INDEPENDENT STATE OF PAPUA NEW GUINEA

STATUTORY INSTRUMENT

No of 2002.

Medicines and Cosmetics Regulation 2002.

Being a regulation,

MADE by the Head of State, acting with, and in accordance with, the advice of the National Executive Council under the ***Medicines and Cosmetics Act 1999.***

PART I. – PRELIMINARY.

1.INTERPRETATION.

In this Regulation, unless the contrary intention appears –

"the act" means the Medicines and Cosmetics Act 1999;
"active ingredient "means the therapeutically active component in a medicinal products final formulation that is responsible for its physiological or pharmacological action;
"antiseptic" means a substance that is intended for application on the body or the mucous membranes of a person or an animal to kill or prevent the growth of a broad range of micro-organisms, and that is not represented to be suitable for internal use;
"batch" A defined quantity of a starting material, packaging material, or product processed in a single process or a series of processes so that it can be expected to be homogeneous;
"clinical trial" means any systematic study on medicinal products in human subjects, whether in patients or other volunteers, in order to discover or verify the effects of, or identify any adverse reaction to, investigational products, or to study the absorption, distribution, metabolism and excretion of the products with the object of ascertaining their efficacy and safety;
"dosage form" means the form of the completed pharmaceutical product, such as tablet, capsule, elixir, injection, suppository and so on;
"disinfectant" means a substance that is intended for application to inanimate objects to kill a broad range of micro-organisms, and that is not represented to be suitable for the internal use in, or dermal use on, a person or an animal;
"poison" means a substance or preparation that is included in a schedule to the poisons standard;
"shelf-life " means the period of time during which a drug product, if stored correctly, is expected to comply with the specification as determined by stability studies on a number of batches of the product;
"Good Manufacturing Practices (GMP)" means the part of the Quality Assurance which, ensures that medicinal products are consistently produced and controlled to the quality standards appropriate to their intended use and the GMP's referred to are those of the World Health Organization (WHO Expert Committee on Specifications for Pharmaceutical Preparations, Thirty-second report, Geneva, World Health Organization, 1992:14-79 - (WHO Technical Report Series, No.823) with supplementary guidelines (WHO Technical Report Series, No.863 of 1996));
"drug regulatory authority" means the national agency responsible for the registration of, and other regulatory activities concerning, pharmaceutical products;
"starting material" means any substance of defined quality used in the production of a pharmaceutical product, but excluding packing materials;
"applicant" means the party applying for product certificate. The applicant is normally the product licence holder. Because certain data are confidential for commercial reasons, the competent authority in the exporting country must always obtain permission to release these data from the product-licence holder or, in the absence of a product licence, from the manufacturer;
"licence holder" means an individual or corporate entity possessing a marketing authorisation for a pharmaceutical product;
"licensee" means an individual or corporate entity responsible for the information and publicity on, and their pharmacovigilance and surveillance of batches of, a pharmaceutical product and, if applicable, for their withdrawal, whether or not that individual or corporate entity is holder of the marketing authorisation;
"prescription" means an order for a medicine or medicines usually written as a formula by a physician, dentist or veterinary surgeon that contains the names and the quantities of the desired substances, with instructions to the pharmacist for the preparation of the medicines and to the patient for the use of the medicine at a particular time;
"production" means all the operations involved in the preparation of pharmaceutical product, from receipt of materials, through processing and packing, to completion of the finished product;

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"registration" means any statutory systems of approval required at national level as a precondition for introducing a pharmaceutical product on to the market;
“dangerous drugs” means narcotic and psychotropic substances or dosage forms containing these;
“pharmacy” means establishments that are registered as a pharmacy under the Medicines and Cosmetics Act 1999;
“prescription only medicine” means a list of medicinal products that can only be dispensed or supplied by a pharmacist on a prescription given by a medical practitioner, a dentist, or a veterinary surgeon;
“pharmacy only medicine” means a list of medicinal products that can be sold or supplied with out prescription issued by a medical practitioner, a dentist or a veterinary surgeon, but under the supervision of a pharmacist;
“over the counter products” means a list of medicinal products that can generally be sold over the counter without the supervision of a pharmacist;
“legal entity” means an individual or corporate entity authorised by the product license holder to import medicinal products.

PART II. -- REGISTRATION OF MEDICINAL PRODUCTS AND DEALERS OF MEDICINAL PRODUCTS.

~~2.~~GENERAL LICENCES.

(1) An application for the grant or renewal of a licence under the Act shall be in the specify Form Number prescribed in schedule 2 to these regulations and shall be accompanied by the appropriate fee.

(2) A product licence issued under this regulation is valid for a period of 5 years unless cancelled or suspended by the licensing authority.

~~(3)~~All licences other than a product license, issued under Subsection (1) shall, unless sooner cancelled, continue in force for a period of 1 year.

~~(4)~~An application for renewal of a licence shall be made either 3 months before its expiry, or within 3 months of its expiry.

~~(5)~~After payment of renewal fees, the licence shall continue to be in force until orders are passed on the application.

~~(6)~~ The licence shall be deemed to have expired if the application for its renewal is not made within 3 months of its expiry.

~~(7)~~ Failure to pay the renewal fees within 3 months of the expiry of the licence shall be considered as a fresh application by the licensing authority.

(8) The licensing authority shall cancel or suspend any licence issued under Division 2 of the Act, for any period, if the licensee -
(*a*) fails to comply with the conditions of the licence; or
(*b*) is found guilty of an offence under the Act; or
(*c*) makes a request for his licence to be cancelled or suspended; or
(*d*) ceases to operate or conduct the business for which the licence was issued; or
(*e*) for any other reasons the licensing authority thinks reasonable to do so on the advice of the Pharmacy Board.

(9) Where a licensee ceases to operate as per the licence, the licensee shall within 14 days after ceasing surrender the original licence to the licensing authority which granted it.

3. APPLICATION FOR REGISTRATION OF A MEDICINAL PRODUCT.
An application for registration of a medicinal product shall be made in Form 6 as prescribed in Schedule 2 to these regulations.

4. GRANT OF A MEDICINAL PRODUCT LICENCE.
~~(1)~~A medicinal product license shall be issued in Form 7 as prescribed in Schedule 2 to these regulations.

(2) A medicinal product licence issued shall be valid for a period of 5 years.

5. APPLICATION FOR LICENCE TO MANUFACTURE MEDICINAL PRODUCT.
An application for licence to manufacture a medicinal product shall be made in Form 1(*b*) as prescribed in Schedule 2 to these regulations.

6. INSPECTION BEFORE GRANT OR RENEWAL OF LICENCE.
(1) Before a licence under this part is granted the licensing authority shall, under the Act, appoint one or more inspectors to inspect the establishment.

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(2) The inspector shall examine the premises, plant and appliances and also inspect the process of manufacture intended to be employed along with the testing procedures, enquire into the professional qualifications of the technical staff, verify statements made in the application in regard to their correctness and capability of the applicant to comply with the requirements of Good Manufacturing Practices, the requirements of plant and equipment and the requirements of maintenance of records.

7. CONDITIONS OF LICENCE.

(1) A licence issued under this section is subject to the following conditions:-

(*a*) a copy of the manufacturing licence issued shall be displayed publicly at the premises specified in the licence; and

(*b*) the licensee must keep records showing -

(i) the materials used in the manufacture of medicinal product and the supplier; and

(ii) quantities of the materials used and details of the tests performed on those materials; and

(iii) the procedures and the controls employed in the manufacture of the medicinal products, including the results of the tests performed during the processing of the medicinal products; and

(iv) details of tests performed on the final medicinal product and the results of those tests; and

(v) the stability studies, if, any, that validate the recommended shelf life and appropriate storage conditions of the medicinal products; and

(*c*) the licensee shall assign a batch number to each batch of the medicinal product when the medicinal products are manufactured in identifiable batches ; and

(*d*) the licensee shall maintain reference samples from each batch of the medicinal product for a period as may be specified by the licensing authority; and

(*e*) the licensee shall keep records of details of manufacture of each batch of medicinal products manufactured by him and such records shall be retained for a period may be specified by the licensing authority; and

(*f*) the licensee shall allow an inspector authorised by the Act to enter the premises with or without prior notice and inspect the process of manufacture or testing or to inspect all the records and registers and to take samples of the medicinal product in accordance with the provisions of the Act; and

(*g*) the licensee shall ensure that the persons nominated by the licence holder as having control of production and quality control are to be employed in the manufacture of medicinal product and maintain that control; and

(*h*) the licensee shall comply with such further requirements, as may be specified by the licensing authority from time to time.

~~8.~~**GRANT OF A LICENCE TO MANUFACTURE MEDICINAL PRODUCT.**

A licence to manufacture medicinal product shall be issued in Form 8 as prescribed in Schedule 2 to these regulations, upon satisfaction of the requirements specified in Section 21 and as confirmed on inspection by the Licensing Authority.

9. APPLICATION FOR LICENCE TO SELL MEDICINAL PRODUCT BY WHOLESALE.

~~(1)~~An application for licence to sell a medicinal product by wholesale shall be made in Form 1(*b*) as prescribed in Schedule 2 to these regulations.

~~(2)~~A separate application shall be made for sale of a medicinal product at more than one place.

10. GRANT OF LICENCE TO SELL MEDICINAL PRODUCTS BY WHOLESALE.

~~(1)~~A licence to sell medicinal products by wholesale shall be issued in Form 3 as prescribed in Schedule 2 to these regulations, upon satisfaction of the requirements specified in Section 22 and as confirmed on inspection by the Licensing Authority.

~~(2)~~ The licence shall be valid only for medicinal products specified therein.

11. APPLICATION FOR LICENCE TO IMPORT MEDICINAL PRODUCT.

~~(1)~~An application for licence to import medicinal product shall be made in Form 1(*b*) as prescribed in Schedule 2 to these regulations.

(2) Before granting an import licence the licensing authority shall take into consideration -

(*a*) whether the medicinal product for which an import application is being made is registered with the licensing authority; and

(*b*) the premises, in which the imported medicinal product will be stocked; and

(*c*) the occupation, trade or business ordinarily carried out by the applicant; and

(*d*) valid business registration issued by the Investment Promotion Authority.

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12. PROHIBITION OF IMPORT OF CERTAIN MEDICINAL PRODUCT OR COSMETIC.

~~(1)~~From such date as may be fixed by the Minister by notification in the National Gazette relating to any prohibition of import, no person shall import -

(*a*) any medicinal product or cosmetic which is not of standard quality; or

(*b*) any misbranded medicinal product or misbranded cosmetic; or

(*c*) any medicinal product without a medicinal product license.

13. CONDITIONS FOR LICENCE HOLDERS.

(1) An import licence shall be subject to the following conditions :-

(*a*) the manufacturer shall at all times observe the undertaking given by him; and

(*b*) the licensee shall allow any inspector authorised by the licensing authority in that behalf to enter with or without notice any premises where the imported medicinal product is stocked, to inspect the means if any, employed for testing the medicinal product and to take samples; and

(*c*) if any samples are found by the licensing authority not to conform to the standards of strength, quality and purity, the licensee shall immediately withdraw the remainder of the batch from sale and recall the issues already made from that batch; and

(*d*) the licensee shall record all sales by him of medicinal products, the import of which a licence is required, showing all the particulars of sales; and

(*e*) the licensee shall comply with such further requirements, if any, applicable to the holders of import licences, as may be specified by the licensing authority from time to time.

14. GRANT OF AN IMPORT LICENCE.

~~(1)~~A licence to import a medicinal product shall be issued in Form 4 as prescribed in Schedule 2 to these regulations, upon satisfaction of the requirements specified in section 23 and as confirmed on inspection by the Licensing Authority.

~~(2)~~A licence issued under Subsection 1 shall be valid only for medicinal products specified therein.

15. APPLICATION FOR LICENCE TO EXPORT MEDICINAL PRODUCT.

An application for licence to export a medicinal product shall be made in Form 1(*b*) as prescribed in Schedule 2 to these regulations.

16. GRANT OF AN EXPORT LICENCE.

~~(1)~~A licence to export a medicinal product shall be issued in Form 5 as prescribed in Schedule 2 to these regulations, upon satisfaction of the requirements specified in section 24 and as confirmed on inspection by the Licensing Authority.

~~(2)~~A licence issued under Subsection 1 shall be valid only for medicinal products specified therein.

17. APPLICATION FOR ISSUE OF A CLINICAL TRIAL CERTIFICATE.

An application for issue of a clinical trial certificate shall be made in Form 9 as prescribed in Schedule 2 to these regulations.

18. CONDITIONS TO BE SATISFIED FOR THE ISSUANCE OF A CLINICAL TRIAL CERTIFICATE.

~~(1)~~Approval of applications for clinical trials shall be based on the requirements of the Guidelines for good clinical practice (GCP) for trials on pharmaceutical products (World Health Organization, 1995, Technical Report Series No. 850).

(2) An application for issue of a clinical trials certificate shall include:-

(*a*) the name, dose and administration of the medicine, its nature and its chemical formula; and

(*b*) the purpose of the trial; and

(*c*) the names and qualifications of the investigators who will conduct the trial; and

(*d*) a written consent to nomination from each of the investigators; and

(*e*) a copy of the information supplied to the investigators, particularly in relation to the safe use of the medicinal product; and

(*f*) a protocol of the trial setting out –

(i) the number of patients to be involved; and

(ii) the form that the trial is to take, and the nature of the records to be kept; and

(iii) the persons or classes of persons (if any) who are to be specially excluded from the trial; and

(iv) any special measures proposed to be taken to ensure the safety of the patients; and

(*g*) ethical clearance of the trial protocol by an independent Ethics Committee for Biomedical Research Involving Human Subjects or other equivalent committee; and

(*h*) information about the medication(s) and the trial which will be provided to the patient(s) or volunteer(s); and

(*i*) information on how patient's or volunteers consent will be obtained; and

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(*j*) the names and addresses of the institutions or laboratories where the medicinal product will be used by approved persons, and a description of the facilities that will be available to those persons.

(3) The licensing authority shall determine every application for its approval under this section within 60 days after receipt of the application and shall notify the applicant of its decision and where it declines the application the reasons for its decision.

(4) At any time after a clinical trial has been approved by the licensing authority, the applicant may apply to the licensing authority for the approval of an investigator, not withstanding that the name of that person did not appear in the application for approval of the clinical trial.

(5) The licensing authority may at any time, by notice in writing given to an applicant, require the applicant to supply such further information and particulars as it thinks appropriate relating to a clinical trial or to identity qualifications of an investigator.

(6) The distribution of any medicinal product under this section shall be subject to the following conditions:-

(*a*) the licensing authority shall be informed, before the medicinal product is so distributed, of the identifying name or mark by which it may be recognised; and

(*b*) every label on every package or container of the medicinal product shall bear the words "to be used by qualified investigators only"; and

(*c*) the importer or manufacturer shall before so distributing the medicinal product, take all the reasonable steps to ensure that every person to whom it is supplied is approved under this section as a registered pharmacist to carry out and has available the necessary facilities for the trial to be conducted by him, and the medicinal product shall be used solely by that person or under his direction for the purposes of the trial; and

(*d*) the importer or manufacturer shall –

(i) keep complete and accurate records of all quantities of the medicinal product supplied under this section; and

(ii) keep the licensing authority informed of the progress of the trial by 6 monthly reports; and

(iii) supply to the licensing authority a copy of the results of the trial on its completion.

(7) The licensing authority may at any time, by notice in writing to the applicant, revoke or suspend his approval of a clinical trial.

19. ISSUANCE OF CLINICAL TRIAL CERTIFICATE.

A clinical trial certificate shall be issued in Form 10 as prescribed in Schedule 2 to these regulations.

PART III. - STANDARDS

20. STANDARD PROVISIONS FOR A MEDICINAL PRODUCT LICENCE.

(1) A licence holder shall report to the licensing authority any changes in his name or address or that of the company to which the licence relates.

(2) A licence holder shall inform the licensing authority of any material change that has been made or that he proposes to make in the particulars contained in his application relating to the -

(*a*) specification of the medicinal product; and

(*b*) composition of the medicinal product; and

(*c*) method of manufacture for the medicinal product; and

(*d*) storage conditions for the medicinal product; and

(*e*) indications for the medicinal product.

(3) A licence holder shall report to the licensing authority -

(*a*) changes on the validity of data which may affect the safety, quality and efficacy of the medicinal product to which the licence relates; and

~~(b)~~any serious adverse drug reactions; and

(*c*) any batch which does not conform to the specification of the medicinal product.

