GNR.1158 of 20 November 2000: Regulation relating to the practice of pharmacy

DEPARTMENT OF HEALTH

The Minister of Health has, in consultation with the South African Pharmacy Council, in terms of section 35A of the Pharmacy Act, 1974 (Act 53 of 1974), as amended, made the regulations in the Schedule.

ME TSHABALALA-MSIMANG
Minister of Health

SCHEDULE

ARRANGEMENT OF REGULATIONS

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

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

"community pharmacy" means a pharmacy wherein or from which some or all of the services as prescribed in regulation 18 of these regulations are provided to persons requiring pharmaceutical services, but excludes an institutional pharmacy;

"consultant pharmacy" means a pharmacy wherein or from which some or all of the services as prescribed in regulation 19 of these regulations are provided to persons requiring pharmaceutical services;

"direct personal supervision" means guidance and support by a pharmacist whilst physically present in a pharmacy;

"dispensing" means the interpretation and evaluation of a prescription, the selection, manipulation or compounding of the medicine, the labelling and supply of the medicine in an appropriate container according to the Medicines Act and the provision of information and instructions by a pharmacist to ensure the safe and effective use of medicine by the patient and **"dispense"** has a corresponding meaning;

"indirect personal supervision" means guidance and support by a pharmacist in accordance with a standard operating procedure approved by the council whilst absent from a pharmacy;

"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 these regulations 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 these regulations are provided to persons requiring pharmaceutical services from or at that private health facility,

but excludes a community 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 these regulations;

"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 these regulations;

"manufacture" means all operations including purchasing of raw material, processing, production, packaging, releasing, storage, quality assurance, importation, exportation of medicine and scheduled substances and related control and **"manufacturing"** has a corresponding meaning;

"manufacturing pharmacy" means a pharmacy wherein or from which some or all of the services as prescribed in regulation 16 of these regulations 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" shall have the same meaning as defined in terms of the Medicines Act;

"Medicines Act" means the Medicines and Related Substances Control Act, 1965 (Act 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 performing the duties as prescribed in regulation 24 of these regulations;

"pharmacist's assistant" means a natural person registered in one of the following categories:

(*a*) pharmacist's assistant (learner basic);

(*b*) pharmacist's assistant (basic);

(*c*) pharmacist's assistant (learner post-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;

"pharmacist initiated therapy" means the supply of medicine to meet the health needs of a patient or group of patients without a prescription of a person authorised to prescribe medicines;

"primary care drug therapy" means diagnosing a health need, prescribing and supplying of medicine to meet the health needs of a patient or group of patients or, where necessary, the referral to another health care provider by a pharmacist who has received the necessary authorisation from council;

"primary health care clinic" means an institution, facility, building, or place where persons receive primary health care treatment, diagnostic or therapeutic interventions or other primary health care services that is owned or controlled by an organ of State;

"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;

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

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

"re-packaging" means the removing of a medicine from its original container and placing it into a patient ready pack and **"pre-packaging"** have corresponding meanings;

"scheduled substance" shall have the same meaning as defined in terms of the Medicines Act;

"sell" shall have the same meaning as defined in terms of the Medicines Act;

"wholesale pharmacy" means a pharmacy wherein or from which some or all of the services as prescribed in regulation 17 of these regulations are provided and who 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. Conditions under which services or acts must be provided or performed.—The services or acts pertaining to the scope of practice of natural persons registered in terms of the Act must be provided or performed in accordance with the Medicines Act and good pharmacy practice and a code of conduct as published by council in rules.

