

Health Services

Cap. 44.

**HEALTH SERVICES (CONTROL OF DRUGS)
REGULATIONS, 1970**

S.I. 1970/212.
1974/99.
1978/111.

Made by the Minister under section 10 of the Health Services Act. Cap. 44.

1. These Regulations may be cited as the Health Services (Control of Drugs) Regulations, 1970.

2. For the purposes of these regulations—

“advertise” means to make any representation to the general public by any means whatever for the purpose of promoting directly or indirectly the sale or disposal of any drug;

“analyst” means the Government Analyst or the accredited qualified analyst of any firm, corporation or laboratory or any other qualified analyst designated by the Minister in accordance with regulation 15;

“Committee” means the Drug Control Advisory Committee appointed by the Minister under section 8 of the Health Services Act, for the purpose of advising him on matters relating to the control of drugs; Cap. 44.

“dentist” means a dentist duly registered under the Dental Registration Act; Cap. 367.

“device” means any instrument, apparatus or contrivance including components, parts or accessories thereof manufactured, sold or represented for the use in the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical state or the symptoms thereof in man or animal;

“drug” means any substance or mixture of substances manufactured, sold or represented for use in— S.I. 1974/99.

(a) the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical state, or the symptoms thereof in man or animal;

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- (b) restoring, correcting or modifying organic functions in man or animal, and includes—
- (c) any substance or mixture of substances in common use when used or intended to be used as a drug;
- (d) any substance or mixture of substances manufactured, sold or represented for use in—
 - (i) cleansing, improving or altering the complexion, skin, hair or teeth, or
 - (ii) disinfection in premises in which food is manufactured, prepared or kept for the control of vermin in those premises;

- Cap. 368. “druggist” means a person registered under the Druggist Act;
- “insanitary conditions” mean such conditions or circumstances as might contaminate a drug with dirt or filth or render the same injurious to health;
- “inspector” means a registered druggist appointed as drug inspector, and includes any person holding a temporary or acting appointment as a drug inspector;
- “label” includes any legend, word or mark attached to, included in, belonging to or accompanying any drug or package;
- Cap. 371. “medical practitioner” means a duly qualified practitioner as defined by the Medical Registration Act;
- “package” includes anything in which any drug is wholly or partly contained, placed or packed;
- “sample” means a specimen or pattern of a drug or device distributed free of charge for the purpose of demonstrating the method of use, the mode of action and the efficacy of the article represented;
- “sell” includes offer for sale, expose for sale, have in possession for sale, and distribute;
- Cap. 374. “veterinary surgeon” means a duly qualified veterinary surgeon as defined by the Veterinary Surgeons Act.

3. The Minister shall consult with the Committee before amending any Schedule.

4. No person shall—

- (a) advertise any drug or device for the treatment, prevention or cure of any of the diseases mentioned in the First Schedule; or First Schedule.
- (b) sell any drug or device that is represented by label or that he advertises for the treatment, prevention or cure of any of the diseases mentioned in the First Schedule. First Schedule.

5. No person shall sell any drug—

- (a) manufactured, prepared, preserved, packaged or stored for sale under insanitary conditions; or
- (b) that is adulterated.

6. No person shall label, package, treat, process, sell or advertise any drug or device in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety.

7. Where a standard for a drug is contained in any publication mentioned in the Second Schedule, no person shall import, label, package or sell any substance in such a manner that it is likely to be mistaken for such drug unless the substance complies with that standard. Second Schedule.

8. (1) No person shall engage in Barbados in the business of manufacturing or producing for sale any drug unless—

- (a) he is licensed to do so;
- (b) the process of manufacturing or producing such drug is in all its stages under the direction and supervision of a druggist;
- (c) each batch of every drug manufactured or produced is numbered and a sample of each batch is submitted to an analyst for such analysis and assay as the Chief Medical Officer may approve;
- (d) every container in which such drug is sold carries a label stating the ingredients and their quantities per unit dose, the batch number of the drug, and, if appropriate, its expiry date.

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(2) An application for a licence shall be in writing in such form as the Chief Medical Officer may approve and shall state—

- (a) the address of the premises where the business is to be carried on;
- (b) the name and address of the druggist responsible for directing and supervising the business;
- (c) the types of drugs to be manufactured or produced; and
- (d) the number of persons to be employed in the business.