(4) A licence holder shall recall any defective or unsafe medicinal product to which the licence relates, from the market, and stop its sale and distribution.

~~(5)~~ A licence holder shall state the medicinal product licence number designated by the licensing authority on the label and package of the medicinal product.

(6) A licence holder shall return the original copy of the licence to the licensing authority within 7 days after the licence has been suspended or revoked.

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(7) A licence holder shall undertake to arrange for such tests as may be directed by the licensing authority and shall submit samples for testing if so requested by the licensing authority.

~~(8)~~A licence holder shall keep and maintain records as prescribed by the licensing authority.

21. STANDARD PROVISIONS FOR A MANUFACTURER'S LICENCE.

(1) Before a licence in Form 8 of Schedule 2 of these regulations is granted, an applicant shall comply with conditions :-

(*a*) the manufacture shall be conducted under the active direction and personal supervision of competent technical staff whose education should include the study of an appropriate combination of pharmaceutical sciences and technology, chemistry (analytical or organic) or biochemistry, chemical engineering, microbiology, pharmacology and toxicology, or other related sciences; and

(*b*) the applicant has at having at least 3 years of experience in the manufacturing and testing of medicinal products.

(2) A licence holder shall inform the licensing authority of any change in his name and the address of the manufacturer to which the licence relates.

(3) A licence holder shall provide and maintain such staff, premises, equipment and plant as are necessary for carrying out the manufacture and assembly of the medicinal product in the exact manner as the specification of the product and shall carry out the manufacturing operation as in the process specified in the application for a licence.

(4) A licence holder shall provide and maintain such staff premises, equipment and facilities for handling, storage and distribution of the medicinal product.

(5) A licence holder shall conduct all manufacturing operations in accordance with Good Manufacturing Practices (WHO Expert Committee on Specifications for Pharmaceutical Preparations, Thirty-second report. Geneva, World Health Organization, 1992:14-79 (WHO Technical Report Series, No.823) with supplementary guidelines (WHO Technical Report Series, No.863 of 1996)) prescribed by the licensing authority and shall ensure that the quality, safety and efficacy of the product are maintained as per specifications contained in the medicinal product licence.

(6) An applicant shall provide and maintain adequate staff, premises and laboratory equipment for carrying out the tests of the quality of the medicinal products.

(7) An applicant shall make adequate arrangements for the storage of medicinal products manufactured by him.

(8) A licence holder shall inform the licensing authority before making any material alteration to the premises or plant used under his licence and any change that he proposes to make in the -

(*a*) person responsible for supervising the production operations; or

(*b*) person responsible for the quality control of the medicinal product being manufactured.

(9) A licence holder shall maintain records of the details of manufacture of each batch of every medicinal product being manufactured and of the tests carried out in such forms as the licensing authority may require.

(10) Such records shall not be destroyed for a period of 2 years from the date when the manufacture of the relevant batch occurred.

(11) A licence holder shall keep such record as required in order to facilitate the withdrawal or recall from sale or supply of any medical product to which the licence relates.

~~(12)~~A licence holder shall return the original copy of the licence to the licensing authority within 7 days from the date when the licence is suspended or revoked.

~~(13)~~A licence holder shall not use the licence for advertising purposes.

22. STANDARD PROVISIONS FOR THE WHOLESALE DEALERS LICENCE.

~~(1)~~The following standard provisions shall apply to a wholesale dealers licence:-

(*a*) a licence holder shall have a valid business registration with the Investment Promotion Authority; and

(*b*) the licence shall be displayed in a prominent place in a part of the premises open to the public; and

(*c*) a licensee shall permit an authorized inspector to inspect the premises and provide any information that is necessary; and

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(*d*) a licensee shall report to the licensing authority any change in the qualified person in-charge within one month of such change; and

(*e*) a licensee shall inform the licensing authority in writing in the event of any change in the constitution of the firm operating under the licence. Where there is a change in the ownership of the firm, the existing licence shall be deemed to be valid for a maximum period of 3 months from the date on which the change takes place, unless in the mean time a fresh licence has been obtained from the licensing authority in the name of the firm with the changed constitution; and

(*f*) a licence holder shall provide and maintain such staff, premises, equipment and facilities for the handling, storage and distribution of the medicinal products which he handles, stores or distributes under his licence, as are necessary to avoid deterioration of the medicinal products and he shall not use the premises for such purposes other than those specified in the licence by the licensing authority; and

~~(g)~~a licence holder shall ensure that the premises are sufficiently secured, preventing unauthorized access; and

~~(h)~~a licence holder shall provide such information as may be requested by the licensing authority concerning the type and quantity of any medicinal product which he currently handles, stores or distributes.

(*i*) where the licence holder has been informed by the licensing authority or by the holder of the product licence that any batch of medicinal product to which the wholesale dealer's licence relates has been found not to conform as regards to the strength, quality or purity with the specification of that product or with the provisions of the Act or of any regulations under the Act that are applicable to the medicinal product, he shall, if so directed, withhold such batch from sale for such period as may be specified by the licensing authority;

(*j*) subject to the provisions of these regulations, no medicinal product to which the wholesale dealer's licence relates shall be sold or offered for sale by way of wholesale dealing by virtue of that licence unless there has been granted in respect of that medicinal product licence which is for the time being in force and any sale or offer for sale shall be in conformity with the provisions of such medicinal product licence.

(*k*) the licence holder, for the purpose of enabling the licensing authority to ascertain whether there are any grounds for suspending, revoking or varying any licence or certificate granted or issued under the Act, shall permit, and provide all necessary facilities to enable the Inspector, to carry out such inspection or to take samples or copies, in relation to things belonging to, or any business carried on by, the licence holder, as such person would have the right to carry out or take under the Act for the purpose of verifying any statement contained in an application or a licence or certificate; and

(*l*) the licence holder shall at all times provide and maintain staff, premises, equipment and facilities that will enable the qualified person who is at his disposal to carry out the said function.

(*m*) the provisions of this subsection shall also not apply where the licence holder handles the imported medicinal product -

(i) in the course of the provision of facilities solely for the transport of the medicinal product; or

(ii) in the course of a business carried on by him as an import agent where he imports the medicinal product solely to the holder of another person who intends, in the course of a business carried on by him, to sell, or offer for sale the medicinal product by way of wholesale dealing or in any other way intends to distribute the medicinal product; or

(iii) the licensee shall comply with such further requirements, if any, applicable to the holders of licences, as may be specified by the licensing authority from time to time; or

(iv) all transactions pertaining to ordering, storage and distribution of medicinal products should be accurately recorded.

23. STANDARD PROVISIONS FOR AN IMPORT LICENCE.

~~(1)~~In addition to requirements for wholesalers contained in Section 22 the following conditions must be met:-

(*a*) a licence holder shall report any changes in his name and address and the address of his company to which the licence relates; and

(*b*) a licence holder shall undertake to arrange for test of the medicinal product and to submit samples of the medicinal product when requested to do so by the licensing authority; and

(*c*) a licence holder shall report to the licensing authority any change in the specification or composition of the medicinal product or the manufacturing procedure of the medicinal product; and

(*d*) a licence holder shall inform the licensing authority of any batch of the medicinal product, which have been found to be harmful or unsafe or does not conform to the product's specification; and

(*e*) a licence holder shall keep and maintain records to which the licence relates in the manner as prescribed by the licensing authority.

(*f*) a licence holder shall inform the licensing authority of any decision to withdraw the importation, sale or supply of the medicinal product to which the licence relates; and

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(*g*) a licence holder shall report to the licensing authority within 7 days from the receipt of any adverse effects or report relating to the medicinal product imported; and

(*h*) a licence holder on a per consignment basis shall state the import licence number designated by the licensing authority on the label and package accompanying the medicinal product; and

(*i*) a licence holder shall recall defective, harmful and unsafe medicinal products from the market and shall immediately stop the distribution and sale of the affected medicinal product; and

(*j*) a licence holder shall return the original copy of the licence to the licensing authority if the licence is suspended or revoked; and

(*k*) the validity of the import licence, in respect of each medicinal product, which the importer is dealing with, shall be subject to the continued validity of the corresponding medicinal product licence; and

(*l*) a licence holder shall not use the licence for advertising purposes.

24. STANDARD PROVISIONS FOR AN EXPORT LICENCE.

(1) The following standard provisions shall apply to an export licence :–

(*a*) a licence holder shall report any changes in his name and address and the address of his company to which the licence relates; and

(*b*) a licence holder shall report to the licensing authority of any change in the specification or composition of the medicinal product; and

(*c*) the licence holder shall inform the licensing authority of any batch of the medicinal product, which have been found to be harmful or unsafe or does not conform to the product's specification.

(*d*) a licence holder shall keep and maintain records to which the licence relates in the manner as prescribed by the licensing authority; and

(*e*) a licence holder shall inform the licensing authority of any decision to withdraw the exportation, sale or supply of the medicinal product to which the licence relates.

25. STANDARDS FOR MEDICINAL PRODUCTS, COSMETICS AND MEDICAL DEVICES.

(1) Any medicinal product for which a standard is otherwise prescribed in these regulations shall, where it is described as conforming to a monograph in a specified publication, conform to the description and tests set out in that publication for that medicinal product.

(2) Any medicinal product that is suitable for application into the eye shall conform to the tests for sterility.

(3) Any medicinal product, for use on the skin of a baby, or on any inflamed, abraded or broken skin, shall be free of pathogenic organisms.

(4) Any medicinal product or cosmetic intended for sale shall not contain any extraneous thing that is harmful, dangerous or offensive.

(5) A surgical dressing that is described as conforming to a monograph in a specified publication shall conform to the description and tests set out in that publication for that surgical dressing.

(6) A medical device that is described as conforming to a particular description shall conform to that description.

PART IV. - PHARMACIES.

26. REGISTRATION OF A PHARMACY.

(1) From such date as may be fixed by the Minister by notification in the National Gazette in this behalf, no person shall conduct a pharmacy in the State of Papua New Guinea unless he has obtained a registration from the licensing authority.

(2) An application for registration of a pharmacy shall be made in Form 1(*a*) as prescribed in schedule 2 to these regulations.

(3) A registration shall be required for each pharmacy and a separate registration shall be required for each of the premises of any person operating a pharmacy in more than one location.

(4) A licence shall not be granted to any person unless the licensing authority is satisfied that the applicant complies with the following requirements:-

(*a*) location and building :-

(i) a pharmacy shall be located in a sanitary place and hygienic conditions shall be maintained in the premises; and

(ii) the place shall be kept dry, adequately lighted and ventilated at all times; and

(iii) the place shall be kept clean and free from dust and creatures likely to contaminate the medicine; and
(iv) the walls, floors and ceilings shall be properly constructed and kept in good repair, and shall be easy to clean; and
(v) the place shall not be used for any purpose that might affect the quality of the medicines or cosmetic; and
(vi) the place shall be provided with a means of drainage, sinks and other sanitary fittings maintained in good, clean and working condition; and
(vii) the place shall be provided with an adequate supply of hot and cold water, and or other detergents; and

(*b*) spacing :-
(i) the premises should be on an area of not less than 10 square metres; and
(ii) there shall be separate prescription compounding and dispensing counter depending on the work load requirements of the pharmacy separated from other areas to prevent admission to the public; and
(iii) a minimum of 1.5 square metres of counter space shall be provided for one pharmacist and, additional counter space shall be provided for each additional pharmacist.

(*c*) staffing :-
(i) a pharmacy shall be under the immediate supervision and control of a registered pharmacist whose name shall be displayed conspicuously in the premises; and
(ii) a registered pharmacist shall be present in the pharmacy at all times except during lunch breaks; and

~~(iii)~~any non-pharmacist owner shall not commit any act of the pharmacist in charge to comply with the laws governing the operation of the pharmacy; and

(*d*) the storage conditions :-
A pharmacy shall be provided with
(i) adequate facilities for preserving the sensitive medicinal products; and
(ii) refrigerators for the storage of vaccines and other biological preparations; and
(iii) adequate cupboards with lock and key for the storage of dangerous drugs; and

(*e*) dispensing equipment :-
A pharmacy shall be provided with adequate equipment necessary for dispensing of official preparations and processing prescriptions. Each item must be clean, in good repair and of suitable material. Following is a minimum list and must be extended according to the requirements of the dispensary.
(i) a suitable means of counting tablets and capsules. This equipment must be cleaned regularly so that cross contamination between products is avoided.
(ii) an accurate dispensing balance.
(iii) a range of graduated, stamped glass measures.
(iv) a refrigerator equipped with a maximum and minimum thermometer and capable of storing products at temperatures between 2 and 8 degrees Celsius. The refrigerator must be cleaned, defrosted and checked periodically to ensure efficient running and unless there are adequate arrangements for separating various items to avoid cross contamination, must be used only for medicinal products.
(v) a suitable range of dispensing containers for medicinal products and child resistant closures complying with the relevant standards.
(vi) a means of mechanically printing dispensing labels. Additional warning slip labels must be available, unless such warnings are printed on the dispensing labels. Where computer software is relied on for warnings and interactions this should be the latest version available.

(*f*) Reference Books :-
A pharmacy shall be provided with any of the following reference books in their current edition:
(i) The British Pharmacopoeia .
(ii) The USP.
(iii) Martindale The Extra Pharmacopoeia.
(iv) British National Formulary.

The availability of the following reference material in their current edition would be useful for consultations:
New Ethicals Catalogue.
A hand book on drug interactions.
A hand book on advice to the patient.
A medical dictionary.

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(*g*) Records and registers to be maintained in a pharmacy -
A pharmacy shall keep and maintain the following records and registers.
(i) the records of dispensing of Narcotics and Psychotropic drugs
(ii) the prescription medicines register.
~~(iii)~~records of medicines sold by retail and by wholesale.

27. GRANT OF LICENCE TO OPERATE A PHARMACY.

~~(1)~~A licence shall be issued in Form 2 as prescribed in Schedule 2 to these regulations, upon satisfaction of the requirements specified in Section 26 and as confirmed on inspection by the Licensing Authority.

~~(2)~~The licence shall be valid only for a period of 1 year.

(3) An application for renewal shall be made 3 months before the expiry of the original licence.

(4) Failure to pay the renewal fees within 3 months of the expiry of the original license the licencee shall be required to pay the full prescribed registration fees.

28. GENERAL DUTIES OF PHARMACIST.

(1) A pharmacist who carries on a business as such or who is in charge of a dispensary shall -
(*a*) ensure that the premises in which the business is carried on or dispensary, is adequately locked and otherwise secured at all times, when the business or the dispensary is not normally open to the public; and
(*b*) maintain the business or the dispensary in a clean, hygienic and orderly condition; and
(*c*) provide and maintain in good order and condition such equipment, necessary for the full and proper conduct of the business or the dispensary,
(*d*) provide and maintain adequate and sufficient stocks of all medicinal products as are reasonably required for the full and proper practice of the profession and as may reasonably be prescribed by a medical practitioner, veterinary surgeon or a dentist; and
(*e*) keep prominently displayed at all times at the premises so as to be readily visible to the public, a notice setting out the normal trading hours of the business or dispensary; and
(*f*) have legibly printed or written, and continually so maintained, in a conspicuous place on the front of the business premises -
(i) his name, in letters not less than 150mm high; and
(ii) his professional qualifications, in letters not less than 50mm high; and
(iii) if he is carrying on business, either, the word "Pharmacy" or "Pharmacist" in charge of a "Pharmacy"; and
(*g*) provide advice on rational drug use to the public and medical profession.
(*h*) maintain his professional knowledge in order to provide quality pharmaceutical care and services; and
(*i*) at all times have regard to the laws and regulations applying to medicinal products and pharmaceutical practices, and maintain a high standard of professional conduct.

(2) A pharmacist or pharmacy technician registered with the Pharmacy Board of Papua New Guinea shall renew his license to practise before 30th March each year.

(3) A pharmacist or pharmacy technician who fails to comply with subsection 2 shall be required to pay the full prescribed registration fees, or otherwise his name shall be removed from the register of pharmacist or pharmacy technicians.

29. NOTICE OF ABSENCE.

(1) A pharmacist who -
(*a*) carries on a business at a shop; and
(*b*) leaves the shop open for business under the control of some other pharmacist for a period of more than 42 days, shall immediately give notice by registered post, to the Chairman of the Pharmacy Board, of his absence and of it's expected duration and the name of that other pharmacist.

