UNITED NATIONS

E/NL.1996/58
24 September 1996

ENGLISH ONLY*

# LAWS AND REGULATIONS

PROMULGATED TO GIVE EFFECT TO THE PROVISIONS OF
THE INTERNATIONAL TREATIES ON NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES

*In accordance with the relevant articles of the international treaties on narcotic drugs and psychotropic substances, the Secretary-General has the honour to communicate the following legislative text.*

BOTSWANA

Communicated by the Government of Botswana

NOTE BY THE SECRETARIAT

(a) Some editing of texts may be done by the Secretariat in the interest of clarity. In this connection, words in square brackets [ ] have been added or changed by the Secretariat.

(b) Only passages directly relevant to the control of narcotic drugs or psychotropic substances have been reproduced in this document. Non-relevant parts of laws and regulations have been deleted by the Secretariat; such deletions are indicated by [...].

## DRUGS AND RELATED SUBSTANCES ACT, 1992

*Note by the Secretariat: This document is a direct reproduction of the text communicated to the Secretariat by the Government of Botswana.

V.96-86187

# DRUGS AND RELATED SUBSTANCES ACT, 1992

No. 18 of 1992

## ARRANGEMENT OF SECTIONS

PART I — *Preliminary*

SECTION
1. Short title, application and commencement
2. Interpretation

PART II —*Control over Drugs*
3. Registration of drugs
4. Suspension or revocation of registration
5. Advisory Board
6. Manufacture of drugs
7. Export, import and distribution of drugs
8. Drugs in transit
9. Classification, dispensing and prescription of drugs
10. Retailing of drugs
11. Advertising of drugs
12. Inspection of premises
13. Delegation of powers
14. Appeals
15. Offences generally

PART III — *Habit-Forming Drugs*
16. Habit-forming drugs
17. Powers of police in respect of habit-forming drugs
18. Special jurisdiction in respect of offences under the Act
19. Vicarious liability in respect of habit-forming drugs
20. Onus of proof

PART IV — *Miscellaneous*
21. Regulations
22. Repeals

**An Act to provide for the control over and regulation of drugs, including habit-forming drugs, and related substances and for matters connected therewith.**
*Date of Assent:* 8th September, 1992.
*Date of Commencement:* 18th September, 1992.
ENACTED by the Parliament of Botswana

## PART I — *Preliminary*

Short title, application and commencement

**1.** (1) This Act may be cited as the Drugs and Related Substances Act, 1992, and shall apply to all drugs and related substances, including habit-forming drugs.

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

Interpretation

**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—

(*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, or restoring, correcting or modifying any somatic or psychic or organic condition, and shall include a related substance and, to the extent that it complies with the above definition, a habit-forming drug;

"habit-forming drug" means any drug, plant, preparation or substance, or mixture of substances, whether or not otherwise complying with the definition of drug, which is prescribed by the Minister to be a habit-forming drug, and in so prescribing the Minister may prescribe different categories of habit-forming drugs and any special conditions relating thereto;

"label" when used as a verb means to 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, related substance or a habit-forming drug;

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

"pharmacy" means premises approved by the Director for the storing, dispensing and selling of drugs and which is under the control of a pharmacist;

"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.

## PART II — *Control over Drugs*

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, hereinafter referred to as "the Director":

Provided that the Minister may, in such special circumstances as he considers constitute justification for such action, by notice in the Gazette —

(*a*) exempt any drug from the requirements of this section; or

(*b*) declare any drug to be a banned drug, in which case it shall not be registered or registrable, or if already registered such registration shall be forthwith null and void.

(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 revisions required under paragraph (*a*); or

(*c*) revoke the registration.

Advisory Board

**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.

(2) In establishing the Drugs Advisory Board, the Minister shall determine its composition and its terms of reference and make all necessary appointments thereto 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.

Manufacture of drugs

**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.

(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 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, whereupon any further such manufacture shall, unless or until the Director resumes his approval, constitute an offence under this Act.

Export, import and distribution of drugs

**7.** (1) Drugs shall not be exported or imported, except by the Central Medical Stores or by a person duly licensed therefor in accordance with any written law requiring such licence, and with the written approval of the Director for such export or import.

