THE FOOD AND DRUGS ACT

REGULATIONS
(*under section 21*)

THE FOOD AND DRUGS REGULATIONS, 1975

(*Made by the Minister on the 3rd day of March, 1975*)

[*4th August, 1975*]

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PART I. *Definitions*

1. These Regulations may be cited as the Food and Drugs Regulations, 1975.

2. In these Regulations unless the context otherwise requires—

"can" means any hermetically sealed container;

"cubic centimetre" and its abbreviated form "cc" shall be interchangeable with the term "millilitre" and its abbreviated form "ml";

"declared" means written on the label attached to or accompanying the food, drug or substance in respect of which the declaration is required, in letters of the prescribed size;

"ice" means the product obtained by freezing potable water which has been kept, stored and delivered under such hygienic conditions as to prevent contamination;

"inner label" means the label on or affixed to an immediate can or package of food, drug, cosmetic or device;

"main panel" means the principal label affixed to the package or container identifying its contents by stating the name of the food, drug, cosmetic or device, the ingredients, weight, manufacturer, place of manufacture and such other information as may be required by these Regulations;

"official method" means a method of analysis or examination designated as such by the Minister for use in the administration of the Act;

"outer label" means the label on or affixed to the outside of a package of a food, drug, cosmetic or device;

"parts per million" means part by weight per million parts by weight except where otherwise stated;

"per cent" means per cent by weight (weight in weight) except where otherwise stated;

"potable water" means water which is clear, colourless and free from any pathogenic micro-organism.

PART II. *Foods, Drugs, Cosmetics and Devices*

Division I. General

3.—(1) A person shall not advertise any food, drug, cosmetic or device unless such advertisement complies with the requirements of the Act and these Regulations.

(2) Unless specifically required to do so by any enactment, no label or advertisement shall either directly or indirectly make reference to the Ministry of Health and Environmental Control or these Regulations.

4.—(1) A person shall not advertise any drug unless he has first been granted approval in writing by the Minister to do so, and such approval has not been withdrawn at the time of publication of the advertisement.

(2) The Minister may refuse to grant approval, or may withdraw the approval granted in respect of any advertisement by notifying in writing the applicant for the approval or the person to whom the approval was granted, as the case may be, in cases where—

(*a*) he has reasonable grounds to believe that the application on which approval in respect of any such advertisement was granted contained false or misleading statements; or

(*b*) the advertisement in respect of which approval was given does not comply with the requirements of these Regulations.

5.—(1) Any information required by these Regulations to be included on a label shall be clearly and prominently displayed thereon, so as to be readily discernible to the public under normal conditions of purchase and of use.

(2) For the purposes of paragraph (1), the name by which any food, drug, cosmetic or device is generally known consisting of more than one word shall be deemed to be clearly and prominently displayed on the main panel of the label if each word other than articles,

conjunctions and prepositions, is in identical type and identically displayed.

6. All information required by these Regulations to be declared shall be in durable characters, and in boldfaced capital letters written in such colour or colours as to afford a distinct contrast with the background.

Division II. Food

7. In this Division—

"artificial (non-nutritive) sweetening agent" means any chemical compound which is sweet to the taste but does not include sugar or other carbohydrate or polyhydric alcohols;

"bulk container" means a container in which more than one duly labelled package of a food and its contents are placed for wholesale purposes, but in which the packages and their contents are not intended to be retailed;

"close proximity" means with reference to a common name, written or graphic matter placed immediately adjacent to that common name;

"common name" means with reference to a food, the name by which the food is generally known;

"food additive" means any substance, including any source of radiation, the use of which results, or may reasonably be expected to result, in it or its by-products becoming a part of or affecting the characteristics of a food excepting—

(*a*) any nutritive material that is used, recognized, or commonly sold as an article or ingredient of food;

(*b*) vitamins, minerals, and amino acids unless added for flavourings;

(*c*) spices, seasoning, flavouring preparations essential oils, oleoresins and natural extractives;

(*d*) pesticides;

(*e*) food packaging materials and components thereof; and

(*f*) drugs recommended for administration to animals that may be a source of food for human beings;

"unstandardized food" means any food for which a standard has not been prescribed.

8. A person shall not prepare, pack, store or transport any food intended for sale in any manner which renders it injurious to health,

or which injuriously affects its nutritive properties, or which renders it unwholesome, nor shall a person sell any food which has become injurious to health, which has had its nutritive properties injuriously affected, or which has become unwholesome.

9. A person shall not sell any canned food the container of which is blown or punctured, or any frozen food which has been thawed in the package and subsequently refrozen.

10. A person shall not use water other than potable water as an ingredient in the manufacture or preparation of any food.

Labelling

11.—(1) A person shall not sell a package of food which is not labelled or which bears a label that does not comply with the provisions of these Regulations.

(2) The provisions of paragraph (1) shall not apply to food packaged from bulk on the premises where that food is retailed, so, however, that where any food so packaged bears any statement, mark or device regarding the ingredients or the substances contained therein other than the name of the food, the name and address of the retailer and the net contents, it shall be labelled as required by the Act.

12.—(1) Unless otherwise specifically provided in these Regulations, every package of food offered for sale shall bear a label stating legibly and conspicuously in conformity with regulations 5 and 6—

(*a*) on the main panel—

(i) the brand name or trade name, if any; and

(ii) the common name of the food; and

(iii) a statement of the weight, volume, number or measure of contents; and

(*b*) on the remainder of the label—

(i) a declaration of added colour, if present; and

(ii) the name and address of the manufacturer, packer, importer, vendor or of any person who assumes the responsibilities of the manufacturer, packer, importer or vendor and indicates in conjunction with his name and address that he is not the manufacturer, packer, importer or vendor.

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(2) Notwithstanding paragraph (i) of sub-paragraph (*b*) of paragraph (1), a list of ingredients is not required to indicate the presence of caramel as a food colour in—

(*a*) non-excisable fermented beverages;

(*b*) spirituous liquors other than gin;

(*c*) wine.

13. Except where the quantity of the contents marked on a package of food is stated in terms of minimum weight, volume, number or measure, there shall be permitted from the stated quantity, variations—

(*a*) due exclusively to weighing, measuring or counting that occur in packaging conducted in compliance with good commercial practice;

(*b*) due exclusively to difference in the capacities of containers resulting solely from unavoidable factors in manufacturing;

(*c*) due exclusively to the ordinary and customary exposure of the package to evaporation under usual atmospheric conditions.

14. Unless otherwise specifically permitted by these Regulations, a person shall not sell a synthetic food as substitute for any food unless—

(*a*) it is clearly indicated on the label or in any advertisement in respect thereof that it is a substitute, imitation, artificial or synthetic food; and

(*b*) the label of every package of such food other than imitation flavouring preparations, includes legibly and conspicuously, the common names of all the ingredients of that food in descending order of their proportionate content.

15. A person shall not sell any food bearing a label which suggests or implies the presence of one or more vitamins, that the food contains vitamins, or that it is rich in vitamins, unless there is written on the label in letters of not less than eight points, the actual vitamin content per 100 grammes of food.

16. Where any colouring or any flavouring has been added to any food, every package to which that colouring or flavouring has been added shall bear a label including the words "artificially coloured", "artificially flavoured" or "artificially coloured and flavoured", as the case may require.

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17. Any colouring substance or mixture of colouring substances which is sold or packaged for use in food shall bear a label on which shall be written legibly and prominently—

(*a*) the name or names of the colouring substance or substances present; and

(*b*) the words "food colour" in letters of not less than $\frac{1}{8}$ inch in height.

Adulteration of Foods and Special Foods.

18. A person shall not add any colouring, flavouring, preservative, or anti-oxidant to any food, extender, stabilizing or modifying agent other than to food in its natural form, or of a standard specified in these Regulations, or add any such substance to any food or sell any food containing any such substance unless the addition or presence of any such substance is specifically permitted by these Regulations.

19.—(1) A person shall not add any artificial sweetening agent, mineral oil, paraffin, mineral salt (except sodium chloride), resin, glycol derivative, coumarin or any substance containing coumarin, to any food, or sell any food containing any such substance unless the addition or presence is permitted by these Regulations.

(2) The provisions of this Regulation with respect to paraffin shall not apply to chewing gum.

20. A person shall not use or sell for use in or upon a food, any ingredient, unless it is of a purity that renders it safe and appropriate for use in foods.

21. A food shall be deemed to be adulterated if any of the following substances or classes of substances are present therein or have been added thereto—

(*a*) mineral oil, paraffin wax, or any preparation thereof;

(*b*) coumarin, extracts of tonka beans, the seed of Dipteryx odorata Willd, or Dipteryx oppositi—folia Willd;

(*c*) synthetic sweetening agents other than saccharin;

(*d*) cottonseed flour that contains more than four hundred and fifty parts per million of free gossypol;

(*e*) fatty-acids and their salts containing toxic factors;

(*f*) dihydrosafarole;

(*g*) isosafrole;

(*h*) oil of American sassafras from sassafras alkidum (nut) Nees;

(*i*) oil of Brazilian sassafras from Ocotea cymbarum H.B.K.;

(*j*) oil of camphor sassafras from Cinnamon camphorum sieb;

(*k*) oil of micranthum Hyata; or

(*l*) safrole;

Provided that—

(i) a food shall not be adulterated if it contains not more than 0.3 per cent mineral oil, where the normal manufacturing practices require the use of mineral oil;

(ii) chewing gum shall not be adulterated if it contains a paraffin wax base;

(iii) fresh fruits and vegetables (with the exception of turnips) shall not be adulterated if they are coated with not more than 0.3 per cent paraffin wax and petrolatum, where normal manufacturing practices require the use of such coating; and

(iv) turnips and cheese shall not be adulterated if they are coated with paraffin wax in accordance with normal manufacturing practice.

22. Except in the case of special formulae, bakery products, and special dietary foods, a person shall not sell a food that is represented as being for babies if that food contains a food additive.

23. Where a statement or claim implying a special dietary use is made on the label of, or in any advertisement for a food, the type of diet for which that food is recommended shall be included in such label or advertisement.

24.—(1) Special dietary foods recommended for carbohydrate or sugar reduced diets shall be foods that contain not more than 50% of the glycogenic carbohydrates normally present in foods of the same class, except that confectionery and pudding powders shall contain not more than 70% of the glycogenic carbohydrates normally present in such foods.

(2) For the purpose of these Regulations a food may be described as "sugarless", "sugar-free" or by any other synonymous term if that food contains not more than 0.25 per cent glycogenic carbohydrates.

(3) Where a statement of claim relating to the carbohydrate, sugar or starch content of any food is made on the label of, or in any advertisement for that food, such label or advertisement shall include a statement of the carbohydrate content in grammes per 100 grammes or on a percentage basis.

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25.—(1) Special dietary foods recommended for calorie reduced diets shall be foods that contain not more than 50 per cent of the total calories normally present in foods of that same type.

(2) Where a statement or claim relating to the calorie content of any food is made on the label of, or in any advertisement for that food, such label or advertisement shall include a statement of the calorie content in calories per 100 grammes.

(3) For the purpose of these Regulations, a food may be described as "low-caloried" or by any other synonymous term if it contains not more than 15k calories per average serving and 30k calories in a reasonable daily intake.