3. Acts specially pertaining to the profession of a pharmacist.—Except as provided for in section 29 (3) of the Act, and sections 23 (2) (*a*) (i) and 34 of the Veterinary and Para-Veterinary Professions Act, 1982 (Act 19 of 1982), the following acts shall be regarded to be acts specially pertaining to the profession of a pharmacist—

(1) the provision of pharmaceutical care by taking responsibility for the patient's medicine related needs and being accountable for meeting these needs, which shall include but not be limited to the following functions:

(*a*) evaluation of a patient's medicine related needs by determining the indication, safety and effectiveness of the therapy;

(*b*) dispensing of any medicine or scheduled substance on the prescription of a person authorised to prescribe medicine;

(*c*) furnishing of information and advice to any person with regard to the use of medicine;

(*d*) determining patient compliance with the therapy and follow up to ensure that the patient's medicine related needs are being met; and

(*e*) the provision of pharmacist initiated therapy;

(2) the compounding, manipulation, preparation or packaging of any medicine or scheduled substance or the supervision thereof;

(3) the manufacturing of any medicine or scheduled substance or the supervision thereof;

(4) the purchasing, acquiring, importing, keeping, possessing, using, releasing, storage, packaging, repackaging, supplying or selling of any medicine or scheduled substance or the supervision thereof; and

(5) the application for the registration of a medicine in accordance with the Medicines Act.

CHAPTER II

4. Scope of practice of a pharmacist.—The following services or acts shall for purposes of the Act be regarded to be services or acts pertaining to the scope of practice of a pharmacist:

(1) the Acts specially pertaining to the profession of a pharmacist as prescribed in regulation 3;

(2) the formulation of any medicine for the purposes of registration as a medicine;

(3) the distribution of any medicine or scheduled substance;

(4) the repackaging of medicines;

(5) the initiation and conducting of pharmaceutical research and development; and

(6) the promotion of public health.

CHAPTER III

5. Scope of practice of a pharmacist intern.—A pharmacist intern may provide or perform all of the services or acts pertaining to the scope of practice of a pharmacist's assistant registered in the category pharmacist's assistant (post-basic) under the direct personal supervision of a pharmacist in a pharmacy.

6. A pharmacist intern may, for the purposes of education and training, provide or perform all of the services or acts pertaining to the scope of practice of a pharmacist under the direct personal supervision of a pharmacist in a pharmacy.

CHAPTER IV

7. Scope of practice of a pharmacy student.—

(1) A pharmacy student may provide or perform all of the services or acts pertaining to the scope of practice of a pharmacist's assistant registered in the category pharmacist's assistant (basic) under the direct personal supervision of a pharmacist in a pharmacy; or

(2) A pharmacy student who has successfully completed his or her second year of study may provide or perform all of the services or acts pertaining to the scope of practice of a pharmacist's assistant registered in the category pharmacist's assistant (post-basic) under the direct personal supervision of a pharmacist in a pharmacy.

8. (1) A pharmacy student may, for purposes of education and training, and under the auspices of a provider approved to offer education and training for a qualification in pharmacy and with whom such student is enrolled, provide or perform all of the services or acts pertaining to the scope of practice of a pharmacist under the direct personal supervision of a pharmacist; and

(2) The services or acts referred to in subregulation 8 (1) must be provided or performed in accordance with a programme developed by the provider and approved by the council.

CHAPTER V
SCOPE OF PRACTICE OF PHARMACY SUPPORT PERSONNEL

9. Pharmacist's assistant (basic).—A pharmacist's assistant registered in the category pharmacist's assistant (basic) may perform the following services or acts under the direct personal supervision of a pharmacist in a pharmacy:

(1) the sale of Schedule 1 medicines or scheduled substances;

(2) assist with the compounding, manipulation or preparation of a non-sterile medicine or scheduled substance according to a formula and standard operating procedures approved by the responsible pharmacist;

(3) assist with the manufacturing of a non-sterile medicine or scheduled substance according to a formula and standard operating procedures approved by the responsible pharmacist;

(4) the re-packaging of medicine;

(5) the distribution and control of stock of Schedule 1 to Schedule 6 medicines or scheduled substances; and

(6) the provision of information to individuals in order to promote health.

10. Pharmacist's assistant (learner basic).—A pharmacist's assistant registered in the category pharmacist's assistant (learner basic) may for the purposes of education and training, provide the services or perform the acts prescribed in regulation 9 under the direct personal supervision of a pharmacist in a pharmacy.

