INDEPENDENT STATE OF PAPUA NEW GUINEA.

CHAPTER NO. 229.

Drugs.

GENERAL ANNOTATION.

ADMINISTRATION.

As at 13 February 1976 (the date of gazettal of the most comprehensive allocation of responsibilities to Ministers and Departments at about the effective date), the administration of this Chapter was vested in the Minister for Health.

Accordingly, except where a different intention is clearly indicated, by note or in the text, as at that date references in or in relation to this Chapter to—

"the Minister"—should be read as references to the Minister for Health;

"the Departmental Head"—should be read as references to the Secretary for Health[1]

"the Department"—should be read as references to the Department of Health[2].

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[1] Previously the Director of Public Health.
[2] Previously the Department of Public Health.

INDEPENDENT STATE OF PAPUA NEW GUINEA.

CHAPTER NO. 229.

Drugs Act.

ARRANGEMENT OF SECTIONS.

PART I.—PRELIMINARY.

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INDEPENDENT STATE OF PAPUA NEW GUINEA.

CHAPTER NO. 229.

Drugs Act.

Being an Act relating to the sale of drugs.

PART I.—PRELIMINARY.

1. Interpretation.

In this Act, unless the contrary intention appears—

"disinfectant" includes deodorizer, germicide, antiseptic, sanitary powder and sanitary fluid;

"drug" means a substance, including tobacco, used in the composition or preparation of medicines, whether for external or internal use;

"Government analyst" means a Government analyst appointed under Section 4;

"Inspector" means an Inspector appointed under Section 3;

"the regulations" means any regulations made under this Act;

"this Act" includes the regulations.

2. Saving of other proceedings, rights, etc.

This Act does not—

(*a*) affect the power of proceeding by indictment, or take away any other remedy, against an offender under this Act; or

(*b*) in any way interfere with—

(i) contracts and bargains between individuals; or

(ii) the rights and remedies belonging to such individuals.

PART II.—ADMINISTRATION.

3. Appointment of Inspectors.

The Minister may appoint persons to be Inspectors for the purposes of this Act.

4. Appointment of Government analysts.

The Minister may appoint persons to be Government analysts for the purposes of this Act.

5. Appearance by the Minister.

The Minister may appear before a court or in any legal proceedings under or for the purposes of this Act, or may be represented by—

(*a*) an Inspector; or

(*b*) an officer authorized generally or in respect of a particular proceeding.

PART III.—STANDARDS OF DRUGS.

6. Prescribed standards.

In any proceedings under this Act with respect to a drug, the standard prescribed in relation to the drug shall be deemed to be the standard for the drug.

PART IV.—INSPECTION AND CONTROL.

7. Inspection, etc.

In exercise of the powers conferred by this Act an Inspector, or an officer authorized for the purpose by the Departmental Head or an Inspector, may—

(*a*) at all reasonable hours have access to—

(i) all public or private sale-rooms occupied or used by merchants, brokers, wholesale dealers or other persons; and

(ii) all public and private warehouses, factories, stores, quays, sheds, ships or barges,

where drugs are offered for sale or deposited for the purpose of sale; and

(*b*) seize or procure samples of any such drugs in any such place; and

(*c*) seize or procure samples of drugs—

(i) at the place of delivery; or

(ii) at a place during transit; or

(iii) on the premises of or elsewhere in the possession of a person for the purposes of carriage; and

(*d*) seize or procure at the port of entry or elsewhere samples of drugs imported as merchandise; and

(*e*) for any of the purposes referred to in Paragraphs (*a*), (*b*), (*c*) or (*d*), break open a parcel, box, barrel, basket, bag, case, tin or other package in which the drugs may be contained.

8. Analysis of drugs.

(1) On payment to a Government analyst of the prescribed fee, the purchaser of a drug is entitled to have the drug analysed by the analyst.

(2) An Inspector, or an officer authorized for the purpose by the Departmental Head or an Inspector, may procure a sample of a drug, and if he suspects it to have been sold to him contrary to any provision of this Act he shall submit it to a Government analyst.

(3) If, when an Inspector or officer referred to in Subsection (2) applies to purchase a drug from a person exposing it for sale and tenders the price for the quantity that he requires for the purpose of analysis (not being more than is reasonably needed for the purpose), the person refuses to sell the drug he is guilty of an offence.

Penalty: A fine not exceeding K20.00.