26.—(1) Where a statement or claim relating to the sodium content of any food is made on the label of, or in any advertisement for that food, such label or advertisement shall include a declaration of the sodium content in milligrammes per 100 grammes.

(2) The number of milligrammes of sodium contributed by a reasonable daily intake of a special dietary food recommended for a sodium reduced diet shall not exceed one-sixth the number of milligrammes contained in a reasonable daily intake of the same food.

(3) For the purposes of these Regulations, a food may be described as "low-sodium" or by any synonymous term if it contains not more than 10 milligrammes sodium in an average serving and 20 milligrammes in a reasonable daily intake.

27.—(1) A person shall not sell a food containing a non-nutritive sweetening agent unless—

(*a*) the label bears a declaration that contains a non-nutritive artificial sweetener and the name of that sweetener;

(*b*) the label includes a statement specifying a special dietary use;

(*c*) that food meets the requirements for special dietary foods prescribed in these Regulations; and

(*d*) the label includes a warning that the food should only be used on the advice of a registered medical practitioner.

First Schedule.

(2) The substances listed in the First Schedule may be used as artificial (non-nutritive) sweetening agents in foods.

28.—(1) Where a standard for a food is prescribed in these Regulations—

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(*a*) that food shall conform to the requirements prescribed in that standard;

(*b*) each ingredient shall be incorporated in the food in a quantity within the limits prescribed for that ingredient; and

(*c*) if the standard includes an ingredient to be used as a food additive for a specified purpose, that ingredient shall be a food additive approved by the Minister for use as an additive to that food for that purpose.

(2) Where a standard for a food is not prescribed in these Regulations—

(*a*) the food shall not contain any food additives other than food additives approved by the Minister for use as additives to that food for that purpose; and

(*b*) each food additive so approved shall be incorporated in the food in a quantity within the limits approved for that food and that food additive.

(3) The provisions of sub-paragraph (*c*) of paragraph (1) and sub-paragraph (*a*) of paragraph (2) shall not apply—

(*a*) the spices, seasonings, flavouring preparations essential oils, oleoresins and natural extractives; or

(*b*) in any case where a standard has been prescribed under any other enactment.

Preservatives

29.—(1) A person shall not use as a preservative in or upon food, or sell as a preservative for food, any substance other than those specified in these Regulations as Class I, Class II, Class III or Class IV preservatives, respectively.

(2) Where any Class II, Class III or Class IV preservative, as the case may be, is sold for use on food, the label thereof shall include adequate directions for use in accordance with the limits prescribed for that preservative in these Regulations.

30.—(1) The following preservatives shall be Class I preservatives for the purposes of these Regulations—

(*a*) alcohol;

(*b*) ascorbic acid and its salts;

(*c*) dextrose;

(*d*) erythorbic acid and its salts;

(*e*) glucose;

(*f*) potassium nitrate;

(*g*) common salt;

(*h*) sodium nitrate;

(*i*) spices;

(*j*) sugar;

(*k*) vinegar; and

(*l*) wood smoke.

(2) Notwithstanding paragraph (1), sodium nitrate or potassium nitrate shall be a Class I preservative in relation to preserved meats if used in quantities not exceeding 200 parts per million of the finished product.

31.—(1) The following preservatives shall be Class II preservatives for the purposes of these Regulations—

(*a*) benzoic acid, including the salts thereof;

(*b*) sulphurous acid, including the salts thereof; and

(*c*) sorbic acid, including the salts thereof.

(2) A person shall not use more than one Class II preservative in or upon any food, except in the case of methyl-p-hydroxybenzoate and propyl-p-hydroxybenzoate, where a mixture of both may be used.

(3) A person shall not use in or upon any food more than—

(*a*) 1,000 parts per million of benzoic acid or its salts calculated as benzoic acid; or

(*b*) 1,000 parts per million of sorbic acid or its salts calculated as sorbic acid.

(4) A person shall not use sulphurous acid or its salts calculated as sulphur dioxide, in amounts greater than—

(*a*) 100 parts per million in beverages prepared for consumption in accordance with label directions;

(*b*) 2,500 parts per million in or upon dried fruits and vegetables; or

(*c*) 500 parts per million in or upon other food.

32.—(1) The following preservatives shall be Class III preservatives for the purposes of these Regulations—

(*a*) propionic acid, including the salts thereof;

(*b*) sodium diacetate; and

(*c*) sorbic acid, including the salts thereof.

(2) A person shall not use in or upon a food, more than 2,000 parts per million of propionic acid or its salts calculated as propionic acid.

(3) No quantitative declaration is required on the label of any Class III preservative used on bread, bakery products, cheese, or processed cheese.

33.—(1) The following preservatives shall be Class IV preservatives for the purposes of these Regulations—

(i) gum quaiacum;
(ii) vegetable oils containing tocopherols;
(iii) lecithin;
(iv) citric, tartaric, or ascorbic acid;
(v) monoisopropyl citrate;
(vi) ascorbyl palmitate;
(vii) n-propyl gallate, or n-octyl gallate, or n-dodecyl gallate;
(viii) butylated hydroxyanisole; and
(ix) butylated hydroxytoluene.

(2) A person shall not sell a food containing—

(*a*) any combination of Class IV preservatives that includes both propyl gallate and nordihydroguaiaretic acid;

(*b*) any combination of Class IV preservatives, including the substance in which they are dissolved, in an amount greater than 0.2 per cent of the finished product;

(*c*) a combination of Class IV preservatives that includes more than three of the following preservatives—
  (i) butylated hydroxyanisole;
  (ii) butylated hydroxytoluene;
  (iii) propyl gallate; or

(*d*) any combination of the Class IV preservatives listed in paragraph (*c*) in an amount greater than 0.02 per cent of the finished product.

34. A person shall not sell or use as a preservative on food—

(*a*) benzoic acid, including the salts thereof;
(*b*) sulphurous acid, including the salts thereof;
(*c*) propyl gallate;
(*d*) butylated hydroxyanisole;
(*e*) butylated hydroxytoluene,

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unless the label of each package includes a quantitative declaration of each of the preservatives present.

Food Additives

35. A person shall not sell a food containing a food additive except as provided in these Regulations.

36. A person shall not sell any substance or mixture of substances for use as a food additive unless the label includes a quantitative statement of the amount of each substance present, and a complete list of the food additives present in descending order of their proportions, as well as directions for their use, which if followed, shall produce a food containing such additives in accordance with the maximum levels of use permitted by these Regulations.

Poisonous Substances in Food

37. A person shall not sell any food in a container that may transmit to its contents any substance that may be injurious to the health of a consumer of the food.

38. Notwithstanding paragraph (*a*) of Section 5 of the Act, the foods listed in the Second Schedule may contain in or upon them— Second Schedule.

(*a*) any or all of the poisonous or harmful substances listed in that Schedule opposite to that food in amounts not exceeding the quantities stated therein in parts per million (p.p.m.) for that food, as determined by the official method; and

(*b*) other poisonous or harmful substances in amounts not considered by the Minister likely to be injurious to health.

Division III. Drugs

39. In this Division—

"adequate directions for use" includes all information as may be necessary for proper use, including cautions as to the possible adverse reactions and contra-indications;

"antibiotic" means any drug or combination of drugs prepared from certain micro-organisms, or which formerly was prepared from micro-organisms but is now made synthetically and which possesses inhibitory action on the growth of other micro-organisms;

"common name" means, with reference to a drug, the name in the English language by which the drug is commonly known;

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"expiration date" means any date prescribed in relation to a particular drug, as the date after which that drug is not recommended for use;

"generic drug" means an unpatented drug product, including a drug whose patent has expired and one which has never been patented;

"generic name" means the official name or international non-proprietory nomenclature;

"internal use" means ingestion by mouth or application for systemic effect to any part of the body in which the drug comes into contact with mucous membrane;

"parenteral use" means administration of a drug by means of a hypodermic syringe, needle or other instrument through or into the skin or mucous membrane;

"pharmacist" or "druggist" means any person registered as such under any enactment for the time being in force relating to the registration of druggists or pharmacists;

"medical practitioner" means any person registered as such under the Medical Act or any enactment for the time being in force relating to practise of medicine;

"pr" means, when used in relation to a List 4 Drug, to be sold on prescription only;

"practitioner" means any dentist, medical practitioner, veterinary surgeon or veterinary practitioner registered respectively as such under any relevant enactment for the time being in force;

"prescription" means an order given by a practitioner directing that a stated amount of any drug or mixture of drug specified therein be dispensed for a person named in the order;

"proper name" means, with reference to a drug, the name in the English language of that drug;

"teaspoon" means for the purpose of calculation of dosage, a volume of five cubic centimetres.

40.—(1) A person shall not sell, manufacture, import or distribute a drug unless—

(*a*) that drug has been registered with the Ministry of Health; and

(*b*) a fee of $25.00 has been paid in respect of such registration.

(2) The Minister may, in his discretion, exempt any person or any drug from the requirements of paragraph (1).

41.—(1) A person shall not manufacture a drug unless he has applied for and been granted a permit to do so by the Minister.

Third Schedule. Form A.

(2) A permit to manufacture a drug shall be in the form set out as Form A in the Third Schedule.

(3) A fee of one thousand dollars ($1,000) shall be paid in respect of each product for which a permit to manufacture is sought.

42.—(1) A person licensed to manufacture a drug pursuant to regulation 41 shall not sell a drug in dosage form unless the drug has been prepared, manufactured, preserved, packaged, stored, labelled and tested under suitable conditions.

(2) For the purposes of paragraph (1) "suitable conditions" require—

(*a*) that the construction, fittings and furnishings in a building where a drug is processed and packaged shall be of such material and finish as to permit the ready and efficient cleaning of all surfaces, to prevent the introduction of extraneous materials into drugs during their processing and testing, and to prevent the migration of dust, in accordance with good pharmaceutical practices;

(*b*) that the premises used for the processing, testing, finishing, distribution and storage of the drug, and all auxiliary facilities, shall be maintained in a clean, sanitary and orderly condition, free from vermin, infestation, accumulated waste or debris;

(*c*) in cases where drugs for parenteral use are processed, that all fillings and aseptic processes shall be carried out in a separate and enclosed area designed for the processing and filling of such drugs and operated in a manner that will prevent contamination of the drug to be compounded and filled;

(*d*) that the personnel used as supervisors in the formulation, processing, testing, packaging and labelling of drugs, and the personnel responsible for the maintenance of machinery, equipment and sanitation shall have such technical training as is deemed necessary by the Minister, having regard to the duties and the responsibilities involved;

(*e*) that each lot or batch of raw bulk material used in the processing of a drug in dosage form shall be tested to ensure the identity and purity of such raw bulk materials;

(*f*) that each lot or batch of a drug in dosage form shall be tested to ensure its identity, potency and purity for its recommended use;

(*g*) that adequate quality controls shall be used, having regard to the nature of each drug;

(*h*) that a system of control shall be applied which will permit a complete and rapid recall of any lot or batch of the drug from the market, if necessary; and

(*i*) that records shall be maintained relating to each drug, in a form and manner satisfactory to the Minister showing—

(i) the tests carried out on each lot or batch of raw bulk materials used in the processing of the drugs;

(ii) the tests carried out on each lot or batch of drugs in the dosage form;

(iii) the quality controls applied;

(iv) all information received pertaining to the quality or hazards of any drug;

(v) the results of tests to determine the stability of each drug; and

(vi) the measures taken to ensure the recall of unsatisfactory lots or batches of drugs from the market.