(2) A person wishing to export or import drugs shall make application for approval therefor to the Director, in such form as may be prescribed, and accompanied by 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 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 by establishments or persons approved by the Director for the sale or distribution of such drugs.

(5) Where the Director is satisfied that drugs are being exported, imported or distributed otherwise than in accordance with the conditions of any licence or any other authority required under any other written law, 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, and shall, in writing, notify the Director as soon as possible, and in any event within 48 hours, when such drugs have left Botswana.

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 is or contains a prescribed habit-forming drug, and must be kept in a pharmacy under the control of a registered pharmacist; such drugs shall be further classified as follows —

Schedule 1A drug — which is highly liable to abuse and which may be dispensed only on written prescription, which prescription must be kept by the dispensing pharmacist for a minimum of three years;

Schedule 1B drug — which is also liable to abuse though not as highly liable as a Schedule 1A Drug, and which may be dispensed only on written prescription;

Schedule 1C drug — which, though widely used therapeutically, is liable to some, but relatively minor, abuse in comparison with a Schedule 1A or a 1B drug, and may be dispensed only on prescription;

Schedule 1D drug — which is unlikely to produce dependence or cause harm if misused, and may be dispensed without prescription;

Schedule 2 drug — a drug, not being or containing a habit-forming drug, which may be dispensed only on written prescription, and which must otherwise be kept in a pharmacy under the control of a registered pharmacist;

(*c*) Schedule 3 drug — a drug which may be sold from a pharmacy without prescription, but which must otherwise be kept in a pharmacy;

(*d*) Schedule 4 drug — a drug which may be sold over the counter by any licensed trader.

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

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

(4) Regulations made by the Minister may provide for the keeping of registers with regard to the prescription, dispensing or sale of Schedule 1A and B drugs, and such other drugs as he may consider necessary or desirable.

Retailing of drugs

**10.** (1) The retailing of drugs, other than Schedule 4 drugs, shall, except as may be otherwise provided in this Act, 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 solely through professional journals and magazines or 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.

Inspection of premises

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.

(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.

Delegation of powers

13. 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.

Appeals

14. 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.

Offences generally

15. (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 in respect of such drugs;

(*b*) prescribes any Schedule 1 or Schedule 2 drug without being authorized thereto by this Act or by the Director;

(*c*) dispenses any Schedule 1A, B or C drug or any Schedule 2 or 3 drug otherwise than in accordance with the provisions of section 9(3);

(*d*) advertises any 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 without prejudice to his liability in accordance with the provisions of subsection (2) or of section 16, shall be liable to a fine of P10 000 and to imprisonment for two years.

(2) Any person who manufactures, imports, exports, distributes, sells, prescribes, dispenses or advertises any drug banned in accordance with a notice by the Minister under section 3(1), or any drug or other substance falsely purporting to be, or intended to or likely to induce anyone to a mistaken belief that it is, a registered drug shall be guilty of an offence and without prejudice to his liability in accordance with the provisions of section 16, shall be liable to a fine of P20 000 and to imprisonment for 5 years.

(3) 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 "Assistant Director of Technical Support Services" or "Chief Pharmacist" respectively.

(4) 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 or other substance 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.

PART III — *Habit-Forming Drugs*

Habit-forming drugs

16. (1) Except to the extent and as may be otherwise provided in Part II of this Act, no person —

(*a*) shall deal in any habit-forming drug or any plant from which any habit-forming drug can be manufactured; or

(*b*) shall possess or use any such drug or plant.

(2) Any person who contravenes the provisions of subsection (1)(*a*), shall be guilty of an offence and shall be sentenced to all of the following punishments, namely, to imprisonment, without the option of a fine, and without the suspension of any part thereof, for not less than 10 years or more than 15 years, and to a fine of not less than P15 000 or in default thereof to an additional term of imprisonment of not less than three years or more than five years:

Provided that, in connection with an offence under this subsection relating to cannabis, the punishment shall be imprisonment, without the option of a fine, and without the suspension of any part thereof, for not less than 5 years or more than 10 years, and to a fine of not less than P7 000, or in default thereof to an additional term of imprisonment of not less than one year or more than two years.