(3) An application for a licence shall be lodged in the office of the Medical Officer of Health for the area in which the business is situated.

(4) The Medical Officer of Health shall submit the application with his report and recommendations thereon to the Chief Medical Officer.

(5) The Chief Medical Officer after considering the application and the report of the Medical Officer of Health may grant or refuse the application or attach such conditions to the grant as he thinks fit.

(6) If the application is granted, a licence shall be issued to the applicant in such form as the Chief Medical Officer may approve, and shall—

- (a) state the name and address of the business premises;
- (b) state the name of the druggist supervising the manufacture or production;
- (c) state the types of drugs in respect of the manufacture or production of which it is granted;
- (d) be, unless previously suspended or cancelled, valid until the 31st day of December next after the date of issue;
- (e) be non-transferable to any person or in respect of any location; and
- (f) bear on its face the date of issue.

(7) The Chief Medical Officer shall cause to be kept a register of all persons licensed under this regulation and the register shall contain the particulars set out in the licence.

(8) No person shall sell any drug manufactured or produced in Barbados unless—

- (a) the report of the analysis carried out under the provisions of paragraph (1) (c) is submitted to the Chief Medical Officer; and
- (b) the Chief Medical Officer, after considering the report, approves of the sale of such drug.

(9) Except with the approval of the Minister acting on the recommendation of the Committee, no person shall manufacture or produce in Barbados any substance consisting wholly or in part of any drug unless—

- (a) a standard for that drug is contained in one of the publications mentioned in the Second Schedule; and Second
Schedule.
- (b) that drug complies with such standard.

(10) Where a standard for a drug is contained in more than one of the publications mentioned in the Second Schedule the standard contained in the first such publication shall be deemed to be the standard for that drug. Second
Schedule.

(11) The provisions of this regulation shall not apply to the compounding or dispensing by a druggist of any prescription issued by a medical practitioner, dentist or veterinary surgeon.

9. (1) Subject to paragraph 4, no person may import any drug mentioned in the Third Schedule except under a licence issued by the Minister. Third
Schedule.

(2) No drug mentioned in the Third Schedule shall be sold except by a druggist under a prescription issued by a medical practitioner, dentist or veterinary surgeon. 1974-99.

(3) No druggist may refill a prescription for any drug mentioned in the Third Schedule, unless the person issuing the prescription so directs and specifies the number of times and the intervals at which the prescription may be refilled.

(4) Paragraph (1) does not apply to the importation of any drug by any of the following—

- (i) a medical practitioner,
- (ii) a dentist,

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- (iii) a veterinary surgeon,
 - (iv) a wholesale dealer,
 - (v) a druggist carrying on a retail business,
 - (vi) a government hospital,
 - (vii) a licensed private hospital,
 - (viii) a licensed nursing home,
 - (ix) a licensed maternity home,
 - (x) the Barbados Family Planning Association in relation to an oral contraceptive.
- (5) Paragraphs (2) and (3) do not apply to—
- (a) the sale by a wholesale dealer of any drug to any of the following—
 - (i) a medical practitioner,
 - (ii) a dentist,
 - (iii) a veterinary surgeon,
 - (iv) another wholesale dealer,
 - (v) a druggist carrying on a retail business,
 - (vi) a government hospital,
 - (vii) a licensed private hospital,
 - (viii) a licensed nursing home,
 - (ix) a licensed maternity home;
 - (b) any drug supplied to his patients by a medical practitioner, dentist or veterinary surgeon;
 - (c) any oral contraceptive supplied under medical supervision by the Barbados Family Planning Association;
 - (d) any drug produced or manufactured for veterinary use only.

Fourth
Schedule.

10. No person may import, manufacture, sell, dispense or use any drug mentioned in the Fourth Schedule except under licence issued by the Minister or a person authorised by him.

11. No person shall distribute or cause to be distributed any drug mentioned in the Third Schedule or device as a sample

except to a medical practitioner, dentist, veterinary surgeon or druggist.

12. (1) Subject to the provisions of these regulations and of any enactment relating to customs or excise or to the importation of drugs, a person may import any drug provided it wholly complies with the law of the country in which it was manufactured or produced and is legally saleable for consumption in that country.