(3) The records required to be maintained by sub-paragraph (i) of paragraph (2) shall be kept until the expiration of three years from the date of the testing of each lot or batch of each drug, or until the expiration date of that drug, whichever first occurs, and an adequate sample of each such batch or lot shall be submitted to the Minister, on his request, for analysis and examination.

43.—(1) A person shall not import a drug unless he has applied for and obtained permission to do so from the Minister and has paid a fee of two hundred dollars ($200) in respect of each permit bearing a maximum of ten products.

(2) A person applying for permission to import a drug pursuant to paragraph (1) may be required by the Minister—

(*a*) to furnish information and evidence satisfactory to establish that the conditions of manufacture described in paragraph (2) of regulation 42 have been met in respect to such drug; and

(*b*) before such drug is released for sale, to conduct tests in Jamaica by an acceptable method, on that drug in the form in which it is sought to be imported.

(3) Where, in the opinion of the Minister, a drug, or lot or batch of drugs, does not conform with the requirements of these Regulations, the drug, or the lot or batch thereof, as the case may be, shall not be admitted into the Island for use as a drug.

44.—(1) Except as otherwise provided in these Regulations, the label of a drug shall include—

(*a*) on the main panel of both the inner and the outer labels—

(i) the proper name; or

(ii) where there is no proper name, the common name;

(*b*) on both the inner and the outer labels—

(i) the name of the manufacturer or distributor of the drug;

(ii) the address of the manufacturer or distributor, except in cases where the immediate container contains 5 millilitres or less, when this statement need not be made on the inner label;

(iii) where a drug is intended for parenteral use, the lot number thereof;

(iv) a quantitative list of the medicinal ingredients contained therein by their proper names, or if they have no proper names, by their common names, except in the case of drugs sold on prescription; and

(v) adequate directions for use;

(*c*) on the outer label—

(i) a correct statement of net contents in terms of weight; and

(ii) where the drug is intended for parenteral use, the name and proportion of any preservative present therein.

(2) All the information required by this regulation to be included on a label shall be clearly and prominently displayed thereon, and shall be readily discernible to the public under the customary conditions of purchase and use.

(3) Where a package of a drug has only one label, that label shall include the information required by these Regulations to be shown on both the inner and outer labels.

[The inclusion of this page is authorized by L.N. 144/1995]

(4) The provisions of paragraph (1) shall not apply to the label of a drug package from bulk on the premises where the drug is retailed, except that the name of the drug shall be included on the label and where the package of a drug bears a statement, mark or device regarding the ingredients declared therein, in addition to the name of the drug, including the name and address of the retailer, the net contents and adequate directions for use, the package shall be labelled as required by these Regulations.

(5) The provisions of this regulation shall not apply to drugs supplied on prescription.

45. Except as otherwise provided in these Regulations, a person shall not sell to the general public for human use, a drug, other than a preparation solely for external use, unless both the inner and outer labels on such drug include a statement of the quantitative content of each drug and the recommended single and daily adult dosage, and where the drug is recommended for children, the statement "dose for children, as directed by the physician".

46.—(1) Both the inner and the outer labels of a drug for which a single or daily dosage or a statement of concentration in excess of the limits herein provided has been recommended shall include a caution that the product is to be used only on the advice of a physician.

(2) The provisions of paragraph (1) shall not apply to a drug supplied on prescription, or to the inner label of a single dose container.

47. The label of every prepacked drug shall include the cautionary phrase—"keep out of the reach of children".

48.—(1) A person shall not sell a drug containing—

(*a*) salicylic acid or its salts, acetylsalicylic acid or its salts or salicylamide, unless, where the drug is recommended for children, both its inner and outer labels include cautionary statements to the effect that the drug may be administered to children under two years of age only on the advice of a physician;

(*b*) hyoscine (scopolamine) or its salts, unless both its inner and outer labels include a cautionary statement to the effect that the drug is not to be used by persons suffering from glaucoma or where the drug causes blurring of the vision or pressure pain within the eye; and

(*c*) phenacetin, either singly or in combination with other drugs, unless its label bears the following statement—

"CAUTION: May be injurious if taken in large doses or for a long time. Do not exceed the recommended dose without consulting a physician."

(2) The provisions of paragraph (1) shall not apply to any preparation containing a drug that is required by anyone to be sold on prescription, or for parenteral or injectable use.

49.—(1) A person shall not sell a corticosteroid drug for ophthalmic use unless—

(*a*) the outer label of the package insert includes as part of the directions for use, the following statements—

"Contraindications—

Viral disease of the cornea and conjuctiva;
Tuberculosis of the eye;
Fungal disease of the eye;
Acute purulent untreated infection of the eye, which like other diseases caused by micro-organisms may be masked or enhanced by the presence of the steroid.

Side effects

Extended ophthalmic use of corticosteroid drugs may cause increased intraocular pressure in certain individuals and in those diseases causing thinning of the cornea, perforation has been known to occur"; and

(*b*) the inner label includes the statement required by sub-paragraph (*a*) of paragraph (1) or instructions to refer to the outer label or package insert for information about contraindications and side effects.

(2) The provisions of paragraph (1) shall not apply to a corticosteroid drug that is dispensed by a registered pharmacist pursuant to a prescription.

(3) A person shall not disseminate to a practitioner promotional literature about corticosteroid drugs for ophthalmic use unless the statements required by sub-paragraph (*a*) of paragraph (1) are included in the literature.

(4) The provisions of paragraphs (1) and (3) shall not apply to a drug sold solely for veterinary use.

List 4 Drugs

Fourth Schedule.

50.—(1) The drugs listed in the Fourth Schedule (hereinafter referred to as List 4 Drugs) are hereby prohibited from being retailed except on or in accordance with a prescription from a practitioner.

(2) A person shall not advertise any List 4 Drugs to the general public.

51.—(1) Subject to regulations 52 and 58, a person shall not sell a List 4 Drug unless he has received a prescription therefor, either in writing or verbally.

(2) A person selling a List 4 Drug pursuant to a written prescription shall retain such prescription for at least two years from the date of the filling thereof.

(3) A person to whom a prescription for a List 4 Drug has been communicated verbally by a practitioner shall forthwith reduce the prescription to writing (which shall be validated by the practitioner within thirty-six hours) and shall upon the filling therefor, retain that written and validated prescription for a period of at least two years from the date of filling thereof.

(4) The person reducing a verbal prescription for a List 4 Drug to writing shall indicate on the written prescription—

(*a*) the date and number of the prescription;

(*b*) the name and address of the person for whom the drug was prescribed;

(*c*) the name and quantity of the drug prescribed;

(*d*) the name and address of the practitioner prescribing the drug;

(*e*) the directions for use given with the prescription, and if that prescription is to be repeated, the number of times and intervals of time at which it may be repeated;

(*f*) the name and address of the person receiving the prescription, if given verbally; and

(*g*) the name and address of the person dispensing the drug pursuant to a verbal prescription which has been reduced to writing.

(5) A person repeating a prescription for a List 4 Drug shall record on the original prescription therefor, in respect of each repeat, the date of the repeat, the quantity of the drug dispensed, and the name and address of the person who dispensed the drug.

51A.—(1) Where a prescription directs the dispensing of a named List 4 Drug and there is available a bioequivalent generic drug which is less costly than the named drug, the registered pharmacist shall, before supplying the drug, inform the person for whom the drug is supplied or the person presenting the prescription—

(*a*) that there is available a bioequivalent generic drug whch is interchangeable with the named drug;

(*b*) that it is less costly than the named drug; and

(*c*) that the generic drug will be dispensed for the one prescribed, except where the person objects or declines to accept the generic presentation.

(2) This regulation shall not apply where there is a direction from the person who issued the prescripton that there shall not be any substitution.

(3) Where a person is supplying a drug for which a prescription is not required and there is available a generic drug which is less costly than the one requested, the pharmacist shall, before supplying the drug, inform the person requesting the drug—

(*a*) that there is available a generic drug which is interchangeable with the drug requested;

(*b*) that is less costly than the drug requested.

52.—(1) A person may sell a List 4 Drug on the strength of a written order duly signed, to—

(*a*) a drug manufacturer;

(*b*) a practitioner;

(*c*) a registered pharmacist;

(*d*) a hospital or any nursing home duly registered under any law for the time being in force relating to the registration of nursing homes;

(*e*) any person to whom a written order signed by the Minister has been issued.

(2) A person selling a List 4 Drug in accordance with paragraph (1) shall, prior to effecting the sale, verify the signature of the person signing the order if there are grounds for reasonable doubt as to the authenticity thereof.

(3) A person selling a List 4 Drug in accordance with paragraph (1) shall retain the order on the strength of which the List 4 Drug was sold, for a period of at least two years from the date on which the sale was effected.

53. A List 4 Drug shall not be imported other than by or for the use of—

(*a*) a practitioner;

(*b*) a drug manufacturer;

(*c*) a registered pharmacist; or

(*d*) a public hospital as defined under the Hospitals (Public) Act or any enactment for the time being in force relating to public hospitals.

54.—(1) Both the inner and outer labels of a package containing a drug represented for use primarily as a disinfectant, germicide, or antiseptic, shall include—

(*a*) the chemical name and proportion or amount of each drug contained therein;

(*b*) the batch number;

(*c*) directions for use;

(*d*) the words "For external use only" or "For internal use only";

(*e*) for preparations of phenolic type of natural oils other than soaps and ointments, as a declaration of the phenol co-efficient of the preparation as determined by the official method;

(*f*) for preparations containing available chlorine, a declaration of the percentage of the available chlorine content.

55.—(1) A person shall not sell aminopyrine or dipyrone (a derivative of aminopyrine) for oral or parenteral use, unless—

(*a*) the inner label includes the following statement—

"WARNING: Fatal agranulocytosis may be associated with the use of aminopyrine and dipyrone. It is essential that adequate blood studies be made. (See enclosed warnings and precautions)"; and

(*b*) the outer label or the package insert includes the following statements—

"WARNING: Fatal and even serious agranulocytosis is known to occur after the administration of aminopyrine or dipyrone. Fatal agranulocytosis has occurred after short term, intermittent and prolonged therapy with the drug; therefore, the use of these drugs should be as brief as possible. Bearing in mind the possibility that such reactions may occur, aminopyrine or dipyrone should be used only when other less potentially dangerous agents are ineffective".

"PRECAUTIONS: It is essential that frequent white blood cell counts and differential counts be made during treatment with these drugs. However, it is emphasized that agranulocytosis may occur suddenly without prior warning. The drug should be discontinued at the first evidence of any alteration of the blood count or sign of agranulocytosis, and the patient should be instructed to discontinue use of the drug at the first indication of sore throat or sign of other infection in the mouth or throat (pain, swelling, tenderness, ulceration)."

(2) A person shall not disseminate to a practitioner promotional literature about aminopyrine or dipyrone unless the statements specified in paragraph (1) are included in such literature.

