations and the provisions of section 22A of the Act must be registered as a close corporation entitled to carry on the business of a pharmacist and be issued with a registration certificate by the registrar, indicating the category of pharmacy in which it may carry on the business of a pharmacist.

61. The member(s) of a close corporation registered in terms of the Act as being entitled to carry on the business of a retail pharmacy, must not in any manner whatsoever dispose of his, her or its member's interest or the direct or indirect beneficial interest therein in contravention of the provisions of the clause contemplated in regulation 59.

62. Removal from the register.—Except as provided for in sections 23, 24 and 39 of the Act, the council may direct the registrar to remove from the register of close corporations entitled to carry on the business of a pharmacist or the register of pharmacy owners, if applicable, the name of a close corporation:

- (1) who does not comply with any of the provisions of section 22A of the Act;
- (2) who contravenes the provisions of regulations 59 and 61;
- (3) if the manager fails to accept responsibility for the duties of the manager as prescribed in regulation 25 of the Regulations Relating to the Practice of Pharmacy;
- (4) if the close corporation fails to comply with good pharmacy practice as published by council in rules; or
- (5) if after an inquiry held in terms of the Act, the council finds that any member, the manager or the nominee of such close corporation, as the case may be, has contravened any provision of the Act,

if, after the close corporation has been given notice in the manner prescribed in regulation 103 of the intention to remove the name of the close corporation from the relevant register and to close such pharmacy business, if applicable, and who has been afforded an opportunity to furnish the council with written reasons, within 14 days after the date upon which the notice is deemed to have been received in terms of sub-regulation 103 (2) fails to furnish acceptable reasons why its name should not be removed from the relevant register.

63. Any company in respect of whose entry a removal as contemplated in regulation 62 has been made must be notified thereof and any certificate issued in respect of the registration in question shall be deemed to be cancelled from the date on which notice has so been given.

64. The close corporation as from the date on which notice of cancellation or withdrawal is deemed to have been received is not entitled to carry on the business of a pharmacist or allow any services or acts pertaining to the scope of practice of a pharmacist to be performed in its business, if applicable.

65. Restoration to the register.—Any close corporation whose registration certificate has been cancelled or withdrawn and whose name has been removed from the register(s) in terms of regulation 62 may be restored to the register by—

- (1) submitting to the registrar:
 - (a) a duly completed application for restoration of its name on a form as approved and provided by council; and
 - (b) acceptable documentary evidence that it again complies with the conditions for registration in terms of these regulations; and
- (2) paying the prescribed restoration fees; and

- (3) furnishing proof to the registrar that the members, manager or nominee are fit and proper person(s) to own or carry on the business of a pharmacist: provided that if the registrar is not satisfied that the close corporation should be restored to the relevant register, the registrar must submit the application to the council for a decision.

66. In the event of a close corporation registered in terms of the Act carrying on the business of a pharmacist at any time whilst so registered without a manager, then the nominee or failing him or her, then the person who signed the application form in sub-regulation 58 (1) (a) shall be accountable to council for any act performed by or on behalf of the close corporation in question, including any omission to perform any act required to be performed by or on behalf of the close corporation, which may involve disciplinary action by council.

CHAPTER XI

67. Requirements and conditions for the registration of a pharmacy.—A person authorised and registered to carry on the business of a pharmacist in terms of the Act who wants to open a pharmacy must—

- (1) not less than sixty (60) days prior to the opening of any pharmacy, submit to the registrar—
 - (a) a duly completed application on a form approved and provided by council for the registration of:
 - (i) the pharmacy in one or more of the prescribed categories of pharmacies;
 - (ii) a responsible pharmacist for each one of the premises wherein or from which he, she or it wants to carry on the business of a pharmacist; and
 - (iii) the person as pharmacy owner; and
 - (b) a copy of any lease agreement, sublease agreement or other agreement in terms of which the applicant has the right to occupy the proposed pharmacy premises;
 - (c) a copy of the site plan of the erf, and floor plan of the building, if applicable, indicating the location of the pharmacy premises in relation to adjoining or surrounding businesses and access to and from such premises;
 - (d) a copy of the plan of the layout of the actual pharmacy premises;
 - (e) a copy of any suretyship(s), financing-, infrastructure-, outsourcing-, sale-purchase or any other agreement(s) relating to the ownership, fixed costs, management, administration, financing or acquisition of the pharmacy; and
 - (f) in the event of a partnership of persons, a copy of the partnership agreement, stating the name of the pharmacist designated to accept responsibility for the duties as prescribed in regulations 24 and 25 of the Regulations Relating the Practice of Pharmacy; and
- (2) pay the registration fees as determined by the council.