(3) Any person who contravenes the provisions of subsection (1)(*b*), shall be guilty of an offence and, except in connection with an offence relating to the possession of less than 60 grams of cannabis, shall be liable to imprisonment for not less than one year or more than five years, and to a fine of not less than P1 500 or more than P5 000, or in default of payment thereof to imprisonment for not less than one year or more than five years:

Provided that where the offence or offences relate to the possession of —

(*a*) such habit-forming drugs as the Minister may prescribe for the purposes of this proviso; or

(*b*) 100 or more tablets, capsules or pills, each consisting of or containing any habit-forming drug; or

(*c*) any preparation containing 40 grams or more of any habit-forming drug, other than cannabis,

the punishment thereof shall be the same as for an offence under subsection (2).

(4) Any person who contravenes the provisions of subsection (1)(*b*) in relation to the possession of less than 60 grams of cannabis shall be guilty of an offence and liable to a fine of P1 000 and to imprisonment for three years.

(5) Where, upon the trial of a person for an offence in terms of subsection (2), the court considers that the offence has not been proved, but is satisfied that the person is guilty of an offence in terms of subsection (3), the court shall find him guilty of such latter offence and convict and sentence him accordingly.

(6) For the purposes of this section —

"cannabis" includes dagga, Indian hemp, intsangu or motokwane, under whatever name it may be described, sold, supplied or otherwise referred to or dealt with, and whether or not referring to the whole or any portion of the plant, or any extract, tincture, preparation or admixture thereof (other than cannabis indica plasters);

"deal in", in relation to any habit-forming drug or any plant from which such a drug can be manufactured, includes performing any act in connexion with the collection, importation, supply, transshipment, administration, exportation, cultivation, manufacture, transmission or prescription thereof;

"possess" includes keep, store or have in custody or under control or supervision.

Powers of police in respect of habit-forming drugs

**17.** (1) If any police officer has reasonable grounds for believing that any person has committed an offence under this Part or any regulations made under this Act in relation to this Part he may —

(*a*) enter without a search warrant upon any land, and there require any such person to produce for his inspection any habit-forming drug in his possession, or any permit or licence or other authorization issued to him or required to be kept by him under the provisions of this Act or any regulations made thereunder;

(*b*) without a search warrant search such person or any animal in the possession of such person, and enter and search any land, building, vehicle, aircraft or boat in the possession or use of such person, and open and search any receptacle or thing in the possession of or under the control of such person:

Provided that whenever a woman is searched the search shall be conducted by a woman with strict regard for decency, and if there is no female member of the Botswana Police Force avail able, the search may be conducted by any woman specially named for the purpose by a peace officer;

(*c*) seize any habit-forming drug or any article or substance which he suspects to be a habit forming drug, or any plant from which any such drug can be derived, extracted, produced or manufactured, or any pipe, receptacle or material for smoking opium, or cannabis, in the possession of such person, and any vehicle, aircraft, boat, receptacle, animal or thing in or upon which such habit-forming drug, article, substance, plant, pipe, receptacle or material was found, and unless he is satisfied that such person will appear and answer any charge which may be preferred against him, arrest him without warrant and detain him;

(*d*) undertake any inspection which he may deem necessary to determine whether the provisions of this Act and any regulations made thereunder in respect of habit-forming drugs are being complied with.

(2) Every person who is detained and everything seized under the provisions of subsection (1) shall be taken as soon as is reasonably possible before a court to be dealt with according to law.

Special jurisdiction in respect of offences under this Part

**18.** (1) Notwithstanding anything to the contrary in any written law, any Magistrate Grade I, Senior Magistrate or Principal Magistrate shall have special jurisdiction to impose any penalties provided in this Act for any contravention of the provisions of this Part, or any regulations made under this Act relating to this Part, or to exercise any of the powers provided therein in respect of such contraventions.

(2) Where any person is found guilty of any contravention of the provisions of this Part or any regulations made under this Act relating to this Part, the court shall order any habit-forming drug, plant, pipe, receptacle or material in respect of which the offence was committed to be forfeited to the State.