(3) The provisions of paragraphs (1) and (2) shall not apply to preparations containing aminopyrine or dipyrone that are dispensed by a pharmacist pursuant to a prescription, or sold for veterinary use only.

56.—(1) A person shall not sell coated tablets containing potassium salts, with or without thiazide diuretics, unless the inner label of the package or the package insert includes the following statement—

"WARNING: A probable association exists between the use of coated tablets containing potassium salts, with or without thiazide diuretics, and the incidence of serious small bowel ulceration. Such preparations should be used only when adequate dietary supplementation is not practical, and should be discontinued if abnormal pain, distention, nausea, vomiting or gastrointestinal bleeding occur."

(2) A person shall not disseminate to a practitioner promotional literature about coated tablets containing potassium salts, with or without thiazide diuretics, unless the statement specified in paragraph (1) is included in such literature.

(3) The provisions of paragraphs (1) and (2) shall apply to coated tablets containing potassium salts with or without thiazide diuretics that are sold for veterinary use only, or are dispensed by a pharmacist pursuant to a prescription.

57. A person shall not sell a drug for veterinary use unless both the inner and the outer labels include, in addition to the requirements of regulation 61, the quantitative content of the drug; and except for

drugs in a form not suitable for human use, the words "For Veterinary Use Only".

58. A person may sell a List 4 Drug on the strength of a prescription from a veterinary surgeon provided that—

(*a*) the drug is in a form not suitable for human use; or

(*b*) the main panel of both the inner and outer labels carries the words "For Veterinary Use Only", immediately following or preceding the proprietary or brand name, proper name or common name, in type not less than one-half as large as the largest type on the label.

59. Both the inner and the outer labels of a veterinary drug represented as containing one or mort vitamins shall include in addition to the requirements of regulation 61—

(*a*) a statement of the amount of each vitamin present in the drug, expressed in terms of the proper name of the vitamin in—

(i) international units per gramme or per millilitre in the case of vitamin A, provitamin A, vitamin D and vitamin E;

(ii) milligrammes per gramme in the case of solid or viscous liquids, or per millilitre in the case of other liquids, thiamine, riboflavin, niacin, niacinamide, pyridoxine, d-pantothenic acid, d-panthenol, folic acid, ascorbic acid and vitamin K;

(iii) microgrammes per gramme in the case of solid or viscous liquids, per millilitre in the case of other liquids, biotin and Vitamin B12;

(iv) oral units for vitamin B12 with intrinsic factor concentrate; and

(v) the specified units per individual dose or dispensing form in the case of vitamin products put up in individual doses or dispensing forms;

(*b*) except for drugs in a form not suitable for human use, the words "For Veterinary Use Only".

60. A person may sell an antibiotic preparation for the treatment of cattle if—

(*a*) the preparation is not to be used for lactating cattle and the inner and outer labels of the preparation include a statement to that effect; or

(*b*) where the preparation may be used for lactating cattle—

(i) there has been submitted to the Minister on request, evidence acceptable to him, to show the period of time required to elapse after the last treatment with the preparation, in order that the milk from lactating animals so treated shall not contain residues of antibiotics, and that period does not exceed ninety-six hours;

(ii) the main panel of the outer label of the preparation and either the inner label or a packaging insert describing the antibiotic preparation includes the words:

"WARNING: MILK TAKEN FROM TREATED ANIMALS WITHIN.....72.....HOURS AFTER THE LATEST TREATMENT WITH AN INTRAMAMMARY MEDICATION SHALL NOT BE USED IN FOOD"; and

(iii) the relevant space on the label is filled in with the appropriate figure.

61. A person shall not sell any substance having oestrogenic activity for administration to poultry which may be used as food for human consumption.

62.—(1) The Minister may from time to time require the manufacturer of a drug recommended for administration to animals which may be used as food for human consumption—

(*a*) to file with him in respect of that drug, a submission in writing, in form and content satisfactory to the Minister, describing in detail, tests carried out to determine that no residues of the drug, other than residues within the limits prescribed by these Regulations remain in meat, meat by-products, eggs or milk obtained from animals treated with that drug; and

(*b*) to print on the main panel of the outer label of any drug recommended for administration to animals which may be used for human consumption and on either the inner label or on a package insert describing the drug, a warning that meat, meat-products, eggs or milk obtained from animals to which the drug has been administered cannot be sold as food for human consumption if they are obtained within such time after administration as may be specified by the Minister.

(2) A manufacturer shall not sell a drug in respect of which the Minister has required a warning to be printed pursuant to paragraph (*b*) of subsection (1), unless that requirement has been complied with.

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63.—(1) A person shall not sell a drug in tablet form, the label of which indicates that it carries an enteric coating or a coating designed to have a similar purpose, unless the tablet—

(*a*) does not disintegrate when exposed to simulated gastric juice for sixty minutes; and

(*b*) disintegrates in not more than an additional sixty minutes in simulated intestinal juice when tested by the official method.

(2) Where a standard of disintegration has not been prescribed for a drug in any of the publications listed in the Second Schedule to the Act or in paragraph (1) of this regulation, a person shall not sell a drug in the form of a tablet that is intended to be swallowed whole, unless the tablet disintegrates in not more than sixty minutes when tested by the official method.

(3) The provisions of paragraphs (1) and (2) shall not apply to tablets containing a drug which has been demonstrated by the official method to the satisfaction of the Minister to be assimilable by the body.

(4) Paragraph (2) shall not apply to tablets that are described on their label as releasing the drug at timed intervals or in sustained quantities over a period of time.

New Drugs

64. In this Division "new drug" means—

(*a*) a drug that contains or consists of a substance, whether as an active or inactive ingredient, carrier, coating, excipient, menstrum or other component, that has not been imported into the Island for use as a drug for a sufficient time and in sufficient quantities prior to the 4th of August, 1975 to establish its efficacy and safety, or is a new drug in the country in which it was manufactured;

(*b*) a combination of two or more drugs, with or without other ingredients which have not been imported into the island prior to the 4th of August, 1975, in that combination or in the proportion in which those drugs are combined;

(*c*) a drug in relation to which the manufacturer prescribes, recommends, proposes or claims a use as a drug, or a condition of use as a drug, including dosage, demonstration or duration of action, and which has not been imported into the Island prior to the 4th of August, 1975, for that use or condition of use; or

(*d*) any other drug which the Minister may prescribe.

65.—(1) A person shall not import, sell, advertise for sale, or manufacture, a new drug unless—

(*a*) he has been issued a licence by the Minister in respect of the importing, sale, or manufacture, as the case may require, of that new drug, and which licence has not been withdrawn in accordance with regulation 69; and

(*b*) he has paid an initial fee of five thousand dollars in respect of that licence instead of the registration fee imposed pursuant to regulation 40.

(2) Any person desirous of obtaining a licence in accordance with paragraph (1) shall make an application to the Minister containing—

(*a*) a description of the new drug, including the name and address of the manufacturer thereof, and a declaration of the proper name, if any, and the name under which it is proposed to be sold;

(*b*) a statement of all the ingredients, the route of administration, the proposed dosage, the therapeutic or diagnostic claims for the new drug, if known, a description of the pharmaceutical dosage form in which the new drug is to be sold, and any known contra-indications and side effects thereof;

(*c*) details of the tests conducted to control the potency, purity and safety of the new drug;

(*d*) a draft of every label proposed to be used in connection with the new drug;

(*e*) samples of the new drug in the finished and pharmaceutical form in which it is to be sold;

(*f*) such samples of the components of the new drug as the Minister may require;

(*g*) a certificate from the competent authority in the country of manufacture or export certifying that the new drug is approved for use in that country and the conditions under which it may be used or sold in that country; and

(*h*) a certificate in the English language in addition to any other language, from the manufacturer, respecting the safety of the new drug conditions of use recommended, and giving the conditions under which it may be sold, issued by an official body or government department having authority to issue such certificate, such official body or government department

having the experience and facilities for testing the safety of a new drug that are considered by the Minister as adequate to ensure the safety of the new drug under the conditions of use recommended.

(3) The Minister may in his discretion, refuse any application for a licence made pursuant to this regulation, or grant any such application which does not comply with the requirements of sub-paragraph (*g*) of paragraph (2) but is accompanied by—

(*a*) detailed reports of the tests made to establish the safety of the new drug for the purpose and under the conditions of use for which it is recommended; and

(*b*) such other information and material as the Minister may in any particular case require.

66. A person shall not import, sell, advertise for sale or manufacture a new drug in respect of which he has been granted a licence, if any material change has been made in respect of that new drug, in—

(*a*) the strength, purity or quality;

(*b*) the pharmaceutical dosage form in which it is sold;

(*c*) the conditions of use, including indications for use and the route of administration;

(*d*) the dosage; or

(*e*) the label,

unless he makes application for a new licence in respect thereof, giving full details of the changes and the manner in which the new drug in respect of which the original licence was granted, is affected by the change.

67. Where a person wishes to import, sell, advertise for sale or manufacture, a new drug in respect of which a licence has been previously granted to another applicant, that person shall make a separate application in accordance with regulation 65.

68. The Minister shall, within one hundred and twenty days after the filing of an application for a licence to import, sell, advertise for sale, or manufacture a new drug—

(*a*) notify the applicant whether or not his application is satisfactory; and

(*b*) if so, may grant a licence to the applicant in accordance therewith.

69.—(1) The Minister may withdraw a licence in respect of any new drug by sending a notice in writing to that effect to the person to

whom a licence has been granted in respect of that new drug, and such a withdrawal may be made where—

(a) evidence obtained from clinical or other experience, or from tests by new methods or by methods not used before the approval was given, reveal that the new drug is not shown to be safe for the use represented in the application made to the Minister in respect of that new drug and on which the approval by the Minister was based; or

(b) the submission filed with the Minister in relation to that new drug and on which approval by the Minister was based, contained any untrue statement of material fact; or

(c) the withdrawal is necessary in the public interest.

(2) Notice of withdrawal of approval in respect of any new drug shall be published for three consecutive weeks in the *Gazette* and in at least one issue of a daily newspaper printed and circulating in Jamaica, for three consecutive weeks.

70. Where any person receives any report of any unexpected side effects, injury, toxicity or sensitivity reaction associated with clinical uses, studies, investigation and tests respecting any new drug, he shall immediately inform the Minister thereof, furnishing him with the full information available.

71.—(1) Notwithstanding anything to the contrary in these Regulations, a new drug may be imported for the use of investigators having such technical qualifications as is deemed necessary by the Minister in the circumstances for the sole purpose of obtaining clinical and scientific data with respect to its safety, stability, dosage or efficiency, if—

(a) the investigators have written authority from the Minister to carry out investigations on the new drug and the facilities for so doing;

(b) before the importation, the Minister is informed of the identifying name or mark by which the new drug may be recognized;

(c) both the inner and outer labels on any package of such new drug bear the statement "To be used for investigational purposes only";

(d) before the sale, the importer ensures that any person to whom the new drug is to be sold has written authority from the Minister to conduct investigations relating to that new drug, and obtains in writing from that person an undertaking that the new drug will be used solely by him or under his direction for investigational purposes.