(4) A person who purchases a drug with the intention of submitting it to analysis shall—

(*a*) immediately notify the seller, or his agent selling the drug, of his intention to have the drug analysed; and

(*b*) offer to divide the amount purchased into three parts to be then and there separated, and each part to be marked and sealed or fastened up, in the presence of the seller or his agent—

(i) in such manner as its nature permits by the purchaser in the presence of the seller or his agent; and

(ii) if the seller or agent desires, with the seal or distinguishing mark of the seller or agent as well as that of the purchaser; and

(*c*) if so required, proceed in accordance with Paragraph (*b*); and

(*d*) deliver one of the parts to the seller or his agent; and

(*e*) retain one of the parts for future comparison; and

(*f*) submit the third part to the analyst if he thinks it right to have the drug analysed.

(5) Where the seller or his agent does not accept the offer of the purchaser made under Subsection (4)(*b*) to divide the drug, the analyst receiving the drug shall—

(*a*) divide it into two parts; and

(*b*) seal or fasten up one of the parts and cause it to be delivered to the purchaser—

(i) when he receives it; or

(ii) when he supplies his certificate to the purchaser.

(6) The purchaser must—

(*a*) retain the part delivered to him under Subsection (5); and

(*b*) produce it if proceedings are afterwards taken in the matter.

(7) If the analyst does not reside within 3.22 km[1] of the residence of the person requiring the drug to be analysed, the drug may be forwarded to the analyst by registered post, and the charge for the postage of the drug shall be deemed one of the charges authorized by this Act or of the prosecution, as the case may be.

(8) In any proceedings, the defendant may require that—

(*a*) the analyst shall be called as a witness; and

(*b*) the parts of the drug retained by the person who purchased it shall be produced.

(9) The court before which a complaint is made or before which an appeal is heard may cause a drug to be sent to a Government analyst to make an analysis or examination of the drug, and the analyst shall give a certificate to the court of the result.

(10) A certificate purporting to be signed by a Government analyst is prima facie evidence of the facts stated in it, and the costs of the analysis shall be paid as the court, in its discretion, directs.

9. Inspection, etc., of imported drugs for adulteration, etc.

(1) The consignee or other person having the custody of an imported drug must permit an Inspector, or an officer authorized for the purpose by the Departmental Head or an Inspector, to take such samples of a consignment of drugs as is necessary for the enforcement of this Act.

[1] Metricated editorially. The original measurement was 2 miles.

(2) When an Inspector or officer referred to in Subsection (1) takes a sample of a consignment of drugs under that subsection, he shall—

(*a*) divide it into three parts; and

(*b*) deliver or send one of the parts to the consignee or his agent; and

(*c*) retain one of the parts for future comparison; and

(*d*) submit the third part to a Government analyst.

(3) Where on analysis or examination under this section—

(*a*) a drug is found to be adulterated or impoverished; or

(*b*) the drug has been mixed with another substance; or

(*c*) a part of the drug has been abstracted so as to affect injuriously its quality, substance or nature,

it shall not be delivered to the consignee except with the permission of the Departmental Head or an Inspector and subject to such terms and conditions as he imposes.

10. Disposal of unfit drug.

If after the conviction under this Act of a person for selling a drug the court that convicts him is of opinion that the drug is unfit for use as a drug, it may order the drug to be forfeited and to be destroyed or otherwise disposed of as it thinks proper.

PART V.—OFFENCES AND LEGAL PROCEEDINGS.

11. Mixture of drugs with injurious ingredients.

(1) Subject to Subsection (2), a person who—

(*a*) except for the purpose of compounding as permitted under this Act—

(i) mixes, colours, stains or powders; or

(ii) orders or permits any other person to mix, colour, stain or powder,

a drug with an ingredient or material so as to injuriously affect the quality or potency of the drug, with the intent that the drug may be sold in that state; or

(*b*) sells a drug so mixed, coloured, stained or powdered,

is guilty of an offence.

Penalty: For the first offence a fine not exceeding K100.00.

For a second or subsequent offence imprisonment for a term not exceeding six months.

(2) It is a defence to a charge of an offence against Subsection (1) in respect of the sale of a drug if the accused person shows to the satisfaction of the court that—

(*a*) he did not know of the drug sold by him being so mixed, coloured, stained or powdered; and

(*b*) he could not with reasonable diligence have obtained that knowledge.

