UNITED NATIONS

E/NL.1994/39-40
13 September 1994
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 relevent articles of the international treaties on narcotic drugs and psychotropic substances, the Secretary-General has the honour to communicate the following legislative texts.

NIGERIA

Communicated by the Government of Nigeria

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 [...].

E/NL.1994/39 NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL DECREE 1993

E/NL.1994/40 DRUGS AND RELATED PRODUCTS (REGISTRATION, ETC.) DECREE 1993

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

V.94-26039

NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL DECREE 1993

ARRANGEMENT OF SECTIONS

Section

Decree No. 15

Commencement. [*See Section 31*]

THE FEDERAL MILITARY GOVERNMENT hereby decrees as follows:-

PART I - ESTABLISHMENT OF THE NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL AND ITS GOVERNING COUNCIL

Establishment of the National Agency for Food and Drug Administration and Control.

1. There is hereby established a body to be known as the National Agency for Food and Drug Administration and Control (in this Decree referred to as "the Agency") which -

(a) shall be body corporate with perpetual succession and a common seal; and

(b) may sue and be sued in its corporate name.

Establishment of the Governing Council.

2.-(1) There is hereby established for the Agency, a Governing Council which shall consist of -

(a) a Chairman who shall be appointed by the President, Commander-in-Chief of the Armed Forces on the recommendation of the Minister;

(b) the Director-General of the Ministry of Health and Social Services or his representative;

(c) the Director and Chief Executive of the National Institute for Pharmaceutical Research and Development or his representative;

(d) the Director-General of the Standards Organisation of Nigeria or his representative;

(e) the Chairman of the National Drug Law Enforcement Agency or his representative;

(f) the Chairman of the Pharmacists Board of Nigeria or his representative;

(g) one person to represent the Pharmaceutical Group of the Manufacturers Association of Nigeria;

(h) one person to represent the Food Beverages Group of the Manufacturers Association of Nigeria;

(i) the Director-General of the Agency; and

(j) three other persons to represent public interest to be appointed by the Minister.

(2) A member of the Council, other than the Chairman, shall be appointed by the Minister on the recommendation of the body, if any, he represents.

(3) The members of the Council shall be paid such allowances as the Federal Military Government may, from time to time, approve.

(4) The provisions of the Schedule to this Decree shall have effect with respect to the proceedings of the Council and the other matters mentioned therein.

Tenure of office.

3.-(1) A member of the Council appointed, otherwise than by office, shall hold office for a term of four years, and subject to the provisions of subsection (2) of this section, shall be eligible for reappointment for only one further term of four years.

(2) The office of a member of the Council shall become vacant if -

(a) he resigns as a member of the Council by notice in writing under his hand addressed to the Minister; or

(b) the Minister is satisfied that it is not in the interest of the Agency for the person appointed to continue in office and notifies the member in writing to that effect.

Removal from office of members of the Council.

4.-(1) If it appears to the Council that a member of the Council, other than an *ex-officio* member, should be removed from office on the grounds of misconduct or inability to perform the functions of his office, the Council shall make a recommendation to the President, Commander-in-Chief of the Armed Forces.

(2) If the President, Commander-in-Chief of the Armed Forces, after making such inquiries as he considers necessary, approves the recommendation, the Minister shall, in writing, declare the office of such a member vacant.

(3) Notwithstanding the provisions of subsection (1) of this section, the President, Commander-in-Chief of the Armed Forces may remove any member of the Council if he is satisfied that it is in the public interest so to do.

PART II - FUNCTIONS AND POWERS

Functions of the Agency.

5. The Agency shall have the following functions, that is, to -

(a) regulate and control the importation, exportation, manufacture, advertisement, distribution, sale and use of food, drugs, cosmetics, medical devices, bottled water and chemicals;

(b) conduct appropriate tests and ensure compliance with standard specifications designated and approved by the Council for the effective control of the quality of food, drugs, cosmetics, medical devices, bottled water and chemicals and their raw materials as well as their production processes in factories and other establishments;

(c) undertake appropriate investigations into the production premises and raw materials for food, drugs, cosmetics, medical devices, bottled water and chemicals and establish relevant quality assurance systems, including certification of the production sites and of the regulated products;

(d) undertake inspection of imported food, drugs, cosmetics, medical devices, bottled water and chemicals and establish relevant quality assurance systems, including certification of the production sites and of the regulated products;

(e) compile standard specifications and guidelines for the production, importation, exportation, sale and distribution of food, drugs, cosmetics, medical devices, bottled water and chemicals;

(f) undertake the registration of foods, drugs, cosmetics, medical devices, bottled water and chemicals;