30. INSPECTION.

A pharmacist shall permit an Inspector, during normal business hours of a pharmacy or dispensary to examine and inspect the pharmacy as per the provisions of this regulation upon presentation of his credentials or identity.

31. CONDITIONS OF DISPENSING.

(1) No person other than a medical practitioner, veterinary surgeon, dentist or a pharmacist shall dispense a prescription medicine and shall not do so, if -
(*a*) the prescription bears the word "cancelled" on it; or
(*b*) the prescription –
(i) is obliterated in whole or in part; or
(ii) is illegible; or

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(iii) is defaced, or appears to have been altered in any way by a person other than the prescriber, or the date of presentation for dispensing is more than 6 months after the date on which the prescription was written.

~~(1)~~Every person dispensing a prescription medicine shall comply with the following requirements :-

(*a*) the prescription shall not be dispensed more than once, unless the prescriber has indicated on the prescription that it may be dispensed on more than one occasion; and

(*b*) if the prescription contains a direction that it may be repeated without any mention of the number of occasions or intervals between the dispensing, or the period of treatment required, it shall be dispensed on not more than two occasions; and

(*c*) if the prescription contains a direction that it may be dispensed a stated number of times without an indication of time that is to elapse between each occasion of dispensing it shall not be dispensed more often than once in every three days; and

(*d*) if the prescription contains a direction that it may be dispensed at stated intervals with out an indication as to the number of times it may be dispensed, it shall not be dispensed more often than 3 times; and

(*e*) no medicinal product shall be sold or stocked by the licensee after the date of expiration of potency recorded on its container or label. Any such medicinal product may be stocked after the date of expiry separately from the trade stocks and all such medicinal product shall be kept in cartons which shall prominently display the words " Not for sale".

32. DISPENSING PROCEDURE.

(1) Before dispensing a medicinal product on a prescription, a pharmacist, doctor, veterinarian or dentist must comply with the following procedures:-

(*a*) he shall copy the prescription in full into the prescription book; and

(*b*) he shall mark on the prescription the same identifying number or letter as recorded in the prescription book; and

(*c*) he shall sign or initial the prescription and show the date of dispensing; and

(*d*) he shall show on the prescription, the name and address of the pharmacy; and

(*e*) in the case of a repeated prescription, he shall -

(i) enter in the Prescription Book the name of the patient, the number of the original prescription and the date of dispensing of the prescription; and

(ii) endorse the prescription with a new number, the date of dispensing; and

(iii) sign or initial the prescription.

(2) The dispensed medicinal product shall be packed in a suitable container and labelled with the name of the patients, name of the medicinal product and instructions for its use.

~~(2)~~Upon delivery to the patient, he shall inform the patient on the correct use of the medicinal product and ensure that the patient has understood the instructions.

33. PARTICULARS OF PRESCRIPTIONS TO BE RECORDED IN THE PRESCRIPTION BOOK.

(1) The particulars to be shown in the prescription register are:-

(*a*) the Serial Number of the entry; and

(*b*) the date on which the medicinal product was sold or supplied; and

(*c*) the name, quantity and, except where it is apparent from the name, the pharmaceutical form and strength of the medicinal product; and

(*d*) the date on the prescription and the name and address of the practitioner giving it; and

(*e*) the name and address of the person for whom, the medicinal product was prescribed; and

(*f*) the initials or other identifying means of the registered pharmacist under whose supervision the medicinal product was made up or supplied.

34. EMERGENCY SUPPLY OF MEDICINAL PRODUCTS.

~~(1)~~In an emergency a person lawfully conducting a retail pharmacy business can sell or supply a Prescription Only Medicine upon request by a doctor or a patient provided that the pharmacist in charge has satisfied himself of the situation and shall comply with the following conditions:-

(*a*) that there is an immediate need for the medicinal product requested and that it is impracticable to obtain a prescription without undue delay; and

(*b*) that an appropriate entry is made in the prescription register; and

(*c*) that the container or package is labelled in accordance with the regulations and with the words "Emergency Supply".

35. PRESCRIPTION BY TELEPHONE.

(1) A medical practitioner, veterinary surgeon or a dentist -

(*a*) may, by telephone, authorise a pharmacist to dispense a medicinal product for a person or an animal; and

(*b*) shall, within 48 hours from the time of authorisation under Paragraph (*a*), send to the pharmacist a written prescription in relation to the medicinal product.

(2) A prescription referred to under Section 35(1) (*a*) shall -

(*a*) comply with Section 31(2)(*b*); and

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(*b*) be recorded and endorsed in accordance with Section 33.

36. SUPPLYING OF MEDICINAL PRODUCT BY PHARMACIST WITHOUT PRESCRIPTION.

~~(1)~~Where, in the course of giving aid or assistance permitted under Section 8(1)(*b*)(*c*) of the Act, a pharmacist shall supply without a prescription the medicinal product belonging to the following category only:-

(*a*) pharmacy only medicine as listed in Schedule 4; or
(*b*) over the counter as listed in Schedule 5.

37. KEEPING OF RECORDS.

A pharmacist shall retain all records of prescriptions entered in the Prescription Book for a period of not less than 5 years after the date of entry.

38. RETURNING OF PRESCRIPTIONS.

(1) Subject to Subsection (2) a pharmacist shall, after dispensing or supplying a medicinal product, on prescription, return the prescription to the person who presented it for dispensing or supplying.

(2) If the medicine dispensed or supplied under Subsection (1) is a dangerous drug, the pharmacist shall retain the prescription and maintain it for a period of not less than two years from the date of dispensing or supplying.

39. STORAGE OF MEDICINAL PRODUCTS.

(1) A pharmacist who dispenses or compounds or makes-up, medicinal product for patients or animals under his professional care, shall-

(*a*) store each medicinal product in a separate receptacle clearly labelled with the name of the medicinal product; and
(*b*) store and maintain each medicinal product in such a manner as to prevent any deterioration arising from inadequate stock management.

40. SUBSTITUTION OF MEDICINAL PRODUCTS.

A pharmacist who dispenses, compounds or makes up any medicinal product in dispensing a prescription, and without the consent of the prescriber, substitutes any other substance for a substance specified in the rescription, is guilty of an offence.

PART V. - LABELLING.

41. PROHIBITION OF SALE OR DISTRIBUTION OF MEDICINAL PRODUCTS UNLESS PROPERLY LABELLED.

With effect from the appointed day and subject to the provisions of these Regulations, no person shall sell or distribute any medicines unless it is labelled in accordance with these Regulations.

~~42.~~ LABELLING OF MEDICINAL PRODUCTS.

~~(1)~~The container of all medicinal products imported, manufactured, processed or packed locally or sold or exposed for sale shall have a label whereon the following information shall be clearly indicated:-

(*a*) the generic, official or approved non-proprietary name found in official pharmacopoeias or formularies; and
(*b*) the brand name(where available); and
(*c*) active ingredient(s) giving generic, official or approved non-proprietary name where available-

~~(i)~~ the amount in which each ingredient is present in each dosage unit; and
(ii) an indication of the net content; and
(*d*) mode of administration or use; and
(*e*) recommended storage condition; and
(*f*) warnings and precautions that may be necessary; and
(*g*) the date of manufacture; and
(*h*) the date of expiry; and
(*i*) the batch number assigned by the manufacturer; and
(*j*) the name and address of the manufacturer.

~~43.~~ MANNER OF LABELLING OF MEDICINAL PRODUCT.

~~(1)~~ Subject to the other provisions of these regulations, every label that is required by these regulations to be borne on a container shall –

(*a*) be conspicuously written in English and for each statement separately required, be in uniform colour contrasting strongly with a uniform background; and
(*b*) be legibly and durably marked on material firmly and securely attached to the container; and
(*c*) be of such nature and material that will not fade to the extent of becoming illegible, or become detached under normal storage conditions; and

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(*d*) be in a position that it will not readily be defaced in the course of normal handling and use; and

(*e*) be in such a position that is not damaged, defaced, destroyed, or removed when the container is opened.

~~(2)~~ Every medicinal product sold or intended for sale, for external use shall bear on the label of its container –

(*a*) directions for use and frequency of use; and

(*b*) the words "Caution, Not to be taken, or for external use only" or words of similar meaning.

(3) Every medicine for Injection in to human body and contains an antiseptic or preservative shall be labelled with a statement of the nature and amount of antiseptic or preservative.

(4) Any label on a container of a medicinal product dispensed with reference to the needs of a particular patient shall contain the following: -

(*a*) the name and the strength of the product; and

(*b*) the name of the patient; and

(*c*) the name and address of the pharmacy which dispensed the medicinal product; and

(*d*) in the case of a medicinal product for internal use, the dose and frequency of dose or as directed by the prescriber; and

~~(e)~~in the case of a medicinal product for external use, a statement of the directions for use and frequency of use and one of the following statements, or words of similar meaning " Caution: Not to be taken", or " For External Use Only"; and

(*f*) the words "KEEP OUT OF THE REACH OF CHILDREN".

~~44.~~ LABELLING OF COSMETICS.

~~(1)~~The container of all cosmetics imported, manufactured, processed or packed locally or sold or exposed for sale shall have a label whereon the following information shall be clearly indicated :-

(*a*) the name of the cosmetic; and

(*b*) a declaration of the net contents; and

(*c*) adequate direction for the safe use; and

(*d*) any warning, caution or special directions for use; and

(*e*) the batch number of the product; and

(*f*) the manufacturing licence number and the name and address of the manufacturer; and

(*g*) the manufacturing date and the expiry date.

45. LABELLING OF MEDICAL DEVICES.

~~(1)~~The container of all medical devices imported, manufactured locally or sold or exposed for sale shall have a label whereon the following information shall be clearly indicated:-

(*a*) the trade name of the medical device; and

(*b*) the appropriate quantitative particulars; and

(*c*) adequate direction for the safe use; and

(*d*) any warning, caution or special directions for use; and

(*e*) the batch number of the product; and

(*f*) the manufacturing licence number and the name and address of the manufacturer.

46. PACKING OF MEDICINAL PRODUCT.

(1) The following are requirements of containers used for packing of medicinal products:-

(*a*) any container either glass or plastic that is used in the packaging of a medicinal product shall comply with all the tests for that type of container specified in the British Pharmacopoeia or some other reference; and

(*b*) any container used in the packing of medicinal product and made of metal shall be impermeable to moisture; and

~~(2)~~Every container used in the packing of a medicinal product and made of metal or plastic shall be made of a material that will not adversely react with the contents of the container.

PART VI. - ADVERTISEMENTS

47. ADVERTISEMENTS FOR MEDICINAL PRODUCT.

~~(1)~~This section does not apply to advertisements directed exclusively to-

(*a*) medical practitioners, psychologists, dentists, veterinary surgeons, pharmacists, physiotherapists, dieticians, scientists working in medical laboratories or nurses; or

(*b*) persons who are-

(i) engaged in the business of wholesaling therapeutic goods; or

(ii) purchasing officers in hospitals; or

(iii) herbalists, homeopathic practitioners, naturopaths and nutritionists.

(*c*) any advertisement for a medical product that the Health Department with agencies or non governmental organisations acting in conjunction with Health Department policies and programmes.

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(2) The Minister shall issue an exemption under Section 4(1) of the Act that exempts contraceptives supported and encouraged by Health Department policies from the restriction on advertising for medicines and devices preventing contraception Section 31(2)(*b*)(ii) of the Act.

(3) Every advertisement for a medicinal product, other than a label or a price list shall include a statement of the active ingredient in the medicinal product.

(4) Only those medical claims documented in the application for medicinal product licence can be included in advertisements for medicinal products.

(5) Quasi medicines or herbal or traditional medicines shall not be advertised.

48. ADVERTISEMENTS FOR COSMETICS.
Every advertisement for a cosmetic, other than a label or a price list, shall include a statement of the uses of the product and a statement of the appropriate precautions to be taken in the use of the cosmetic.

49. ADVERTISEMENT FOR MEDICAL DEVICES.
~~(1)~~Every advertisement for a medical device, other than a label or a price list, shall include, where appropriate the following :–

(*a*) an accurate description of the medical device; and
(*b*) a statement of the uses of the medical device; and
(*c*) a statement of the appropriate precautions to be taken in the use of the medical device; and
(*d*) a statement of any contraindication in the use of medical device.

50. CLASSIFICATION OF MEDICINAL PRODUCTS.
(1) The Minister may from time to time establish, maintain, review and publish the list of Prescription only medicine, Pharmacy only medicine and Over the Counter medicine.

~~(2)~~All medicinal product specified in Schedule 3 to these regulations are hereby declared to be Prescription only medicines.

~~(3)~~All medicinal product specified in Schedule 4 to these regulations are hereby declared to be Pharmacy only medicines.

~~(4)~~All medicinal product specified in Schedule 5 to these regulations are hereby declared to be over the counter medicines.

PART VII. - INSPECTION.

51. QUALIFICATIONS OF INSPECTORS.
(**1**) A person who is appointed as an Inspector under the Act shall be a person who has a degree in Pharmacy or similar qualification from a University established in Papua New Guinea by law or any other recognised institution.
(2) Duration of Inspectors permits.
An inspector's permit issued under these regulations is valid for a period of five (5) years unless uspended or revoked by the licensing authority.

~~(3)~~Revoking of Inspectors permit.
The licensing authority shall suspend or revoke an inspector's permit if he -
(*a*) fails to perform his duties under these regulations to the satisfaction of the licensing authority; or
(*b*) is found guilty of an offence by a court of law in Papua New Guinea.

52. DUTIES AND POWERS OF INSPECTORS.
~~(1)~~Subject to the instructions of the Licensing authority, it shall be the duty of a certified inspector to inspect a manufacturer, wholesaler, retailer, importer and exporter of medicinal products.

(2) An inspector shall –
(*a*) inspect all establishments licensed for the sale of medicinal product within the area assigned to him; and
(*b*) satisfy himself that the conditions of the licences are being observed; and
(*c*) procure and send for test or analysis, if necessary, imported packages which he has reason to suspect contain medicinal product being sold or stocked or exhibited for sale; and
(*d*) procure and send for testing any medicinal product which he thinks is not of standard quality; and
(*e*) investigate any complaint in writing which may be made to him; and
(*f*) institute prosecutions in respect of breaches of the Act and regulations thereunder; and
~~(g)~~maintain a record of all inspections made and action taken by him in the performance of his duties, including taking of samples and the seizure of stocks and to submit copies of such records to the controlling authority; and
~~(h)~~make such enquires and inspections as may be necessary to detect the sale of drugs in contravention of the Act –

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(i) the premises in or from which the medicinal product are dispensed, sold or supplied; and
(ii) the stock, equipment and contents of the premises; and
(iii) the Prescription Book and all records of prescriptions, medicinal product dispensed, sold or supplied in or from the premises, and to take copies of, or extracts from, any book or record in relation to anything referred to in Paragraph (*a*); and

~~(i)~~provide professional advice to licence holders and potential licence holders on pharmaceutical requirements.

(2) A person to whom this section applies shall not –
(a) fail to answer a question; or
(b) give a false answer to a question by an authorised person on any item or aspect referred to in Paragraph (*h*).

53. PROHIBITION OF DISCLOSURE OF INFORMATION.
An inspector shall not disclose to any person any information acquired by him except for the purpose of official business under the direction of the Departmental Head or when required by a court of law.

54. TAKING OF SAMPLES FOR TESTING.
~~(1)~~When an Inspector takes a sample of any medicinal product for testing he must give the person from whom the sample was taken, a notice setting out the details of the products taken.

~~(2)~~ An inspector in subsection (1) shall ensure that the sample is appropriately packed, sealed, stored and transported as per the directions on the label and as soon as practicable submit the samples to the Analyst for testing.

PART VIII. - MISCELLANEOUS

55. QUALIFICATIONS OF ANALYST.
A person who is appointed as an Analyst under the Act shall be a person who has a degree in Pharmacy or similar qualifications from a University established in Papua New Guinea by law or any other recognised institution with a minimum of 2 years experience in testing of Pharmaceutical products in any reputed Quality Control Laboratory.