12. Sale of drugs not of nature, substance or quality demanded.

(1) Subject to Subsection (2), a person who sells a drug that is not of the nature, substance or quality of the article demanded by the purchaser, is guilty of an offence.

Penalty: A fine not exceeding K40.00.

(2) An offence shall not be deemed to be committed under this section when—

(*a*) any matter or ingredient that is not injurious to health has been added to the drug because the matter or ingredient is required for the production or preparation of the drug as an article of commerce in a state fit for carriage or consumption and not fraudulently to increase the bulk, weight or measure of the drug or to conceal the inferior quality of the drug; or

(*b*) the drug is a proprietary medicine or is the subject of a patent in force in the country, and is supplied in the state required by the specification of the patent; or

(*c*) the drug is compounded as permitted under this Act; or

(*d*) the drug is unavoidably mixed with some extraneous matter in the process of collection or preparation.

13. Sale of compounded drugs.

A person who sells a compounded drug that is not composed of ingredients in accordance with the demand of the purchaser, is guilty of an offence.

Penalty: A fine not exceeding K40.00.

14. Disinfectants.

(1) A person who sells or exposes for sale a substance or compound under the name or description of, or with intent that it may be used as, a disinfectant or preservative, without disclosing the name or names of the substance or compound and the percentage of the active ingredients contained in it by a label distinctly and legibly written or printed on or with the substance or compound, is guilty of an offence.

Penalty: A fine not exceeding K100.00.

(2) The provisions of this Act relating to the analysis or examination of drugs apply to all substances and compounds referred to in this section.

15. General defences.

(1) A person is not guilty of an offence in respect of the sale of a drug mixed with any matter or ingredient—

(*a*) not injurious to health; and

(*b*) not intended fraudulently—

(i) to increase its bulk, weight or measure; or

(ii) to conceal its inferiour quality,

if at the time of delivering the drug he supplies to the person receiving it a notice, by a label distinctly and legibly written or printed on or with the drug, to the effect that the drug is mixed and stating the nature or composition of the mixture.

(2) A label referred to in Subsection (1) shall be deemed not to be distinctly and legibly written or printed if it is so written or printed that the notice of mixture given by the label is obscured by other matter on the label.

(3) In a prosecution for selling a drug that is not of the nature, substance or quality of the article demanded by the purchaser, it is not a defence to prove that the purchaser bought it only for analysis, but if the defendant proves that—

(*a*) he purchased the drug as being the same in nature, substance and quality as that demanded of him by the purchaser and with a written warrant to that effect from some responsible person carrying on business in the country; and

(*b*) he had no reason to believe at the time when he sold it that the drug was in nature, substance or quality other than that demanded; and

(*c*) he sold it in the same state as he purchased it,

he shall be discharged.

(4) When a defendant is discharged by virtue of Subsection (3), he is liable to pay all costs incurrred by the purchaser unless he gave due notice to him that he would rely on the defence provided for by that subsection.

16. Burden of proof of statutory defences.

In any legal proceedings under this Act, if the defendant desires to rely on an exception or proviso contained in this Act, proof of the exception or proviso is on him.

17. Recovery of penalties.

Proceedings for the recovery of a penalty under this Act shall not be had or taken by a person other than a party aggrieved or the Departmental Head, without the written consent of the Public Prosecutor.

PART VI.—MISCELLANEOUS.

18. Breach of contract on sale of drugs.

(1) Subject to Subsection (2), in an action brought by a person for a breach of contract on the sale of a drug, he may recover, alone or in addition to any other damages, the amount of—

(*a*) a penalty imposed for an offence of which he had been convicted under this Act; and

(*b*) the costs paid by him on the conviction; and

(*c*) the costs incurred by him in and about his defence to the charge,

if he proves that—

(*d*) the drug the subject of the conviction was sold to him as and for a drug of the same nature, substance and quality as that which was demanded of him; and

(*e*) he purchased it not knowing it to be otherwise; and

(*f*) he sold it in the same state in which he purchased it.

(2) The defendant in the action may prove that—

(*a*) the conviction was wrongful; or

(*b*) the amount of costs awarded or claimed was unreasonable.