(g) control the exportation and issue quality certification of food, drugs, cosmetics, medical devices, bottled water and chemicals intended for export;

(h) establish and maintain relevant laboratories or other institutions in strategic areas of Nigeria as may be necessary for the performance of its functions under this Decree;

(i) pronounce on the quality and safety of food, drugs, cosmetics, medical devices, bottled water and chemicals after appropriate analysis;

(j) undertake measures to ensure that the use of narcotic drugs and psychotropic substances are limited to medical and scientific purposes;

(k) grant authorisation for the import and export of narcotic drugs and psychotropic substances as well as other controlled substances,

(l) collaborate with the National Law Enforcement Agency in measures to eradicate drug abuse in Nigeria;

(m) advise Federal, State and Local Governments, the private sector and other interested bodies regarding the quality, safety and regulatory provisions on food, drugs, cosmetics, medical devices, bottled water and chemicals;

(n) undertake and co-ordinate research programmes on the storage, adulteration, distribution and rational use of food, drugs, cosmetics, medical devices, bottled water and chemicals;

(o) issue guidelines on, approve and monitor the advertisement of food, drugs, cosmetics, medical devices, bottled water and chemicals;

(p) compile and publish relevant data resulting from the performance of the functions of the Agency under this Decree or from other sources;

(q) sponsor such national and international conferences as it may consider appropriate:

(r) liaise with relevant establishments within and outside Nigeria in pursuance of the functions of the Agency; and

(s) carry out such activities as are necessary or expedient for the performance of its functions under this Decree.

Functions of the Council.

6. The Council shall -

(a) advise the Federal Military Government generally on the national policies on the control and quality specifications of food, drugs, cosmetics, medical devices, bottled water and chemicals;

(b) designate, establish and approve quality specifications in respect of food, drugs, cosmetics, medical devices, bottled water and chemicals necessary for their certification;

(c) establish the relevant guidelines and measures for quality control of food, drugs, cosmetics, medical devices, bottled water and chemicals in conformity with the Agency's standard specifications;

(d) appoint, promote and discipline employees necessary for the proper discharge of the functions of the Agency;

(e) establish committees as may be expedient which shall be charged with specific functions delegated by the Council;

(f) establish appropriate programmes for the quality, safety and rational use of the food, drugs, cosmetics, medical devices, bottled water and chemicals;

(g) encourage and promote activities related to the process, standard specifications, guidelines on importation, exportation, sale and distribution of food, drugs, cosmetics, medical devices, bottled water and chemicals;

(h) utilise and promote the expansion of research, experiments, surveys and studies by public or private agencies, institutions and organisations concerning the quality, safety and use of food, drugs, cosmetics, medical devices, bottled water and chemicals and such other matters related to this Decree as the Agency may, from time to time, determine as necessary or useful;

(i) establish, encourage and promote training programmes for the employees of the Agency and other appropriate persons from public or private organisations; and

(j) carry out such other activities which are connected with its other functions.

Powers of the Council.

7. The Council shall have power -

(a) to open and operate ordinary and domiciliary accounts for the Agency in recognised banking institutions in Nigeria;

(b) subject to section 8 of this Decree, to specify the management system of the Agency, including financial approval ceilings for officers of the Agency;

(c) to enter into agreement with public or private organisations and individuals to develop, utilise, co-ordinate and share such information as are determined to be appropriate by the Council for the performance of its functions under this Decree; and

(d) to do such other things as are necessary for the successful performance of its functions under this Decree.

PART III - STRUCTURE OF THE AGENCY

Structure of the Agency

8. The Agency shall have -

(a) an Administration and Finance Directorate to be headed by a Director, who shall serve as the Secretary of the Agency;

(b) a Planning, Research and Statistics Directorate to be headed by a Director;

(c) a Narcotics and Controlled Substances Directorate to be headed by a Director;

(d) a Regulatory and Registration Directorate to be headed by a Director;

(e) an Inspectorate Directorate to be headed by a Director;

(f) a Laboratory Services Directorate to be headed by a Director; and

(g) such other Directorates as may be required for the proper performance of the functions of the Agency.

PART IV - STAFF OF THE AGENCY

Appointment of Director-General and other staff of the Agency.

9 -(1) There shall be appointed for the Agency by the President, Commander-in-Chief of the Armed Forces, on the recommendation of the Minister, a Director-General who shall be a person with good knowledge of pharmacy, food and drugs.

(2) The Director-General shall be -

(a) the chief executive of the Agency;

(b) responsible for the day-to-day administration of the Agency and keep the books and records of the Agency; and

(c) subject to the supervision and control of the Chairman and the Council.