(3) Where any person is found guilty of any contravention of the provisions of this Part or any regulations made under this Act relating to this Part, the court shall order that any vehicle, aircraft, boat, animal, receptacle or thing in or upon which such habit-forming drug, plant, pipe, receptacle or material was found to be detained for a period of 28 days, and, if within such period no successful application is made under subsection (4), it shall be thereafter forfeited to the State.

(4) If, upon application being made to it within 28 days of the date of the order made under subsection (3) by a person claiming ownership, the court is satisfied that—

(*a*) such vehicle, aircraft, boat, animal, receptacle or thing is not the property of the person convicted; and

(*b*) the claimant is the owner; and

(*c*) that he did not know that it was being used for an illegal purpose, or was not able to prevent its use by the person convicted,

it may, if it considers it to be equitable and expedient to do so, order the return thereof to the claimant.

(5) If the convicted person used any motor vehicle to carry or convey the drug, plant, pipe, receptacle or material in respect of which the offence was committed, the court may suspend any driver's licence issued to that person, and disqualify him from driving for a period not exceeding five years, and may cancel any licence issued in respect of that vehicle in terms of the Road Traffic Act, and may order that such vehicle should not be relicensed for a period not exceeding five years.

(6) If the convicted person is the holder of any licence issued under the provisions of any written law relating to the issue of trading licences, and it is proved to the satisfaction of the court that he used the licence to conceal or assist him in concealing the offence, the court may cancel the licence, and may declare that person to be disqualified from obtaining another such licence for a period not exceeding five years.

(7) For the avoidance of doubt, it is hereby declared that the provisions of subsections (2), (3), (5) and (6) shall be in addition to and not in derogation of any other penalties imposed under this Act.

(8) Anything forfeited to the State under the provisions of this section shall be disposed of as the Minister may direct.

Vicarious liability relating to habit-forming drugs

19. (1) Any duly registered medical practitioner, dentist or pharmacist shall be deemed guilty of and shall be liable to the penalties prescribed for contraventions of this Part in respect of habit-forming drugs where the act or default constituting an offence was that of a partner, manager, clerk, agent, apprentice or servant associated with or employed by him, unless he satisfies the court that such act or default was committed without his knowledge and was not due to his negligence in the supervision or direction of such partner, manager, clerk, agent, apprentice or servant.

(2) Every director and manager of a company, who is resident in Botswana, shall be liable for and subject to the penalties prescribed for any contravention of the provisions of this Part in relation to habit-forming drugs by such company.

Onus of proof

20. (1) If in any charge under this Part it is alleged that cannabis, as defined in section 16, was being cultivated, evidence that such cannabis was found in cultivated land shall be sufficient proof that it was being cultivated with the knowledge of the owner or occupier of such land, unless the contrary is proved.

(2) Any person who is upon or in charge of or who accompanies any vehicle, aircraft or animal in or upon which there is any habit-forming drug, or any plant or portion of a plant from which any such drug can be extracted, derived, produced or manufactured shall, until or unless the contrary is proved, be deemed for the purposes of this Part, to be the possessor of such drug, plant or portion of a plant.

(3) The burden of proving any fact which would be a defence to a charge of contravening any provision of this Part shall lie upon the person charged.

(4) Every person required by this Part to be in possession of a permit, licence, prescription, approval or any other authority shall be deemed to be without such permit, licence, prescription, approval or authority unless he produces or gives satisfactory proof of possessing the same.

(5) In any indictment, summons or other form of charge under this Part, it shall be sufficient to set forth the offence charged in the words of this Part or in similar words, without negativing any exception, exemption or qualification.

PART IV — *Miscellaneous*

Regulations

**21.** (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 —

(*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;

(*h*) the control, conduct and regulation of clinical trials of any drug, or any scientific or medical experiments in relation to habit-forming drugs.

(2) Regulations under this Act may provide penalties for breaches thereof of fines up to a maximum of P2 000 and imprisonment for not more than one year.

Repeal

**22.** The Drugs Act, 1991 and the Habit-Forming Drugs Act are hereby repealed.

PASSED by the National Assembly this 3rd day of August, 1992.

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