11. Pharmacist's assistant (post-basic).—A pharmacist's assistant registered in the category pharmacist's assistant (post-basic) may perform the following services or acts under the direct personal supervision of a pharmacist in a pharmacy:

(1) the sale of Schedule 1 and Schedule 2 medicines or scheduled substances;

(2) assist with the compounding, manipulation or preparation of a non-sterile or sterile medicine or scheduled substance according to a formula and standard operating procedures approved by the responsible pharmacist;

(3) assist with the manufacturing of a non-sterile or sterile medicine or scheduled substance according to a formula and standard operating procedures approved by the responsible pharmacist;

(4) the re-packaging of medicine;

(5) the distribution and control of stock of Schedule 1 to Schedule 7 medicines or scheduled substances;

(6) the ordering of medicine and scheduled substances up to and including Schedule 7 according to an instruction of a person authorised in terms of the Medicines Act to purchase or obtain such medicine or scheduled substance;

(7) the reading and preparation of a prescription, the selection, manipulation or compounding of the medicine, the labelling and supply of the medicine in an appropriate container following the interpretation and evaluation of the prescription by a pharmacist;

(8) the provision of instructions regarding the correct use of medicine supplied; and

(9) the provision of information to individuals in order to promote health.

12. Notwithstanding the provisions in regulation 11, a pharmacist's assistant registered in the category pharmacist's assistant (post-basic) may perform the acts or provide services as prescribed in subregulations 11 (5), 11 (6), 11 (8) and 11 (9), as well as the reading and preparation of a prescription, the selection, manipulation or compounding of medicine and the labelling and supply of medicine in an appropriate container under the indirect personal supervision of a pharmacist: provided that such indirect personal supervision will take place only under the following circumstances:

(1) the services are provided or acts are performed at a primary health care clinic or any other facility as approved by council;

(2) only re-packaged medicines or patient ready packs are provided;

(3) written and updated protocols and standard operating procedures are available describing clearly the responsibility of the pharmacist's assistant and pharmacist under whose indirect personal supervision the pharmacist's assistant performs the acts and provides the services; and

(4) the pharmacist under whose indirect personal supervision the pharmacist's assistant performs the acts and provides the services visits the pharmacist's assistant at the primary health care clinic or other facility as approved by council for purposes of supervision and support, which visits must be documented and take place at least once a month.

13. Pharmacist's assistant (learner post-basic).—A pharmacist's assistant registered in the category pharmacist's assistant (learner post-basic) may for the purposes of education and training, provide or perform the services or acts prescribed in regulation 11 under the direct personal supervision of a pharmacist in a pharmacy.

14. Supervision of pharmacy support personnel.—A pharmacist may not—

(1) have under his or her direct personal supervision more than three pharmacists' assistants in a pharmacy; or

(2) subject to regulation 12, have more than five pharmacists' assistants (post-basic) under his or her indirect personal supervision.

15. Notwithstanding regulation 14 the council may approve a written application for an increase in the ratio as stipulated in regulation 14: provided that—

(1) each application is treated on its own merit;

(2) the motivation for such application is to the satisfaction of council; and

(3) any increase in the ratio approved by council shall apply in that specific circumstance or situation only and be subject to such conditions as the council may determine.

CHAPTER VI
SERVICES WHICH MAY BE PROVIDED IN THE VARIOUS CATEGORIES OF PHARMACIES

16. Manufacturing pharmacy.—Except as provided for in the Medicines Act, only the following services pertaining to the scope of practice of a pharmacist, may be provided in a manufacturing pharmacy—

(1) the manufacturing of any medicine or scheduled substance;

(2) the purchasing, acquiring, keeping, possessing, using, supplying or selling of any medicine or scheduled substance;

(3) the furnishing of information and advice to any person with regard to medicine manufactured by him, her or it;

(4) the application for the registration of a medicine or medical device;

(5) the formulation of medicine for the purposes of registration as a medicine;

(6) the distribution of medicine or scheduled substances;

(7) the repackaging of medicine in accordance with the Medicines Act;

(8) the initiation and conducting of pharmaceutical research and development; and

(9) any other health service as may be approved by council from time to time.