(2) The onus of proof that any drug imported complies with the preceding paragraph shall rest on the person importing such drug.

13. (1) An inspector may at any time—

- (a) enter any place where on reasonable grounds he believes any article to which these regulations apply is manufactured, produced, prepared, preserved, packaged, stored or sold, examine any such article and take samples thereof, whether or not he makes any payment therefor, and examine anything that he reasonably believes is used or capable of being used for such manufacture, production, preparation, preservation, packaging or storing;
- (b) open and examine any receptacle or package that on reasonable grounds he believes contains any article to which these regulations apply;
- (c) examine any books, documents or other records found in any place mentioned in paragraph (a) which he reasonably believes contains any information relevant to the enforcement of these regulations with respect to any article to which they apply, and make copies thereof or extracts therefrom; and
- (d) seize and detain for such time as may be necessary any article by means of or in relation to which he reasonably believes any provision of these regulations has been contravened.

(2) For the purpose of paragraph (1) (a) the expression “article to which these regulations apply” includes—

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- (a) any drug;
- (b) anything used for the manufacture, preparation, preservation, packaging or storing thereof; and
- (c) any labelling or advertising material.

(3) Where a sample of a drug taken under paragraph (1) is found on analysis to be below the required standard, the drug manufacturer or his agent concerned in the manufacture or distribution, as the case may be, of that drug may be required to reimburse the Crown in respect of any expense incurred by the Crown in the analysis of that sample.

(4) Any expense incurred by the Crown pursuant to paragraph (3) may be recovered as a debt due to the Crown in civil proceedings before a magistrate of District A.

14. (1) The owner or person in charge of a place entered by an inspector in accordance with regulation 13, and every person found therein, shall give the inspector all reasonable assistance and furnish him with such information as he may reasonably require.

(2) No person shall remove, alter or interfere with any article seized under these regulations without the authority of an inspector.

(3) Any article seized under these regulations may at the option of an inspector be kept or stored in the building or place where it was seized or may at the direction of an inspector be removed to any other proper place.

15. (1) For the purposes of these regulations the Minister on the recommendation of the Committee may designate any person, firm, corporation or laboratory in or out of Barbados as approved for carrying out tests, analyses or assays.

(2) Any sample taken or article seized under these regulations may be submitted to an analyst for such examination and report as the Chief Medical Officer may require.

(3) Every inspector seizing an article or taking a sample which may be submitted to analysis shall immediately inform the owner or his agent that the article or the sample, as the case

may be, may be submitted to analysis and shall then and there divide the article or the sample into three parts, each part to be marked and sealed or fastened in such manner as its nature will permit and shall—

- (a) if required to do so deliver one part to the owner or his agent;
- (b) retain one part for future comparison;
- (c) submit one part to the Chief Medical Officer.

Provided that if the article or sample is packaged in containers of convenient size which are labelled with the batch number of the manufacturer or producer, three such containers each bearing the identical batch number shall be deemed for the purposes of these regulations to be three parts of the same article or sample.

(4) Any report issued by an analyst in accordance with paragraph (2) shall be receivable as evidence in any court of law.

16. (1) Where an inspector has seized an article under these regulations and the owner thereof or the person in whose possession the article was at the time of seizure consents to the destruction thereof, the article shall thereupon be forfeited and may be destroyed or otherwise disposed of as the Chief Medical Officer may direct.

(2) Where a person has been convicted of an offence under these regulations, the court may order that any article or thing by means of or in relation to which the offence was committed be forfeited, and upon such order being made, such article or thing shall be disposed of as the Chief Medical Officer may direct.

(3) The cost of destruction or disposal of any article seized under these regulations shall be recoverable from the owner or person in charge of the article.

17. The Minister may cancel or suspend a licence granted in accordance with these regulations—

- (a) where a notice has been served under section 11 of the Act and there has been no appeal therefrom or the

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appeal has been dismissed and the owner or occupier of the premises has not within the time specified in the notice or within the time specified by the Judge on the dismissal of the appeal, carried out the work required by the notice;

- (b) for failure to comply with any of the provisions of these regulations.

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18. A person who contravenes these regulations is guilty of an offence and liable on summary conviction to a fine not exceeding five thousand dollars, or imprisonment for a term not exceeding twelve months, or both, and, in the case of a continuing offence, to a further fine not exceeding two hundred dollars for each day or part thereof during which the offence continues after a conviction is first obtained.