56. DUTIES OF ANALYSTS.
~~(1)~~In addition to the other powers and functions of an official analyst, an official analyst may -
(*a*) upon receipt of a sample, determine the tests that are to be performed on the sample; and
(*b*) determine whether the sample needs to be forwarded to any other approved laboratory overseas for special tests; and
(*c*) determine whether the sample is appropriately packaged, fastened and sealed; and
(*d*) if the sample is appropriately packaged store the sample under secure conditions that are appropriate to the kind of goods; and
(*e*) examine the label and package of the product to determine whether the medicinal products comply with the labelling and packaging requirements; and
(*f*) determine whether the medicinal product label provides appropriate and clear instructions for use; and
(*g*) as soon as practicable and within the available facilities carry out all the relevant tests to establish the quality of the sample and to determine whether the medicinal products comply with the standards specified in the label; and
(*h*) examine medicinal product suspected to be of questionable efficacy or safety, and to demonstrate and document any evidence of deterioration, contamination, or adulteration; and
(*i*) check the stability of medicinal products under local conditions of storage; and
(*j*) furnish a report of the results of the analysis to the licensing authority.

57. CERTIFICATE OF GOVERNMENT ANALYST.
~~(1)~~The analyst should review the results as soon as possible after all the tests have been completed to determine whether the medicinal product meets the specification stated on the label.

(2) After recording all conclusions the analyst shall issue a certificate of analysis.

~~(3)~~The analyst must send a copy of the certificate, signed by the analyst to the licensing authority, a copy to the Inspector and a copy to the person from whom the samples were taken, within a reasonable time.

58. APPOINTING A LABORATORY FOR TESTING.
The licensing authority shall for the purposes of these Regulations appoint a laboratory for testing the medicinal products either within the country or overseas until such time the Department establishes its own laboratory, for testing and evaluation of medicinal products.

59. THE REQUIREMENTS WITH RESPECT TO LEAFLETS RELATING TO MEDICINAL PRODUCTS.
~~(1)~~The medicinal product information should include all necessary information on the proper use of the product -

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(*a*) name of the medicinal product; and
(*b*) quantitative list of active ingredients; and
(*c*) dosage form; and
(*d*) indicating -
(i) dosage; and
(ii) mode of administration; and
(iii) duration of use, where appropriate; and
(iv) adverse effects if any; and
(v) over dosage information; and
(vi) contraindications, warnings, precautions and drug interactions used in pregnancy and lactation; and

(2) The languages shall be one of the three national languages; English, Motu or Pidgin.

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SCHEDULE 1.

FEES FOR LICENCES.

Product license:

For a licence issued to a medicinal product	K20 per product

Import or Export licences:

(*a*) For licence issued to import or export medicinal product	K1000
(*b*) Renewal of import or export licence for a medicinal product	K500
(*c*) For licence issued to a Papua New Guinea legal entity to Import a product or a range of products from the licence holder of those medicinal product.	K500

Wholesale Dealer's Licence:

(*a*) Licence to sell a medicinal products by wholesale dealing	K4000
(*b*) For Renewal of licence to sell a medicinal product by wholesale dealing	K1000

Manufacturer's Licence:

(*a*) For each licence to manufacture a medicinal product	K4000
(*b*) Renewal of licence to manufacture a medicinal product	K1000

Pharmacy registration:

(*a*) Fees for registration of a pharmacy	K4000
(*b*) Renewal fees of licence for registration of a pharmacy	K1000

Clinical trials:

Fees for issue of a clinical trial certificate	K1000

Variation or amendment:

Any variation or amendment to a licence on any single occasion	K20

Pharmacists & Pharmacy Technicians Registration:

(*a*) Fees for registration of a pharmacist	K100
(*b*) Annual renewal fees to practise as a pharmacist	K50
(*c*) Fees for registration of a pharmacy technician	K25
(*d*) Annual renewal fees to practise as a pharmacy technician	K15
(*e*) Fees for provisional registration of pharmacist	K25
(*f*) Fees for provisional registration of pharmacy technician	K15

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S C H E D U L E 2

INDEPENDENT STATE OF PAPUA NEW GUINEA

***Medicines and Cosmetics Act* 1999.**

Act. Sec. 24 Form 1 (a).
Reg. Sec. 25 (2)

Medicines and Cosmetics

PHARMACY REGISTRATION APPLICATION FORM

To be Completed by Applicant

Applicant's Name	
Business Name	
Postal Address	
Telephone Number	
Fax Number	
E mail Address	
Business Address	**(Section & Lot.No.)**
IPA Number	
Fees Enclosed	

I/We…….hereby apply for Pharmacy Registration and agree to comply with all conditions in accordance with the Medicines and Cosmetics Act 1999 and its Regulations.

Signature:……. Date:……

Witnessed by:-……
Commissioner for Oaths (Print Name)

Date:	

Pharmacy Board Use Only

Licence Number:	
Date Issued:	
Date of Previous Licence:	
Date of Expiration:	
Date of Inspection:	

Send to: Pharmacy Board of Papua New Guinea
P.O.Box 807
Waigani NCD
Papua New Guinea
Phone : (675) 3013886
Fax : (675) 3231631

INDEPENDENT STATE OF PAPUA NEW GUINEA

***Medicines and Cosmetics Act* 1999.**

Act. Sec. 11 Form 1 (b).
Reg. Sec. 9,11,5 and 15

LICENCE APPLICATION FORM

A separate application must be completed for each licence type.

Medicines and Cosmetics

Licence Type	Wholesale	Import	Manufacturer	Export
(Tick applicable)				

To be Completed by Applicant

Applicant's Name	
Business Name	
Postal Address	
Telephone Number	
Fax Number	
E mail Address	
Business Address	**(Section & Lot.No.)**
IPA Number	
Person Responsible	
Name	
Qualification	
Type of Application	**New/Renewal (✓) applicable)**
Fees Enclosed	

I/We…….hereby apply for Pharmacy Registration and agree to comply with all conditions in accordance with the Medicines and Cosmetics Act 1999 and its Regulations.

Signature:…….Date:……

Witnessed by:-……
Commissioner for Oaths (Print Name)

Date:	

Pharmacy Board Use Only

Licence Number:	
Date Issued:	
Date of Previous Licence:	
Date of Expiration:	
Date of Inspection:	

Send to: **Pharmacy Board of Papua New Guinea**
P.O.Box 807, Waigani NCD
Papua New Guinea
Phone : (675) 3013886
Fax : (675) 3231631

INDEPENDENT STATE OF PAPUA NEW GUINEA

***Medicines and Cosmetics Act* 1999.**

Act. Sec. 25 Form 2.
Reg. Sec. 26 (1)

PHARMACY BOARD OF PAPUA NEW GUINEA

Medicines and Cosmetics

License to Operate

Pharmacy

License No. **: «LincenseNo»**

(«ClientUniqueID»)

Issue date : Date Month Year

Expiration date : «Expiration_Date»

Licensee : «Name_of_Pharmacy»

Address : «Village1», «District1», «Province1»

Pharmacist : «Name_of_Exporter»

Occupation : «Occupation»

This license is subjected to the following conditions:

1. The licensee shall comply with the relevant provisions of the Medicines and Cosmetics Act 1999 and the regulations there under.
2. The license shall be displayed in a prominent place in a part of the premises open to the public.
3. The operations of the pharmacy shall not take place other than the premises mentioned above.
4. The licensee shall report to the licensing authority any change in the qualified person within one month of such change.
5. Failure to pay the renewal of license fees within 3 months of the notice shall be considered as a new license.
6. The licence shall be valid only for a period of one year.
7. Any further conditions imposed by the licensing authority shall be notified.

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Authorized Signature

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Chairman – Pharmacy Board

INDEPENDENT STATE OF PAPUA NEW GUINEA

***Medicines and Cosmetics Act* 1999.**

Act. Sec. 11
Reg. Sec. 10 (1) Form 3.

National Department of Health
Port Moresby, Papua New Guinea

Medicines and Cosmetics

License To operate

Wholesaler

License No. : **«LincenseNo»**

(«ClientUniqueID»)

Issue date : dd/mm/yyyy

Expiration date : «Expiration_Date»

Licensee : «Name_of_Pharmacy»

Address : «Village1», «District1», «Province1»

Pharmacist : «Name_of_Exporter»

Occupation : «Occupation»

This license is subject to the following conditions:

~~1.~~The licensee shall comply with the relevant provisions of the ***Medicines and Cosmetics Act*** 1999 and the regulations there under.

~~2.~~The sale of the medicinal products shall not take place other than the premises mentioned above.

~~3.~~The licensee shall report to the licensing authority any change in the qualified person within one month of such change.

~~4.~~The license shall be displayed in a prominent place in a part of the premises open to the public.

~~5.~~The license shall be valid only for a period of one year.

~~6.~~Any further conditions imposed by the licensing authority shall be notified.

Authorized Signature

_____

Licensing Authority

INDEPENDENT STATE OF PAPUA NEW GUINEA

***Medicines and Cosmetics Act* 1999.**

Act. Sec. 11
Reg. Sec. 14 (1) Form 4.

National Department of Health

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Medicines and Cosmetics

Port Moresby, Papua New Guinea

License To operate

Importer

License No. **: «LincenseNo»**

(«ClientUniqueID»)

Issue date : Date Month Year

Expiration date : «Expiration_Date»

Licensee : «Name_of_Pharmacy»

Address : «Village1», «District1», «Province1»

Pharmacist : «Name_of_Exporter»

Occupation : «Occupation»

This license is subjected to the following conditions:

1. The licensee shall comply with the relevant provisions of the Medicines and Cosmetics Act 1999 and the regulations there under.
2. The licence shall be displayed in a prominent place in a part of the premises open to the public.
3. The operations of the importer shall not take place other than the premises mentioned above.
4. The licensee shall report to the licensing authority any change in the qualified person within one month of such change.
5. The licence shall be valid only for a period of one year.
6. Any further conditions imposed by the licensing authority shall be notified.

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Authorized Signature

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Licensig Authority

INDEPENDENT STATE OF PAPUA NEW GUINEA

***Medicines and Cosmetics Act* 1999.**

Act. Sec. 11
Reg. Sec. 16 (1) Form 5.

National Department of Health

Port Moresby, Papua New Guinea

License To operate

Medicines and Cosmetics

Exporter

License No. : **«LincenseNo»**

(«ClientUniqueID»)

Issue date : dd/mm/yy

Expiration date : «Expiration_Date»

Licensee : «Name_of_Pharmacy»

Address : «Village1», «District1», «Province1»

Pharmacist : «Name_of_Exporter»

Occupation : «Occupation»

This licence is subjected to the following conditions:

1. The licensee shall comply with the relevant provisions of the Medicines and Cosmetics Act 1999 and the regulations there under.
2. The licence shall be displayed at a prominent place in a part of the premises open to the public.
3. The operations of the exporter shall not take place other than the premises mentioned above.
4. The licensee shall report to the licensing authority any change in the qualified person within one month of such change.
5. The licence shall be valid only for a period of one year.
6. Any further conditions imposed by the licensing authority shall be notified.

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Authorized Signature

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Licensing Authority

INDEPENDENT STATE OF PAPUA NEW GUINEA

***Medicines and Cosmetics Act* 1999.**

Act. Sec. 11 Form 6.
Reg. Sec. 3

APPLICATION FOR DRUG REGISTRATION
PNG MEDICAL SUPPLIES SERVICES, DEPARTMENT OF HEALTH

PART I.	APPLICANT INFORMATION	
Address	*Street:*	

	Area:	
	City	
	Province	
	Country	
Telephone		
Fax		
Email address		
IPA permit #		
Contact person		
PART II.	**MANUFACTURER INFORMATION**	
	(see requirement #8)	
Address	*Street:*	
	Area:	
	City	
	Province	
	Country	
Telephone		
Fax		
Email address		
PART III.	**PRODUCT INFORMATION**	
	(see requirement # 9)	

Active ingredients			
Name	*Strength*	*Name*	*Strength*
1.		*4.*	
2.		*5.*	
3.		*6.*	
Inactive ingredients			
Name	*Strength*	*Name*	*Strength*
1.		*5.*	
2.		*6.*	
3.		*7.*	
4.		*8.*	

Storage Conditions								
Shelf Life								
Primary packaging								
Packing Size								***(see package insert)***
Dispensing category	***OTC***		***Prescription***		***Pharmacy***		***Dangerous***	
ATC Classification								
Pharmacologic Classification								
Listed in PNG Essential Drugs List ?	***Yes***							
Description	***Colour***		***Shape***		***Size***		***Coating***	
	Other descriptions							
Indications								
Contraindications								
Side effects								
Unit price								
PART IV.	**REGISTRATION INFORMATION (IMPORTATION)**							
Registration No. *(in country of origin)*								
Date of registration	***(dd/mm/yy)***							

I declare that the particulars given in this application are true and correct, and that all accompanying reports and documents supplied for the registration of medicinal products in PNG are true and are authentic copies.

Date: ……..At: ……... Authorized signature: _____

INDEPENDENT STATE OF PAPUA NEW GUINEA

***Medicines and Cosmetics Act* 1999.**

Act. Sec. 11
Reg. Sec. 4 (1)

Form 7.

DEPARTMENT OF HEALTH

Medicines and Cosmetics

PORT MORESBY
PAPUA NEW GUINEA.

TEL: 301-3886
FAX: 323-1631

Registration Number:	**«Registration_No»**

«Brand_Name»

Dosage Form:	**«Dosage_Form»**
Active Ingredient/s:	**«Ingredients»**
Description:	**«Description»**
Size of packaging unit:	«Primary_Packaging», «Packing_Size»
Indications:	**«Indications»**
Registration/Permit No. (issued by exporting country):	**«Registration_No_importing_country»**

Manufactured by: «Name1»	
Address: «Street1», «District1», «Province1», «Country1», «Zip_Code1»	
Telephone: «Telephone_Number1»	Fax number: «Fax_Number1»
Name of importer in PNG: «Name»	
Address: «Street», «District», «Province», «Country», «Zip_Code»	
Telephone: «Telephone_Number»	Fax number «Fax_Number»

This Certificate is issued to attest that the product described above has met the minimum standards required for drug registration undertaken by the **Medical Supplies Branch, Department of Health, Papua New Guinea**.

This certificate expires, unless previously suspended or revoked, on «Date_of_expiration».

_____ Port Moresby, Papua New Guinea.

Director
Medical Supplies Branch.

INDEPENDENT STATE OF PAPUA NEW GUINEA

***Medicines and Cosmetics Act* 1999.**

Act. Sec. 11
Reg. Sec. 8 Form 8.

National Department of Health

Port Moresby, Papua New Guinea

Medicines and Cosmetics

License To operate

Manufacturer

License No. : **«LincenseNo»**

(«ClientUniqueID»)

Issue date : Date Month Year

Expiration date : «Expiration_Date»

Licensee : «Name_of_Pharmacy»

Address : «Village1», «District1», «Province1»

Pharmacist : «Name_of_Exporter»

Occupation : «Occupation»

This license is subjected to the following conditions:

1. The licensee shall comply with the relevant provisions of the Medicines and Cosmetics Act 1999 and the regulations there under.
2. The licence shall be displayed in a prominent place in a part of the premises open to the public.
3. The operations of the manufacturer shall not take place other than the premises mentioned above.
4. The licensee shall report to the licensing authority any change in the qualified person within one month of such change.
5. The licence shall be valid only for a period of one year.
6. Any further conditions imposed by the licensing authority shall be notified.

Authorized Signature

_____

Licensing Authority

INDEPENDENT STATE OF PAPUA NEW GUINEA

***Medicines and Cosmetics Act* 1999.**

Act. Sec. 54, (r,1)
Reg. Sec. 2, (24-26) Form 9

Application for issue of a clinical trial certificate

1. I……resident of ……by occupation ……..hereby apply for licence to import the medicinal products mentioned below for the purposes of conducting clinical trials at ……from…….

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……..and I undertake to comply with the conditions applicable to the licence and in accordance with the Medicines and Cosmetics Act and regulations.

Name of the Medicinal Product……Quantity……..

2. I enclose the fee of…….

Signature of applicant……

Date…….

INDEPENDENT STATE OF PAPUA NEW GUINEA

***Medicines and Cosmetics Act* 1999.**

Act. Sec. 54(r, ii)
Reg. Sec. 19 Form 10.

Licence to import medicinal products for conducting clinical trials

Licence No……..

Name of Licensee…….

Address of licensee……

Medicines and Cosmetics

Address of premises authorized for conducting the clinical trial…….