(2) A person who imports a new drug for the purpose of sale to any other person authorized by the Minister to carry out investigations in relation to that new drug, shall keep accurate records of such sales, and shall make these records available for inspection by inspectors duly designated under the Act.

72. Notwithstanding anything to the contrary in these Regulations, the Minister may grant permission in writing to any person to import any specified quantity of a new drug, for submission as a sample with an application for a licence in relation to that new drug.

73. Notwithstanding any other provision in these Regulations, the Minister may grant any emergency licence to a practitioner for the importation of a new drug, the application for which does not comply with the requirements of these Regulations, if that drug is required for the treatment of an urgent case, and the Minister is satisfied that it is in the best interest of the patient for whom the drug is intended, that the importation be effected without delay.

Controlled Drugs

74. In this Division—

"controlled drug" means any drug listed in the Fifth Schedule and includes a mixture containing any such drug; Fifth Schedule.

"licensed dealer" means any person licensed to manufacture or sell a controlled drug, authorized by the Minister to have a controlled drug in his possession, or granted a permit to import or export a controlled drug pursuant to regulations 75 and 76 respectively.

75.—(1) A person shall not manufacture or sell a controlled drug unless he has been granted a licence to do so by the Minister nor shall a person have a controlled drug in his possession unless he has authorization from the Minister to do so.

(2) A person shall not import or export a controlled drug unless he has first obtained a permit to do so from the Minister.

76.—(1) The Minister may, on application therefor—

(*a*) issue a licence in the form set out as Form B in the Third Schedule to any person to manufacture or sell a controlled drug; or Third Schedule.

(*b*) issue a permit to any person to import or export a controlled drug subject to such terms and conditions as he may think fit.

(2) A fee of $10.00 is payable by the applicant in respect of each licence or permit, as the case may be, issued pursuant to paragraph (1), in addition to any registration fee payable in respect of that drug pursuant to regulation 40.

(3) The Minister may revoke or suspend a licence or a permit issued pursuant to paragraph (1) if, in his opinion, the person to whom it is issued, or any person in his employ, has violated or failed to comply with any term or condition of such licence or permit or any provision of these Regulations.

(4) A licence issued pursuant to paragraph (1), unless it is sooner revoked, shall expire on the 31st day of March next following the date on which it is issued and may be renewed by the Minister on the appropriate application being made to the Minister in respect thereof. Where a licence has been suspended it has no validity during the period of suspension.

77. Subject to the terms and conditions of his licence, and to the requirements of these Regulations a licensed dealer may supply a controlled drug—

(*a*) to another licensed dealer or to a practitioner, if he receives a written order therefor from such dealer or practitioner, and he verifies the signature affixed to the order prior to supplying same; and

(*b*) to a hospital, if he receives a written order signed by a pharmacist, practitioner or other official duly authorized by the hospital to place such an order, and he verifies the signature affixed to the order prior to supplying same.

78.—(1) A licensed dealer who is a pharmacist carrying on the business of a pharmacy, or a pharmacist employed by him for the purposes of conducting that business, may supply a controlled drug to any person if—

(*a*) the drug forms part of the stock in trade of the pharmacy;

(*b*) he has first received a prescription in writing authorizing the dispensing of that drug;

(*c*) the prescription has been dated and signed by the practitioner who issued it;

(*d*) the prescription includes the full name and address of the prescribing practitioner; and

(*e*) the signature of the practitioner is verified prior to effecting the sale.

(2) A pharmacist shall not repeat a prescription for a controlled drug unless the practitioner issuing the original prescription specifies therein the number of times it may be repeated, and the intervals at which it may be repeated.

79.—(1) Every licensed dealer and every pharmacist in control of a place of business carrying on the business of a pharmacy shall keep a separate register in relation to controlled drugs in which he shall enter or cause to be entered within 48 hours of every receipt or dispensation of any controlled drug, the following—

(*a*) the name, quantity and form of any controlled drug received by him, the name and address of the person from whom he received it, and the date on which it was received;

(*b*) the name, quantity and form of any controlled drug supplied, the name and address of the person to whom it was supplied, the date on which it was supplied, and if supplied pursuant to a prescription, the name and address of the person for whom it was prescribed and the name and address of the practitioner who issued the prescription;

(*c*) the name and quantity of any controlled drug used in manufacturing, the name and quantity of any controlled drug manufactured, and the date any manufactured controlled drug was placed in stock; and

(*d*) the name, quantity and form of all controlled drugs in his stock at the end of each month.

(2) A licensed dealer in both the business of a wholesaler dealing in drugs and the business of a pharmacy, shall keep separate registers as required by paragraph (1), in relation to each business.

(3) Every licensed dealer and every pharmacist shall maintain all vouchers relative to receipts and disposals of controlled drugs in separate files, in sequence of number and date, for a period of at least two years from the date on which each transaction took place and such vouchers shall be kept in a manner that will enable an audit thereof to be made at any time.

80. Every licensed dealer shall take all necessary steps to protect controlled drugs in his possession or under his control against loss or theft and shall report to the Minister any such loss or theft of a controlled drug within ten days of the discovery of such loss or theft.

Division IV. Cosmetics

81.—(1) A person shall not sell a cosmetic which is not labelled in accordance with these Regulations.

(2) Except as otherwise provided in these Regulations there shall be included—

(*a*) on both the inner and outer labels of a cosmetic—

(i) the name, if any, of the cosmetic, and the identification thereof; and

(ii) the name and address of the place of business of the manufacturer or distributor and if he has more than one place of business, the address of his principal place of business;

(*b*) on the label of a cosmetic a declaration of the net contents expressed in terms of—

(i) weight for solids;

(ii) fluid measure for liquids; and

(iii) weight for semi-solids,

so, however, that in all cases fluid measurement may be used if it conveys accurate information in respect of the net content, and is in accordance with established commercial practice, and where a hazard exists, adequate directions for safe use shall be included as well as any warning, caution or special direction required by these Regulations.

82. A person shall not sell a cosmetic on the label or in any advertisement for which is included any symbol or device suggesting that the cosmetic has been prepared or compounded in accordance with a prescription.

PART III. *Administration*

83. A certificate of designation to be furnished to an inspector pursuant to subsection (4) of section 19 of the Act, shall be in the form set out as Form C in the Third Schedule.

Third Schedule. Form C.

84. When taking a sample in accordance with the provisions of section 19 of the Act, an inspector shall, after procuring a suitable quantity of the article in question, forthwith notify the owner thereof or the person from whom the sample was obtained, of his intention to have that sample examined or analysed and—

(*a*) where in his opinion, division of the procured quantity would not interfere with analysis or examination, the inspector shall—

(i) divide the quantity into three parts;

(ii) identify the three parts as the owner's portion, the sample, and the duplicate sample, and where only one part bears the label, that part shall be identified as the sample;

(iii) seal each part in such a manner that it cannot be opened without breaking the seal;

(iv) deliver the part identified as the owner's portion to the owner or to the person from whom the sample was obtained, and have the sample and the duplicate analysed or examined; or

(*b*) where, in his opinion division of the procured quantity would interfere with analysis or examination, the inspector shall—

(i) identify the entire quantity as the sample;

(ii) seal the sample in such a manner that it cannot be opened without breaking the seal; and

(iii) have the sample analysed or examined;

(*c*) where the owner or the person from whom the sample was obtained objects to the procedure followed by an inspector at the time the sample was obtained, the inspector shall follow both procedures specified in this regulation, if the owner or the person from whom the sample was obtained supplies him with a sufficient quantity of the article to do so.

85.—(1) A certificate of examination or analysis of an article or sample detained by an inspector shall be in the form set out as Form D in the Third Schedule. Third Schedule. Form D.

(2) Where as a result of an examination or analysis it is reported that a food, drug, cosmetic or device, would, if sold in the Island. constitute a violation of the Act or these Regulations, that food, drug, cosmetic or device, shall not be admitted into the Island, for use as a food, drug, cosmetic or device, and the inspector shall send a written report of the analysis or examination to the Collector-General and a copy of such report to the importers.

86. Where a food, drug, cosmetic or device sought to be admitted into the Island, would, if sold in the Island, be contrary to the provisions of the Act or these Regulations, the food, drug, cosmetic or device may be admitted into the Island for the purpose of being relabelled or reconditioned under the supervision of an inspector in compliance with such conditions as may be specified in the report, and where such relabelling or reconditioning is not satisfactorily carried out within three months after the report is made or such lesser period as may be specified in the report, such food, drug, cosmetic or device

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shall be re-exported and, if not re-exported within a further period of three months shall be disposed of as the Minister may direct, so, however, that the Minister may, in his discretion, extend the time for complying with the conditions for re-exporting the said goods.

PART IV. *Offences and Penalties*

87. Any person who fails to comply with any of these Regulations shall be guilty of an offence, and upon summary conviction before a Resident Magistrate shall be liable to a fine not exceeding two thousand dollars or to a term of imprisonment not exceeding twelve months.

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FIRST SCHEDULE (Regulation 27 (2))

Artificial non-nutritive sweetening agents

Item	Additive	Preparation usually added to	Max. Level of Use
1.	Ammonium Saccharin	Special dietary foods recommended for carbohydrate or sugar reduced diets, and special dietary food recommended for reduced diets.	Good manufacturing practice.
2.	Saccharin	Special dietary foods recommended for carbohydrate or sugar reduced diets, and special dietary food recommended for calorie reduced diets.	—do—
3.	Sodium Saccharin	—do—	—do—

SECOND SCHEDULE (Regulation 38)

POISONOUS SUBSTANCES PERMITTED

FOOD	SUBSTANCE				
	Arsenic parts per million	Lead parts per million	Copper parts per million	Zinc parts per million	Fluorine parts per million
Citric Acid	1	10	50	50	2
Tartaric Acid	1	10	50	50	2
Cream of Tartar	2	20	50	50	2
Sodium Bicarbonate	2	5	50	50	2
Baking Powder	2	10	50	50	10
Phosphoric Acid	4	5	30	30	20
Calcium Phosphate	4	5	30	30	30
Sodium Potassium and Ammonium Phosphates	4	5	30	30	20

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SECOND SCHEDULE, *contd.*

POISONOUS SUBSTANCES PERMITTED, *contd.*

FOOD	SUBSTANCE				
	Arsenic parts per million	Lead parts per million	Copper parts per million	Zinc parts per million	Fluorine parts per million
Sodium and Potassium Nitrates ..	1	10	50	50	2
Sodium Nitrite	1	20	50	50	2
Aluminium Compounds	3	10	50	50	2
Marine and Fresh Water Animal Products	5	10	100	100	25
Liver	1	2	152	100	2
Fresh Fruits	2	7	50	50	2
Fresh Vegetables	1	2	50	50	2
Gelatin	2	7	30	100	60
Gelling Agents except Gelatin ..	2	20	50	200	2
Dried Herb and Spices	5	10	50	50	20
Apple Juice, Cider, Wine and Beer ..	0.2	0.5	2	5	2
Fruit Juice except Apple Juice ..	0.1	0.2	2	5	1
Beverages as Consumed and Bottled Water	0.1	0.2	2	5	2
Tea	1	10	150	50	100
Edible Bone Meal	1	10	20	150	650

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THIRD SCHEDULE

FORM A (Regulation 41 (2))

The Food and Drugs Act

Permit to Manufacture a Drug

..... Name and address of Licensee.

of.....