17. Wholesale pharmacy.—Except as provided for in the Medicines Act, only the following services pertaining to the scope of practice of a pharmacist, may be provided in a wholesale pharmacy—

(1) the wholesale distribution of any medicine or scheduled substance through the purchasing, acquiring, keeping, possessing, using, supplying or selling of any medicine or scheduled substance;

(2) the furnishing of information and advice to any person with regard to medicine distributed by him, her or it;

(3) the application for the registration of a medicine or medical device;

(4) the initiation and conducting of pharmaceutical research and development; and

(5) any other health service as may be approved by council from time to time,

Provided that regulation 17 shall not prohibit the repackaging of medicine in wholesale pharmacies owned or controlled by an organ of the State in accordance with the Medicines Act.

18. Community or institutional pharmacy.—Except as provided for in the Medicines Act, the following services pertaining to the scope of practice of a pharmacist may be provided in a community or institutional pharmacy—

(1) the provision of pharmaceutical care by taking responsibility for the patient's medicine related needs and being accountable for meeting these needs, which shall include but not be limited to the following functions:

(*a*) evaluation of a patient's medicine related needs by determining the indication, safety and effectiveness of the therapy;

(*b*) dispensing of any medicine or scheduled substance on the prescription of an authorised prescriber;

(*c*) furnishing of information and advice to any person with regard to medicine;

(*d*) determining patient compliance with the therapy and follow up to ensure that the patient's needs are being met; and

(*e*) provision of pharmacist initiated therapy;

(2) the compounding, manipulation or preparation of any medicine or scheduled substance;

(3) the purchasing, acquiring, keeping, possessing, using, supplying or selling of any medicine or scheduled substance;

(4) the application for the registration of a medicine or medical device;

(5) the re-packaging of medicine;

(6) the promotion of public health in accordance with guidelines and standards as determined by a competent authority which includes but shall not be limited to:

(*a*) the provision of information and education regarding the promotion of human health;

(*b*) the provision of immunisation, mother and childcare, blood pressure monitoring; health education; blood-glucose monitoring; screening tests for pregnancy; family planning; cholesterol screening tests; HIV screening tests; urine analysis; and visiometric and audiometric screening tests;

(*c*) the provision of animal health care services which includes:

(i) the compounding and dispensing of prescriptions written by veterinarians and ensuring the optimal use of veterinary medicines;

(ii) the immunisation of animals;

(iii) the handling of minor and/or self-limiting ailments in animals; and

(iv) the provision of information and education regarding the promotion of animal health.

(7) the initiation and conducting of pharmaceutical research and development;

(8) the provision of primary care drug therapy with prior authorisation from council; and

(9) any other health service as may be approved by council from time to time.

19. Consultant pharmacy.—Only the following services pertaining to the scope of practice of a pharmacist may be provided in a consultant pharmacy—

(1) the provision of pharmaceutical care with the goal of improving compliance with medicine therapy and which shall be limited to the following functions:

(*a*) evaluation of a patient's medicine regimen with respect to the indications, safety and effectiveness of therapy;

(*b*) the provision of information and advice to any person with regard to the use of medicine; and

(*c*) determining patient compliance with the therapy and follow up to ensure that the patient's medicine related needs are being met;

(2) the initiation and conducting of pharmaceutical research and development;

(3) the application for the registration of a medicine or medical device;

(4) the promotion of public health; and

(5) any other health service as may be approved by the council from time to time.

CHAPTER VII

20. Conditions under which a pharmacy shall be conducted.—The services provided or acts performed in the various categories of pharmacy shall be performed in accordance with—

(1) good pharmacy practice as published by council in rules; and

(2) the code of conduct as published by council in rules for pharmacists and other persons registered in terms of the Act; and

(3) the provisions of applicable legislation.

21. Only pharmacists or pharmacist interns and pharmacist's assistants under the direct personal supervision of a pharmacist, may handle scheduled substances in a pharmacy.

22. Every pharmacy shall, except in such circumstances and subject to such conditions as may be published in rules by the council, be conducted under the direct personal supervision of a responsible pharmacist whose name must be displayed conspicuously over the main entrance of such pharmacy.

23. The name of the pharmacist(s) on duty must be displayed conspicuously in the pharmacy for purposes of identification of such person(s) by the public.

