Establishing the AMRH Partnership Platform

African-Chapter of the WHO Coalition of Interested Partners

CALL FOR EXPRESSION OF INTEREST TO JOIN THE AMRH PARTNERSHIP PLATFORM

February 2018

African Medicines Regulatory Harmonization (AMRH) Programme

African Union

World Health Organization

NEPAD
TRANSFORMING AFRICA

THE WORLD BANK
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BILL & MELINDA GATES foundation

1. About AMRH

The African Medicines Regulatory Harmonisation (AMRH) Programme aims to improve access to medicines through harmonisation of regulatory requirements to ensure quality, safe and efficacious medicines are available to African citizens. AMRH is a framework which provides an enabling regulatory environment for pharmaceutical sector development in Africa by promoting the harmonisation of medicines regulation among African countries through Regional Economic Communities (RECs), Regional Health Organizations (RHOs) and National Medicines Regulatory Authorities (NMRAs).

NEPAD Agency and its AMRH Partners[1] are supporting RECs, RHOs and their member states in reviewing medicines regulatory policies, structures and systems and strengthening legal and institutional frameworks for effective medicines regulation. This is demonstrated by the increased use of harmonized policies and regulatory frameworks by member states, increased human and institutional capacity for regulation of medical products and technologies, and improved regulatory standards and practices through knowledge generation and shared learning.

2. Rationale for AMRH Partnership Platform

As part of its strategy to strengthen medical products regulatory capacity, the AMRH Programme is in the process of establishing the AMRH Partnership Platform (APP). The partnership platform is intended to serve as a robust coordination mechanism to enhance efficiency and effectiveness in the implementation of the medical products regulatory systems strengthening and harmonization agenda in Africa, through optimal coordination of the different partners and stakeholders providing regulatory support on the continent.

The establishment of the AMRH Partnership Platform aligns with the direction the World Health Organization (WHO) is undertaking and serves as the African-chapter of the WHO-Coalition of Interested Partners (CIP). This is a collective multi-stakeholder mechanism with a continent-wide common perspective to ensure that partners build on progress made in the implementation of AMRH and various regulatory systems strengthening programmes and harmonization initiatives.

Strategically, the AMRH PP is expected to;

a) Increase collaboration among stakeholders supporting regulatory systems development in Africa;
b) Foster mutual responsibility, accountability and shared impact; and ultimately;
c) Minimize duplication; and
d) Coordinate efforts at all levels of implementation of the medical products regulatory work in Africa.

[1] The AMRH Partnership includes African national medicines regulatory agencies (NMRAs), regional economic communities (RECs), NEPAD Agency, Pan African Parliament (PAP), African Union Commission (AUC), World Health Organization (WHO), World Bank (WB), Bill and Melinda Gates Foundation (BMGF) and the UK Department for International Development (DFID)

3. Categories of Partners

Partners investing in different thematic areas of medical products regulatory systems strengthening and harmonization will be identified and categorized in the following thematic areas;

a) Dossier review and registration
b) GMP inspections
c) Pharmacovigilance
d) Clinical trials
e) Post marketing surveillance
f) Quality control and quality assurance
g) Medical devices & diagnostics
h) Blood and Blood Products
i) Policy and regulatory reforms
j) Regulatory capacity building
k) Other (Specify)

4. Eligibility criteria for selection of AMRH Partners

Members shall be institutions or representative of any other legal entity namely; organizations, companies or corporations that share the same goals, principles and values of jointly advancing the medical product regulatory systems strengthening and harmonization agenda across the African Continent.

Members shall be drawn from the following groupings; intergovernmental organizations, funders/donors, pharmaceutical industry, civil society organizations (CSOs), research and academic institutions and private sector among others.

The following shall constitute requirements for consideration as an AMRH Partner:

a) Members shall be ready to comply with the operating principles of the platform (Refer to the Accountability Framework for AMRH Stakeholders).
b) Clearly defined statement of roles and responsibilities towards achieving the AMRH overall goal in line with identified and agreed thematic areas of support e.g. technical, financial or policy advocacy.
c) Willingness to align and harmonize efforts with like-minded partners in order to avoid duplication and ensure clarity.
d) A duly completed expression of interest form indicating the area of interest, competency and existing expertise will be filled by members intending to join the AMRH Partnership Platform as per **Annex I** below**.**

5. Selection Process

The selection process for becoming an AMRH Partner will include:

a) Application: Submission of expression of interest form to the AMRH Secretariat
b) Assessment: Assessment of expressions of interest, short-listing and audits

c) Selection : Selection shall be based on the eligibility criteria outlined above
d) Performance Evaluation/Review: monitoring for continued performance based on agreed targets and metrics

6. Where to send applications and supporting documents

NEPAD Agency as the Secretariat to the AMRH Steering Committee invites eligible partners to express an interest to become an AMRH Partner in the categories of regulatory functions and streams of work outlined above.

If you require more information on the above subject, please visit the AMRH Programme on the NEPAD website www.nepad.org or email all inquiries to nancyn@nepad.org or call Nancy Ngum at +27 11 256 3557.

Applications should clearly state the scope of functions and/or category of product/s applied for together with comprehensive supporting documentation on meeting the eligibility criteria outlined.

All applications with supporting documentation should be addressed to:

Margareth Ndomondo-Sigonda
Head, Health Programs
African Union-NEPAD Planning and Coordinating Agency
Email: margarets@nepad.org and copy to nancyn@nepad.org

Deadline: Applications should be received on or before **15th March 2018**

Disclaimer: The NEPAD Agency, AMRH Programme and AMRH Partners reserve the right to accept or reject any application without assigning reasons.

ANNEX 1: EXPRESSION OF INTEREST FORM TO JOIN THE AMRH PARTNERSHIP PLATFORM

1. **NAME OF ORGANISATION/INSTITUTION:**

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2. **NAME OF NOMINATED REPRESENTATIVE:**

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3. **POSITION OF THE NOMINATED REPRESENTATIVE IN THE ORGANIZATION:**

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4. **CONTACT DETAILS**

   a) **NOMINATED REPRESENTATIVE DETAIL (PHONE AND EMAIL):**

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   b) **ORGANIZATION DETAILS (PHONE AND EMAIL)**

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5. **AREA OF INTEREST:**

   a. Dossier review and registration
   b. GMP inspections
   c. Pharmacovigilance
   d. Clinical trials
   e. Post marketing surveillance
   f. Quality control and quality assurance
   g. Medical devices & diagnostics
   h. Blood and Blood Products
   i. Policy and regulatory reforms
   j. Regulatory capacity building
   k. Other (Specify)

6. STATE ROLES AND RESPONSIBILITIES(Based on current work in Africa- Maximum 3 paragraphs) :

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7. PROVIDE SUMMARY OF TECHNICAL COMPETENCY AND EXISTING EXPERTISE:

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8. DATE: ---

9. NAME AND SIGNATURE BY OFFICIAL SIGNATORY:
