

DRUGS ACT, 1991

No. 3



of 1991

ARRANGEMENT OF SECTIONS

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An Act to provide for the control over and regulation of drugs and related substances and for matters connected therewith.

Date of Assent: 6th March, 1991.

Date of Commencement: 22nd March, 1991.

ENACTED by the Parliament of Botswana

1. (1) This Act shall be cited as the Drugs Act, 1991, and shall apply to all drugs and related substances other than those covered by the Habit Forming Drugs Act.

Short title
application
and
commence-
ment

(2) This Act shall come into operation on such date or dates as the Minister may, by notice in the Gazette, appoint.

2. (1) In this Act, unless the context otherwise requires —
“advertisement”, in relation to a drug, means any written, pictorial, visual or other descriptive matter or verbal statement or reference —

Interpret-
ation

(a) appearing in any newspaper, magazine, pamphlet or other publication; or

- (b) distributed to members of the public; or
- (c) brought to the attention of the public in any manner whatsoever,

which is intended or has the effect of promoting the sale of that drug, and "advertise" shall have a corresponding meaning;

"drug" means any substance or mixture of substances used or purporting to be suitable for use, or manufactured or sold for use in the diagnosis, treatment, alleviation, modification or prevention of disease, illness, abnormal physical or organic condition or the symptoms thereof in human beings, or restoring, correcting or modifying any somatic or psychic or organic condition in human beings, and shall include a related substance;

"label" when used as a verb means brand, mark or otherwise designate or describe, and when used as a noun means any brand or mark or any written, printed or graphic matter on the immediate container, or the outside container or wrapper, or attached to or packed with and referring to the contents of the container;

"manufacture" includes all operations involved in the production, processing, compounding, formulation, filling, packaging, re-packing and labelling of a drug;

"pharmacist" means a person registered as a pharmacist under the Medical, Dental and Pharmacy Act;

"pharmacy" means a retail business licensed to sell drugs;

"related substance" means any substance or mixture of substances which the Minister, by notice in the Gazette, declares to be a substance to which the provisions of this Act shall apply.

Registration
of drugs

3. (1) No drug shall be imported into or exported from Botswana, or manufactured, distributed or sold unless such drug has been and is registered by the Director of Health Services.

(2) The Director shall keep and maintain, or cause to be kept and maintained, a register in which shall be recorded all drugs registered by him under this section.

(3) The register shall be open for inspection by the public at such times and places and on such terms as may be determined by the Director.

(4) Application for the registration of a drug shall be made to the Director in such form and accompanied by such further information as may be prescribed.

(5) The registration of a drug shall cease to be valid if any significant change has been made in the composition of the product, the dosage form or the conditions of its manufacture, without the prior approval of the Director to such change.

Suspension or
revocation
of registration

4. If, in the opinion of the Director, information not previously available indicates that a registered drug may not be safe and effective when used in the manner and for the purposes approved at the time of its registration, he may —

- (a) require such revisions in the composition of the drug, its packaging, labelling or advertising as he may consider necessary or desirable to ensure safety and efficacy;

- (b) suspend the registration for a specified period or pending compliance with any requirements made under paragraph (a); or
- (c) revoke the registration.

5. (1) The Minister may establish a Drugs Advisory Board, the function of which shall be to advise the Director as to whether a drug should be registered or not, or as to the conditions subject to which it should be registered, or whether those conditions should be revised in accordance with section 4 (a), or whether registration should be suspended or revoked. Advisory Board

(2) In establishing the Drugs Advisory Board, the Minister shall determine its composition, its terms of reference and make the necessary appointments by notice published in the Gazette.

(3) Members of the Drugs Advisory Board shall hold office for three years but shall be eligible for re-appointment.

6. (1) The manufacture of drugs may only be undertaken in an establishment licensed therefor under the Industrial Development Act, 1988, and with the written approval of the Director. Manufacture of drugs

(2) A person wishing to manufacture drugs shall make application therefor to the Director in such form as may be prescribed, and shall supply such further information as the Director may require to satisfy himself that the premises to be used are satisfactory for the purpose, and will be operated in accordance with standards of good practice in the manufacture and quality control of drugs.

(3) The manufacture of drugs shall be under the control of persons with qualifications approved for the purpose by the Minister, which qualifications shall not be less than those of a registered pharmacist.

(4) Where the Director is satisfied that the conditions of any licence, or of any approval by him, are not being observed, or that the manufacture is not being carried out in accordance with the provisions of this Act and in a satisfactory manner, he may withdraw his approval and give notice thereof to the manufacturer.

7. (1) Drugs shall be exported, or imported and distributed, only by the Central Medical Stores or by a person duly licensed therefor in accordance with the Trade and Liquor Act and with the written approval of the Director for such export, import or distribution. Export, import and distribution of drugs

(2) A person wishing to export or import drugs or distribute drugs wholesale, shall apply to the Director for approval in such form as may be prescribed, together with such information as the Director may require to satisfy himself that the applicant has satisfactory premises and that the business will be operated in accordance with good professional standards.

(3) The business of exporting or importing drugs or distributing drugs wholesale shall be under the control of a technical manager with such qualifications as the Director may approve.

(4) The distribution of drugs may only be made to establishments approved by the Director for the sale or dispensing of such drugs.

(5) Where the Director is satisfied that drugs are being exported, im-

ported or distributed otherwise than in accordance with the conditions of any licence issued under the Trade and Liquor Act, or any approval given by the Director, or the provisions of this Act, or that the business is not being operated in accordance with good professional standards, he may by written notice to the exporter, importer or distributor concerned withdraw his approval for the continued operation of the business, either absolutely or pending compliance with such directions as he considers necessary or desirable.

Drugs in transit

8. Where drugs are to be imported into Botswana in the course of transit to another country, the importer shall, before such importation, notify the Director in writing, stating —

- (a) the type and quantity of the drugs;
- (b) the expected time of arrival and departure of the drugs;
- (c) the expected method and place of arrival and departure of the drugs; and
- (d) the ultimate destination of the drugs.

Classification dispensing and prescription of drugs

9. (1) Drugs shall be classified according to the following classifications and descriptions —

- (a) Schedule 1 Drug — a drug which may be dispensed on prescription only, and must be kept in a pharmacy under the control of a registered pharmacist;
- (b) Schedule 2 Drug — a drug which must be kept in a pharmacy, but which may be sold from a pharmacy without prescription;
- (c) Schedule 3 Drug — a drug which may be sold over the counter by any licensed trader.

(2) Registered medical practitioners and dentists may prescribe Schedule 1 drugs in the exercise of their professions, and the Director may in suitable circumstances authorize limited powers of prescription of such drugs by registered nurses and other medical personnel.

(3) The dispensing of Schedule 1 and Schedule 2 drugs shall be by pharmacists through pharmacies, or through institutions approved by the Director, and regulations made by the Minister may provide for pharmacy technicians or other health personnel to dispense drugs to such extent or in such circumstances as may be specified.

Retailing of drugs

10. (1) The retailing of drugs, other than Schedule 3 drugs, shall be through a pharmacy duly licensed as such under the Trade and Liquor Act, and approved for the purpose by the Director, and shall be under the control of a pharmacist.

(2) If the Director is of the opinion that a pharmacy is being operated in an unsatisfactory manner, or not in accordance with good professional standards, he may, in writing to the pharmacy, withdraw his approval, either absolutely or pending compliance with such directions as he considers necessary or desirable.

Advertising of drugs

11. (1) The advertising of any drug shall not, by word or by illustration, give any false, misleading or deceptive information concerning the properties of the drug, or which is likely to encourage wrong or excessive use of the drug.

(2) The advertising of drugs which may be sold on prescription only shall be disseminated through professional journals and magazines only to persons authorized to dispense, prescribe or administer such drugs.

(3) The advertising of drugs which may be dispensed without prescription may be addressed to the public but shall not include promises of unfailing results or expressions or illustrations of a nature likely to offend or intimidate members of the public, or make reference to symptoms in a manner likely to induce members of the public to make wrong diagnoses.

12. (1) All premises where drugs are stored, handled, dispensed, manufactured or sold shall be subject to periodical inspection by persons authorized by the Director in writing for the purpose, and such persons shall be given unhindered access to such premises with the right to take samples, without payment, of any drugs on the premises, and to carry out any investigations that he considers necessary or desirable.

Inspection
of premises

(2) The licence holder of any such premises as are referred to in subsection (1), or the person in charge thereof, shall on demand by the person so authorized by the Director, provide any economic or statistical information required of him, and provide all other necessary assistance required by the authorized person for the performance of his duties.

13. (1) The Minister may make regulations for the better carrying out of the provisions and purposes of this Act, and without prejudice to the generality of the foregoing, such regulations may provide for —

Regulations

- (a) any matter to be prescribed under this Act;
- (b) the procedure for the registration of drugs, and the cancellation or suspension of such registration;
- (c) the procedure for obtaining the approval of the Director in any matter where the approval of the Director is required under this Act, and for the withdrawal or suspension of such approval;
- (d) the control and regulation of the manufacture, import, export, distribution and sale of drugs;
- (e) the labelling and advertising of drugs;
- (f) forms to be used and fees to be paid in respect of applications under this Act;
- (g) the inspection of premises under this Act.

(2) Regulations under this Act may provide penalties for breaches thereof of fines up to a maximum of P500 and imprisonment for not more than three months.

14. The Director may, by writing under his hand, delegate to the Assistant Director of Technical Support Services or to the Chief Pharmacist, any of his powers under this Act.

Delegation
of powers

15. Any person aggrieved by any decision of the Director, the Assistant Director of Technical Support Services or the Chief Pharmacist under this Act may appeal to the Minister against such decision, and the Minister's decision thereon shall be final and not subject to appeal in any court.

Appeals

Offences

16. (1) Any person who contravenes or fails to comply with any of the provisions of this Act, or who —

- (a) manufactures, imports, exports, distributes or sells drugs without first obtaining the Director's approval;
- (b) prescribes any Schedule 1 drug without being authorized thereto by this Act or by the Director;
- (c) dispenses any Schedule 1 or Schedule 2 drug otherwise than in accordance with the provisions of section 9 (3);
- (d) advertises a drug otherwise than in accordance with the provisions of section 11; or
- (e) obstructs or fails to comply with any reasonable request or demand made by the Director, in the exercise of his powers and the performance of his duties under this Act,

shall be guilty of an offence and liable to a fine of P10 000 and to imprisonment for two years.

(2) With regard to any matter in respect of which the Director has delegated his powers to the Assistant Director of Technical Support Services or to the Chief Pharmacist, subsection (1) and section 9(3) shall be read as though for "Director" were substituted the words "Director or the Assistant Director of Technical Support Services or the Chief Pharmacist".

(3) Where any person is convicted of an offence against this Act or any regulations made thereunder, the court may, at the request of the Director, order any drug in respect of which the offence was committed to be seized and disposed of as the Director may require, and the Director may at the same time withdraw any approval or authorization previously given by him to that person.

Transitional

17. Any person who, on the date of the coming into operation of this Act, was engaged in the manufacture, import, export, distribution or sale of drugs shall be afforded a period of grace of three months from such date to comply with the provisions of the Act.

PASSED by the National Assembly this 22nd day of February, 1991.

C.G. MOKOBI,
Clerk of the National Assembly.