(3) The Director-General shall hold office for a period of 5 years on such terms and conditions as may be specified in his letter of appointment and be eligible for re-appointment for another period of 5 years.

(4) The Council may, from time to time, appoint such other persons as members of staff of the Agency as it may deem necessary, to assist the Agency in the performance of its functions under this Decree.

(5) The members of staff of the Agency appointed under subsection (4) of this section shall be appointed on such terms and conditions of service as the Council may, after consultation with the Federal Civil Service Commission, determine.

Cap. 62 LFN.

(6) The members of staff of the Agency shall be public officers as defined in the Constitution of the Federal Republic of Nigeria, as amended.

Pension. Cap. 346 LFN.

10.-(1) Service in the Agency shall be approved service for the purposes of the Pensions Act and, accordingly, officers and other persons employed in the Agency shall be entitled to pensions, gratuities and other benefits as are prescribed thereunder.

(2) Notwithstanding the provisions of subsection (1) of this section, the Agency may appoint a person to any office on terms which preclude the grant of a pension, gratuity or other retirement benefits in respect of that office.

(3) For the purpose of the application of the provisions of the Pensions Act, any power exercisable thereunder by a Minister or other authority of the Government of the Federation, other than the power to make regulations under section 23 thereof, is hereby vested in and shall be exercisable by the Agency and not by any other person or authority.

Removal and Discipline of senior staff.

11.-(1) If it appears to the Council that there are reasons for believing that any person employed as a member of the senior staff of the Agency, other than the Director-General, should be removed from office on grounds of misconduct or inability to perform the functions of his office, the Council shall-

(a) give notice of those reasons to the person concerned.

(b) afford the person an opportunity of making representation on the matter to the Council in person;

(c) if the person concerned or any three members of the Council so request within the period of one month beginning with the date of the notice, make arrangement -

(i) for a committee of the Council to investigate the matter and to report on it to the Council; and

(ii) for the person in question to be afforded an opportunity of appearing before and being heard by the investigating committee on the matter.

(2) If the Council, after considering the report of the investigating committee, is satisfied that the person in question should be removed as aforesaid, the Council may remove the person concerned by an instrument in writing signed on the direction of the Council.

(3) The Director-General of the Agency may, in a case of misconduct by a member of staff which in the opinion of the Director-General is prejudicial to the interest of the Council suspend such member of staff and any such suspension shall forthwith be reported to the Council.

(4) For good cause, any member of staff may be suspended from office or his appointment may be terminated by the Council and for the purposes of this subsection, "good cause" means -

(a) any physical or mental incapacity which the Council, after obtaining medical advice, considers to render the person concerned unfit for the discharge of the functions of his office; or

(b) conduct of a scandalous or other disgraceful nature which the Council considers to be such as to render the person concerned unfit to continue to hold his office; or

(c) conduct which the Council considers to be such as to constitute failure or inability of the person concerned to discharge the functions of his office or to comply with the terms and conditions of his service.

(5) Any person suspended pursuant to this section shall be placed on half pay and the Council shall before the expiration of a period of three months after the date of such suspension consider the case against that person and come to a decision as to -

(a) whether to continue such person's suspension and if so on what terms (including the portion of his emoluments to be paid to him); or

(b) whether to reinstate such person to his office, in which case the Council shall restore his full emoluments to him with effect from the date of the suspension; or

(c) whether to terminate the appointment of the person in question in which case such a person shall not be entitled to the portion of his emolument withheld during the period of the suspension; or

(d) whether to take such lesser disciplinary action against such person (including the restoration of such portion of his emolument that might have been withheld) as the Council may determine.

(6) In any case where the Council, pursuant to this section, decides to continue a person's suspension or decides to take further disciplinary action against a person, the Council shall, before the expiration of a period of three months from such decision, come to a final determination in respect of the case concerning that person.

(7) It shall be the duty of any person who signed the instrument of removal by virtue of this section to serve or cause to be served on the person concerned, a copy of the instrument.

(8) Nothing in the foregoing provisions of this section shall prevent the Council from making such regulations for the discipline of other categories of staff and workers of the Council as it may think fit.

Discipline of junior staff.

12.-(1) If any junior member of staff is accused of misconduct or inefficiency, the Director-General may suspend him for not more than three months and forthwith shall direct the matter to the Junior Staff Appointment and Promotion Committee to -

(a) consider the case; and

(b) make recommendation as to the appropriate action to be taken by the Director-general.

