A BILL

FOR

AN ACT TO AMEND THE NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL ACT, CAP. N1, LAWS OF THE FEDERATION OF NIGERIA 2004, TO INCLUDE THE REGULATION OF HERBAL DRUGS (AGBO) AND FOR RELATED MATTERS, 2025

Sponsored by Hon. Jesse Okey-Joe Onuakalusi

[ ] Commencement

BE IT ENACTED by the National Assembly of the Federal Republic of Nigeria as follows-

1. There shall be established an Act to amend the National Agency for Food and Drug Administration and Control Act, Cap. N1, Laws of the Federation of Nigeria 2004 (The principal Act) hereinafter referred to as, 'The Amendment Act 2025' Establishment

2. This amendment is to, as one of National Agency for Food and Drug Administration and Control (NAFDAC) functions, include Regulation, Monitoring, Control the Production, Importation, Exportation, Advertisement, Distribution, Sales and use of Herbal Medicine popularly known as Agbo in Yoruba language. Objectives

3. (A) The Principal Section 5 and the Amendments: Amendment of Sections

Subsection (a) 'regulate and control the importation, exportation, manufacture, advertisement, distribution, sale, and use of food, drugs, cosmetics, medical devices, bottled water and chemicals' is amended to read,

Subsection (a) 'regulate, monitor and control the production, importation, exportation, advertisement, distribution, sale and use of herbal drugs, including but not limited to Agbo, alcoholic beverages and other traditional medicinal products'.

Subsection (k) 'grant authorization for the import and export of narcotic

drugs and psychotropic substances as well as other controlled substances', is amended to read,

Subsection (k) 'grant authorization for the import and export of narcotic drugs and psychotropic substances as well as other controlled substances, to register, certify and regulate all her drugs and traditional medicinal products, ensuring their safety, efficacy and quality'.

Subsection (I) 'collaborate with the National Drug Law Enforcement Agency in measures to eradicate drug abuse in Nigeria,' is amended to read:

Subsection (I) 'collaborate with the National Drug Law enforcement Agency in measures to eradicate drug abuse in Nigeria, to establish standards for the production, packaging, labeling and advertisement of herbal drugs and traditional medicinal products;'

Subsection (m) 'advise Federal, State and Local government, the private sector and other interested bodies regarding the quality, and regulatory provisions on food, drugs, cosmetics, medical devices, bottled water and chemicals;' is amended to read:

Subsection (m) 'advise Federal, State and Local government, the private sector and other interested bodies regarding the quality, and regulatory provisions on food, drugs, cosmetics, medical devices, bottled water and chemicals, to conduct regular inspections of facilities producing herbal drugs and traditional medicinal products to ensure compliance with Good Manufacturing Practices (GMP);'

Subsection (n) 'undertake and coordinate research programmes on the storage, adulteration, distribution and rational use of food, drugs, cosmetics, medical devices, bottled water and chemicals;' is amended to read,

Subsection (n) 'undertake and coordinate research programmes on the storage, adulteration, distribution and rational use of food, drugs, cosmetics, medical devices, bottled water and chemicals, to monitor and evaluate the safety and efficacy of herbal drugs and traditional medicinal products through clinical trials, laboratory analysis, and post-market surveillance;'

Subsection (o) 'issue guidelines on, approve and monitor the advertisement of food, drugs, cosmetics, medical devices, bottled water and chemicals;' is amended to read,

Subsection (o) 'issue guidelines on, approve and monitor the advertisement of food, drugs, cosmetics, medical devices, bottled water and chemicals, to collaborate with traditional medicine practitioners, researchers, and other stakeholders to promote the safe use of herbal drugs and traditional medicinal products:

Subsection (p) 'compile and publish relevant data resulting from the performance of the functions of the Agency under this Act or from other sources;' is amended to read:

Subsection (p) 'compile and publish relevant data resulting from the performance of the functions of the Agency under the Act or from other sources, to educate the public on the risks associated with unregulated herbal drugs and the benefits of using certified products:

Subsection (r) 'liaise with relevant establishments within and outside Nigeria in pursuance of the functions of the Agency;' is amended to read:

Subsection (r) 'liaise with relevant establishments within and outside Nigeria in pursuance of the functions of the Agency to regulate, control, and ensure the safety, efficacy, and quality of herbal drugs, commonly known as Agbo, and other traditional medicines prepared for sale, distribution, or public consumption."

(B) The Principal Act Section 8 and the Amendments:

Section 8 of the Principal Act is amended to have Subsections 1 and 2 to read:

Section 8 Subsection (1); The Establishment of Traditional Medicine Advisory Committee (TMAC);

Subsection (1) There is hereby established a Traditional Medicine Advisory Committee (TMAC) within the Agency.

