



NAFDAC
TERMS OF REFERENCE FOR ENGAGEMENT OF EXPERTS

NAFDAC-TOR- XXX-01-00:

REGULATORY FUNCTION:

1. Introduction

There is established a National Drug Safety Advisory Committee (NDSAC) made up of members that possess a minimum of medical and pharmaceutical expertise. Members of the Committee shall be appointed by the Minister of Health on the recommendation of the Director-General of NAFDAC. The Committee shall provide medical and scientific advice on current and emerging issues related to Pharmacovigilance. The Committee Chair shall be elected by the members of the Committee and the Head of the National Pharmacovigilance Centre shall serve as the Secretary of the Committee.

2. Purpose

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

3. Responsibilities

- *Provide medical and scientific advice on current and emerging issues related to Pharmacovigilance.*
- *Assess safety issues related to rational use of medicine.*
- *Validate assessments including causality assessment of ICSRs and possible medication errors*
- *Recommend pharmacoepidemiologic or other research activities related to safety of medicines*
- *Make appropriate recommendation to the Director- General of NAFDAC on any necessary regulatory actions and/or information dissemination related to medicine safety.*
- *Advice on specific issues related to Pharmacovigilance.*
- *Assist in the promotion of Pharmacovigilance activities.*

4. Membership

The members of the Committee shall be professionals with medical and pharmaceutical expertise/specialty from fields including:

- *Clinical Medicine*

- *Pharmacy*
- *Pharmacology*
- *Toxicology*
- *Epidemiology*
- *Herbal Medicine*
- *Other Medical/Pharmaceutical specialties that are deemed necessary when pertinent issues of medicine safety arise.*

5. 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.*

6. Meetings

The Committee shall meet on a quarterly basis (every 3 months) and urgent meetings can be held when medicine safety emergencies arise.

A Quorum for a meeting shall be by a simple majority of the members of the committee are present and decisions shall be made by the members arriving at a consensus.

The secretary of the committee shall be the Director Pharmacovigilance and Post Market Surveillance (PMS).

The meeting outcome will be highlighted in details in Minutes which will be circulated to all members. The recommendation in the minutes will be used to take necessary regulatory decision.

7. Standard of Conduct Expected of members

- 7.1 *In carrying out their duties, members of committee must;*
- 7.1.1 *Uphold ethical standards by acting to foster public confidence in the advisory committee's ability to act in the public interest and for long term public good.*
- 7.1.2 *Demonstrate integrity, honesty, good judgement and professionalism.*
- 7.1.3 *Make decisions in the interest of advisory committee, with a view to the public interest, and with regard to the merits of each case.*
- 7.1.4 *Disclose fully any private or professional interests that could affect advisory committee actions or that could present a potential conflict of interest and put ethical practice at risk.*

8. Conflict of Interest

- 8.1 *A conflict of interest occurs when an individual has an interest that competes with the interests of the advisory committee. The competing interest may be real, potential or perceived, direct or indirect.*
- 8.3 *All activities that involve research, commercial or financial interests, whether real, potential or perceived, which may conflict with an interest of the CTAC or with the duties of an individual member, must be disclosed promptly to NAFDAC.*

9. Remuneration

- 9.1 *Committee members shall be compensated for their time and expertise through moderate remuneration of their*

transport, accommodation and sitting allowance, paid per sitting.

10. Misconduct

- 10.1 The following shall constitute a misconduct.
- 10.1.1 Misleading the advisory committee or misrepresenting the advisory committee
- 10.1.2 Abuse of privileged information
- 10.1.3 Fabrication or falsification of reports
- 10.1.4 Failure to disclose a material conflict of interest
- 10.1.5 Divulging confidential information to a third party without permission
- 10.1.6 Failure to attend a minimum of two consecutive advisory committee meetings.

Prepared by: Dr Abiodun Abiola-S. Date: 2/05/2020

Approved by: Phem Uchebo Elenwa Date: 2/05/2020

Legend

TOR - Terms of Reference
XXX- Originating directorate
01- Serial number
00- Version number