(2) In all cases under this section, the junior member of staff shall be informed in writing of the charges against him and be given reasonable opportunity to defend himself.

(3) The Director-General may, after considering the recommendation made pursuant to subsection (1) (b) of this section, dismiss, terminate, retire or downgrade the junior member of staff concerned.

(4) Any person aggrieved by the Director-General's decision under subsection (3) of this section may, within a period of 21 days from the date of receipt of the letter communicating the decision to him, address a petition to the Council to reconsider his case and the Council's decision thereon shall be final.

PART V - FINANCIAL PROVISIONS

Fund of the Agency.

13.-(1) The Agency shall establish a fund from which shall be defrayed all expenditure incurred by the Agency for the purposes of this Decree.

(2) There shall be paid and credited to the fund of the Agency -

(a) fees charged for services rendered by the Agency;

(b) all sums accruing to the Agency by way of gifts, endowments, bequests or other voluntary contributions by persons and organisations;

(c) foreign aid and assistance from bilateral agencies; and

(d) subventions and extra-budgetary allocations from the Federal Government.

Expenditure of the Agency.

14. The Agency shall, from time to time, apply the funds at its disposal

(a) the cost of establishing and maintaining the Head Office of the Agency at the Federal Capital Territory, Abuja and its other offices located in other places in Nigeria;

(b) pay allowances and other benefits of members of the Council and of its committees;

(c) pay the emoluments and entitlement of the Director-General and other members of staff of the Agency;

(d) pay the personnel, overhead, allowances, benefits and other administrative costs of the Agency;

(e) the training of members of staff of the Agency;

(f) provide scholarships & awards for specialised training of personnel;

(g) publicise and promote the activities of the Agency;

(h) support national and international scientific and professional organisations and pay annual and other contributions to such bodies;

(i) undertake any other activity in connection with all or any of the functions of the Agency.

Exemption from income tax.

15. All income derived by the Agency from the sources specified in section 13 (2) of this Decree shall be exempt from income tax and all contributions to the fund of the Agency shall be tax deductible.

Capital production income.

16. Subject to the approval of the Minister, the Agency may invest in the profitable production of capital goods by joint-venture, partnerships, share-holding or as sole proprietor, as the case may be, and the net incomes so generated shall be paid into the fund of the Agency.

Disposal of surplus funds.

17. The Council may invest any surplus funds in profit yielding ventures, and notwithstanding that power, the Minister may issue to the Agency directives as he may think necessary as to the disposal of any surplus funds of the Agency.

Annual estimates.

18. The Council shall submit to the Minister, not later than 31st October each year, its programme of work and estimates of its income and expenditure for the following year.

Accounts and audit.

19.-(1) The Council shall keep proper accounts of the Agency and proper records in relation to those accounts.

(2) The accounts of the Agency shall be audited, not later than six months after the end of the year to which it relates, by auditors appointed by the Agency from the list and in accordance with the guidelines supplied by the Auditor-General of the Federation.

Annual report.

20. The Agency shall prepare and submit to the Minister, not later than 30th June in each year, a report on the activities of the Agency during the immediately preceding year, and shall include in such report a copy of the audited accounts of the Agency for that year and the auditors report thereon.

PART VI - MISCELLANEOUS

Offices and premises. Cap. 202 LFN.

21.-(1) For the purpose of providing offices and premises necessary for the performance of its functions, the Agency may, subject to the Land Use Act -

(a) purchase or take on lease any interest in land, building or property; and

(b) build, equip and maintain offices and premises.

(2) The Agency may, subject to the Land Use Act, sell or lease out any office or premises held by it, which is no longer required for the performance of its functions under this Decree.

Power to borrow.

22.-(1) The Agency may, from time to time, borrow by overdraft or otherwise such sums as it may require for the performance of its functions under this Decree.

(2) The Agency shall not, without the approval of the Minister, borrow money which exceeds, at any time, the limit set by the Minister,

(3) Notwithstanding subsection (1) of this section, where the sum to be borrowed is in foreign currency the Agency shall not borrow the sum without the prior approval of the Minister.

Power to accept gifts.

23.-(1) The Agency may accept gifts of land, money or other property, upon such terms and conditions, if any, as may be specified by the person or organisation making the gift.

(2) The Agency shall not accept any gift if the conditions attached by the person or organisation making the gift are inconsistent with the functions of the Agency.

Power to enter the premises, etc.