CHAPTER VIII

24. Authority, duties and responsibilities of the nominee, managing director of a company or manager of a close corporation entitled to carry on the business of a pharmacist.—The nominee appointed as such for a company or close corporation entitled to carry on the business of a pharmacist must—

(1) complete and submit the application forms approved and provided by council in respect of the registration of the company or close corporation entitled to carry on the business of a pharmacist and if applicable, its pharmacy business;

(2) ensure that the company or close corporation which owns a pharmacy does not carry on the business of a pharmacist without a managing director or manager, as the case may be;

(3) pay the applicable fees as determined by council in respect of the company or the close corporation and if applicable, its pharmacy business;

(4) furnish the information prescribed in terms of the Regulations Relating to the Registration of Persons and the Maintenance of Registers; and

(5) ensure that there is compliance at all relevant times—

(*a*) with the requirements which entitled such company or close corporation to own a pharmacy; and

(*b*) with the conditions of registration of the pharmacy.

25. The managing director of a company or the manager of a close corporation entitled to carry on the business of a pharmacist must—

(1) undertake the overall administration of the pharmacy business, which includes but is not limited to the regulation of pharmacy matters, human resources, or matters relating to processes regarding medicines or scheduled substances including procedures and record keeping and shall be responsible to council for any act performed by or on behalf of such company or close corporation, including any omission to perform an act required to be performed by or on behalf of such owner which may involve disciplinary action by council, unless he or she can satisfy council that the responsibility for such act rests upon the nominee, responsible pharmacist or a pharmacist other than him-, or herself employed by such company or close corporation;

(2) ensure that there is compliance with good pharmacy practice as published by council in rules;

(3) ensure that a responsible pharmacist is appointed for each pharmacy wherein or from which the company or close corporation conducts business;

(4) be part of the decision making process affecting the pharmacy business;

(5) supervise every responsible pharmacist appointed by the owner of a pharmacy business, if applicable;

(6) ensure that the pharmacy owner complies with all the conditions of—

(*a*) ownership of such pharmacy business; and

(*b*) registration of the pharmacy; and

(7) ensure that no person is appointed to perform any act falling outside the scope of practice of the category in which such person is registered or which he/she is not authorised to perform in terms of the Act;

(8) report in writing any non-compliance with subregulations 25 (2), 25 (3), 25 (5) or 25 (6) to the management of such pharmacy business and furnish Council with a copy thereof; and

(9) not introduce or carry out any instruction or order from management with regard to the pharmacy business of the pharmacy owner which could amount to a contravention of legislation applicable to such pharmacy business.

26. A pharmacist who owns a pharmacy as a sole owner shall have the duties and responsibilities as set out in regulations 24 and 25 of these regulations relating to his or her pharmacy business.

27. A pharmacist designated in the partnership agreement of partnership of persons who owns a pharmacy shall have the duties and responsibilities as set out in regulations 24 and 25 of these regulations relating to such pharmacy business.

28. The responsible pharmacist contemplated in regulation 25 (3) must—

(1) ensure that he or she in fact continuously supervises the pharmacy in which he or she has been appointed;

(2) have appropriate qualifications and experience in the services being rendered by such pharmacy;

(3) ensure that persons employed in such pharmacy and who provide services forming part of the scope of practice of a pharmacist are appropriately registered with council;

(4) notify council immediately upon receiving knowledge that his/her services as responsible pharmacist have been or will be terminated;

(5) take corrective measures in respect of deficiencies with regard to inspection reports of council or in terms of the Medicines Act; and

(6) in addition to the general responsibilities also—

(*a*) ensure that unauthorised persons do not obtain access to medicines or scheduled substances or the pharmacy premises outside of normal trading hours;

(*b*) establish policies and procedures for the employees of the pharmacy with regard to the acts performed and services provided in the pharmacy;

(*c*) ensure the safe and effective storage and keeping of medicine or scheduled substances in the pharmacy under his or her direct personal supervision; and

(*d*) ensure correct and effective record keeping of the purchase, sale, possession, storage, safekeeping and return of medicines or scheduled substances.

29. Repeal.—The regulations published under Government Notice No. R.2848 of 21 December 1979 are hereby repealed.