NAFDAC GOOD MANUFACTURING PRACTICE (GMP) EXPERT ADVISORY COMMMITTEE

TERMS OF REFERENCE

1. Introduction

The NAFDAC Good Manufacturing Practice (GMP) Expert Advisory Committee (NGMP-EAC) is an independent external advisory body to provide NAFDAC with scientific advice on issues related to Good Manufacturing Practice of pharmaceutical, cosmetics, herbal medicines and medical device products. The NGMP-EAC offers expert recommendations to assist the Agency in making appropriate regulatory decisions, however, the decision-making responsibility remains with NAFDAC.

The NGMP-EAC operates in accordance with the NAFDAC cGMP for Medicinal Products Regulations 2021 and all other NAFDAC Regulations and Guidelines applicable to ensuring manufacture of quality, safe and efficacious pharmaceutical products, herbal medicines and medical devices as well as safe and quality cosmetics products.

2. Purpose

The purpose of the Terms of Reference is to define the responsibilities, composition, and standard of conduct of NAFDAC GMP Expert Advisory Committee.

3. Responsibilities

3.1 The primary focus of the Committee's deliberations should be the protection of public health by providing advice that will ensure only pharmaceutical, herbal, medical devices and cosmetics products manufactured in compliance with the GMP regulations and guidelines are approved by the Agency.

3.2 The Committee should provide advice to enable the establishment of systems that support continued compliance of the manufacturing industry with regulatory requirements.

3.3 The Committee should submit recommendations to the DG (NAFDAC).

4. Membership

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

4.2 The DG (NAFDAC) appoints not less than four (4) members of the Committee with expertise in GMP Regulations and Guidelines as well as Inspectorate operations.

4.3 The Chairperson of the Committee is appointed by the DG (NAFDAC).

4.4 The appointment shall be for a renewable period of two (2) years.

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

4.6 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.

4.7 A member who fails to observe Committee meeting attendance requirements, who fails to carry out duties and assigned 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. Meetings

5.1 The Committee meets twice in a year, and may meet as often as required, to review and provide recommendations regarding GMP-related matters.

5.2 A quorum consists of a simple majority (fifty per cent plus one).

5.3 Decisions should be reached by consensus if possible. When a vote is required, a simple majority serves, with the Chairperson having a casting vote in addition to his/her deliberative vote, should the vote be tied.

5.4 Records of meetings must be made available to DG (NAFDAC).

6. Standard of Conduct Expected of Members

6.1 In carrying out their duties, members of the Committee must:

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

6.1.2 Demonstrate integrity, honesty, good judgment, and professionalism.

6.1.3 Make recommendations in the interest of the Committee, with a view to benefit public interest, and with regard to the merits of each case.

6.1.4 Disclose fully any private or professional conflict of interests that could affect the Committee's actions or that could present a potential conflict of interest and put ethical practice at risk.

7. Conflict of Interest and Confidentiality

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

7.2 All activities that involve GMP inspections, commercial or financial interests, whether real, potential or perceived, which may conflict with an interest of the Committee or with the duties of an individual member, must be disclosed promptly in writing to the DG-NAFDAC.

7.3 Committee members shall treat all information obtained or accessed during the performance of their duties with utmost confidentiality and shall not divulge such information to a third party without permission of the DG-NAFDAC.

8. Remuneration

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

9. Misconduct

9.1 The following shall constitute misconduct:

9.1.1 Misleading or misrepresenting the Committee.

9.1.2 Abuse of privileged information.

9.1.3 Fabrication or falsification of reports.

9.1.4 Failure to disclose conflict of interest.

9.1.5 Divulging confidential information to a third party without permission.

9.1.6 A failure to attend a minimum of two consecutive Committee meetings.