I. Introduction and Context

Country Context
Access to medicines is a key element of a well-functioning health system. Strong governance of the pharmaceutical sector and effective, independent, and transparent regulatory systems provide the necessary foundation for greater access to medicines.

Every country is obligated to regulate the pharmaceutical products sold within its borders. This includes, among others, pre-approval scientific assessment of essential medicines (registration) so that citizens can access these medicines and be assured that they meet acceptable standards of safety, quality, and efficacy. But several constraints exist in fulfilling these obligations in developing countries especially in the Africa Region. The five countries in the East Africa Region lack sufficient regulatory capacity to approve medicines for sale in a timely manner ensuring acceptable quality, safety, and efficacy standards. Manufacturers on their part are confronted with numerous and different regulatory requirements, delays in registration, and little process transparency. As a result, the availability of some much-needed medicines is delayed.

Global experiences, especially from the European Union, suggest that collective action at the regional level helps in promoting harmonization. A regional approach helps member countries to develop regionally relevant norms and standards and adhere to such norms through appropriate institutional capacity building for implementation. This approach also helps the member countries to collectively voice their needs in regional and international forums and share information. In the Africa Region, there is a strong ownership both at national and regional levels for such a coordinated approach facilitated by regional economic blocks.

Sectoral and Institutional Context
The East African Community (EAC) is a regional intergovernmental organization consisting of five partner states (Burundi, Kenya, Rwanda, Tanzania and Uganda) with combined estimated population of about 120 million distributed over a land area of 2 million square kilometers. Together, their combined gross domestic product is USD 41 Billion. The EAC member or partner states are committed to a regional cooperation and integration framework. This commitment is outlined in the EAC Treaty which calls for partner states to effectively align areas of common interest. The EAC has 6 National Medicine Regulatory Agencies (NMRAs) which vary widely in institutional capacity and infrastructure as well as requirements to register new medicines. As a result, manufacturers have to fill multiple forms to obtain licenses to market new products which delays access to new medicines to the people of East Africa. Moreover, this inefficiency adversely affects the growth of the local industry which is important for improving access to essential medicines for regionally important neglected diseases such as malaria and onchocerciasis. Also, with variations in capacity and licensing requirements among the NMRAs, there is a high risk of poor quality medicines moving across the EAC member states.

The African Medicines Registration Harmonization (AMRH) initiative has been in existence for about three years and has benefitted from the involvement and the provision of grant funding from the Bill & Melinda Gates Foundation (BMGF) to the World Health Organization (WHO) and the New Partnership for Africa’s Development (NEPAD) Coordinating Agency in the last two years. The more recent involvement of the World Bank serves to create a standardized approach to implement and scale-up AMRH, utilizing funds from various sources, including the BMGF and other donor agencies.
With its strong convening power, ongoing engagement and policy dialogue at country and regional levels, and proven ability to develop and scale-up standardized approaches for public sector reforms to improve services for the poor, the World Bank is uniquely placed to support AMRH. Furthermore, the Bank can also take the lessons learned from the AMRH effort and promote them in other regions where relevant needs exist through the global multi-donor trust fund being established by the HNP Anchor.

In consultation with member states and with technical support from NEPAD and WHO, the East African Community (EAC) has prepared the first comprehensive regional proposal for receiving the AMRH grant. The EAC proposal has well-defined results framework and implementation arrangements to promote regulatory harmonization among the 6 NMRAs in the region. There is strong regional commitment to medicine harmonization as articulated by the EAC Treaty. The AMRH proposal, including approval for incremental staffing required for institutional strengthening, has been endorsed by the EAC Council of Ministers. Taken together, these reasons justify the selection and inclusion of the EAC as a grantee in the first phase of AMRH.

Relationship to CAS
The proposed grant is fully consistent with the #Africa Regional Strategy# which aims to enhance governance and public sector capacity to improve systems for delivering basic health services and manage accounts. Medicines regulation is a core public health function and improved governance and harmonization with international standards will improve availability of more efficacious medicines for neglected diseases as well as promote the growth of local industry. It is also consistent with the Regional Integration Assistance Strategy (RIAS) approved by the Board in April 2008. Specifically, it fits under the Pillar III of the RIAS (Coordinated Interventions to provide Regional Public Good), as it will (i) build capacities of NMRAs to harmonize policies, strategies and actions for the registration of essential medicines and vaccines and (ii) promote coordinated cross country response in the EAC region for the improved quality of essential medicines.