24.-(1) An officer of the Agency may, in the course of his duty, at any reasonable time and on production of his certificate of designation if so required-

(a) enter (if need be by force) any premises in which he reasonably believes that any article to which this Decree or the regulations apply is manufactured, prepared, preserved, packaged, stored or sold;

(b) examine any article in the premises which appears to him to be an article to which this Decree or the regulations apply or anything in the premises which he reasonably believes is used or is capable of being used for the manufacture, preparation, preservation, packaging, storage or sale of any such article;

(c) take a sample or specimen of any article to which this Decree or the regulations apply or which he has power to examine under paragraph (b) of this subsection;

(d) open and examine, while on the premises, any container or package which he reasonably believes may contain anything to which this Decree or the regulations apply or which may help in his investigations;

(e) examine any book, document or other record found on the premises which he reasonably believes may contain any information relevant to

the enforcement of this Decree or the regulations and make copies thereof or extracts therefrom; and

(f) seize and detain for such time as may be necessary for the purpose of this Decree, any article by means of or in relation to which he reasonably believes any provision of this Decree or the regulations has been contravened.

(2) The owner or person in-charge of any premises entered by an officer of the Agency in pursuant of this section, and every person found thereon, shall give all reasonable assistance in their power to the officer and shall make available to the officer all such information as the officer may reasonably require for the purposes of this Decree.

(3) Any article seized under this Decree shall be kept or stored in such a place as the officer of the Agency may direct and shall be returned to the owner or the person from whom it was seized if the article upon analysis or examination is found to conform with the requirements of this Decree and regulations.

(4) Any article seized by an officer of the Agency pursuant to this Decree or the regulations may be submitted to an analyst for analysis or examination and the analyst upon making such analysis or examination shall issue a certificate or report in the prescribed form setting forth the result of such analysis or examination and, the officer of the Agency shall on demand deliver a copy of such certificate or report to the owner of the article if the article is to be the subject of a proceeding under this Decree.

(5) In this section, the expression "article to which this Decree or the regulations apply" means -

(a) any food, drug, cosmetic, medical device, bottled water or chemical;

(b) anything used for the manufacture, preparation, preservation, packaging or storage of any food, drug, cosmetic, medical device, bottled water or chemical; and

(c) any labelling or advertising material relating to or for use in connection with any food, drug, cosmetic, medical device, bottled water or chemical but does not include a live animal.

Offence.

25. A person who obstructs an officer of the Agency in the performance of his duties under section 24 of this Decree is guilty of an offence and liable on conviction to a fine of ₦5000 or to imprisonment for a term not exceeding 2 years or to both such fine and imprisonment.

Legal proceedings.

26.-(1) No suit shall be commenced against the Agency before the expiration of a period of one month after written notice of intention to commence the suit shall have been served on the Agency by the intending plaintiff or his agent and the notice shall clearly and explicitly state -

(a) the cause of action;

(b) the particulars of the claim;

(c) the name and place of abode of the intending plaintiff; and

(d) the relief which he claims.

(2) The notice referred to in subsection (1) of this section and any summons, notice or other document required or authorised to be served on the Agency under the provisions of this Decree or any other enactment or law, may be served by -

(a) delivering the same to the Director-General; or

(b) sending it by registered post addressed to the Director-General at the Head Office of the Agency.

(3) In any action or suit against the Agency, no execution or attachment or process in the nature thereof shall be issued against the Agency, but any sums of money which may, by the judgment of the court, be awarded against the Agency shall, subject to any directives given by the Agency, be paid from the fund of the Agency.

Power of Minister to give directives.

27. The Minister may give directives of a general or special character to the Agency relating to the performance by the Agency of any or all of its functions under this Decree, and it shall be the duty of the Agency to comply and give effect to the directives.

Dissolution of Food and Drug Administration and Control Department.

28.-(1) On the commencement of this Decree, the Food and Drug Administration and Control Department of the Federal Ministry of Health and Social Services (in this section referred to as "the Department") shall cease to exist.

(2) Accordingly, the Department is hereby dissolved and the provisions of the Second Schedule to this Decree shall apply in relation to the employees in the Department, the assets and liabilities of the Department and the other matters connected with the Department set out therein.

Power to make regulations.

29. The Council may, with the approval of the Minister, make regulations -

(a) to prescribe the methodologies for private-sector payments into the fund of the Agency;

(b) to prescribe the fees to be paid for services rendered by the Agency;

(c) generally for the purposes of carrying out or giving full effect to the provisions of this Decree.

Interpretation.