19. Regulations.

The Head of State, acting on advice, may make regulations, not inconsistent with this Act, prescribing all matters that by this Act are required or permitted to be prescribed, or

that are necessary or convenient to be prescribed, for carrying out or giving effect to this Act, and in particular prescribing matters for or in relation to—

(*a*) the fees to be paid by persons for the analysis or examination of drugs, disinfectants or preservatives; and

(*b*) standards for the composition of drugs, disinfectants and preservatives and the amount of dilution (if any) to be allowed in the sale by retail of drugs, disinfectants and preservatives; and

(*c*) standards of the amount of deterioration or natural poverty (if any) in a drug to be permitted without prosecution under this Act; and

(*d*) the wording on labels to be used in the sale of mixed or altered drugs, disinfectants or preservatives; and

(*e*) penalties of fines not exceeding K100.00 for offences against the regulations.

INDEPENDENT STATE OF PAPUA NEW GUINEA.

CHAPTER NO. 229.

Drugs Regulation.

ARRANGEMENT OF SECTIONS.

1. Interpretation—
"the British Pharmacopoeia"
"the Codex"
"the Formulary".
2. Editions in force.
3. Standards of drugs, etc.

INDEPENDENT STATE OF PAPUA NEW GUINEA.

CHAPTER NO. 229.

Drugs Regulation.

MADE under the *Drugs Act*.

1. Interpretation.

In this Regulation—

"the British Pharmacopoeia" means the British Pharmacopoeia as published in the United Kingdom under the direction of the General Medical Council, in the edition for the time being in force, together with any Addendum to the British Pharmacopoeia so published;

"the Codex" means the British Pharmaceutical Codex published in the United Kingdom by direction of the Council of the Pharmaceutical Society of Great Britain, in the edition for the time being in force, together with any Supplement to the British Pharmaceutical Codex so published;

"the Formulary" means the Australian Pharmaceutical Formulary (A.P.F.) published in Australia by the Pharmaceutical Association of Australia, in the edition for the time being in force.

2. Editions in force.

The Departmental Head may, by notice in the National Gazette, declare which edition of the British Pharmacopoeia, the Codex or the Formulary, and which Addendum to the British Pharmacopoeia or Supplement to the British Pharmaceutical Codex, is for the time being in force for the purposes of the Act and this Regulation.

3. Standards of drugs, etc.

For the purposes of the Act—

(*a*) the standards for the composition of drugs, disinfectants and preservatives; and

(*b*) the amount of dilution (if any) to be allowed in the sale by retail of drugs, disinfectants and preservatives; and

(*c*) the standards of the amount of deterioration or natural poverty (if any) in a drug to be permitted without prosecution under the Act,

are as laid down—

(*d*) in the British Pharmacopoeia; or

(*e*) if there be no such matter laid down in the British Pharmacopoeia in the particular case—in the Codex; or

(*f*) if there be no such matter laid down in the British Pharmacopoeia or the Codex in the particular case—in the Formulary.

INDEPENDENT STATE OF PAPUA NEW GUINEA.

CHAPTER NO. 229.

Drugs.

SUBSIDIARY LEGISLATION.

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1. Regulation, Section 2—Declaration of editions of Pharmacopoeia, etc., in force.

British Pharmacopoeia, 1968 Edition.

British Pharmaceutical Codex, 1968 Edition.

Australian Pharmaceutical Formulary, 1964.

INDEPENDENT STATE OF PAPUA NEW GUINEA.

CHAPTER NO. 229.

Drugs.

APPENDIXES.

APPENDIX 1.

SOURCE OF THE DRUGS ACT.

Part A.—Previous Legislation.

Drugs Act 1952 (No. 2 of 1953).

Part B.—Cross References.

Section, etc., in Revised Edition.	Previous Reference[1].	Section, etc., in Revised Edition.	Previous Reference[1].
1	3	11	6
2	19 (1)	12	7
3	4 (2)	13	8
4	5	14	16
5	4 (3)	15	9, 12
6	14	16	18
7	11	17	17
8	10	18	19 (2)
9	15	19	20
10	13		

[1] Unless otherwise indicated, references are to the Act set out in Part A.

APPENDIX 2.

SOURCE OF THE DRUGS REGULATION.

Part A.—Previous Legislation.

Drugs Regulations 1958 (Regulations No. 38 of 1958).

Part B.—Cross References.

Section, etc., in Revised Edition.	Previous Reference[1].
1	2
2	3
3	4

[1] Unless otherwise indicated, references are to the regulations set out in Part A.