IS HEREBY LICENSED, subject to the provisions of the Food and Drugs Act, and the Regulations made thereunder, and to the subjoined conditions, to manufacture at premises situated at—

.....

.....

the following—

.....

Conditions

1. This Licence shall expire on the.....day of.....

19.....

2. This licence is not transferable.

3. The Minister of Health may at any time revoke this licence upon the failure of the licensee to comply with all or any of the conditions contained therein, or in the Regulations.

4. Nothing in this licence shall be deemed to authorize the licensee to keep any drugs or poisons for the purpose of sale.

Dated at.....this.....day of.....19.....

.....
Minister of Health and Environmental Control.

FORM B (Regulation 76 (1))

The Food and Drugs Act

Licence to Manufacture or Sell a Controlled Drug

..... Name and address of Licensee.

of.....

IS HEREBY LICENSED, subject to the provisions of the Food and Drugs Act and the Regulations made thereunder, and to the subjoined conditions, to manufacture/sell the controlled drugs set out hereunder—

[The inclusion of this page is authorized by L.N. 144/1995]

THIRD SCHEDULE, *contd.*

Exact description of drugs to be manufactured/sold. .....

.....

.....

Quantity of drugs to be manufactured/sold. .....

.....

.....

Conditions

1. This Licence shall expire on the 31st day of March, 19.....

2. The Minister may revoke at any time this Licence upon failure to comply with all or any of the conditions contained therein, or in the Regulations.

3. This Licence is not transferable.

Dated at.....this.....day of.....19.....

.....
Minister of Health and Environmental Control.

FORM C (Regulation 84)

The Food and Drugs Act

Certificate of Designation of Inspector

This is to certify that

Mr./Mrs./Miss.....

has been designated an Inspector for the purposes of section 17 of the Food and Drugs Act.

.....
Signature of Inspector

Minister of Health and Environmental Control.
(OFFICIAL STAMP)

FORM D (Regulation 86)

The Food and Drugs Act

Certificate of Examination or Analysis

I.....

.....being a

person duly designated an inspector/analyst under the Food and Drugs Act do hereby certify—

THIRD SCHEDULE, *contd.*

(1) that on the.....day of.....19.....
I received from.....a sealed package, which said package was unopened and the seals thereon unbroken;

(2) that I broke the seals and opened the said package and removed therefrom a sample, submitted as a sample of.....
taken from.....of.....

(3) that I duly analysed or examined the said sample for the purpose of determining if same conformed to the requirements of the Food and Drugs Act, and the Regulations made thereunder, and I obtained the following results—

Dated this.....day of.....19.....

.....
Inspector / Analyst

FOURTH SCHEDULE (Regulation 50)

LIST 4 DRUGS

Part I

A

Acebutolol Hydrochloride
Acetocoumarol
Acepromazine
Acetanilide: Alkyl Acetanilides
Acetazolamide Sodium
Acetohexamide
Acetomenaphthone
Acetrizoic Acid and its salts
Acetyl Choline
Acyclovir
Adenosine and its salts
Adipiodone and its salts
Adrenaline Tartrate (1-1000 Injection)
Adrenocorticotrophic Hormone and its derivatives
Alclofenac
Allopurinol
Allylisopropylacetylurea
Almitrine Dimesylate
Alphadolone Acetate
Alphaxalone and its salts
Alprazolam
Alprenolol Hydrochloride
Amantadine Hydrochloride and Sulphate

FOURTH SCHEDULE, *contd.*

A, *contd.*

Amidopyrine; its Salts and Derivatives; except when contained in ointments or in preparations for the prevention and treatment of disease in poultry.

Amiloride Hydrochloride

Amino-Acids; preparations for Intravenous Administration

Aminocaproic Acid

Aminoglutethimide

Aminopentamide and its salts

Aminophylline

Aminopromazine Fumarate

Aminopterin and its salts

Aminosalicyclic Acid and its salts

Amitriptyline Hydrochloride

Amoxapine

Amphetamine and its salts

Amrinone

Anaesthetics; for ophthalmic or parenteral use, including—

- Amethocaine and its salts
- Benzocaine and its salts
- Butacaine and its salts
- Cinchocaine and its salts
- Cyclomethycaine and its salts
- Dimethisoquin and its salts
- Diperodon and its salts
- Lidocaine and its salts
- Piperocaine and its salts
- Pramoxine and its salts
- Proxymetacaine and its salts

Androgenic, Oestrogenic and Progestational Substances; their Esters (except when combined as an Oral Contraceptive) including—

- Allyloestrenol
- Benzoestrol
- Boldenone
- Chlormadinone
- Clomiphene
- Conjugated Estrogens
- Dienoestrol
- Diethylstilboestrol
- Dimethisterone
- Dydrogesterone
- Epioestriol
- Ethinyloestradiol
- Ethisterone
- Ethyloestrenol
- Ethynodiol
- Fluoxymesterone
- Gestronol
- Hexoestrol
- Gestodene
- Medrogestrone
- Hydroxyprogesterone
- Megestrol
- Lyngestrenol
- Mestranol
- Medroxyprogesterone
- Methandriol
- Mesterolone
- Methyloestradiol
- Methandienone
- Nandrolone
- Methenolone
- Norethynodrel
- Methyltestosterone

FOURTH SCHEDULE, *contd.*

A, *contd.*

- Notethandrolone
- Norethisterone
- Norgestrel
- Oestriol
- Oxymesterone
- Piperazine Oestrone Sulphate
- Quinestrol
- Stilboestrol
- Oestradiol
- Oestrone
- Oxymetholone
- Progresterone
- Stanozolol
- Testosterone

Antazoline and its salts

Antihaemophilic Factor

Apramycin

Atenolol and its salts

Atracrium Besylate

Atropine and its salts

Auranofin

Azacyclonol Hydrochloride

Azaperone

Aztreonam

B

B—Aminopropylbenzene and B—Aminoso—Propylbenzene; their derivatives, and analogues except Ephedrine, Methylephedrine, Ethylphedrine, Norephedrine and Prenalymine.

Baclofen

Bamethan Sulphate

Barbexaclone

Barbituric Acid, its salts; derivatives of Barbituric Acid, their salts including—

- Allobarbitone
- Amylobarbitone
- Barbitone
- Butobarbitone
- Cyclobarbitone
- Heptabarbitone
- Hexobarbitone
- Metharbitone
- Methylphenobarbitone
- Nealbarbitone
- Pentobarbitone
- Phenobarbitone
- Phenylmethylbarbituric Acid
- Quinalbarbitone
- Secbutobarbitone
- Vinbarbitone

[The inclusion of this page is authorized by L.N. 144/1995]

FOURTH SCHEDULE, *contd.*

B, *contd.*

Barium Sulphate
Beclamide
Belladonna and its alkoloids
Benactyzine Hydrochloride
Bencyclane and its salts
Bendazac and its salts
Bendrofluazide
Benfluorex Hydrochloride
Benserazide Hydrochloride
Benzetimide Hydrochloride
Benzhexol Hydrochloride
Benzocaine
Benzoctamine
Benzoyl Peroxide (10%)
Benzphetamine Hydrochloride
Benztropine and its Homologues, their salts
Benzydamie Hydrochloride
Bemegride
Betahistine and its salts
Betaxolol and its salts
Bethanidine and its salts
Biperiden and its salts
Bitolterol and its salts
Bretylium Tosylate
Bromazepam
Bromhexine and its salts
Bromocryptine and its salts
Bronvaletone
Broxaldine
Broxyquinoline
Buclosamide
Buflomedil Hydrochloride
Bumetanide
Buphenine Hydrochloride
Buspirone Hydrochloride
Busulphan Hydrochloride
Butaperazine Hydrochloride
Butorphanol Tartrate
Butryptiline Hydrochloride

[The inclusion of this page is authorized by L.N. 144/1995]

FOURTH SCHEDULE, *contd.*

C

Calciferol
Calcium Disodium Versenate Injection
Calcium Gluconate Injection
Calcium Iodide Injection
Calcium Sodium Edetate
Cannabinoids (of Cannabis Sativa)
Captodiamine and its salts
Captopril
Carbamazepine
Carbachol
Carbamide
Carbenoxolone and its salts
Carbimazole
Carbidopa
Carbromal and its derivatives
- Acetylcarbromal
- Allylisopropylacetylurea
- Bromisoval
- Diethylbromacetamide

Carisoprodol
Carmustine
Carphenazine and its salts
Cefroxadine
Ceftazidime
Ceftriaxone
Cefuroxime
Cephapirin Sodium
Cetylpyridinium
Chenodeoxycholic Acid
Choral and its derivatives
Chloralose
Chloral Hydrate
Chloralamide
Chloralodol
Chlorambucil and its salts and derivatives
Chloracyzine (except preparations for external use only)
Chloradiazepoxide and its salts
Chlorhexidine and its salts
Chlorisondamine and its salts
Chlormethiazole and its salts
Chlormezanone
Chloroquin and its salts
Chlorothiazide and its salts and derivatives

[The inclusion of this page is authorized by L.N. 144/1995]

FOURTH SCHEDULE, *contd.*

C, *contd.*

Chlorphentermine Hydrochloride
Chlorphenoxamine
Chlorpromazine and its salts
Chlorpropamide and its salts
Chlorprothixene and its salts
Chlorquinaldol
Chlorthalidone
Chlorzoxazone
Cholestyramine and its salts
Chymotrypsin
Cisplatin
Cimetidine
Cinnarizine
Clebopride Acid Maleate
Clemastine and its salts
Clemizole
Clidinium Bromide
Clioquinol
Clobazam
Clobenzorex
Clobetasone Butyrate
Clofazimine
Clofibrate
Clomiphene
Clomipramine Hydrochloride
Clonazepam
Clonidine Hydrochloride
Clopenthixol Hydrochloride
Cloprostenol Sodium
Clorazepate Sodium
Clotrimazole
Clozapine
Colchicine
Colimix
Collagen (Bovine)
Corticotrophin
Corticosteriods and their salts and derivatives including—

Aldosterone	Flunisolide
Amcinonide	Fluocinolone
Beclomethasone	Fluocinonide
Betamethasone	Flucortolone
Clobetasol	Fluorometholone
Clocortolone	Halcinonide

[The inclusion of this page is authorized by L.N. 144/1995]

FOURTH SCHEDULE, *contd.*

C, *contd.*

Cortisone
Desoxymethasone
Dexamethasone
Diflucortolone
Fluclorolone
Flumethasone
Hydrocortisone (other than 0.5% and 1% Hydrocortisone Cream and 0.5% and 1% Hydrocortisone Ointment)
Methylprednisolone
Mometasone
Predinisolone
Prednisone
Triamcinolone

Cotrimoxazole
Cromoglycate Sodium
Cromoglycic Acid and its salts
Crotamiton
Cyclandelate
Cyclizine
Cyclobenzaprine
Cyclopentamine Hydrochloride
Cyclopenthiazide
Cyclophosphamide
Cycrimine and its salts
Cymevene
Cyproterone and its salts
Cytarabine and its salts