Subsection (l)(i) The Traditional Medicine Advisory Committee (TMAC)

shall consist of:

(a) a Chairperson, who shall be an expert in pharmacognosy or traditional medicine:

(b) representatives of traditional medicine practitioners:

(c) representatives of the Ministry of Health:

(d) representatives of relevant research institutions:

(e) representatives of the pharmaceutical industry; and

(f) such other members as the Agency may determine.

Subsection (l)(ii) The functions of the Traditional Medicine Advisory Committee (TMAC)-

(a) advising the Agency on matters relating to the regulation of herbal concoctions and traditional medicinal products:

(b) facilitating the documentation and standardization of traditional knowledge and practices:

(c) promoting research and development in the field of traditional medicine:"

(d) fostering collaboration between traditional medicine practitioners and the Agency.

Section 8 Subsection (2); Structure Of The Agency;

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.

(C) The Principal Act Section 25 (Offences) and ahe Amendments: Section 25 of the Principal Act (Offenses) is amended to have subsections 1 to 6 to read;

(1) Any person who manufactures, distributes, sells, or administers herbal drugs (Agbo) without registration, standardization, or compliance with the guidelines prescribed by the Agency, commits an offence and shall be liable upon conviction to a fine of not less than N5.000,000 (Five Million Naira) or imprisonment for a term not exceeding five (5) years, or both.

(2) A person who obstructs an officer of the Agency in the performance of his duties under section 24 of this Act shall be guilty of an offence and liable on conviction to a fine of N5,000 or to imprisonment for a term not exceeding two years or to both such fine and imprisonment.

(3) Any person who contravenes the provisions of any regulation made under this Act is guilty of an offence and liable on conviction to the penalties specified in the regulations (no. 19 of 1999.).

(4) Where no penalty has been specified, the person shall be liable to a fine of #50,000 or imprisonment for a term of one year or to both such fine and imprisonment

(5) Where an offence under this Act which has been committed by a body corporate is proved to have been committed with the consent or connivance of, or to be attributable to any neglect on the part of any director, manager, secretary or other similar officer of the body corporate or any person purporting to act in any of those capacities, he as well as the body corporate, shall be deemed to be guilty of the offence and shall be liable on conviction to a fine of N100,000.

(6) The Federal High Court shall have exclusive jurisdiction to try offences under this Act. (no. 62 of 1999.)

(D) The Principal Act Section 30 is amended to have subsection 1,2 & 3.

Section 30(1) Power ro make regulations;

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 act.

Section 30(2) Establishment of Herbal Drugs and Traditional Medicine Regulatory Department;

There is established within the Agency a department to be known as the Herbal Drugs and Traditional Medicine Regulation Department (hereinafter referred to as "the Department"), which shall be responsible for:

(a) Registering all herbal Drugs (Agbo) and ensuring compliance with safety and hygiene standards;

(b) Conducting research, testing, and certification of herbal preparations to ascertain their safety and efficacy:

(c) Issuing guidelines and standard procedures for the preparation, packaging, and sale of herbal drugs;

(d) Collaborating with traditional medicine practitioners, herbalists, and relevant stakeholders to ensure best practices in herbal medicine production; and

(e) Carrying out public awareness campaigns on the risks and benefits associated with herbal drugs."

Section 30(3}Registration of Products with the Agency;

(3)(a) All producers, importers, exporters, distributors and sellers of herbal drugs and traditional medicinal products shall, within 12 months from the commencement of this Amendment, register their products with the

Agency and comply with the standards set forth under this Act;

(b) The Agency shall, during the transitional period, conduct public awareness campaigns to educate stakeholders on the requirements of this Amendment.

(E) The Principal act Section 31 'Enterpretation' is amended to add Herbal Drugs (Agbo);

The Principal Act is amended by including the definition:

“Herbal drugs (Agbo)" means any preparation derived from plants, roots, leaves, barks, seeds, or other natural sources, traditionally used for therapeutic, medicinal, or health purposes, whether mixed with other substances or not, and intended certified for human consumption."

4. This Bill may be cited as the National Agency for Food and Drug Administration and Control (Amendment) Bill, 2025. Citation

EXPLANATORY MEMORANDUM

This Bill seeks to amend the National Agency for Food and Drug Administration and Control (NAFDAC) to regulate herbal drugs, including Agbo, and other traditional medicinal products. The Amendment aims to ensure the safety, efficacy and quality of these products, protect public health and promote the growth of the traditional medicine sector in Nigeria.