

NEPAD seeks champions

The New Economic Partnership for African Development (NEPAD) is looking for experts around Africa to join it in moving the African Medicines Regulation agenda forward

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. It 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 Organisations (RHOs) and National Medicines Regulatory Authorities (NMRAs).

NEPAD Agency and its AMRH Partners 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 harmonised 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.

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 harmonisation 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

Interested? 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-SigondaHead, Health Programmes, African Union-NEPAD Planning and Coordinating Agency: Email: margarets@nepad.org and copy to nancyn@nepad.org

partners build on progress made in the implementation of AMRH and various regulatory systems strengthening programmes and harmonisation 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) minimise duplication; and (d) coordinate efforts at all levels of implementation of the medical products regulatory work in Africa.

Partners investing in different thematic areas of medical products regulatory systems strengthening and harmonisation will be identified and categorised 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.

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

Members shall be drawn from the following groupings; intergovernmental organisations, funders/donors, pharmaceutical industry, civil society organisations (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 harmonise 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.

The selection process for becoming an AMRH Partner will include the assessment of submitted expression of interest forms. Organisations or individuals selected will expect to be monitored for continued performance based on agreed targets and metrics.