The licence shall be in force from…….to……

Medicinal products to be imported: **Quantity:**

Date……. Licensing Authority……

This licence is subjected to the following conditions:

1. The licensee shall comply with the relevant provisions of the Medicines and Cosmetics Act 1999 and the regulations there under.
2. The licensee shall comply with any further conditions imposed by the licensing authority.

INDEPENDENT STATE OF PAPUA NEW GUINEA

***Medicines and Cosmetics Act* 1999.**

Act. Sec. 22 (b),(d)
Reg. Sec. 28(2) Form 11.

PHARMACY BOARD OF PAPUA NEW GUINEA

This certifies that

…(Name of Person)…

Medicines and Cosmetics

was this day registered as a

…(Pharmacist/Pharmacy Technician where appropriate)...

under the Medicines and Cosmetics Act 1999

Given at Port Moresby under the Common Seal of the Pharmacy Board of Papua New Guinea on the ……day of…….(Month)…….(Year)…….

Chairman – Pharmacy Board

Registration No……..

INDEPENDENT STATE OF PAPUA NEW GUINEA

***Medicines and Cosmetics Act* 1999.**

Act. Sec. 22 (b, d)
Reg. Sec. 28(2) Form 12.

PHARMACY BOARD OF PAPUA NEW GUINEA

PROVISIONAL LICENCE TO PRACTICE AS A PHARMACIST/PHARMACY TECHNICIAN
(where appropriate)

Medicines and Cosmetics

(NAME OF PERSON)

OF

(ADDRESS)

having duly paid the prescribed fees is hereby provisionally licenced to practice as a Pharmacist/Pharmacy Technician(where appropriate)

This provisional licence confers no entitlement to practice independently as a (Pharmacist/Pharmacy Technician where appropriate) and the final registration shall not be effected without the approval of the Pharmacy Board.

Given at Port Moresby under the Common Seal of the Pharmacy Board of Papua New Guinea on the ……day of…….(Month)…….(Year)

Chairman – Pharmacy Board

Licence No. ……..

INDEPENDENT STATE OF PAPUA NEW GUINEA

***Medicines and Cosmetics Act* 1999.**

Act. Sec. 22 (b, d)
Reg. Sec. 28(2) Form 13.

PHARMACY BOARD OF PAPUA NEW GUINEA

ANNUAL LICENCE TO PRACTICE AS A PHARMACY TECHNICIAN

NAME OF PERSON

OF

Medicines and Cosmetics

(ADDRESS)

having duly paid the prescribed fees is hereby licensed to practise as a ***PHARMACY TECHNICIAN*** under the Medicines and Cosmetics Act 1999 and is authorised to dispense drugs only.

Given at Port Moresby under the Common Seal of the Pharmacy Board of Papua New Guinea on the ……day of……..(Month)……(Year)

This licence expires on……. (day)……. (month)……. (Year)

Licence No. PT……..

…….

Chairman – Pharmacy Board

INDEPENDENT STATE OF PAPUA NEW GUINEA

***Medicines and Cosmetics Act* 1999.**

Act. Sec. 22(b), (d) Form 14.
Reg. Sec. 28(2)

PHARMACY BOARD OF PAPUA NEW GUINEA

ANNUAL LICENCE TO PRACTICE AS A PHARMACIST

(NAME OF PERSON)

Medicines and Cosmetics

OF

(ADDRESS)

having duly paid the prescribed fees is hereby authorised to practice as a ***PHARMACIST*** under the Medicines and Cosmetics Act 1999 and is authorised to mix, compound, prepare, dispense and sell drugs and poisons.

Given at Port Moresby under the Common Seal of the Pharmacy Board of Papua New Guinea on the ……day of…….(Month)……(Year)

This Licence expires on …….(day)……..(month)…….(Year)

Licence No. P ……..

…….

Chairman – Pharmacy Board

INDEPENDENT STATE OF PAPUA NEW GUINEA

***Medicines and Cosmetics Act* 1999.**

Act. Sec. 6 (4)
Reg. Sec. 60(2)(*c*) Form 15.

Application for issue of import license by a product license holder to a legal entity to import medicinal products

I.	Type		New	Renewal	
II.	Applicant Information				
1.	Name				
2.	Address				
3.	Telephone				
4.	Fax				
5.	Email address				
6.	Contact person (pharmacist)				

III Product License Holder	
~~1.~~Name	
~~2.~~Address	
~~3.~~Telephone	
~~4.~~Fax	
~~5.~~Email address	
~~6.~~Letter of consent/authority	
IV Product Information	
~~3~~ Brand name/strength	
~~4~~ Generic name/strength	
IV Medical Supplies Branch use only	
1 License #	
2 Date issued	
3 Date expired	

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I ……. undertake to comply with the conditions applicable to the license and in accordance with the Medicines and Cosmetic Act and the regulations.

I enclose the fee of……..

Printed name / Signature (Applicant): _____Date:_____

INDEPENDENT STATE OF PAPUA NEW GUINEA

***Medicines and Cosmetics Act* 1999.**

Act. Sec. 6 (4)
Reg. Sec. 60(2)(*c*) Form 16.

National Department of Health
Port Moresby, Papua New Guinea

License granted by a product license holder to a legal entity to import medicinal products.

License No. : licensee No

Issue date :

Medicines and Cosmetics

Expiration date :

Licensee : Name of Pharmacy

Address :

Pharmacist : Name of Exporter

Occupation :

This license is subject to the following conditions:

~~1.~~The licensee shall comply with the relevant provisions of the Medicines and Cosmetics Act, 1999 and the regulations.
~~2.~~The license shall be displayed in a prominent place of the premises open to the public.
~~3.~~The licensee shall report to the licensing authority any change in the qualification within one month of such change.
~~4.~~The license shall be valid only for one year.
~~5.~~Any further conditions imposed by the licensing authority shall be notified.

Authorized signature

_____

Licensing Authority

INDEPENDENT STATE OF PAPUA NEW GUINEA

***Medicines and Cosmetics Act* 1999.**

Act. Sec. 22 (b), (d)
Reg. Sec. 28(2) Form 17.

PHARMACY BOARD OF PAPUA NEW GUINEA

APPLICATION FORM - PROVISIONAL REGISTRATION

(PHARMACIST)

To: The Chairman
Pharmacy Board of Papua New Guinea
PO BOX 807
WAIGANI.
PAPUA NEW GUINEA

Phone: 675 301 3886
Fax: 675 323 1631

1. I……

(Surname) (Other Names in Full)

hereby apply for Provisional Registration as a Pharmacist.

2. (a) Qualification……

(Provide certified copies of Diploma, Degree, transcript etc)

(b) I enclose herewith the amount of ;

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(i) K25 – Pharmacist Provisional Registration fee

3. I forward the following particulars:

(a) Address:- (i). Residential……

Province:……..……

Telephone:……

(ii) Office or Business Premises:-

Name:……

Address:……

Telephone:……

(iii) Are you in Public/Private Practice?……

4. I hereby certify that the particulars submitted herein are true.

Declared at…….. this…… day

of……200…… (Signature of Applicant)

Before me:……..

Commissioner of Oath/Justice of Peace/Notary Public

OFFICE USE ONLY

(a) Is the application approved or rejected?……

(b) If rejected, state reason(s)……..

(c) Signed by……Date ……

Note: Every registered Pharmacist should send immediate notice of any change of address to the Chairman Pharmacy Board of Papua New Guinea, PO BOX 807 WAIGANI, PAPUA NEW GUINEA.

INDEPENDENT STATE OF PAPUA NEW GUINEA

***Medicines and Cosmetics Act* 1999.**

Act. Sec. 22 (b), (d) Form 18.
Reg. Sec. 28(2)

PHARMACY BOARD OF PAPUA NEW GUINEA

APPLICATION FORM - FULL REGISTRATION

(PHARMACIST)

To: The Chairman
Pharmacy Board of Papua New Guinea
PO BOX 807
WAIGANI.
PAPUA NEW GUINEA

Phone: 675 301 3886
Fax: 675 323 1631

1. I……
(Surname) Other Names in Full

hereby apply for Full Registration as a Pharmacist

2. (a) Qualification……

(Provide certified copies of Diploma, Degree, transcript, etc)

(b) I enclose herewith the amount of

~~(i)~~K100 – Pharmacist Full Registration fee

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~~3.~~ I forward the following particulars:

(a) Address: (i) Residential:……

Province:……

Telephone:……

(ii) Office or Business Premises:-

Name:……
Address:……

Telephone:……

(iii) Are you in Public/Private Practice?……

~~4.~~ **I hereby certify that the particulars submitted herein are true.**

Declared at……

This…… day of……200…… (Signature of Applicant)

Before me:……
Commissioner of Oath/Justice of Peace/Notary Public

OFFICE USE ONLY

(a)	Is the application approved or rejected?……
(b)	If rejected, state reason(s)……
(c)	Signed by…… Date……

Note: **Every registered Pharmacist should send immediate notice of any change of address to the Chairman Pharmacy Board of Papua New Guinea, PO BOX 807 WAIGANI, PAPUA NEW GUINEA.**

INDEPENDENT STATE OF PAPUA NEW GUINEA

***Medicines and Cosmetics Act* 1999.**

Act. Sec. 22 (b), (d)
Reg. Sec. 28(2) Form 19.

PHARMACY BOARD OF PAPUA NEW GUINEA

APPLICATION FOR RETENTION OF NAME IN THE REGISTER

(PHARMACIST)

To: The Chairman
Pharmacy Board of Papua New Guinea
PO BOX 807
WAIGANI.
PAPUA NEW GUINEA

Phone: 675 301 3886
Fax: 675 323 1631

1. I……
(Surname) (Other Names in Full)
Full Registration Number……

require my name to be retained in the register and hereby apply for a Practising Licence as a Pharmacist.

2. (a) Qualification……

(Any new qualification?)

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(b) I enclose herewith the amount of;

(i) K50 – Pharmacist Annual renewal fee

3. I forward the following particulars:

(a) Address:- (i) Residential:……

Province:……
Telephone:……

(ii) Office or Business Premises:-
Name……
Address……
Telephone……

(iii) Are you in Public/Private Practice?……

Last year's Licence to practise as a Pharmacist

Number……Date:……

~~3.~~**I hereby certify that I am a registered Pharmacist and that the particulars submitted herein are true.**

Declared at…… this day…….. day of……..200……..
(Signature of Applicant)

Before me :……..

Commissioner of Oath/Justice of Peace/Notary Public

OFFICE USE ONLY

(a) Is the application approved or rejected?……

(b) If rejected, state reason(s)……

(c) Signed by……Date ……

Note: **Every registered Pharmacist should send immediate notice of any change of address to the Chairman Pharmacy Board of Papua New Guinea, PO BOX 807 WAIGANI, PAPUA NEW GUINEA.**

INDEPENDENT STATE OF PAPUA NEW GUINEA

***Medicines and Cosmetics Act* 1999.**

Act. Sec. 22 (b), (d)
Reg. Sec. 28(2) Form 20.

PHARMACY BOARD OF PAPUA NEW GUINEA

APPLICATION FORM - PROVISIONAL REGISTRATION

(PHARMACY TECHNICIAN)

To: The Chairman
Pharmacy Board of Papua New Guinea
PO BOX 807
WAIGANI.
PAPUA NEW GUINEA

Phone: 675 301 3886
Fax: 675 323 1631

1. I……

(Surname) Other Names in Full

hereby apply for Provisional Registration as a Pharmacy Technician.

2. (a) Qualification……

(Provide certified copies of Diploma, transcript, etc)

(b) I enclose herewith the amount of

~~(i)~~ K15 – Pharmacy Technician Provisional Registration fee

~~3.~~ I forward the following particulars:

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(a) Address:- (i) Residential:……

Province:……

Telephone:……

~~(ii)~~Office or Business Premises:-

Name:……
Address:……

Telephone:……

(iii) Are you in Public/Private Practice?……

~~4.~~ **I hereby certify that the particulars submitted herein are true.**

Declared at……...

This…… day of……200…… (Signature of Applicant)

Before me:……
Commissioner of Oath/Justice of Peace/Notary Public

OFFICE USE ONLY

~~(a)~~Is the application approved or rejected?……

~~(b)~~If rejected, state reason(s)……

~~(c)~~Signed by …… Date ……

Note: **Every registered Pharmacy Technician should send immediate notice of any change of address to the Chairman Pharmacy Board of Papua New Guinea, PO BOX 807 WAIGANI, PAPUA NEW GUINEA.**

INDEPENDENT STATE OF PAPUA NEW GUINEA

***Medicines and Cosmetics Act* 1999.**

Act. Sec. 22 (b), (d)
Reg. Sec. 28(2) Form 21.

PHARMACY BOARD OF PAPUA NEW GUINEA

APPLICATION FORM - FULL REGISTRATION

(PHARMACY TECHNICIAN)

To: The Chairman
Pharmacy Board of Papua New Guinea
PO BOX 807
WAIGANI.
PAPUA NEW GUINEA

Phone: 675 301 3886
Fax: 675 323 1631

1. I……

(Surname) Other Names in Full

hereby apply for Full Registration as a Pharmacy Technician.

2. (a) Qualification……

(Provide certified copies of Diploma, transcript, etc)

(b) I enclose herewith the amount of

(i) K25 – Pharmacy Technician Full Registration fee

3. I forward the following particulars:

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(a) Address:- (i) Residential:……
Province:……
Telephone:……
(ii) Office or Business Premises:-
Name:……
Address:……
Telephone:……

~~(iii)~~Are you in Public/Private Practice?……

4. I hereby certify that the particulars submitted herein are true.

Declared at……...

This…… day of……200…… (Signature of Applicant)

Before me:……
Commissioner of Oath/Justice of Peace/Notary Public

OFFICE USE ONLY

(a) Is the application approved or rejected?……

~~(b)~~ If rejected, state reason(s)……

(c) Signed by…….. Date …….

Note: Every registered Pharmacy Technician should send immediate notice of any change of address to the Chairman Pharmacy Board of Papua New Guinea, PO BOX 807 WAIGANI, PAPUA NEW GUINEA.

INDEPENDENT STATE OF PAPUA NEW GUINEA

***Medicines and Cosmetics Act* 1999.**

Act. Sec. 22 (b), (d)
Reg. Sec. 28(2) Form 22.

PHARMACY BOARD OF PAPUA NEW GUINEA

APPLICATION FOR RETENTION OF NAME IN THE REGISTER

(PHARMACY TECHNICIAN)

To: The Chairman
Pharmacy Board of Papua New Guinea
PO BOX 807
WAIGANI.
PAPUA NEW GUINEA

Phone: 675 301 3886
Fax: 675 323 1631

1. I……
(Surname) Other Names in Full

Full Registration Number……
require my name to be retained in the register and hereby apply for a Practising Licence as a Pharmacy Technician.

2. (*a*) Qualification……
(Any new qualification?)

(*b*) I enclose herewith the amount of
~~(i)~~K15 – Pharmacy Technician Annual renewal fee.

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3. I forward the following particulars:
(*a*) Address:- (i). Residential:……..
Province:……
Telephone:…….
(ii) Office or Business Premises:-
Name……
Address……
Telephone……
(iii) Are you in Public/Private Practice?……..

Last year's Licence to practise as a Pharmacy Technician:-

Number…… Date:……

4. I hereby certify that I am a registered Pharmacy Technician and that the particulars submitted herein are true.

Declared at……..
this day…….. day of……..200……... (Signature of Applicant)

Before me :…….
Commissioner of Oath/Justice of Peace/Notary Public
OFFICE USE ONLY

(a)	Is the application approved or rejected?……
(b)	If rejected, state reason(s)……
(c)	Signed by…… Date ……

Note: Every registered Pharmacy Technician should send immediate notice of any change of address to the Chairman Pharmacy Board of Papua New Guinea, PO BOX 807 WAIGANI, PAPUA NEW GUINEA.

INDEPENDENT STATE OF PAPUA NEW GUINEA

***Medicines and Cosmetics Act* 1999.**

S C H E D U L E 3

Act. Sec. 8
Reg. Sec. 50

PRESCRIPTION ONLY MEDICINES:

Acarbose
Acebutolol and its salts
Acetarsol and its salts
Acetazolamide and its salts
Acetohexamide
Acetyl strophanthidin
Acetylcarbromal
Acetylcholine and its salts
Acetylcysteine Injection
Acetyldigitoxin
Aconite root
Actinomycin C
Actinomycin D
Adrenal Extract
Adrenaline Injection
Albumin fraction (saline) human
Albumin, human.
Albuterol
Alclofenac
Alclometasone
Alcuronium Injection
Aldosterone
Alendronate
Alendronate sodium
Alfacalcidol
Allergens
Allopurinol
Allyloestrenol
Alphadolone acetate
Alphaxalone
Alprazolam
Alprenolol
Alseroxylon
Aluminium clofibrate
Amantadine and its salts.
Ambutonium Bromide
Amcinonide
Ametazole Hydrochloride
Amethocaine
Amidopyrine
Amikacin sulphate
Amiloride hydrochloride
Aminocaproic acid
Aminodarone
Aminoglutethimide
Aminometradine
Aminopterin
Aminorex
Aminosalicylic acid
Amiphenazole
Amisometradine
Amitriptyline
Amitriptyline embonate
Amitriptyline Hydrochloride
Amlodipine
Ammonium bromide
Amoxapine
Amoxycillin
Amoxycillin Sodium
Amoxycillin trihydrate
Amoxycillin with clavulanic acid
Amphoteracin B
Ampicillin
Ampicillin sodium
Ampicillin trihydrate
Amrinone
Amylocaine hydrochloride
Ancrod
Androsterone
Aneurine Hydrochloride Injection
Antiotensin amide

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Anterior Pituitary extract
Antigens
Antihuman lymphocyte immunoglobulin
Antimony barium tartrate
Antimony Dimercaptosuccinate
Antimony Lithium thiomalate
Antimony Pentasulphide
Antimony Potassium tartrate
Antimony Sodium tartrate
Antimony Sodium thioglycollate
Antimony Sulphate
Antimony Trichloride
Antimony Trioxide
Antimony Trisulphide
Apiol
Apomorphine
Apomorphine hydrochloride
Apronal
Aprotinin
Arecoline hydrobromide
Arsenic
Arsenic Triiodide
Arsenic Trioxide
Arsphenamine
Artesunate Injection
Atenolol Injection and tablets
Atracurium
Atropine Sulphate Injection.
Auranofin
Azacyclonol
Azapetine
Azapropazone
Azaribine
Azathioprine
Azathioprine Sodium
Azidocillin Potassium
Azithromycin
Azlocillin
Bacampicillin hydrochloride
Baclofen
Bamethan
Bambermycin
Barbituric acid
Barium carbonate
Barium chloride
Barium sulphide
Beclamide
Beclomethasone and its salt except in formulations for inhalation.
Bemegride
Bemegride sodium
Benactyzine
Benapryzine hydrochloride
Benathamine penicillin
Benazepril hydrochloride
Bendrofluazide
Benoxaprofen
Benperidol
Benserazide
Benzathine penicillin
Benzbromarone
Benzhexol hydrochloride
Benzilonium bromide
Benzoctamine Hydrochloride
Benzodiazepine
N-Benzoyl sulphanilamide
Benzquinamide
Benzthiazide
Benztropine Injection
Benztropine mesylate
Benzydamine
Benzylpenicillin
Beta-adrenergic receptor blocking medicines
Betahistine hydrochloride
Betamethasone
Betamethasone and its salt except in topical preparation containing less than 0.1%
Bethanicol chloride
Bethanidine sulphate
Bezafibrate
Biperiden hydrochloride
Biperiden Lactate
Bismuth glycollylarsanilate
Bismuth subsalicylate
Bisoprolol fumarate
Bitolterol mesylate
Bleomycin
Blood corpuscles, concentrated human red
Blood, dried human
Bretylium Tosylate
Bromazepam
Bromocriptine Mesylate
Bromvaletone
Bronchodilators
Broxyquinoline
Budesonide
Bufexamac
Bumetanide
Buphenine hydrochloride
Bupivacaine
Bupivacaine hydrochloride
Buprenorphine
Buprenorphine Hydrochloride
Busprirone Hydrochloride
Busulphan
Butacaine sulphate
Butorphanol
Butriptyline hydrochloride
Butylaminobenzoate
Butylchloral hydrate
Calciferol
Calcitocin
Calcitonin
Calcitriol
Calcium bromide
Calcium benzylaminodiasalicylate
Calcium amphonycin
Calcium bromo lactobionate
Calcium carbamide
Calcium folinate
Calcium sulphaloxate
Calcium Gluconate Injection
Calcium polystyrene sulphonate
Calcium sodium edetate Injection
Candicidin
Cantharidin
Capreomycin sulphate
Captopril
Carbachol
Carbamazepine
Carbaryl
Carbenicillin sodium
Carbenoxolone sodium
Carbidopa
Carbimazole
Carbocisteine
Carboplatin Injection
Carboxy methyl cysteine
Carbromal
Carbutamide
Carbuterol
Cardiac glycosides
Carfecillin sodium
Carindacillin
Carisoprodol
Carmustine
Carperidine
Carprofen
Cefaclor
Cefadroxil
Cefoperazone
Cefotaxime
Cefotiam
Cefsulodin
Ceftazidime Injection
Ceftriaxone
Cefuroxime
Cephalexin
Cephalexin sodium
Cephalothin sodium
Cefaloridin
Cephazolin sodium
Cephradine
Cerium oxalate
Chenodeoxycholic acid
Chloral hydrate
Clarithromycin
Chlorambucil
Chloramphenicol except in topical preparations
Chloramphenicol cinnamate
Chloramphenicol palmitate
Chloramphenicol sodium succinate
Chlorhexadol
Chlorimadinone Acetate
Chlormerodrin
Chlormethiazole

Chloromethiazole edisylate
Chlormezanone
Chlorphenoxamine hydrochloride
Chlorpromazine hydrochloride
Chlorpromazine
Chlorpropamide
Chlorprothixene
Chlortetracycline
Chlortetracycline calcium
Chlortetracycline Hydrochloride
Chlorthalidone
Chlorthiazide
Chlorzoxazone
Chorionic gonadotrophin
Cimetidine Injection
Cinchocaine hydrochloride.
Cinchopen
Cinoxacin
Cisplatin Injection
Clenbuterol hydrochloride
Clidinium bromide
Clindamycin
Clindamycin Hydrochloride hydrate
Calmitate hydrochloride
Clindamycin Phosphate
Clobetasol 17-propionate
Clobetasone butyrate
Clofazimine
Clofibrate
Clomiphene Citrate
Clomipramine
Clomipramine hydrochloride
Clomocycline
Clomocylline sodium
Clonidine
Clonidine Hydrochloride
Clopamide
Clorexolone
Cloxacillin
Codeine phosphate except in compound formulation containing 10 mg or less
Cotrimoxazole
Coumarins
Crocus sativus
Curare; alkaloids of; curare bases
Cyclandelate
Cyclobenzaprine; and its salts
Cyclofenil
Cycloheximide
Cyclopenthiazide
Cyclopentolate hydrochloride
Cyclophosphamide Injection and Tablets
Cyclopropane
Cycloserine Tablets
Cyclosporin
Cycrimine; and its salts
Cyproterone; and its esters
Cytarabine Injection
Cytotoxic medicines
Dacarbazine
Dactinomycin
Danazol
Dantrolene sodium
Dapsone
Dapsone ethane orthosulphonate
Daunorubicin Hydrochloride
Dibenzepin
Demecarium bromide
Deanol bitartrate
Debrisquine sulphate
Demeclocycline;
Demeclocycline calcium;
Demeclocycline hydrochloride
Demethylchlortetracycline; and its salts
Deoxycortone Acetate
Deoxycortone Pivalate
Deoxymethasone
Deptropine Citrate
Dequalinium chloride
Deserpidine
Desferrioxamine mesylate
Desfluoro triamcinolone
Desipramine hydrochloride
Deslanoside
Desmopressin; and its salts
Desogestrel
Desonide
Dexamethasone; and its esters
Dextromethorphan hydrobromide except in cough formulations
Dextrothyroxine Sodium
Diazepam; and its salts
Diazoxide; and its salts
Dichloral phenazone
Dichlorphenamide
Diclofenac; and its salts
Dicyclomine Dydrochloride
Dienoestrol; and its esters
Diethanolamine fusidate
Diethyl propion hydrochloride
Diflunisal
Difluocortolone; and its esters
Digitalis leaf
Digitalis
Digotoxin
Digoxin
Dihydrallazine sulphate
Dihydroergotixine; and its slats
Dihydrotachysteriol
Di-iodohydroxyquinoline,
Diltiazem; and its salts
Dimercaprol
Dimethisoquin hydrochloride
Dimethisterone
Dimethothiazine mesylate
Dimethyl sulphoxide
Dimethyl tubocurarine bromide
Dimethyl tubocurarine chloride
Dimethyl tubocurarine Iodide
Dinoprost
Diphenidol; and its salts
Dipivefrin; and its salts
Dipyridamole
Disopyramide; and its salts
Distigmine; and its salts
Disulfiram
Disulphamide
Diuretics, oral
Dobutamine; and its salts
Domperidone
Dopamine; and its salts
Dothiepin; and its salts
Doxantrozole; and its salts
Doxapram; and its salts
Doxepin; and its salts
Doxycycline; and its salts
Droperidol
Drostanolone; and its esters
Dydrogesterone
Dyflos
Econazole; and its salts; except in dermatological medicines
Ecothiopate; and its salts
Ectylurea
Edrophonium; and its salts
Embutramide
Emepronium; and its salts and its complexes
Emetine and its salts
Enalapril maleate
Epicillin; and its salts
Epithiazide
Ergometine; and its salts
Ergot
Ergotamine Tartrate
Erythomycin; and its salts; and its esters
Estramustine; and its salts
Estrogens
Etafedrine hydrochloride
Ethacrynic acid; and its salts
Ethambutol; and its salts
Ethamivan
Ethamsylate
Ethiazide
Ethinyloestradiol
Ethionamide
Ethisterone
Ethoglucid
Ethoheptazine; and its salts
Ethopropazine hydrochloride
Ethosuximide
Ethotoin
Ethoxzolamide
Ethyl biscoumacetate
Ethylene
Ethyloestrenol
Ethynodiol; and its esters
Etidronate disodium

Etomidate
Etoposide
Etretinate
Factor ix fraction, dried human
Fazadinium bromide
Fenbufen
Ferrous aresenate
Fibrin foam, human
Flavoxate hydrochloride
Flecainide; and its salts
Fluanisone
Fluclorolone acetonide
Flucloxacillin Capsule, Injection and Suspension
Flucytosine
Fludrocortisone; and its esters
Flufenamic acid; and its salts
Flumethasone; and its esters
Flumethiazide
Flunisolide
Flunitrazepam; and its salts
Fluocinolone; and its derivatives
Fluocinonide; and its esters
Fluocortolone; and its esters
Fluorescein Injection
Fluorometholone and its esters
Fluorouracil Injection
Fluouracil
Fluoxy mesterone
Flupenthixol; and its esters
Fluperolone acetate
Fluphenazine Decanoate Injection
Fluphenazine; and its salts and esters
Fluprednisolone
Fluprostenol sodium salt
Flurandrenolone
Flurazepam; and its salts
Flurbiprofen
Fluroxene
Fluspirilene
Flutamide
Folinic acid; and its salts
Fosfestrol tetrasodium
Framycetin; and its salts
Frusemide Injection and Tablets
Furaltadone
Furazolidaone
Fusafungine
Fusidic acid; and its salts
Gallamine triethiodine
Gastronol hexanoate
Gentamicin Injection
Centamicin sulphate
Gestronol
Glibenclamide Tablets
Glibornuride
Glipizide
Gliquidone
Glycopyrronium bromide
Glymidine
Gonadorelin
Gonadotropin Sabadilla
Human Growth hormone
Guanethidine monosulphate
Guanoclor sulphate
Guanoxan sulphate
Hachimycin
Halcinonide
Halofenate
Haloperidol
Halothane
Halquinol; except in medicines for external use
Heparin
Hepatitis B Vaccine
Hexachlorophane, except in medicines containing 3 percent
Hexamethonium
Hexamethonum; and its salts
Hexamime phenyl cichoninate
Hexetidine
Hexetidine, except in medicine for external use
Hexobendine; and its salts
Hexoestrol
Hexoprenaline; and its salts
Histamine
Homatropine Methylbromide
Hydantoin; and its derivatives, except allantoin
Hydragraphen, except in medicines for external use
Hydralazine
Hydrobromic acid
Hydrobronide
Hydrochlorothiazide
Hydrocortisone and its salt except in topical preparation containing 1% or less
8-hydroxyquinoline; and its halogenated and alkyl derivatives and their salts except in medicines for external use
Hydroflumethiazide
Hydroxyphenamate
Hydroxyurea
Hydroxyzine; and its salts
Hymoleptic medicines
Hypothalamus, the active principles of.
Ibufenac
Ibuterol; and its salts
Idoxusidine
Ifosfamide
Ignatius bean
Imipramine
Indapamide hemihydrate
Idomethacin
Idoprofen
Idoramin; and its salts
Influenza and Coryza vaccines
Idothiouracil
Iothyronines Sodium
Ipratropium bromide
Iprindole; and its salts
Iproniazid; and its salts and esters
Isoaminiles; and its salts
Isocarboxazid
Isoconazole; and its salts; except in dermatological medicines
Isoetharine
Isoflurane
Isonazid; and its salts and esters
Isoprenaline; and its salts in medicines for inhalation or for parenteral use.
Isopromide iodide
Isotretinoin
Isoxicam
Isoxsuprine; and its salts
Jaborandi
Kanamycin and its salts
Ketamine
Ketazolam
Ketoconazole
Ketoprofen
Ketotifen
Labetalol; and its salts
Lanatoside
Lead; and its salts and oxides
Levallorphan
Levodopa
Levonorgestrel
L-Histidine hydrochloride
Lidoflazine
Lignocaine except in topical preparations
Lincomycin
Lithium
Lithoyronine sodium
Lofepramine hydrochloride
Lomustine
Loprazolam
Lorazepam
Lormetazepam; and its salts
Loxapine; and its salts
Luteinising hormone
Lymecycline
Lynoestrenol
Lypressin
Magenta, except in medicines for external use
Magnesium fluroride
Maldison, except in medicines containing 2 percent or less of maldison
Mandragora autumnalis
Mannomustine; and its salts
Maprotiline; and its salts
Measles Virus Vaccine
Mebanazine

Mebeverine; and its salts
Mebutamate
Mecamylamine; and its salts
Mecillinam; and its salts
Meclocycline; and its salts
Meclofenamate; and its salts
Medigion
Medroxy Progesterone
Medrysone
Megestrol
Melphalan
Menotrophin
Mepenzolate bromide
Mephenesin
Mephentermine; and its salts
Mepindolol; and its salts
Mepiracaine hydrochloride
Mequitazine
Mercaptomerin; and its salts
Mercaptopurine
Mercury oxides
Mercury, ammoniated
Mercury; and its salts; and its compounds, except oxides of mercury
Merruside
Mersalyl
Meruderamide
Mesterolone
Mestranol
Metamuric acid
Metaraminol
Metformin
Methacholine
Methacholine; and its salts
Methallnestril
Methicillin
Methimazole
Methisazole
Methizene; and its salts
Methocarbamol
Methoclopramide
Methohexitone; and its salts
Methoin
Methotrexate
Methotrimeprazine; and its salts
Methoxsalen
Methoxyflurane
Methsuximide
Methyclothiazide
Methyl Ergometrine Maleate
Methyl Prednisolone
Methyl Testosterone
Methyl Thiouracil
Methyldopa
Methylpentymol and its derivatives
Methysergide; and its salts
Metoprolol
Metriphonate
Metrizamide
Metronidazole
Metyrapone; and its salts
Mexiletine; and its salts
Mezlocillin; and its salts
Mianserin
Midazolam
Minocycline
Molindone; and its salts
Monoamine oxidase inhibitors
Monobenzole
Mopersone; and its salts
Morazone; and its salts
Motretinide
Moxalactam; and its salts
Mustine; and its salts and its derivatives
Nadolol
Naftideofuryl Oxalate
Naftidrofuryl; and its salts
Nalbuphine; and its salts
Nalidixic Acid
Nalorphine
Naloxone
Naltrexone hydrocloride
Nandrolone and its esters
Natamycin except in topical preparation
N-Benzoyl sulphaninlamide
Nefopam; and its salts
Neomycin
Neostigmine and its salt
Netilmicin
Neuromuscular blocking medicines
Nialamide
Nicofuranose
Nicoumalone
Nifedipine
Nifenazone
Nikethamide
Nimorazole; and its salts
Niridazole
Nitrazepam
Nitrofurantoin
Nitrogen mustrard; and its salts and its derivatives
Nitroxoline
Nomifensine; and its salts
Noradrenalina Acid Tartrate
Noradrenaline
Norethandrolone
Norethisterone
Norethynodrel
Norfloxacin
Norgestrel
Nortriptyline; and its salts
Novobiolin
Noxiptyline; and its salts
Nuxvomica Seed
Octalosactoin
Octamylamine; and its salts
Oestradiol
Oestriol
Oestriol Di – Henu Sucuinade
Oestrogens
Oestrones
Opipramol; and its salts
Oral diuretics
Orciprenaline
Ornipressin
Orphenadrine; and its salts
Orthocaine
Ouabain
Oxamniguine
Oxandrolone
Oxantei Pamoate
Oxazepam
Oxedrine Tartrate
Oxethazaine; and its salts
Oxolamine
Oxolinic acid
Oxpentifylline
Oxprenolol; and its salts
Oxybuprocaine
Oxymetholone
Oxypertine
Oxypetine Hydrochloride
Oxyphenbutazone
Oxyphencyclimine
Oxyphenisatin; and its esters
Oxyphenonium Bromide
Oxytetracycline
Oxytocin
Pancuronium and its salts
Para aminobenzene sulphonamide
Paraldehyde; except in medicines containing 1 percent or less of paraldehyde
Paramethadione
Paramethasone Acetate
Parathyroid Gland
Pargyline Hydrochloride
Pecazine
Pacazine; and its salts
Pemoline
Pempidine; and its salts
Penamecillin
Penicillamine
Penicillamine and its salts
Pentazocine
Penthienate Metho Bromide
Pentifylline
Pentolinium; and its salts
Perhexiline; and its salts
Pericyazine
Perilocin
Perphenazine; and its salts
Phenacetin
Phenaglycodol
Phenazone
Phenazone and Cafteine Citrate
Phenazone Sali Cylate

Phebutrazate Hydrochloride
Phenelzine
Phenethicillin Potassium
Phenformin
Phenglutarimide; and its salts
Phenindione
Phenisatin
Phenothiazine
Phenoxy Benzamine Hydro Chloride
Phenoxybenzamine; and its salts
Phenoxymethyl penicillin
Phenprocoumon
Phensuximide
Phentolamine
Phenyl propanolamine
Phenylbutazone
Phenytoin
Phenytoin Sodium
Phthalyl Sulphacetamide
Phthalyl sulphathiazole
Physostigmine and its salts
Picrotoxin
Pilocaepine
Pilocaepine Hydrochloride
Pilocaepine Nitrate
Pimoxide Mafenide; and its salts
Pimozide
Pindolol
Pipen zolate Bromide
Piperacillin
Piperazine Oestrone Sulphate
Piperidolate Hydrochloride
pipothiazine Palmitate
Pirbuterol; and its salts
Pirenzepine; and its salts
Piroxicam
Pirprofen
Pituitary gland extract
Pivampicllin
Pizotifen

Pizotifen Hydrogen Maleate
Pizotifen; and its salts
Plasmin
Platinum diamminodichloride
Pneumococcal vaccine
Poldine Methyl Sulphate
Polidexide
Polidexide; and its salts
Poliomyelitis vacine
Polyesttradiol; and its esters
Polymyxin; and its salts except in topical preparations
Polynoxylin
Polyoestradiol Phosphate
Polythiazide
Potassium Arsenate
Potassium Bromide
Potassium Perchlorate
Practolol
Pralidoxime
Prazepam
Prazosine
Prednisolone
Prednisone
Prenalterol; and its salts
Prenylamine lactate
Prilocaine
Primidone
Probucol
Procainamide
Procaine Hydrochloride
Procaine Penicillin
Procarbazine
Prochloperazine
Procyclidine
Progestogens
Proglumide; and its salts
Prolactin
Proligestone
Prolintane; and its salts
Promazine
Promoxolane
Propanidid
Propantheline Bromide
Proparidid
Propranolol
Propylhexedrine; and its salts
Propylthiouracil
Proquazone
Proscillaridin
Prostagladin
Protamine sulphate, except in insulins
Prothionade
Prothipendyl
Protoveratrines
Protriphyline
Protriptyline; and its salts
Proxymetacaine Hydrochloride
Psychomotor stimulants
Pyrazinamide
Pyridinolcarbamate
Pyridostigmine
Quazepam
Quinestradol
Quinestrol
Quinethazone
Quingestaniol
Quinidine
Quinidine Bisulphate
Quinidine Phenylethyl Barbitrate
Quinidine Polygalaturonate
Rabies vaccine
Rauwolfia species; and alkaloids of rauwolfia; and their salts
Razoxane
Reniterol HBV
Reprotherol; and its salts, in medicines for inhalation or for parenteral use.
Rescinnanine
Reserpine
Rifampicin
Rifamycin
Ritodrine; and its salts
Rolitetracycline; and its salts
Rosoxacin
Rubella vaccine
Salcatonin
Salmefamol
Salsalate
Serum Gonadotropin
Sisomycin
Sodium Antimonygluconate
Sodium Fusidate
Sodium Monofluoro phosphate
Sodium Stibogluconate
Sodium Amino Salicylate
Sodium Arsatrilate
Sodium Arsenate
Sodium Arsenite
Sodium bromide
Sodium calcium edetate
Sodium chromoglycate
Sodium Ethacrynate
Sodium nitroprusside
Sodium polystyrene sulphonate
Sodium valproate
Solcoseryl
Sotalol Hydrochloride
Sparteine; and its salts; and its derivatives
Spectinomycin
Spiramycin
Spiramycin Adipate
Spironolactone
Stanolone
Stanozolol
Stilboestrol
Streptodornase
Streptokinase
Streptomycin Sulphate
Streychnine Arsenate
Strontium bromide
Strophanthin
Strychimine Hydrochloride
Strychnine
Styramate
Succinyl Sulphathiazole
Sulfacytine
Sulfadoxine
Sulfamono methoxine
Sulindac
Sulphacetamide; and its salts except in eye preparations
Sulphadiazine; and its salts
Sulphadimethoxine
Sulphadimidine; and its salts
Sulphafurazole; and its salts
Sulphaguanidine
Sulphaloxic Acid

Sulphamerazine; and its salts
Sulphamethizole
Sulphamethoxydiazine
Sulphamethoxypyridazine
Sulphametrole
Sulphametroxazole
Sulphamoxole
Sulphanilamide
Sulphapyridine; and its salts
Sulphasalazine
Sulphathiazole; and its salts
Sulphaurea
Sulphinpyrazone
Sulphona; and alkyl sulphonals
Sulphonamide derivatives, for use as oral diuretics
Sulpiride
Sultametopylazine
Sulthiame
Suphaphenazole; and its derivatives
Suprofen
Sutilains, except in medicines for external use.
Suxamethonium; and its salts
Suxethonium; and its salts
Tacrine; and its salts
Talampicillin
Talampicillin Hydrochloride
Talampicillin Napsylate
Tamoxifen; and it salts
Temazepam
Teniposide
Terbutaline; and its salts; except in formulation for inhalation
Testosterone; and its esters
Tetanus antitoxin
Tetanus toxoid
Tetrabenazine
Tetracosactrin; and its salts
Tetracycline; and its salts
Tetraethylammonium salts
Tetroxoprim
Thallium Acetate
Thiambutosine
Thiazide derivatives
Thiethylperazine; and its salts
Thiobarbituric acid; and its salts
Thiocarlide
Thioguanine
Thiopentone; and its salts
Thiopropazate; and its salts
Thioproperazine; and its salts
Thioridazine and it's salts
Thiosinamine
Thiotepa
Thiothizene; and its salts
Thiouracil
Thrombin, dried human
Thymoxamine Hydrochloride
Thyroid; and its synthetic derivatives; and their salts
Thyrotrophin
Thyrotrophin-releasing factor
Thyroxine; and its salts
Tiamterene
Tiamulin Fumarate
Tiaprofenic acid; and its salts
Tiaramide; and its salts
Ticarcillin; and its salts.
Tigloidine Hydrobromide
Tiletamine; and its salts
Tinidazole
Tioconazole, in medicines for intra-vaginal use
Tobramycin; and its salts
Tocainide; and its salts
Tofenaum Hydro-chloride
Tolazamide
Tolazoline; and its salts
Tolbutamide; and its salts
Tolmetin; and its salts
Tranexamic acid; and its salts and esters
Tranylcypromine; and its salts
Trazodone
Treosulphan
Tretamine
Triacetyloleandomycin
Triaziquone
Triclofos Sodium
Triazine derivatives, for use as oral diuretics.
Triazolam
Tribromoethyl alcohol
Trichlormethiazide
Trichloroethylene
Trilostane
Triethylene thiophosphoramide
Trifluoperazine; and its salts
Trifluperidol
Triflupromazine
Trilostane
Trimcinolone; and its salts;
Trimeprazine; and its salts
Trimetaphan; and its salts
Trimetazidine and it's salt
Trimethoprim
Trioxsalen
Triperidol
Triple antigen
Trmipramine; and its salts
Tropicamide
Troxidone
Tryptophan
Tubocurarine; and its salts
Tulobutero; and its salts in medicines for inhalations.
Tylosin
Tyrothriun
Urokinase
Uramustine
Urea Stibamine
Urethane
Uridine 5-triphosphoric acid
Vaccines
Valproic acid
Vancomycin
Vasopressin
Vasopressin tannate
Vecuronium bromide
Verapamil
Veratrine
Veratrum
Vidarabine
Viloxazine
Vinblastine
Vincristine
Vindesine
Vinyl ether
Viomycin Pantothenate
Viomycin sulphate
Warfarin
Warfarin sodium
Xanthinol nicotinate
Xipamide
Xylazine Hydrochloride
Yohimbine Hydrochloride
Zimeldine
Zoxazolamine

Any new drug not yet listed by the Pharmacy Board.

INDEPENDENT STATE OF PAPUA NEW GUINEA

S C H E D U L E 4

Act. Sec. 8
Reg. Sect. 50

PHARMACY ONLY MEDICINES:

Acetanilide
Acetic Acid
Acetomenaphthone
Acetyclysteine
Aconite
Acriflavine
Acyclovir and its salts
Adrenaline and its salts
Albendazole
Alcohol, absolute
Alcohol, isopropyl
Aloes
Aloin
Aloxiprin
Aluminium Acetate
Aluminium Chloride
Aluminium hydroxide
Aluminium Subacetate
Aluminium sulphate
Aminacrine
Aminophylline
Ammonium mandelate
Ammonium chloride
Amodiaquine
Amyl nitrite
Amyldimethylamino benzoate
Anhydrous Ianolin or mineral oil or hydrocortisone
Antazoline
Artesunate tablets
Aspirin
Astemizole
Atropine
Azatadine
Bacitracin and its salts in topical preparations
Bamifylline hydrochloride
Belladonna
Benorylate
Bentiromide
Benzocaine
Benzoic Acid
Benzoyl peroxide
Benzyl benzoate
Bephenium Hydroxynaphthoate
Bisacodyl
Bismuth Carbonate
Bismuth Oxide
Bismuth Oxyquinolinate
Bismuth Subgallate
Bismuth Subnitrate
Borates
Boric Acid
Brochodilators
Bromhexine
Bromhexine hydrochloride
Brompheniramine
Broxaldine
Broxyquinoline
Brucine
Buclosamide
Budesonide
Butoxyethyl nicotinate
Butyl aminobenzoate picrate
Cadmium Sulphide
Calcium mandelate
Calamine
Calcium-hypochlorite
Calcium-salicylate
Carbetapentane
Carbuterol
Cardamom compound
Catechu
Cetyl pyridinium chloride
Chlorcyclizine
Chlorhexidine
Chloroform
Chloroquine Phosphate
Chloroquine Sulphate
Chlorphenesin
Cholestyramine
Choline Salicylate
Choline Theophyllinate
Chorbutol
Chorpheniramine maleate
Chromium trioxide
Ciclopirox olamine
Clemizole
Clioquinol
Coaltar
Colchicine
Cold sore balm
Colloidal bismuth subcitrate
Colocynth
Coniine
Copaiba Balsam
Cotarnine
Cresols
Crotamiton
Crystal Violet
Cyanides
Cyanocobalamin
Cyclizine
Cyproheptadine

Ciclopirox olamine 8%
Danthron
Dequalinium
Diamthazole hydrochloride
Dichlofenthion
2,4 – dichlorobenzyl alcohol
Dichlorophen
Dicophane
Dicyclomine hydrochloride
Diethylcarbamazine Citrate
Dimenhydrinate
Dioctyl sodium sulphosuccinate
Diphenhydramine hydrochloride
Diphenylpyraline
Dithranol
Ephedra
Ether
Ethyl nicotinate
Ethyl salicylate
Ethylchloride
Famotidine
Fenoterol
Fenticlor
Ferrous sulphate
Fibrinolysin
Fluorides
Folic Acid
Formaldehyde
Formic Acid
Galactose
Gamma Benzenehexachloride
Gentian violet
Glutaraldehyde
Glycerine suppository
Clyceryl Trinitrate
Glycol Salicylate
Gramicidin
Griseofulvin
Guaiphenesin
Haloprogin
Hexamine Hippurate
Hexamine Mandelate
Hexylnicotinate
Hyaluronidase
Hydrargaphen
Hydrochloric acid
Hydrocyanic acid
Hydrogen peroxide
Hydroxocobalamin
Hydroxychloroquine
Hydroxyprogesterone
Hyoscine
Hyoscine N-Butylbromide
Hyoscyamine
Ibuprofen
Ichthammol
Idoxuridine
Indanazoline
Inositol Nicotinate
Insulins
Intrinsic factor
Iodine
Iodoform
Ipecacuanha
Ipomoea resin
Irrigation medicines
Isopropyl alcohol
Isopropyl myristate
Jalap resin
Kenalog in orabase
Lactulose
Levocabastine
Lobelia
Loperamide hydrochloride
Loratidine
Mandelic Acid
Mannityl hexanitrate
Mebendazole
Mebhydrolin Napadisylate
Meclozine
Menadiol Sodium diphosphate
Mepyramine
Mercurochrone
Methdilazine
Methoxamine
Methoxy Phenamine
Methyl Nicotinate
Methyl Salicylate
Methyl Undecylenate
Methylene Blue
Miconazole
Minoxidil
Monoacetin
Monosulfiram
Mometasone furoate
Mupirocin
Mycostatin oral suspension
Naphazoline
Naproxen
Neomycin in topical preparations
Niclosamide
Nicorette Patches, chewing gum, nasal spray
Nicotine patches, gums
Nicotinic Acid
Nystatin
Nitrofurazone
Nitrous ether spirit
Noscapine
Nuxvomica
Octyl nitrite
Orciprenaline
Oxymetazoline hydrochloride
Pancretin
Papaverine
Paracetamol
Paraformaldehyde
Pentaeythritol Tetranitrate
Pentagastrin
Pentazocine hydrochloride/lactate
Pepsin
Phenazopyridine Hydrochloride
Pheniramine
Phenol
Phenolphthalein
Phenoxyethanol
Phenylephrine hydrochloride
Pholcodine
Phytomenadione
Picric Acid
Piperonyl Butoxide
Podophyllum Extracts
Polymycin and its salt in topical formulation
Potassium Carbonate
Potassium Chlorate
Potassium Choride
Potassium Citrate
Potassium Guaiacolsulphonate
Potassium Hydroxide
Potassium Iodate
Potassium Iodide
Potassium Nitrite
Potassim Permanganate
Providone iodine
Primaquine
Probenecid
Promethazine
Propyl undecylenate
Propylene Glycol
Propylhexedrine
Propylphenazone
Proquanil
Pseudoephedrine
Pumilio pine oil
Pyrantel
Pyrantel pamoate
Pyrethrins
Pyrimethamine
Quarternary ammonium compounds
Quassia
Quinine
Ranitidine
Retinol
Ribonuclease
Rimiterol hydrobromide
Salbutamol
Salicylamide
Salicylic acid
Scilarin
Scopolamine
Selenium sulphide
Senega
Silver and its salts
Silver protein
Silver sulphadiazine
Sodium benzoate
Sodium bicarbonate
Sodium bitartrate
Sodium citrate
Sodium fluoride
Sodium hyaluronate

Sodium hydroxide
Sodium Iodide
Sodium nitrite
Sodium perborate
Sodium salicylate
Sodium sulphide
Solanaceous alkaloids
Sorbide
Squill
Stannous chloride
Stannous oxide
Stramonium Strontium chloride
Sucralfate
Sulconazole nitrate
Sulphurate potash
Tannic acid
Tar
Terebene
Terbinafine
Terfenadine
Terpin hydrate
Tetra chloroethylene
Tetrahydrozoline
Theobromine
Theophylline
Theophylline; and its salts; in solid dose forms
Thiabendazole
Thiaminoheptane Sulphate
Thiomersal
Thioxolone
Thurfyl salicylate
Timolol; and its salts
Tioconazole
Tolnaftate
Tramazoline
Triamcinolone
Tretinoin
Trichloroacetic acid
Triclosan
Tripotassium dicitratobismuthate
Tripolidine
Trypsin
Tulobuterol
Tyloxapol
Undecenoic acid
Viprynium embonate
Vitamin A
Vitamin D
Xylometazoline
Zinc chloride
Zinc oxide
Zinc salts

Formulation of hormones marketed as contraceptives pills or tablets in 21 or 28 day.

INDEPENDENT STATE OF PAPUA NEW GUINEA

S C H E D U L E 5

Act. Sec. 8

Reg. Sec. 50

OVER THE COUNTER MEDICINES:

Accomin adult mixture
Accomin capsules
ACI gel
Acidophilus bioglan
Acnederm ointment or wash
Adsorbed activated charcoal tablets
Affinity condoms
Aiken mediated powder
Albalon – A liquifilm
Albalon 8 HR
Albalon relief
Alcon preserved saline
Allergen preserved saline
Aloe vera juice
Alphosyl cream or lotion
Alphosyl shampoo with conditioner
Ammens powder
Amonsan mouthwash sachets
Antassa herbal liquid antacid
Aosept
Aplha keri tar bath oil
Applicaine gel or liquid
Aquacare HP cream
Aquaear solution
Aquasun cream or gel or lotion
Aquatite earplugs
Aqueous cream
Asorbic acid
Ascoxal
Awesome heavy gainer chocolate
B and L eye multipurpose solution
Bausch and lomb protein removal tablets
BCM vitamin liquid
Berroca effervescent tablets
Berroca effervescent vitamin B tablets
Berroca super B energy
Berroca super B stress
Billy boy
Bioglan amino acid complex capsules
Bioglan ascorbic acid powder
Bioglan betacarotene
Bioglan cal C powder
Bioglan Cal C tablets
Bioglan Iysine tablets
Bioglan natural E caplets
Bioglan neo stress form
Bioglan panazyme tablets
Bioglan pyridoxine
Bioglan vitamin B complex
Bioglan Vitamin B complex anti-stress
Bioglan Zinc chelate
Bioglan ZNA –C formula
BK bath oil or lotion
Bonjela
Bonningtons irish moss
Boston advance conditioner solution
Brevoxyl
Brolene eye drops or ointment
Brylcreem-anti-dandruff blue
Brylcreem-regular red
Calcium compound
Calcium Lactate
Cal-sup
Caltrate
Caltrate and vitamin D tablets
Calvita
Cearasil skin ton medicated
Cellufresh
Cellufresh eye drop
Cellvisc
Centrum multi vitamin capsules
Cepacaine oral solution
Cepacol anaesthetic discs
Cepacol cough
Cepacol eucalypt or menthol lozenges
Cepacol lozenges regular
Cepacol solution
Citravescent sachets
Citravite
Clean – N – soak
Clear eyes
Clearasil facewash
Clearasil tinted cream
Clearasil ultracream
Clearasil vanish cream
Clearasil vanish medicated
Clements iron
Clements tonic red
Clove Oil
Complan
Complete all in one

Medicines and Cosmetics

Condyline paint
Contac
Cream E45
Curash family powder medicated
Dangard
De Gas capsules
De-lact infant
Deep heat rub
Deep heal sports spray
Degest
Dencorub
Dencorub arthritis cream
Dencorub x strength gel
Depends disposal underpads
Dequacaine
Dequadin lozenges
Derbac – M
Derm freeze
Dermalife
Dermalife plus
Dermatech liquid
Dermazole
Dermocaine gel
Dettol
Dettol antibacterial liquid cream
Dettol antibacterial liquid wash
Dettol antiseptic gel
Dettol antiseptic liquid
Dettol fresh
Dewitts antacid powder
Dewitts pills
Dexsal lemon flavour
Dexsal regular
Dia-chek tablets
Diasalt orange flavour
Duraclean
Duratears
Ear plug surgi pack
Ear plug antinoise
Efamol
Efamol marine
Effacscent oil
Ego acnederm ointment
Ego egocappol
Ego hair or science shampoo normal
Ego hair or science shampoo oily
Ego pinetarsol
Ego Q.V. bath oil or cream or wash
Ego sebi-rinse conditioner
Ego sebitar
Ego seborrol lotion
Ego sunsense
Ego sunsensitive
Elizaberth arden sunsense SPF 15
Elmetacin
Enfalac
Enfamilk
Eno lemon
Eno regular
Eno sachets lemon
Eno sachets regular
Ensure
Enuclene
Epogam
Epson salts sachet
Equal sachets
Equal sweeteners tablets
Eskinol Clear
Eskinol dermaclear C soap
Eskinol facial wash
Eskinol facial wipes
Eskinol lemon
Eucalyptus oil
Eucalyptus rub
Eucerin ointment
Evening primrose oil capsules
Eversun
Eye stream
Farex
Fibyrax-extra tablets
Finalgon cream
Fongitar
Fortisep
Fungizid
Fybogel orange sachets
Garlic odourless capsule VV
Gastrolyte powder or tablet or sachet
Gelusil tablets
Gelusil butterschotch
Gelusil liquid antacid
Gilseal clove oil
Glad B effervescent tablets
Glucodin tablets
Goanna heat cream
Goanna oil liniment
Goanna salve ointment
Gold cross antioxidant
Gold cross B Complex
Gold cross C tablets orange
Gold cross calcium and iron
Gold cross childrens multivitamin
Gold cross cod liver oil
Gold cross herbal arthritis
Gold cross herbal cold and flu
Gold cross herbal insomnia
Gold cross herbal PMS
Gold cross herbal stress
Gold cross horseradish and garlic
Gold cross maxepa
Gold cross multivitamin
Gold cross vitamin E
Gold cross womens multivitamin
Granocol
Hairscience conditioner or shampoo
Haliborange
Hamilton bath oil
Hardy's indigestion powder
Heatheries chelated zinc tablets
Heatheries vitamin A, B, D and E tablets
Hepasol vitamin tonic
Herbal insomnia
Hermasetas tablets
Hibitane obstetric cream
Hidrosol
Holdtite powder
Hydrocare preserved solution
Hydroderm
Hypol emulsion
Ichthamol ointment
Importal
Infacol
Infasoy
Ionil plain
Ionil rinse
Ionil scalp cleaner
Ionil T shampoo
Isogel
Isomil
Kamilosan
Karicare follwn on milk food
Maricare goat milk follow on
Karicare goat milk infant formula
Karicare soya infant formula
Karvol capsules
Konsyl
Konsyl orange
Kruschen salts
Kwells
KY jelly
Lac-hydrin
Lacrilube
Lacto-calamine
Lanoline ointment
Lanosil ointment
LC 65
Lecithin capsules
Lemsip analgesic sachets
Lemsip flu sachets
Lemsip throat lozenges orange
Lenactin
Lens plus
Lid-care
Lifestyle
Liniment methyl salicylate
Lipobase
Liquifilm forte
Liquifilm wetting solution
Listermint crystal fresh
Listermint mouthwash
Lobob
Luborant
Lucozade
Macro antistress capsules
Macro C + garlic or zinc capsules
Macro garlic capsules
Macro M multivitamin capsules
Macro maxepa capsules
Macro multivitamin and minerals
Medic aerosol spray
Medicated oil gold medal spray
Medicated oil regular green axe
Medicreme
Medi-pulv

Medicines and Cosmetics

Medislim weight control tablets
Metamucil orange or smooth
Metamucil original or
Methylsalicylate ointment
Metsal
Milton sterilizing solution
Milton sterilizing unit
Miraflow
Mozi free infant
Mucaine suspension
Mucilax
Murine eye drops
Mylanta II liquid
Mylanta II tablets
Mylanta plain
Mylanta plus
Mylicon drops
N/life assorted protein
N/life assorted protein
N/life body bulk chocolate
N/life carboplex
N/life mass low weight gainer vanilla
N/life mass muscle build chocolate
N/life mass weight gainer chocolate
N/life mass weight gainer vanilla
N/life super pro chocolate
N/life weight gainer chocolate
N/way cozyme Q10 capsules
Natural vitamin E
Nature's way garlic and horsdish tablets
Nature's way vitamin C tablets
Naxen
Neat feat
Neat one
Neat one
Neo-deca eye or ear drops
Neutrogena
Neutrogena soap normal skin
Nilodor
Nizoral shampoo or cream
No doz tablets
No gas capsules
No odour spray
Nurture plus
Nutra plus
Oil of ulan moist cream
Oil of ulan protein renew cream
Oilatum plus antibacterial bath
Olive oil
Omnicare daily cleaner
Optifree enzymatic cleaner
Optifree multi action
Opti-plus active cleaner
Opti-soak
Optrex eye lotion
Optrex hayfever allergy
Optrex lotion small/large
Optrex medicated eye drops
Optrex red eye drops
Optrex red eye relief
Oral B paed drops
Oral B tablets
Oral gel peppermint
Oral life peppermint
Oral rehydration sachets
Ora-sed jel
Oscal
Oscal D
Otrivin antihistin
Otrivin menthol spray
Otrivin nasal drops adult
Oxy 5 and 10
Oxy 5 skin tond
Oxy 5 or 10 vanishing
Oxy antiseptic medicated skin wash
Oxy daily skin wash
Oxy lotion or cream or liquid
Oxylin
Oxysept 1 s or lens solution
Oxysept 1/2
Panoxyl AQ. 10
Paraffin soft white
Pawpaw ointment
Pentavite chewable tablets
Pentavite infant drops
Pentavite syrup child
Phisophex
Phisohex face wash
Pickly heat powder
Pigeon nose cleaner
Pinetar
Pinetarsol
Pinetarsol bar
Pinetarsol bath oil
Pinetarsol gel
Pinetarsol shower spray
Pliagel
Pluravit and vitamin C
Pluravit capsules
Polident dentlu crème
Poly cal
Poly cleans II
Poly tar liquid
Poly tar plus
Poly tears
Poly tears free
Polycose
Polytar emollient
Polyzym
Ponoxylan gel
Power plus energy drink
Prantal powder
Prefrin liquifilm
Prefrin Z
Prosobee
Pryndette syrup
Psoriacreme
Psoriagel
Puritabs
Pyrantel suspension or tablets
Pyrenel foam
Pyrisone tablets
Q.V. bath oil
Q.V. cream
Q.V. skin lotion or bar
Quick-eze antacid tablets
Rapaid powder or spray or cream
Redoxin orange effervescent tablets
Refresh eye drops
Rendell plus
Rennies tablets
Rheumatism medicated oil
Ribena
Rikoderm bath oil or lotion
Rosken skin repair
Royal jelly capsules
RV paque
S26 progress
Saccharin tablets
Sandocal effervescent tablets
Savlon cream or liquid
Seba med shampoo
Sebirinse
Sebitar
Seborrol
Selsun
Sensodyne toothpaste
Shark liver oil
Shield
Sigma glucose liquid
Silic 15 cream
Simeco
Similac
SM 33 liquid or gel
SMA
Soaclens
Soft wear sterile saline
Softab
Softmate comfort
Softmate concept 1 and 2
Softmate saline
Soov bite or burn
Soov cream
Soov prickly heat powder
Sore throat gargle
Staminade powder lemon or lime
Star flower oil
Statavar tablets
Stingose spray
Stopm itch cream
Strepsils + vitamin C lozenges
Strepsils honey and lemon
Strepsils regular or menthol
Sucaryl tablet or liquid
Sugarless sweetner granules or sachets
Sulphenol
Sunsense
Superfade cream
Supradyn effervescent tablet
Sustagen hospital formula vanilla
Sustagen regular vanilla
Sustagen sport chocolate
Sustagen vanilla

Swedish bitter triad
Sweet almond oil
Sweetext
Tea tree oil ointment
Tear drops
Tears naturale
Temetsol soap
Tiger balm red/white
Total
Transoak
Transvasin
Ultrazyme protein remover
UV ultrablock
Valda
Vaseline jelly
Vendrol syrup
Vi-daylin
Vita plus B
Vitadol C
Vitaglow lecithin capsules
Vitamin C tablets orange
Vitamin E cream
Vitaplex and iron vitamin C tablets
Vitaplex celery seed
Vitaplex chelated zinc tablets
Vitaplex cod liver oil capsules
Vitaplex goodnight formula
Vitaplex iron chelate tablets
Vitaplex valerian tablets
Vitelle vitamin B6 tablets
Wate on tablets
White flower embrocation
White flower fragrant
Witch hazel
Zinc cream
Zinc triple strength tablets

MADE this day of , 2002.

ACTING GOVERNOR-GENERAL.

INDEPENDENT STATE OF PAPUA NEW GUINEA.

No. of 2002.

***Medicines and Cosmetics Regulation* 2002.**

Medicines and Cosmetics

ARRANGEMENT OF SECTIONS.

PART I. - PRELIMINARY.

1 Interpretation

PART II. - REGISTRATION OF MEDICINAL PRODUCTS AND DEALERS OF MEDICINAL PRODUCTS.

2 General licences.
3 Application for registration of a medicinal product.
4 Grant of a medicinal produce licence.
5 Application for licence to manufacture medicinal product.
6 Inspection before grant or renewal of licence.
7 Conditions of licence.
8 Grant of a licence to manufacture medicinal product.
9 Application for licence to sell medicinal product by wholesale.
10 Grant of licence to sell medicinal products by wholesale.
11 Application for licence to import medicinal product.
12 Prohibition of import of certain medicinal product or costmetic.
13 Conditions for licence holders.
14 Grant of import licence.
15 Application for licence to export medicinal product.
16 Grant of an export licence.
17 Application for issue of a clinical trial certificate.
18 Conditions to be satisfied for the issuance of a clinical trial certificate.
19 Issuance of clinical trial certificate.

PART III. - STANDARDS.

20 Standard provisions for a medicinal product licence.
21 Standard provisions for a manufacturer's licence.
22 Standard provisions for the wholesale dealers licence.
23 Standard provisions for an import licence.
24 Standard provisions for an export licence.
25 Standards for medicinal products, cosmetics and medical devices.

PART IV - PHARMACIES.

26 Registration of a Pharmacy.
27 Grant of licence to operate a Pharmacy.
28 General duties of pharmacists.
29 Notice of absence.
30 Inspection.
31 Conditions of dispensing.
32 Dispensing procedure.
33 Particulars of prescriptions to be recorded in the prescription book.
34 Emergency supply of medicinal products.
35 Prescription by telephone.
36 Supplying of medicinal product by pharmacists without prescription.
37 Keeping of records.
38 Returning of prescriptions.
39 Storage of medicinal products.
40 Substitution of medicinal products.

PART V - LABELLING.

41 Prohibition of sale or distribution of medicinal products unless properly labelled.
42 Labelling of medicinal products.

43 Manner of labelling of medicinal product.
44 Labelling of cosmetics.
45 Labelling of medical devices.
46 Packing of medicinal product.

PART VI - ADVERTISEMENTS.

47 Advertisements for medicinal product.
48 Advertisements for cosmetics.
49 Advertisement for medical devices.
50 Classification of medicinal products.

PART VII - INSPECTION.

51 Qualifications of inspectors.
52 Duties and powers of inspectors.
53 Prohibition of disclosure of information.
54 Taking of samples for testing.

PART VIII - MISCELLANEOUS.

55 Qualifications of inspectors.
56 Duties of analyst.
57 Certificate of Government analyst.
58 Appointing a laboratory for testing.
59 The requirements with respect to leaflets relating to medicinal products.

SCHEDULE 1 – FEES FOR LICENCES.
SCHEDULE 2 – FORMS.
SCHEDULE 3 – PRESCRIPTION ONLY MEDICINE.
SCHEDULE 4 – PHARMACY ONLY MEDICINE.
SCHEDULE 5 – OVER THE COUNTER MEDICINES.