THE PHARMACY AND POISONS (AMENDMENT) ACT, 1992

No. 12 of 1992

Date of Assent: 28th October, 1992

Date of Commencement: 6th November, 1992

An Act of Parliament to amend the Pharmacy and Poisons Act

ENACTED by the Parliament of Kenya, as follows:—

Short title.

1. This Act may be cited as the Pharmacy and Poisons (Amendment) Act, 1992.

Amendment of section 2 of Cap. 244.

2. Section 2 of the Pharmacy and Poisons Act, in this Act referred to as the principal Act, is amended—

(*a*) by inserting the following new definitions in their proper alphabetical sequence—

"manufacture" means any process carried out in the course of making a product or medicinal substance and includes packaging, blending, mixing, assembling, distillation, processing, changing of form or application of any chemical or physical process in the preparation of a medicinal substance or product; but does not include dissolving or dispensing the product by diluting or mixing it with some other substances used as a vehicle for administration;

"medicinal substance" means any medicine, product, article, or substance which is claimed to be useful for any of the following purposes—

(*a*) treating, preventing or alleviating disease or symptoms of disease;

(*b*) diagnozing disease or ascertaining the existence, degree or extent of a physiological condition; or

(*c*) preventing or interfering with the normal operation of a physiological function whether permanently or temporarily and whether by way of

terminating, reducing, postponing or increasing or accelerating the operation of the function in human beings or animals;

"pharmaceutical analyst" means an analyst registered by the Board for the purposes of this Act;

"pharmaceutical inspector" means any person appointed as a pharmaceutical inspector by the Board;

(*b*) in the definition of "authorized officer" by—

(i) inserting the expression "pharmaceutical analyst" and "pharmaceutical inspector" immediately after "registrar"; and

(ii) deleting the expression "Assistant Inspector" and inserting "Superintendent".

Insertion of new Parts in Cap. 244.

3. The principal Act is amended by inserting the following new Parts immediately after section 35—

PART IIIA—MANUFACTURE OF MEDICINAL SUBSTANCES

Licence to manufacture medicinal substances.

35A. (1) No person shall manufacture any medicinal substance unless he has been granted a manufacturing licence by the Board.

(2) Each manufacturing licence shall expire on the 31st December of every year and the renewal thereof shall be subject to compliance with conditions prescribed by the Board.

(3) No person shall manufacture any medicinal substance for sale unless he has applied for and obtained a licence from the Board in respect of each substance intended to be manufactured.

(4) Any person who intends to manufacture a medicinal substance shall make an application in the prescribed form for the licensing of the premises; and the application shall be accompanied by the prescribed fee.

(5) The Director of the National Drug Quality Control Laboratory or any member of the Laboratory staff authorized by him shall have power to enter and sample any medicinal substance under production in any manufacturing premises and

certify that the method of manufacture approved by Board is being followed.

Compliance with good manufacturing practice.

35B. Every person who is granted a manufacturing licence under section 35A shall comply with the good manufacturing practices prescribed by the Board.

PART IIIB—NATIONAL QUALITY CONTROL LABORATORY

Interpretation of Part.

35C. In this Part, unless the context otherwise requires—

"Director" means the Director of the National Quality Control Laboratory appointed under section 35 H;

"Laboratory" means the National Quality Control Laboratory established under section 35D.

Establishment of the National Drug Quality Control Laboratory.

35D. (1) There shall be established a National Quality Laboratory which shall be used as a facility for—

(*a*) the examination and testing of drugs and any material or substance from or with which and the manner in which drugs may be manufactured, processed or treated and ensuring the quality control of drugs and medicinal substances;

(*b*) performing chemical, biological, biochemical, physiological and pharmacological analysis and other pharmaceutical evaluation; and

(*c*) testing, at the request of the Board and on behalf of the Government, of locally manufactured and imported drugs or medicinal substances with a view to determining whether such drugs or medicinal substances comply with this Act or rules made thereunder.