68. The registrar must—

- (1) if he or she is satisfied that an application in terms of regulation 67 complies with the requirements of these regulations or the Act register such pharmacy; or
- (2) if he or she is not satisfied that the application complies with the requirements of these regulations or the Act submit such application for consideration to the council and the council may—
 - (a) refuse to register the pharmacy; or
 - (b) register the pharmacy subject to such conditions as it may deem fit; or
 - (c) register such pharmacy.

69. Every pharmacy registered in terms of regulation 68 must be issued with a registration certificate by the registrar.

70. A pharmacy must, subject to such conditions as may be determined by the council, if applicable, be conducted under the direct personal supervision of a responsible pharmacist, in accordance with good pharmacy practice as published by council in rules.

71. The council may inspect premises in which the business of a pharmacist is carried on and may provide the pharmacy owner with a written report of the findings of such inspection, if it is found that the such pharmacy does not comply with the prescribed requirements or is, in the opinion of the council unsuitable for the conduct of a pharmacy business.

72. Removal from the register.—Except as provided for in sections 23, 24 and 39 of the Act, the council may direct the registrar to remove from the register of pharmacies, the name of pharmacy—

- (1) which does not comply with any of the conditions of registration of such pharmacy;
- (2) if the responsible pharmacist fails to perform the duties of a responsible pharmacist as prescribed in terms of regulation 27 of the Regulations Relating to the Practice of Pharmacy;
- (3) if the managing director or nominee of a company or the manager or nominee of a close corporation who owns a pharmacy fails to perform the duties as prescribed in regulations 24 or 25, as the case may be, of the Regulations Relating to the Practice of Pharmacy; or
- (4) if the pharmacy fails to comply with good pharmacy practice as published by council in rules,

if, after the pharmacy owner has been given notice in the manner prescribed in regulation 103 of the intention to remove the name of the pharmacy from the relevant register and to close such pharmacy business and who has been afforded an opportunity to furnish the council with written reasons, within 14 days after the date upon which the notice is deemed to have been received in terms of sub-regulation 103 (2) and who fails to furnish acceptable reasons why its name should not be removed from the relevant register and why the pharmacy should not, as a result of such removal, be closed: provided that if the registrar is of the opinion that it is in the interest of the public, he or she may dispense with the required notice.

73. The pharmacy shall, as from the date on which notice of cancellation or withdrawal is deemed to have been received, be considered to be unsuitable for the carrying on of the business of a pharmacy.

74. Temporary closure of a pharmacy.—The council may, if it has received a complaint constituting *prima facie* evidence of a contravention of the Medicines Act or the Act which is deemed to constitute a risk to public health and safety, apply to a Magistrate for the district in which the person or pharmacy practises or carries on the business of a pharmacist, and upon good cause being shown, obtain a warrant authorising an officer or inspector duly appointed by the council in terms of section 4 (v) of the Act to either alone or with the assistance of the South African Police for a period not exceeding 90 days close a pharmacy pending an investigation: provided that the council shall provide reasons for the continued closure of the pharmacy concerned.

75. Restoration to the register.—The owner of a pharmacy whose pharmacy registration certificate has been cancelled or withdrawn and the name of the pharmacy has been removed from the register in terms of regulation 72 may have the name of the pharmacy restored to the register by—

- (1) submitting to the registrar:
 - (a) a duly completed application for restoration of the name of the pharmacy on a form as approved and provided by the council; and
 - (b) acceptable documentary evidence that the pharmacy again complies with the conditions for registration in terms of these regulations; and
- (2) pay the prescribed restoration fee; and
- (3) furnishing proof to the registrar that the pharmacy owner or responsible pharmacist, as the case may be, are fit and proper person(s) to own or conduct a pharmacy business: provided that if the registrar is not satisfied that the name of the pharmacy should be restored to the relevant register, the registrar must submit the application to the council for a decision.

76. Transitional arrangements.—A pharmacy registered in terms of the Act at the commencement of these regulations shall be deemed to be registered in terms of regulation 68.

CHAPTER XII

77. Appeals and appeal procedure.—The council must at its first meeting of every year appoint an appeal committee consisting of—

- (1) a chairperson appointed on account of his or her knowledge of the law;
- (2) a pharmacist registered with council, and resident in the Republic of South Africa; and
- (3) one additional person.