30. In this Decree, unless the context otherwise requires -

"Agency" means the National Agency for Food and Drug Administration and Control established by section 1 of this Decree;

"Council" means the Governing Council of the Agency established by section 2 of this Decree;

"Chairman"means the Chairman of the Council;

"drug" includes any substance of vegetable, animal or mineral origin or any preparation or admixture thereof manufactured, sold or advertised for use in -

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

(b) restoring, correcting or modifying organic functions in man or in animal;

(c) disinfection or the control of vermin, insects or pests; or

(d) contraception;

"medical device" means any instrument, apparatus or contrivance (including components, parts and accessories thereof) manufactured, sold or advertised for internal or external use in the diagnosis, treatment, mitigation or prevention of any disease, disorder, abnormal physical state or the symptom thereof, in man or in animal;

"member" means a member of the Council and includes the Chairman;

"Minister" means the Minister or Secretary charged with matters relating to health;

"public service" has the meaning assigned to it in the Constitution of the Federal Republic of Nigeria; and

"regulated products" means food, drugs, cosmetics, medical devices, bottled water and chemicals.

Citation and commencement.

31. This Decree may be cited as the National Agency for Food and Drug Administration and Control Decree 1993 and shall be deemed to have come into force on 1st October 1992.

SCHEDULES

FIRST SCHEDULE *Section* 2(4)

SUPPLEMENTARY PROVISIONS RELATING TO THE BOARD AND THE AGENCY

Proceedings of the Board

1. Subject to this Decree and section 27 of the Interpretation Act, the Council may make standing orders regulating the proceedings of the Council and any committee thereof.

2. Every meeting of the Council shall be presided over by the Chairman and if the Chairman is unable to attend a particular meeting, the members present at the meeting shall elect one of their number to preside at the meeting.

3. The quorum at a meeting of the Council shall consist of the Chairman (or in an appropriate case, the person presiding at the meeting pursuant to paragraph 2 of this Schedule) and six other members.

4. The Council may on any special occasion, co-opt any person to be member of the Council for as many meetings as it may deem necessary, and that person while so co-opted shall have all the rights and privileges of a member, except that he shall not be entitled to vote or count towards a quorum.

Committees

5.-(1) Subject to its standing orders, the Council may appoint such number of standing and ad-hoc committees as it thinks fit to consider and report on any matter with which the Agency is concerned.

(2) Every committee appointed under the provisions of sub-paragraph (1) of this paragraph shall be presided over by a member of the Council and shall be made up of such number of persons, not necessarily members of the Board, as the Council may determine in each case.

6. The decision of a committee shall be of no effect until it is confirmed by the Agency.

Miscellaneous

7. The fixing of the seal of the Agency shall be authenticated by the signature of the Chairman and of the Director-General of the Agency or such other member authorised generally or specially by the Council to act for that purpose.

8. Any contract or instrument which, if made by a person not being a body corporate, would not be required to be under seal, may be made or executed on behalf of the Agency by the Director-General or by any other person authorised generally or specifically by the Council to act for that purpose.

9. Any document purporting to be a contract, an instrument or other document signed or sealed on behalf of the Agency shall be received in evidence and, unless the contrary is proved, be presumed without further proof, to have been so signed or sealed.

10. The validity of a proceeding of the Council or of a committee thereof shall not be adversely affected -

(a) by any vacancy in the membership of the Council; or

(b) by any defect in the appointment of a member of the Council or

(c) by reason that a person not entitled to do so took part in the proceeding.

11. A member of the Council or committee who has a personal interest in any contract or arrangement entered into or proposed to be considered by the Council or committee shall forthwith disclose his interest to the Council or committee and shall not vote on any question relating to the contract or arrangement.

SECOND SCHEDULE *Section 27*

TRANSITIONAL PROVISIONS RELATING TO THE EMPLOYEES, ASSETS AND LIABILITIES OF THE FOOD AND DRUGS ADMINISTRATION AND CONTROL DEPARTMENT OF THE FEDERAL MINISTRY OF HEALTH AND SOCIAL SERVICES

1. By virtue of this Decree, there shall be vested in the Agency immediately at the commencement of this Decree, without further assurance, all assets, funds, resources and other movable or unmovable property which immediately before the commencement of this Decree were vested in the Food and Drugs Administration and Control Department of the Federal Ministry of Health and Social Services (in this Schedule referred to as "the Department").

2. As from the commencement of this Decree -

(a) all rights, interests, obligations and liabilities of the Department existing immediately before the commencement of this Decree under any contract or instrument, or at law or in equity apart from any contract or instrument, shall by virtue of this Decree be assigned to and vested in the Agency;

(b) any contract or instrument as mentioned in sub-paragraph (a) of this paragraph shall be of the same force and effect against or in favour of the Agency and shall be enforceable as fully and effectively as if, instead of the Department, the Agency had been named therein or had been a party thereto; and

(c) the Agency shall be subject to all obligations and liabilities to which the Department was subject immediately before the commencement of this Decree, and all other persons shall as from the commencement of this Decree have the same rights, powers and remedies against the Agency as they had against the Department immediately before the commencement of this Decree.