Incorporation of the Laboratory.

35E. (1) The Laboratory shall be a body corporate with perpetual succession and a common seal and shall have power to sue and be sued in its corporate name and to acquire, hold and dispose of movable and immovable property for its own purposes.

Board of management.

35F. (1) There shall be a Board of Management for the Laboratory which shall consist of nine members to be appointed by the Pharmacy and Poisons Board.

(2) A member of the Board of Management appointed under subsection (1) shall hold office for three years but shall be eligible for re-appointment.

(3) A quorum of the Board of Management shall be five members.

(4) The Board of management shall meet not less than four times each calendar year.

(5) The Director shall be the secretary of the Board of Management.

(6) Subject to this subsection, the Board of Management may regulate its own procedure.

Functions of the Board of Management.

35G. The functions of the Board of Management shall be—

(*a*) to administer the property and funds of the Laboratory in such manner and for such purposes as shall, in the opinion of the Board of Management, promote its best interests;

(*b*) to receive, on behalf of the Laboratory, grants-in-aid, gifts, donations, fees, subscriptions or other moneys and make disbursements therefrom;

(*c*) to make regulations governing the appointment, conduct and discipline of employees of the Laboratory;

(*d*) in consultation with the Minister, to draw up a scheme of service for employees of the Laboratory;

(*e*) to administer the approved terms and conditions of service, including appointments, dismissals, remuneration and retiring benefits of employees of the Laboratory; and

(*f*) to appoint such employees upon terms and conditions to be laid down by the Board

of Management, after consultation with the Minister, as it considers necessary for the proper and efficient administration of the Laboratory.

Director.

35H. (1) The Board of Management shall appoint a Director who shall be the chief executive of the Laboratory responsible to the Board of Management for the day to day management of the Laboratory.

(2) The Director shall hold office on such terms and conditions of service as may be specified in the instrument of his appointment.

Powers of the Director.

35I. The Director shall have power—

(*a*) to develop and administer a data bank on quality assurance on behalf of the Board of management;

(*b*) to inspect premises and issue certificates of compliance; and

(*c*) to advise and obtain advice from the Board of Management in regard to any matter within his purview under this Act.

Financial provisions.

35J. (1) The funds to be used for the management of the Laboratory shall consist of all moneys received or recovered under this Part and any moneys provided by Parliament.

(2) The Laboratory may accept gifts, donations, subscriptions, fees and other moneys for the implementation of approved programmes.

(3) The financial year of the Laboratory shall be the same as the Government financial year.

(4) The estimates for the expenditure of the Laboratory shall be submitted through the Minister for approval by the Treasury and shall make provisions for—

(*a*) the payment of salaries, allowances and all other charges in respect of the employees of the Laboratory;

(*b*) the payment of pensions, gratuities and all other charges in respect of retirement benefits payable out of the funds of the Laboratory;

(*c*) the procurement, proper maintenance, repair and replacement of equipment and other immovable property of the Laboratory;

(*d*) the proper maintenance of the buildings and grounds of the Laboratory;

(*e*) the creation of such reserve funds to meet future or contingent liabilities in respect of retiring benefits, insurance or replacement of building or equipment or in respect of such other matters as the Board of Management may think fit;

(*f*) the cost of Board of Management meetings; and

(*g*) capital expenditure.

(4) The Board of Management shall cause to be kept and the Director shall keep all proper books of accounts of the Laboratory.

(5) The accounts of the Laboratory shall be audited by the Auditor-General (Corporations).

(6) The disposal of fixed assets by the Board of Management shall be subject to the approval of the Treasury.

Certificate of analysis.

35K. (1) A certificate of analysis shall be issued and signed by the Director for every analysis done.

(2) The certificate of analysis issued under subsection (1) shall be in the prescribed form.

Amendment of section 44 of Cap. 244.

4. Section 44 of the principal Act is amended by inserting the following new paragraph—

(*mm*) prescribing the qualification for registration of pharmaceutical analysts.