Regulation 4.

FIRST SCHEDULE

Alcoholism
Appendicitis
Arteriosclerosis
Blood poisoning
Bright's or other Kidney Disease
Cancer
Cataract
Diabetes
Diphtheria
Disorders of Menstrual Flow
Disorders of the Prostatic Gland
Dropsy
Epilepsy
Gallstones, Kidney Stones, Bladder Stones
Gangrene
Glaucoma
Goitre
Heart Diseases
Hernia (Rupture)
High Blood Pressure
Locomotor Ataxia

Meningitis
 Obesity
 Pleurisy
 Pneumonia
 Poliomyelitis (Infantile Paralysis)
 Scarlet Fever
 Sexual Impotence
 Small Pox
 Tetanus (Lockjaw)
 Trachoma
 Tuberculosis
 Tumours
 Typhoid or Paratyphoid Fever
 Ulcers of the Gastro-Intestinal Tract
 Venereal Disease

SECOND SCHEDULE

Regulation 7.

- (i) The British Pharmacopoeia
- (ii) The British Pharmaceutical Codex
- (iii) Martindales Extra Pharmacopoeia
- (iv) The Pharmacopoeia of the United States of America
- (v) The International Pharmacopoeia
- (vi) The British National Formulary
- (vii) The Canadian Formulary

THIRD SCHEDULE

Regulation 9.

The following drugs, their derivatives, preparations and compounds:

Amidopyrine
 Aminopterin
 Amitriptyline, Protriptyline, Imipramine and all other anti-depressant substances
 Amphetamine, Methyl Phenidate Hydrochloride, Pipradrol Hydrochloride and all other stimulants of the Central Nervous System, except caffeine and ephedrine
 Apiol

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- Barbituric Acid
 Bromoform
 Calcium Carbimide and all other drugs used in the treatment of alcoholism
 Carbromal, Paraldehyde, Sulphonal and all other hypnotic substances
 Carbutamide, Tolbutamide, Phenformin and all other anti-diabetic substances for oral use
 Chloral Hydrate (except in preparations for external use containing not more than 1% W/V of Chloral hydrate)
 Chlorcyclizine (except in preparations for external use only)
 Chloroquine, Hydrochloroquine
 Chlorpromazine, Promazine, Diazepam and all other tranquilising substances
 Corticotrophin, Cortisone, Prednisone and all other organic or synthetic adrenocortical substances
 Cyclizine
 1974/99. Dithiazanine Iodide
 Ectylurea
 Ergot
 Heparin, Dicoumarol, Phenindione, Warfarin and all other anti-coagulants except when used as rodenticides
 1974/99. Hexachlorophene except in preparations containing 0.1% or less of hexachlorophene
 Hexamethonium, Pentamethonium, Rauwolfia, Veratrum and all other hypotensive substances
 Indomethacin
 Isoniazid, Para-aminosalicylic acid, Ethionamide, Pyrazinamide and all other anti-tuberculosis substances for oral use
 Meclizine
 Mefenamic Acid, Flufenamic Acid
 Mustine, Busulphan, Melphalan and all other anti-neoplastic substances
 Nitrofurazone, Furazolidone, Nitrofurantoin, and all other Furan derivatives
 Para-aminobenzene sulphonamide
 Penicillin, Chloramphenicol, Streptomycin, Tetracycline and all other antibiotics whether produced synthetically or by living micro-organisms
 Phenylbutazone
 Phenyleinchoninic Acid, Salicycinchoninic Acid
 Phenelzine, Pheniprazine and all other monoamine oxidase inhibitors
 Phenytoin, Paramethadione, Primidone and all other anti-convulsant substances

Procaine, Lignocaine, Benzocaine and all other local anaesthetic substances (except when included in preparations used exclusively for external application)

Sex Hormones, except in cosmetic preparations which are demonstrated to be without systemic effects

Thiabendazole 1974/99.

Thiouracil and all other anti-thyroid substances

Thyroid and all other organic or synthetic Thyroid-like substances

FOURTH SCHEDULE

Regulation
10.

Thalidomide

Lysergic acid diethylamide (L.S.D.)

Mescaline and all other hallicinogenic substances. 1974/99.

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