78. Any person whose rights may be adversely affected by any decision of the council, a committee of council, or the registrar regarding the registration, suspension or cancellation of the registration of a pharmacy, or him- or her- or itself, or of the nominee, or managing director of a company or manager of a close corporation entitled to carry on the business of a pharmacist in terms of the Act, may appeal against such decision to the appeal committee in the manner set out hereafter.

79. The appellant shall lodge his, her or its appeal against a decision referred to in regulation 78 within fourteen (14) days after notice of such decision in writing is deemed to have come to the notice of the appellant in terms of regulation 102 (2).

80. The notice of appeal must be in writing and under oath, stating in full the decision against which the appeal is lodged, the grounds on which such appeal is lodged, and must nominate a physical address, being not more than ten (10) kilometres from the offices of council where the appellant will accept delivery of all documents relevant to the appeal.

81. The notice of appeal must be lodged with the registrar together with:

- (1) payment of the fee as determined by council; and
- (2) four (4) copies of the record of appeal consisting of the decision appealed against, the written reasons for such decision, and all relevant documents, duly indexed and paginated,

after having served a copy thereof on all interested parties, who are hereafter referred to as the respondents.

82. The registrar must upon receipt of the notice of appeal, allocate a case number and notify the appellant, and all the respondents thereof.

83. The respondents may within fourteen (14) days of delivery to them, of the notice of appeal, deliver answering affidavits to the registrar, and must, if applicable, serve copies thereof on the appellant and all other respondents.

84. The appellant may within fourteen (14) days of delivery to him, her or it of the answering affidavits, deliver a replying affidavit.

85. The registrar must on the expiry of the period referred to in regulation 83 allocate a date for the hearing of the appeal and give the appellant and all respondents, written notice of the date of and venue for the hearing, whereupon the appeal is set down for hearing accordingly.

86. The registrar must inform members of the appeal committee of the date and venue for the hearing and furnish them with copies of the appeal record and the affidavits delivered by the appellant and the respondents.

87. Not less than seven (7) days before the appeal is to be heard the appellant must deliver to the appeal committee, and all respondents, one copy of a concise and succinct statement of the main points which he, she or it intends to argue on appeal, and provide a list of the authorities to be used in support of each point.

88. The respondents in an appeal, must deliver a statement similar to the one contemplated in regulation 88 to the appeal committee and the appellant five (5) days prior to the date of the hearing.

89. If an appeal has been properly noted, the decision appealed against and any execution thereof shall be suspended pending the outcome of the appeal, unless the appeal committee, upon the urgent motion of the council or the registrar, is, on the strength of *prima facie* proof, of the opinion that it is in the public interest that a temporary suspension order should be granted and imposed pending the outcome of the appeal.

90. The appeal committee may dismiss an appeal or, if it is of the opinion that the council, or a committee of council or the registrar, has not acted in accordance with the provisions of the Act, or that the decision constitutes an unjustified and unreasonable breach of the appellant's fundamental rights in terms of Chapter 2 of the Constitution of the Republic of South Africa, 1996 (Act 108 of 1998), it may make an order reversing, or modifying the decision appealed against and uplift the temporary suspension if applicable, or it may remit the matter to the decision making body or officer for further consideration, or make such other order, including an order as to costs, as it may deem appropriate.

CHAPTER XIII

91. Requirements and conditions for registration of providers of pharmacy education and training.—Only providers who comply with the minimum criteria for the approval of providers of pharmacy education and training as determined and published by council, shall be entitled to offer pharmacy education and training for purposes of conferring a qualification in pharmacy or a certificate of qualification or for purposes of continuing professional development.

92. Any person or institution who complies with the minimum criteria for the approval of providers of pharmacy education and training may register with council: provided that no person or institution must be registered as a provider, unless he, she or it complies with the provisions of regulation 93.

93. Any person or institution who applies for registration as a provider must—

- (1) submit to the registrar:
 - (a) a duly completed application on a form as approved and provided by council; and
 - (b) acceptable documentary evidence that such applicant adheres to the minimum criteria as determined by council for the approval of providers; and
- (2) pay the fees as determined by the council.

94. A person or institution which complies with the requirements of regulation 93 must be issued with a registration certificate by the registrar, subject to conditions as may be determined by council.

CHAPTER XIV

95. Requirements and conditions for registration of assessors of pharmacy education and training.—A pharmacist who complies with the minimum criteria for the approval of assessors of pharmacy education and training as determined by council from time to time shall be entitled to assess persons for purposes of registration as a pharmacist or pharmacist's assistant or for purposes of continuing professional development.

96. Any pharmacy approved by the council as an assessor of pharmacy education and training must register with the council: provided that no person must be registered as an assessor unless he or she complies with the provisions of regulation 97.