3. Any proceeding or cause of action pending or existing immediately before the commencement of this Decree by or against the Department in respect of any right, interest, obligation or liability of the Department may be commenced, continued or enforced by or against the Agency as if this Decree had not been made.

4. Notwithstanding the provisions of this Decree but subject to such directions as may be issued by the Agency, any person who immediately before the date of commencement of this Decree held office in the Department shall be deemed to have been transferred to the Agency on terms and conditions not less favourable than those obtaining immediately before the commencement of this Decree; and service under the Department shall be deemed to be service under the Agency for purposes of pension.

5. The Minister, if he thinks fit, may, within the twelve months after the commencement of this Decree, by order published in the *Gazette*, make additional transitional or saving provisions for the better carrying out of the objectives of this Schédule.

MADE at Abuja this 27th day of January 1993.

GENERAL I. B. BABANGIDA,
President, Commander-in-Chief
of the Armed Forces,
Federal Republic of Nigeria.

EXPLANATORY NOTE

(This note does not form part of the above Decree but is intended to explain its purport)

The Decree establishes the National Agency for Food and Drug Administration and Control with functions, amongst others, of regulating and controlling the importation, exportation, manufacturing, advertisement, distribution, sale and use of food, drugs, cosmetics, medical devices, bottled water and chemicals.

DRUGS AND RELATED PRODUCTS (REGISTRATION, ETC.) DECREE 1993

ARRANGEMENT OF SECTIONS

Section

Decree No. 19

[*27th January 1993*] Commencement.

THE FEDERAL MILITARY GOVERNMENT hereby decrees as follows:-

Prohibition of the manufacture, etc.of unregistered drugs, etc.

1.-(1) No drug, drug product, cosmetic or medical device shall be manufactured, imported, exported, advertised, sold or distributed in Nigeria unless it has been registered in accordance with the provisions of this Decree or regulations made under it.

(2) Notwithstanding the provisions of subsection (1) of this section, the National Agency for Food and Drug Administration and Control (in this Decree referred to as "the Agency") may grant a permit for the importation or manufacture of a sample of drug, drug product, cosmetic or medical device for the purpose of registration or clinical trial, and the importation or manufacture shall be in accordance with the conditions specified in the permit.

Application for registration.

2.-(1) Application for the registration of a drug, drug product, cosmetic or medical device shall be made in writing to the Agecny in such form as the Agency may, from time to time, prescribe and shall-

(a) contain the particulars and description of the drug, drug product, cosmetic or medical device in respect of which the application is made; and

(b) be accompanied by such fee as the Agecny may, from time to time, prescribe.

(2) The Agency, in considering an application -

(a) may ask the applicant to supply such other information as he may require to enable it to reach a decision on the application;

(b) shall satisfy itself that there is need to have the drug, drug product, cosmetic or medical device registered in Nigeria.

(3) Where the Agency is satisfied that there is need to register the drug, drug product, cosmetic or medical device it shall do so and issue to the applicant a certificate of registration, subject to such conditions as he may deem necessary.

(4) The registration of a drug, drug product, cosmetic or medical device under this Decree shall, unless cancelled earlier, be valid for a period of five years and may be renewed.

(5) The Agency shall, from time to time, publish a notice in the *Gazette* notifying the registration of a drug, drug product, cosmetic or medical device under this Decree.

3.-(1) No person shall disclose an information supplied to the Agency in pursuance of section 2 of this Decree except -

(a) with the written consent of the person who supplied the information; or

(b) in accordance with the directive of the Agency; or

(c) for the purpose of a proceeding under this Decree.

4.-(1) The Agency may suspend or cancel the registration of a drug, drug product, cosmetic or medical device if -

(a) the grounds on which the drug, drug product, cosmetic or medical device was registered were later found to be false or incomplete; or

(b) the circumstances under which the drug, drug product, cosmetic or medical device was registered no longer exists; or

(c) any of the conditions under which the drug, drug product, cosmetic or medical device was registered has been contravened; or

(d) the standard of quality, safety or efficacy as prescribed in the documentation for registration is not being complied with; or

(e) the premises in which the drug, drug product, cosmetic or medical device or part thereof is manufactured, assembled or stored by or on behalf of the holder of the certificate of registration are unsuitable for

the manufacturing, assembling or storage of the drug, drug product, cosmetic or medical device.

