NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL (NAFDAC)

TERMS OF REFERENCE FOR ENGAGEMENT OF EXPERTS

REGULATORY FUNCTION: DRUG REGISTRATION AND REGULATORY AFFAIRS [NAFDAC Drug Registration External Advisory Committee]

1.0 Introduction

The NAFDAC Drug Registration External Advisory Committee (NDREAC), an advisory body, shall make technical recommendation and advise the Agency on quality, safety and efficacy issues to support NAFDAC in fulfilment of her regulatory functions. However, the decision-making responsibility remains with NAFDAC.

The NAFDAC Drug Registration External Advisory Committee (NDREAC) operates in accordance with the NAFDAC Act (Cap N1. LFN),2004 section 12 of the Food, Drug and Related Products (Registration, etc) Act (Cap.F33, LFN)2004 which empowers NAFDAC to regulate and control the manufacture, importation, exportation, distribution, advertisement, sale and use of drugs in Nigeria.

2.0 Purpose

The purpose of the Terms of Reference is to define the responsibilities, composition, and standard of conduct of the NDREAC of the National Agency for Food and Drug Administration and Control (NAFDAC).

3.0 Responsibilities

3.1.0 The advisory committee will, among other deliverables:

3.1.1 Study and recommends ways to encourage the availability of an adequate supply of safe, quality and effective drugs in the Nigeria

3.1.2 Recommends measures that will enhance drug safety and efficacy.

3.1.3 Advice on appropriate risk management plans and guide the Agency on the development of sound public health policy aimed at reducing incidence of drug-related adverse events.

3.1.4 Review and evaluate data concerning the safety, effectiveness, appropriate use of drugs, related drug products which are intended for use in the prevention, treatment or diagnosis of human diseases.

3.1.5 To advice and make recommendations relating to drug safety on novel chemical entities and adjuvants.

3.1.6 To advice on technical regulations in line with global best practice.

3.1.7 Provide advice on drug dosages and adverse event following drug usage/administration.

3.1.8 To make recommendation on communication to the public on drug safety

3.1.9 Advise on such other matters relating to drug and related products as may be necessary or expedient for advancement of public safety.

3.1.10 The committee shall adhere to laid down documented procedures.

3.1.11 The committee shall submit recommendations to the DG.

4.0 Membership

4.1 The NDREAC is composed of multidisciplinary members, independent in its reflection, advice and decision. It is constituted and operates under the authority of the Director-General (DG) of NAFDAC.

4.2 The DG (NAFDAC) appoints not less than four (4) external members of the committee who are experts in pharmaceutical science, regulatory science, drug development including, clinical evaluation programs, allergy, therapeutic medicine, and other relevant sciences.

Other members include:

4.3 The Director, Drug Registration and Regulatory Affairs Directorate shall be a co-chairperson of the NDREAC with an external expert appointed by the DG (NAFDAC).

4.4 The Director, Drug Evaluation and Research Directorate.

4.5 The Director, Pharmacovigilance Directorate.

4.6 The Director, Ports Inspection Directorate.

4.7 The Director, Drug Laboratory Services Directorate. (D-LSD shall serve as the secretariat)

5.0 Tenure

5.1 The appointment shall be for a period of two (2) years which is renewable.

5.2 A member may resign or be requested to do so by the DG (NAFDAC) for good cause on the written recommendation of the Chairperson.

5.3 When a member resigns, the DG (NAFDAC) should fill the vacancy by appointing a person for the unexpired portion of the term of office of the Committee.

5.4 A member who fails to observe committee meeting attendance requirements, who fails to carry out duties and allocated tasks as required by the Chairperson, or who discloses a significant conflict of interest that cannot be managed appropriately may be requested to resign from the committee.

5.0 **Meetings**

5.1 Scheduling: The Agency shall be saddled with responsibility of scheduling regular advisory meeting so that any matter for consideration by the committee can be presented within 4 weeks of its being ready for review. The matter is considered for review when the Agency and applicant have completed all initial preparatory work and communicate same to the Agency.

5.2 Frequency- Meeting shall be held quarterly. However, emergency meeting may be scheduled at reasonably short notice to members.

5.3 Quorum- Two thirds of the member need to be present to hold an advisory committee meeting, all members of the committee should be VOTING member except Ad-hoc members.

5.4 Secretariat- D-LS directorate shall serve as the secretariat and the Director will appoint a secretary to the committee on a level not lower than Assistant Chief Regulator Officer.

5.5 Meeting outcome: The records and outcome of the meeting is to be made available by the secretariat to NAFDAC management through Director-General for consideration and further necessary action.

6.0 **Standard of Conduct Expected of Members.**

In carrying out their duties, members of committee must.

6.1 Uphold ethical standards by acting to foster public confidence in the NDREAC' s ability to act in the public interest and for long term public good.

6.2 Demonstrate integrity, honesty, good judgement, and professionalism.

6.3 Make decisions in the interest of NDREAC, with a view to the public interest, and with regard to the merits of each case.

6.4 Disclose fully any private or professional interests that could affect NDREAC actions or that could present a potential conflict of interest and put ethical practice at risk.

7.0 **Conflict of Interest**

7.1 A conflict of interest occurs when an individual has an interest that competes with the interests of the NDREAC. The competing interest may be real, potential or perceived, direct or indirect.

7.2 All activities that involve research, commercial or financial interests, whether real, potential or perceived, which may conflict with an interest of the NDREAC or with the duties of an individual member, must be disclosed promptly to NAFDAC.

8.0 **Remuneration**

Committee members shall be compensated for their time and expertise through moderate remuneration of their transport, accommodation and sitting allowance, paid per sitting.

9.0. **Misconduct**

The following shall constitute a misconduct:

9.1. Misleading the NDREAC or misrepresenting the NDREAC

9.2. Abuse of privileged information

9.3. Fabrication or falsification of reports

9.4. Failure to disclose a material conflict of interest.

9.5. Divulging confidential information to a third party without permission

9.6. Failure to attend a minimum of two consecutive NDREAC meetings.

Legend

TOR – Terms of Reference

NDREAC - NAFDAC Drug Registration External Advisory Committee.

DR&R- Drug Registration and Regulatory Affairs Directorate.

DER-Drug Evaluation and Research

PID-Ports Inspection Directorate

PV-Pharmacovigilance Directorate

PMS-Post Marketing Surveillance Unit (DGs-Office)

D-LSD Vaccine, Drug Laboratory Services Directorate