D

Danazol
Dantrolene Sodium
Dapsone
Debrisoquine Sulphate
Demecarium Bromide
Deproteinised Extract of Blood
Dequalinium
Desipramine
Deslanoside
Desmopressin Acetate
Desonide
Dexfenfluramine and its salts
Dextropropoxyphene Hydrochloride
Diaphenylsulfone
Diatrizoate and its salts
Diazepam
Diazoxide and its salts
Dibasic Calcium Phosphate
Dichlorphenamide and its salts
Dichlorvos
Diclofenac and its salts (other than Diclofenac topical preparation)

[The inclusion of this page is authorized by L.N. 54/2000]

FOURTH SCHEDULE, *contd.*

D, *contd.*

Diethylcarbamazine Citrate
Diethylpropion Hydrochloride
Diflorasone Diacetate
Diflunisal
Digitalis, its glycoside or derivatives, or preparations including—

Acetyldigitoxin	Digitoxin
Acetyldigoxin	Digoxin
Deslanoside	Lanatoside
Digitalis Leaves	

Dihydroergocristine Maleate/Clopamide/Reserpine
Dihexyverine Hydrochloride
Dihydralazine and its salts
Diltiazem and its salts
Dimenhydrinate Inspection
Dimethyl Sulfoxide
Diminazene Aceturate
Dinoprost and its salts
Diosmin
Diphenidol Hydrochloride
Diphenoxylate Hydrochloride
Dipyridamole
Dipyrone and its salts
Disopyramide and its salts
Disulfiram
Dobutamine
Dopamine Hydrochloride
Dothiepin Hydrochloride
Doxepin and its salts
Droperidol and its salts
Drotaverine and its salts
Diflucortolone

E

Echothiophate Iodine
Econazole Nitrate
Ectylurea
Edrophonium Chloride
Electrolyte Mixtures
Emylcamate
Enalapril Maleate
Endralazine
Enzymes, including—

Amylolytic	Lipolytic
Cellulolytic	Mucolytic
Febrinolytic	Proteolytic

[The inclusion of this page is authorized by L.N. 54/2009]

FOURTH SCHEDULE, *contd.*

E, contd.

Ephedrine Hydrochloride doses of 30mg or more
Ephedrine Sulphate Injection
Epinephrine and its salts
Ethacrynic Acid
Ethambutol Hydrochloride
Ethchlorvynol
Ethinamate
Ethionamide
Ethoheptazine Citrate
Ethosuximide
Ethylchloride
Ethylenediamine
Ethylefrine and its salts
Etodolac
Etretinate
Ergot, its alkaloids and their salts including—
- Dihydroergotamine
- Dihydroergotoxine
- Ergometrine
- Ergotamine
- Ergotoxine

F

Famotidine
Felypressin
Fenfluramine Hydrochloride
Feniprostalene
Fenmetozole
Fenoprofen and its salts
Fenoterol and its salts
Fentanyl and its salts
Fentiazac and its salts
Feprazone
Folic Acid
Flavonoids (Extracts from Rutaceae)
Flavoxate and its salts
Flecainide and its salts
Flucytosine
Flunarizine and its salts
Fluocinlone
Fluorouracil and its derivatives
Fluoxetine and its salts
Flupentixol and its salts
Fluphenazine and its salts

[The inclusion of this page is authorized by L.N. 144/1995]

FOURTH SCHEDULE, *contd.*

F, contd.

Fluprostenol Sodium
Flurazepam
Flurbiprofen
Fluspirilene
Flutamide
Furaltadone Hydrochloride
Furazolidone
Furosemide (Frusemide)

G

Gallamine and its salts
Gemfibrozil
Gestodene
Glafenine
Glibenclamide
Gliclazide
Glucagon and its salts
Glutamic Acid and its salts
Glutethimide and its salts
Glyceryl Trinitrate
Glycopyrronium and its salts
Glymidine and its salts
Gonadorelin and its salts
Gonadotrophin
Guanabenz Acetate
Guanethidine and its salts
Guanfacine and its salts

H

Halomnetason
Haloperidol
Halothane
Heparin and its derivatives
Hexamethonium and its salts
Hexapropymate
Hexyldimethylxanthine
Histapyrodine and its salts
Homatropine and its salts
Hyaluronidase
Hydantoin Derivatives
Hydralazine and its salts

[The inclusion of this page is authorized by L.N. 144/1995]

FOURTH SCHEDULE, *contd.*

H, *contd.*

Hydrochlorothiazide
Hydroflumethiazide
Hydroxypropyl Cellulose
Hydroxyzine and its salts
Hyoscine and its salts
Hyoscyamine and its salts
Hypromellose

I

Ibuprofen and its salts except strength 200mg
Idoxuridine
Ifosfamide
Imipenem
Imipramine and its salts
Immunoglobulin
    Antihepatitis B
    Anti-D RHo
    Tetanus Immune Globulin
Indapamide
Indomethacin
Indoramin and its salts
Inosine Pranobex
Inositol
Inosine
Insulin
Interferon (alpha 2a rbe)
Iohexol
Iopidine
Iopromide
Iotrolan
Ipratropium Bromide
Iproniazid and its salts
Iron Dextran
Iron Sorbitol
Isocarboxazide
Isoconazole Nitrate
Isoetharine Hydrochloride
Isometheptene and its salts
Isoniazid and its salts
Isoprenaline Hydrochloride
Isosorbide and its salts
Isoxsuprine Hydrochloride
Isradipine
Itraconazole

K

Ketamine Hydrochloride
Ketazolam

[The Inclusion of this page is authorized by L.N. 33A/2005]

FOURTH SCHEDULE, *contd.*

K *contd.*

Ketoconazole
- Cream 2%
- Ovules 400mgn
- Shampoo 2%
- Suspension 200mg/ml
- Tablets 200mgn

Ketoprofen
Ketotifen and its salts

L

Labetalol Hydrochloride
Lanatoside
Latamoxef
Leucovorin Calcium
Levamphetamine and its salts
Levodopa and its salts
Levonordefrin and its salts
Lidoflazine
Liothyronine and its salts
Lisinopril and its salts
Lithium and its salts
Lomustine
Loperamide and its salts
Lorazepam
Lormetazepam
Lovastatin
Loxapine and its salts
L-Thyroxine Sodium
Lypressin

M

Mafenide and its salts
Mannitol
Maprotiline and its salts
Mazindol
Mebanazine
Mecamylamine and its salts
Meclozine (Meclizine) and its salts
Meclofenamate
Meclofenoxate
Medazepam
Menadiol
Menaphthone (Menadione)
Mepazine
Mephenesin and its salts
Mephentermine and its salts

[The Inclusion of this page is authorized by L.N. 33A/2005]

FOURTH SCHEDULE, *contd.*

M, *contd.*

Mepindolol and its salts
Mepivacaine
Meprobamate
Meptazinol and its salts
Mequitazine
Mercaptopropionic Acid
Mercaptopurine
Murcuric Oxide
Mersalyl
Mesalazine
Mescaline and its salts
Mesoridazine and its salts
Metamizol and its salts
Metaraminol Tartrate
Metaxalone
Metformin and its salts
Methamphetamine and its salts
Methapyrilene and its salts
Methaqualone and its salts
Methenamine and its salts
Methixene and its salts
Methohexitone
Methotrexate and its salts
Methotrimenprazine and its salts
Methoxyflurane
Methoxsalen
Methyclothiazide
Methyldopa and its salts
Methylene Blue (Injection)
Methylergometine and its salts
Methyclothiazide
Methylpentynol and its salts
Methylphenidate and its salts
Methylsergide and its salts and derivatives
Methypryon
Metoclopramide and its salts
Metolazone
Metomidate Hydrochloride
Metoprolol Tartrate
Metrizamide
Metronidazole
Meconazole and its salts
Midazolam
Milrinone and its salts
Minoxidil

[The inclusion of this page is authorized by L.N. 144/1995]

FOURTH SCHEDULE, *contd.*

M, *contd.*

Misoprostol
Mometasone Furoate
Mitoxantrone and its salts
Monoethanolamine Hemisuccinate
Mupirocin

N

Nabumetone
Nadolol
Nalidixic Acid and its salts
Naloxone and its salts
Naphazoline and its salts
Narasin
Nedocromil Sodium
Neostigmine and its salts
Nialamide
Nicardipine
Nifedipine
Niflumic Acid
Nifuratel
Nikethamide and its salts
Nitrazepam
Nitrofurantoin and its salts
Nitrofurazone
Nomifensine and its salts
Noradrenalin
Norgestomet
Nortriptyline and its salts
Noscapine

O

O—(B-Hydroxyethyl) — Rutoside
Ondansetron
Opipramol and its salts
Opium Alkaloids
Orciprenaline and its salts
Orgotein
Ornidazole
Orphenadrine Acetate
Oxazepam
Oxitriptyline
Oxprenolol and its salts
Oxymetholone

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FOURTH SCHEDULE, *contd.*

O, *contd.*

Oxypertine and its salts
Oxyphenbutazone
Oxyphenonium and its salts
Oxytocin

P

Pancreatin
Pancuronium Bromide
Papaverine and its salts
Paramethazone and its salts
Pargyline and its salts
Pecazine
Pemoline and its salts
Penicillamine
Pentaerythrtol and its salts
Pentazocine and its salts
Pentetrazol
Pentifylline
Pentolinium
Pentoxifylline
Pericyazine and its salts
Perindopril
Perphenazine
Petazocine
Pethidine and its salts
Phenaglycodol
Phenazopyridine and its salts
Phendimetrazine and its salts
Phenelzine and its salts
Phenformin and its salts
Phenmetrazine and its salts
Phenothiazine derivatives and their salts
Phentermine and its salts
Phentolamine and its salts
Phenylbutazone and its salts
Phenylephrine and its salts
Phenylhydantoin its derivatives and their salts
Phenylpropanolamine and its salts
Phenytoin and its salts
Physostigmine and its salts
Pilocarpine and its salts
Pimozine
P-Inactivated Lactobacilli
Pindolol

[The Inclusion of this page is authorized by L.N. 33A/2005]

FOURTH SCHEDULE, *contd.*

P, *contd.*

Pipercuronium and its salts
Piperylone
Pirenzepine and its salts
Piroxicam (other than Piroxicam topical preparation)
Pirprofen
Pituitary Gland and its principles
Plasmin
Polythiazide
Potassium Iodide (Oral Dosage Forms)
Pramoxine
Prasterone
Prazinamide
Prazosin and its salts
Prednisolone, Prednisone
Prenylamine and its salts
Primidone
Primycinum
Probenecid
Procainamide and its salts
Prochlorperazine and its salts
Procyclidine and its salts
Promazine and its salts
Promethazine and its salts
Propantheline and its salts
Propoxyphene and its salts
Propofol
Propranolol and its salts
Propylthiouracil and its salts
Prostaglandin
Protriptyline and its salts
Pyrazinamide
Pyridostigmine and its salts
Pyrrobutamine and its salts

Q

Quinapril and its salts
Quinethazone
Quinfamide
Quinidine and its salts

R

Ranitidine

Injection	50 mg/5ml
Syrup	150mg/10ml
Tablets	150mg and 300 mgn

Rauwoflia alkaloids of, and their salts, including—

FOURTH SCHEDULE, *contd.*

R, *contd.*

- Alseroxylol
- Deserpidine

Raubasine
Rescinnamine
Reserpine
Rilmenidine
Rimeterol Hydrochloride
Roxaudine and its salts
Rutoside
Roferon A
Roxatidine Acetate Hydrochloride