The AMRH initiative is well aligned with Bank#s global strategies in two main areas (i) #The post crisis directions# give strategic thrust to vulnerability and resilience; and the orientation of IDA-16 to support initiatives which foster regional integration. Finally, the health sector strategies of five EAC countries (Burundi, Kenya, Rwanda, Tanzania and Uganda) recognize the burden of communicable diseases and the need to control them. Country Assistance/Partnership Strategies also aim to strengthen the health systems and promote regional integration. The ongoing IDA operations have strong focus on strengthening governance and accountability in the sector and improve systems for procurement and supply chain of essential medicines and medical supplies. Therefore, the proposed grant is fully consistent with the country strategies and ongoing Bank operations.

II. Proposed Development Objective(s)

Proposed Development Objective(s)
To strengthen capacities of the East African Community partner states to harmonize medicines registration systems and to improve efficiency and enhance transparency in medicines registration.

Promoting the harmonization of medicines registration in Africa as a means to increase access to safe, effective, and good-quality essential medicines is an integral part of a well-functioning health system and therefore has a strong strategic fit with the health systems strengthening (HSS) focus of the Bank. Furthermore, there is a strong economic justification to be made as harmonizing registration systems and protocols across several countries helps in reducing inefficiencies. This is expected to promote growth of local pharmaceutical industry and make the region more attractive for potential foreign investors/manufacturers.

The success of the AMRH initiative is expected to result in a continuum of change, starting with the use of harmonized protocols by the countries and gradually moving towards a system of mutual recognition by countries within the regional economic block. Finally, it could result in a broader harmonized regulatory environment that extends beyond the EAC to other RECs in the African region.

Key Results
1. NMRAs using EAC harmonized formats for at least half of the new medicines registered (Target 4)
2. NMRAs using electronic submission of applications for registering medicines (Target 3) (Target: 3).
3. NMRAs sharing regulatory policies, legislation, guidelines and information (e.g. registered medicines, counterfeit and substandard drugs etc) on their websites (Number).
4. NMRAs in the EAC region which received International Standards Organization (ISO) certification on quality management system (Target 3).
5. Direct project beneficiaries (Number)

III. Preliminary Description

Concept Description
To achieve the development objectives, the project proposes to have two components:

**a) Regional Coordination and Capacity Building for Medicines Regulatory Harmonisation (USD 5.80 million):** This activity will be led by the EAC and includes the establishment of the regional steering Committee, project coordination team, regional technical working groups, regional capacity building at EAC level and support to country focal points for developing harmonized protocols for medicines registration and GMP inspections. The intermediate outcomes will include harmonized guidelines, standard operating procedures and manuals by 2012, and the establishment of the EAC Commission on Medicines and Food Safety by 2015. The activities supported will include operating costs at EAC level but most of the funds are expected to be used for the direct benefit of the NMRAs in EAC countries.

The EAC will contract an ICT consulting agency to undertake a comprehensive systems requirement study for medicines registration at the national and regional levels, and to develop a national and regional web-based data management information system for effective sharing of information on medicines registration by 2013. Countries are expected to start using the information management system for medicines registration from 2014.

**b) Institutional Development and Strengthening of National Medicines Regulatory Authorities (USD 4.2 Million):** The support to NMRAs will be based on the institutional assessments undertaken by NEPAD and WHO. The project will support additional staff for newly established NMRAs and training of staff in areas of project management (25); quality assessment and safety of medicines (24); GMP inspections (24); and assessments and exchange visits for regulatory staff within and outside the region. The project will also support twinning of newly established NMRAs with existing NMRAs in the region including implementation of quality management systems as well as internal and external audits to enable a number of the NMRAs to achieve ISO certification in quality management system by 2015.

The activities supported include personnel, training, consultant support, supply of ICT equipment and software, ISO certification, country level workshops and meetings. The project will support appropriate ICT hardware and software procurement, consultant support including licensing, maintenance and training at NMRA and EAC levels and any required capacity building activities. It is expected the NMRAs will be using a common information management system for medicines regulation from 2014 onwards. Among participating NMRAs, the project will support the development of regional centres for regulatory excellence covering areas such as Quality Management Systems, ICT, Registration, Pharmacovigilance and GMP. It is expected that from 2013, these centres of excellence will serve as training facilities for in-service training of the regulatory staff and help the countries to move toward effective implementation of the mutual recognition policy frameworks and guidelines.

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**VI. Contact point**

**World Bank**

Contact: Gandham N.V. Ramana  
Title: Lead Health Specialist  
Tel: 5368+6376  
Email: gramana@worldbank.org

Borrower/Client/Recipient
VII. For more information contact:
The InfoShop
The World Bank
1818 H Street, NW
Washington, D.C. 20433
Telephone: (202) 458-4500
Fax: (202) 522-1500
Web: http://www.worldbank.org/infoshop