97. A pharmacist who applies for registration as an assessor must—

- (1) submit to the registrar:
 - (a) a duly completed application on a form approved and provided by the council; and
 - (b) acceptable documentary evidence that such applicant adheres to the minimum criteria as determined by council for the approval of assessors of pharmacy education and training; and
- (2) pay the fees as determined by council.

98. Each assessor who complies with the requirements of regulation 98 must be issued with a registration certificate by the registrar, subject to such conditions as may be determined by council.

CHAPTER XV

99. Requirements and conditions for the keeping and maintenance of registers.—For purposes of registration of pharmacies in terms of the Act, there shall be the following categories of pharmacies:

- (1) manufacturing pharmacy;
- (2) wholesale pharmacy;
- (3) institutional pharmacy;
- (4) community pharmacy; and
- (5) consultant pharmacy

which shall be registered by council in registers kept for this purpose.

100. Any person or pharmacy registered or required to be registered in terms of the Act or these regulations, must furnish the registrar with:

- (1) a postal address within the Republic which shall be deemed to be the registered address for all purposes in terms of the Act or these regulations;
- (2) a physical address being the main place of business of such person, company, close corporation or pharmacy;
- (3) a telefax address; and
- (4) an electronic mail address, if available.

101. A person registered in terms of the Act may at any time change the addresses registered in terms of regulation 100 by giving written notice to the registrar at the postal or telefax address of the registrar as published in official stationary of the council from time to time, of the change of one or more or all of such addresses; provided that the new addresses must include a postal, physical, telefax, and, if available, an electronic mail address, in the Republic.

102. Any notice to be given in terms these regulations:

- (1) must be in writing and addressed to and may be sent by registered mail to the registered address, or may be delivered by hand to the physical address, or may be sent by telefax to the telefax address, or may be forwarded by electronic mail to the relevant address, recorded by the registrar in terms of regulation 100; and
- (2) shall be deemed to have been properly given and to have been received and to have come to the notice of the addressee:
 - (a) within ten (10) days after the day on which the notice or document was sent by pre-paid registered post, if posted;
 - (b) within one (1) day after the date and at the time (if any) which appears on the acknowledgement of receipt of the notice or document, if delivered by hand;
 - (c) within three (3) days after the date appearing on the telefax control sheet of the sender, if sent by telefax;

- (d) within three (3) days after the date appearing on the electronic mail message, if sent by electronic mail.

103. A certificate issued by the registrar will be deemed to be *prima facie* proof until the contrary has been proved by any person challenging receipt of any notice or document—

- (1) that notice was given or that the document was sent or delivered;
- (2) of the date upon which such notice was given, or document was sent or delivered; and
- (3) of the date upon which the notice or document is deemed to have been received and to have come to the notice of the addressee.

104. Keeping of registers.—The registrar must in accordance with the provisions of the Act keep the following registers:

- (1) a register of pharmacy students, in which must be entered the name of every person registered with a provider of a qualification in pharmacy and who has complied with the requirements prescribed for registration as a pharmacy student, as well as his or her registration number, date of registration and the name of the provider with which he or she is registered and such other information as may be determined by the registrar;
- (2) a register of pharmacist interns, in which must be entered the name, address and qualifications of every person who has entered into a contract of internship referred to in regulation 9, registration number and such other information as may be determined by the registrar;
- (3) a register of pharmacists, in which must be entered the name, address, qualifications, date of initial registration, registration number and such other information as may be determined by the registrar;
- (4) a register of specialist pharmacists, in which must be entered the name, address, qualifications, date on which such qualification was obtained and the date of initial registration and such other information as may be determined by the registrar;
- (5) a register of pharmacists' assistants in which must be entered the name, address, registration number, date of registration, category of persons entitled in terms of this Act to be registered as a pharmacist assistant and such other information as may be determined by the registrar;
- (6) a register of companies entitled to carry on the business of a pharmacist in which must be entered the name, registration number, address, name of managing director and nominee and such other information as may be determined by the registrar;
- (7) a register of close corporations entitled to carry on the business of a pharmacist in which must be entered the name, registration number, address, name of manager and nominee and such other information as may be determined by the registrar;
- (8) a register of providers in which shall be entered the name, address, registration number, date of registration and such other information as may be determined by the registrar;
- (9) a register of assessors in which shall be entered the name, address, registration number, date of registration and such other information as may be determined by the registrar;
- (10) a register of pharmacy owners in which shall be entered the name, address, registration number and date of registration and, if applicable, the name of the

managing director, manager and the nominee and such other information as may be determined by the registrar;

- (11) a register of pharmacies in which shall be entered the:
 - (a) name and address of the pharmacy;
 - (b) name and address of the pharmacy owner;
 - (c) name of the responsible pharmacist;
 - (d) name of the managing director or manager, as the case may be;
 - (e) name of the nominee, if applicable;
 - (f) category in which such pharmacy is registered; and
 - (g) such other information as may be determined by the registrar; and
- (12) such other registers as may be determined by council.

105. Maintenance of registers.—

- (1) No qualification in pharmacy, certificate of qualification, diploma, certificate or registration or any other information must be entered in a register unless the registrar is satisfied that the person claiming to possess such degree, diploma or certificate is entitled thereto or such information is correct;
- (2) Any entry into the register which is proved to the satisfaction of the council to have been made in error or through misrepresentation or in circumstances not authorised by this Act, may be removed from the register; and
- (3) A person in respect of whose entry a removal as contemplated in sub-regulation (2) has been made, must be notified thereof and any certificate issued in respect of the registration in question shall be deemed to be cancelled as from the date on which notice has so been given.

106. Every person registered in terms of these regulations must renew such registration annually by paying the annual fee(s) as determined by council.

107. The pharmacy owner or the nominee or managing director of a company, or manager or nominee of a close corporation who is entitled to carry on the business of a pharmacist, as the case may be, must, within 30 days:

- (1) after the forwarding by the registrar of a written inquiry by registered mail requesting information relating to the ownership or any direct or indirect beneficial interest in a pharmacy, furnish the registrar with such information and acceptable documentary evidence in support thereof;
- (2) after the occurrence of any of the following notify the registrar in writing of:
 - (a) the closure of a pharmacy;
 - (b) a change of beneficial interest in shares or members' interest for which purpose a change in the effective control of a company, close corporation shall be deemed to be a change in ownership;

- (c) a change in:
 - (i) the shareholders or directors of a company entitled to carry on the business of a pharmacist;
 - (ii) the members of a close corporation entitled to carry on the business of a pharmacist;
 - (d) a change of premises of a pharmacy;
 - (e) a change of the responsible pharmacist or managing director or manager or nominee;
 - (f) the managing director or manager ceasing to in fact manage the professional aspects of the pharmacy business; or
 - (g) a change in his or her or its physical or postal address; or
- (3) of the forwarding by the registrar of a written enquiry by registered mail requesting information which is reasonably necessary or which may be regarded as reasonably necessary for the performance or exercising of the functions or powers of the council or the registrar in terms of the Act, answer such enquiry in writing and furnish the registrar with all the necessary documentary and other proof in support of the furnished information.

108. The pharmacy owner or the nominee or managing director of a company, or manager or nominee of a close corporation, as the case may be, who is entitled to carry on the business of a pharmacist must within seven days of the date of the designation of a new managing director or manager or nominee—

- (1) submit to the registrar:
 - (a) a duly completed application for the registration of the new nominee or managing director or manager, as the case may be, on a form as approved and provided by the council;
 - (b) a copy of the letter:
 - (i) addressed to the person who is to be registered as the nominee or the manager or the managing director, as the case may be;
 - (ii) from the person so appointed accepting the appointment as nominee or managing director or manager, as the case may be; and
- (2) pay the registration fee as determined by council.

109. The managing director of a company or the manager of a close corporation who is entitled to carry on the business of, or who owns a retail pharmacy must on or before the thirty first day of January of each year furnish the registrar with schedules, certified as correct by auditors or the accounting officer of such company or close corporation, of the directors and shareholders or members, as the case may be, of such company or close corporation.

110. Every natural person registered in terms of the Act who changes his or her name or address must in writing notify the registrar thereof within thirty days after such change.

111. Transitional arrangements.—The managing director of a company or the manager of a close corporation entitled to carry on the business of a pharmacist and who is registered as such with council at the commencement of these regulations, shall be deemed to be the managing director and nominee of such company or manager and nominee of such close corporation, as the case may be.

112. The manager of a pharmacy who is registered in terms of the Act at the commencement of these regulations shall be deemed to be the responsible pharmacist of such pharmacy.

Repeal

The regulations or rules published under Government Notice No. R.348 of 21 February 1975; Government Notice No. R.1477 of 1 August 1975; Government Notice No. R.1489 of 1 August 1975; Government Notice No. R.826 of 25 April 1980; Government Notice No. R.720 of 8 April 1983; Government Notice No. R.348 of 2 March 1984; and Board Notice 79 of 18 December 1987 are hereby repealed.