(2) Where the registration of a drug, drug product, cosmetic or medical device is suspended or cancelled, the Agency shall order the withdrawal from circulation of that drug, drug product, cosmetic or medical device and shall accordingly cause the suspension, cancellation or withdrawal to be published in the *Gazette*.

Clinical trials.

5.-(1) No person shall, in the cause of his business -

(a) import or supply a drug, drug product, cosmetic or medical device; or

(b) procure the importation or supply of a drug, drug product, cosmetic or medical device; or

(c) procure the manufacture or assembly of a drug, drug product, cosmetic or medical device,

for the purpose of a clinical test, unless he is a holder of a valid clinical trial certificate and the trial is to be carried out in accordance with the terms of the certificate and the provisions of any regulation in force.

(2) Application for a clinical trial certificate shall be made to the Agency in such form and manner as the Agency may prescribe by regulations.

Offences.

6.-(1) A person who contravenes a provision of this Decree or a regulation made under it is guilty of an offence and liable on conviction -

(a) in the case of an individual, to a fine not exceeding ₦ 50,000 or to imprisonment for a term not exceeding two years or to both fine and imprisonment; and

(b) in the case of body corporate, to a fine not exceeding ₦100,000.

Offences by bodies corporate, etc.

7. Where an offence under this Decree is committed by a body corporate or firm or other association of individuals -

(a) every director, manager, secretary or other similar officer of the body corporate; or

(b) every partner or officer of the firm; or

(c) every trustee of the body concerned; or

(d) every person concerned in the management of the affairs of the association; or

(e) every person who was purporting to act in a capacity referred to in paragraphs (a) to (d) of this section,

is severally guilty of that offence and liable to be proceeded against and punished for that offence in the same manner as if he had himself committed the offence unless he proves that the act or omission constituting the offence took place without his knowledge, consent or connivance.

Establishment of Drug Registration Committee.

8.-(1) There is hereby established a committee to be known as the Drug Registration Committee (in this Decree referred to as "the Committee") which shall consist of a Chairman and such number of other persons, as the Agency may deem necessary, who possess the knowledge and experience relevant to this Decree.

(2) The Committee shall-

(a) evaluate the formation, method of preparation, packaging, labelling, safety, efficacy and usefulness of drugs, drug products, cosmetics or medical devices for which applications are made; and

(b) advise the Agency as appropriate in respect of those applications and the cancellation, withdrawal or suspension of any registration made in pursuance of the provisions of this Decree.

(3) The Agency shall, on the appointment of the Chairman and members of the Committee, specify their tenure of office.

(4) Members of the Committee shall be eligible for payment of such allowances as may be approved, from time to time, by the Agency with the approval of the Minister, but a person shall not, by reason only of his membership of the Committee, be treated as holding an office of emolument in the civil service of Federation.

(5) Subject to this section, the Committee shall determine its quorum and otherwise regulate its own procedure.

Interpretation.

9. In this Decree, unless the context otherwise requires -

"Agency" means the National Agency for Food and Drug Administration and Control;

"cosmetic" includes any substance or mixture of substance intended to be rubbed, poured, sprinkled or sprayed, introduced into or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness or altering the complexion, skin, hair or teeth and includes deodorants;

"drug" includes any substance of vegetable, animal or mineral origin, or any preparation or admixture thereof manufactured, sold or advertised for use in -

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

(b) restoring, correcting or modifying organic functions in man or in animal;

(c) disinfection or the control of vermin, insects or pests; or

(d) contraception;

"drug product" means any formulating of a drug;

"medical device" means any instrument, apparatus or contrivance (including components, parts and accessories thereof) manufactured, sold or advertised for internal or external use in the diagnosis, treatment, mitigation or prevention of any disease, disorder, abnormal physical state or the symptom thereof, in man or in animal;

"Minister" means the Minister or Secretary charged with the responsibility for matters relating to health.

Citation.

10. This Decree may be cited as Drugs and Related Products (Registration, etc.) Decree 1993.

MADE at Abuja this 27th day of January 1993.

GENERAL I. B. BABANGIDA,
President, Commander-in-Chief
of the Armed Forces,
Federal Republic of Nigeria.

EXPLANATORY NOTE

(This note does not form part of the above Decree but is intended to explain its purpose)

The Decree, among other things, prohibits the manufacture, importation, advertisement, sale or distribution of drugs, drug products, cosmetic or medical devices which are not registered under its provisions.

The Decree also establishes a Drug Registration Committee to evaluate the formation and method of preparation of drugs, drug products, cosmetics and medical devices.