S

Salbutamol and its salts
Selegiline and its salts
Serums
- Immune Serum Globulin
- Normal Serum Globulin

Sodium Aurothiomalate
Sodium Calciumedetate
Sodium Cromoglycate
Sodium Hyaluronate
Sodium Iodide
Sodium Nitroprusside
Sodium Polystyrene Sulfonate
Sodium Tyropanoate
Sodium Valproate
Parenteral Solutions of—
- Dextrans
- Dextrose
- Mannitol Sorbitol
- Potassium Chloride
- Sodium Bicarbonate
- Sodium Chloride
- Sodium Lactate

Sorbide Nitrate
Sotalol and its salts
Sparteine and its salts
Spironolactone
Stanozolol
Styramate
Sucralfate
Sulbutiamine

[The inclusion of this page is authorized by L.N. 144/1995]

FOURTH SCHEDULE, *contd.*

S, *contd.*

Sulindac
Sulphonamides and their salts and derivatives including—
Mafenide
Sulphabezamide
Sulphadiazine
Sulphadimethoxine
Sulphadimerazine
Sulphadoxine
Sulphafurazole
Sulphaguanidine
Sulphamethazine
Sulphamethazine
Sulphamethizole
Sulphamethoxazole
Sulphamethoxypyridazine
Sulphamethoxydiazine
Sulphametrole
Sulphanilamide
Sulphanitran
Sulphaphenazole
Sulphapyridine
Sulphaquinoxaline
Sulphasalazine
Sulphathiazole
Sulphinpyrazone
Sulphonal and alkyl sulphonals
Suprarenal Glands Medulla its active principles and their salts
Suxamethonium and its salts
Syrosingopine

T

Tamoxinfen and its salts
Tenoxicam
Temazepam
Terazosin and its salts
Terconazole
Tertatolol and its salts
Tetanus Antitoxins
Tetrabenazine and its salts
Theophylline and its salts
Thiacetarsamide Sodium
Thiocarlide
Thiocolchicoside

[The inclusion of this page is authorized by L.N. 144/1995]

FOURTH SCHEDULE, *contd.*

T, *contd.*

Thioguantine
Thiopentone Sodium
Thioridazine
Thiotepa
Thiothixene and its salts
Thiouracil and its derivatives
Throthricin
Thyroid Glands, its active principles, their salts
Thyroxine and its salts
Tiamulin and its salts
Tiaprofenic Acid and its salts
Ticarcillin Disodium
Ticlatone
Timolol and its salts
Tinidazole
Tofizopam
Tolazamide
Tolazoline and its salts
Tolbutamide and its salts
Tamoxifen Acetate Zitazonium
Toxocara Antigen
Tranylcypromine and its salts
Tretinoin
Triacetarsamide Sodium
Triamterene and its salts
Triazolam
Tribromoethanol
Trichlormethiazide
Trichloroethylene
Triflucidine
Trifluoperazine Hydrochloride
Trifluperidol and its salts
Triflupromazine and its salts
Trihexyphenipyl and its salts
Trilostane
Trimetaphan Camsylate
Trimethadione
Trimethazidine and its salts
Trimethoprim
Trimeprazine and its salts
Trimipramine and its salts
Tromethamine
Tropenziline
Tropicamide
Troxidone

[The inclusion of this page is authorized by L.N. 144/1995]

FOURTH SCHEDULE, *contd.*

T, *contd.*

Tubocurarine Chloride
Tybamate
Tylosin Intermediate
Tyrothricin

V

VACCINES
- Bursal Disease Vaccine Killed
- Canine Distemper — Adenovirus Type 2
- Canine Distemper — Hepatitis Vaccine
- Canine Distemper — Hepatitis with Leptospira
- Clostridium — Chauvoei — Septicum — Novyi — Sordelli — Perfringens Types C + D Bacterin Toxoid
- Clostridium Chauvoei — Septicum Pasturella Haemolytic Multocida
- Coryza Vaccine
- Diptheria and Tetanus
- Distemper/Hepatitis/Parainfluenza and Leptospira
- Fowl Pox Vaccine
- Gas Gangrene Antitoxin
- Killed E. Coli Culture
- Killed Virus Esquine Rhinopneumonitis
- Marek's Disease Live Turkey, Herpes Virus
- Measles, Mumps, Rubella Live Vaccine
- Newcastle Bronchitis Disease
- Newcastle Disease Vaccine
- Newcastle Disease Water Vaccine
- Parvovirus Vaccine
- Pigeon Pox Vaccine
- Pneumococal Vaccine
- Tetanus Antitoxin
- Tetanus Toxoid
- Tetanus Vaccine
- Tuberculin PPD

Valmitrine
Vecuronium Bromide
Verapamil and its salts
Vinblastine and its salts
Vincamine and its salts
Vincristine and its salts
Vinpocetine
Vitamin A for internal or parenteral use in human, with a daily dosage of more than 10,000 international units.
Vitamin B-12, with Intrinsic Factor Concentrate (for parenteral use)
Vitamin D, for internal or parenteral use in human, with a daily dosage of more than 1,000 international units.

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FOURTH SCHEDULE, *contd.*

V, *contd.*

Vitamin E, (dl-Alpha Tocopherol)
Vitamin K

W

Warfarin and its salts

X

Xantinol and its salts

Z

Zeranol
Zidovudine
Zinc Sulphate
Zopiclone
Zoxazolamine and its salts
Zuclopenthixol Acetate

Antibiotics including the following and their salts and derivatives—

Actinomycin-D
Amikacin
Amoxycillin
Amphomycin
Amphotericin
Ampicillin
Aparamycin
Bacampicillin
Bacitracin
Benethamine Penicillin
Benzathne Penicillin
Benzyl Penicillin
Candicidin
Carbenicillin
Carfecillin
Cefachlor
Cefadroxil
Cefamandole Cephalosporine
Cefoxitin
Cefuroxime
Cephalexin
Cephaloridine
Cephalothin
Cephapirin
Cephazolin
Chloramphenicol
Chlortetracycline
Cinoxacin
Clindamycin
Clomocycline
Cloxacillin
Colistin
Cycloserine
Demeclocycline
Dihydrostreptomycin
Doxorubicin
Doxycycline
Erthromycin
Floxacillin
Framycetin
Francomycin
Fusidic Acid
Gentamicin
Gramicidin
Giseofulvin
Kanamycin
Lincomycin
Meclocycline

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FOURTH SCHEDULE, *contd.*

Methacycline
Methicillin
Minocycline
Neomycin
Novobiocin
Nystatin except Topical Preparation
Oleandomycin
Oxytetracycline
Paromomycin
Penicillin G & V
Phenoxymethyl Penicillin
Pivampicillin
Pivmecillinam
Polymyxin B
Potassium Clavulanate
Potassium Penicillin
Rifampicin
Rifamycin
Rolitetracycline
Roxithromycin
Salinomycin
Spectinomycin
Spiramycin
Streptomycin
Tetracycline (other than 3% Tetracycline skin ointment)
Ticarcillin
Tobramycin
Tylosin
Tyrothricin
Vancomycin
Viomycin

List 4 Drugs

Part II

Morphine and its salts, and any solution or dilution of morphine or its salts in an inert substance whether liquid or solid containing any proportion of morphine, and any preparation, admixture, extract or other substance (not being such solution or dilution as aforesaid) containing not less than one-fifth of one per cent morphine (calculated in respect of anhydrous morphine);

Cocaine (including synthetic cocaine) and ecgonine and their respective salts, and any solution or dilution of cocaine or its salts in an inert substance, whether liquid or solid, containing any proportion of cocaine, and any preparation, admixture, extract or other substance (not being such a solution or dilution as aforesaid) containing not less than one-tenth of one per cent of cocaine or any proportion of ecgonine;

Acetyldihydrocodeinone
Alphaprodine
Alphameprodine
Benzylmorphine
Betameprodine
Betaprodine
Diethylthiambutene
Dihydrodesoxymorphine (also known as desomorphine)
Dihydromorphine
1: 3–Dimethyl–4–phenyl–4–propionyloxyhexamethyleneimine
Dimethylthiambutene
Dioxaphetyl butyrate (4–morpholino–2: 2–diphenyl ethyl butyrate)
Didipanone
Ethylmethylthiambutene
Hydrocodone (also known as dihydrocodeinone or dicodide)
Hydromorphone (also known as dihydromorphinone or dilaudide)
Hydroxypethidine
Isomethadone (also known as isoamidone)
Ketobemidone

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FOURTH SCHEDULE, *contd.*

Levomethorphan
Levorphanol
Methadol
Methadone (also known as amidone)
Methadyl acetate
Methyldesomorphine (6–methyl–6–desoxymorphine)
1–Methyl–4–phenylpiperidine–4–carboxylic acid isopropyl ester
Metopon (also known as methyldihydromorphinone)
Morphine–N–oxide (also known as genomorphine)
Normethadone
Oxycodone (also known as dihydrohydroxycodeinone or eucodal)
Pethidine
Phenadoxone
Phenomorphan (3–hydroxy–N–phenethylmorphinan)
Racemethorphan
Racemorphan
Thebaine

The esters of morphine (other than diacetylmorphine), ecogonine, Oxycodone, hydrocodone, hydromorphone, acetyldihydrocodeinone and dihydromorphine; the ethers of morphine (other than benzylmorphine, codeine, ethylmorphine, and pholcodine); the morphine–N–oxide derivatives, and any other pentavalent nitrogen morphine derivatives

LIST 4 DRUGS

Part III

Amphotericin B
Bacitracin
Cephaloridine
Chloramphenicol
Chloramphenicol and its salts
Colistin Sulphate
Cycloserine
Erythromycin
Framycetin
Griseofulvin
Kanamycin sulphate
Lincomycin hydrochloride
Neomycin
Novobiocin
Nystatin
Paromomycin sulphate
Penicillin G
Benzyl penicillin sodium or potassium salt
Procaine penicillin
Fortified procaine, penicillin and other long-acting preparations
Benzathine penicillin
Phenoxy-methyl penicillin
Penicillin V, free base or potassium salt or calcium salt
Phenbenicillin
Phenoxybenzyl penicillin
Phenethicillin potassium

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FOURTH SCHEDULE, *contd.*

Propicillin potassium
Cloxacillin sodium
Methicillin sodium
Ampicillin
Polymyxin-B sulphate
Ristocetin
Spiramycin
Streptomycin sulphate
Streptomycin penicillin mixtures
Dihydro-streptomycin
Sulphomyxin sodium
Tetracyclines
Chlortetra-cycline
Oxytetracyline
Tetracycline
Demethylchlor-tetracycline
Lymecycline
Methacycline
Triacetyloleando-mycin
Tyrothricin
Vancomycin
Viomycin sulphate
Viomycin pantothenate and sulphate

FIFTH SCHEDULE (Regulation 74)

Controlled Drugs

Chenopodium Oil
Coumarin
Dinitrobenzene
Lysergic Acid Diethylamide
Tetrahydrocannabinoe

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