I. Project 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. A recent assessment by WHO led to the conclusion that the countries in the East Africa Region do not have sufficient regulatory capacity to approve medicines for sale in a timely manner ensuring acceptable quality, safety, and efficacy standards. Lack of standardization, cumbersome and non-transparent processes for medicine registration create uncertainty and high costs for the manufacturers registering new drugs. They are often confronted with numerous and different regulatory requirements, delays in registration, and lack of transparency in the process. As a result, the availability of some much-needed medicines and vaccines for the neglected tropical diseases and high burden diseases is delayed. Manufacturers may also decide that it is not worth registering additional brands of well-known generic medicines, reducing effective competition and contributing to high medicine prices adversely affecting the poor.

Harmonization of medicines regulation is a global trend, being led by the International Conference for Harmonization (ICH). Through ICH, developed countries have been working together for several decades to align their regulatory processes and establish a framework for division of labor and mutual recognition. While full global harmonization will be difficult to achieve, there has been an increasing convergence of technical standards and risk assessment concepts between the leading global agencies (USA, Europe and Japan) that is increasingly being adopted by large developing countries with significant exports into the developed world.

The ICH Global Cooperation Group (GCG) facilitates effective engagement and coordination among different regional medicine regulatory harmonization initiatives. Recognizing the efforts being made by the East African Community (EAC) to promote medicine regulatory harmonization, the ICH has formally accepted EAC as a member of the GCG. This development acknowledges the progress already made on the political level. The EAC Treaty (1999 and amended in 2007) which establishes the community and sets principles for regional cooperation, mentions medicines regulatory harmonization as a goal. This commitment is further reinforced by the endorsement of the comprehensive EAC region proposal for medicine regulatory harmonization by the Council of Ministers. The membership in the GCG will enhance global scrutiny of progress made by the EAC region in medicine regulatory harmonization.

While the ultimate long term goal is a fully harmonized global framework, the 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 enables 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. The African Union is fully committed to such an approach.

II. 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 133.5 million (2010) distributed over a land area of 2 million square kilometers. Together, their combined gross domestic product is USD 74.5 Billion (2009). 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 Authorities (NMRAs) which vary widely in institutional capacity and
African Community Partner States.

the EAC Treaty. The AMRH proposal, including approval for incremental staffing required for institutional strengthening, has been endorsed by the EAC Council of Ministers. In consultation with its Partner States and with technical support from NEPAD and WHO, the EAC has prepared the first comprehensive regional

Given the challenges that health systems face as a result of limited access to quality medicines, several development partners have been collaborating with African regulators through capacity building activities. As an example, the WHO with funding from the European Union (EU) and the BMGF established an exchange program in technical staff working in the WHO Prequalification Program in Geneva to participate in WHO-led inspections. USAID supports a training center for medicines quality testing in Tanzania and assists regulators in upgrading their national control labs. The German International Development Agency (GIZ) assisted the Pharmacy and Poisons Board (PPB) of Kenya for several years in strengthening their national drug quality control lab until it achieved WHO prequalification. The Tanzanian Food and Drug Authority (TFDA) has already secured International Standards Organization (ISO) 9001 certification for quality systems and achieved WHO Prequalification for its drug quality control lab. Several of the current heads of NMRAs in the EAC region have participated in these activities, which will facilitate collaboration between the NMRAs and ensure that the experience from the past are applied to the current project.

Another important contextual element is the developments in the regional pharmaceutical industry. With assistance mainly from Germany and United Nations Industrial Development Organization (UNIDO), professional associations are built and training is offered for local manufacturers to better understand modern regulatory concepts and allow them to compete in international markets (for example enable them to bid for Global Fund financed procurements). There is a positive feedback loop between those more advanced manufacturers and the regulators: manufacturers are supportive of stricter regulation that keeps sub-standard competitors out of their markets. They also demand transparency of the regulatory process and adherence to global standards in the required documentation # the current system requires putting together a separate dossier for each country, which is costly and time consuming for industry. The expected benefits for the regional industry are an important factor behind the political support for AMRH in EAC and all over Africa. The Pan-African Parliament is working, with support from NEPAD Agency, on a model law for the pharmaceutical sector to facilitate the regional harmonization efforts and ensure compatibility across regions.

Global donors that finance research and development of new products for the treatment of neglected diseases are concerned that these products cannot be made available to their target population in time in the current regulatory environment. This may be the main motive behind Gates Foundation#s decision to support harmonization of medicines regulation and support being provided by EU through WHO to build capacities of National Medicine Regulatory Agencies in the region.

In summary, there are several synergistic developments with significant, ongoing external funding that support the project objectives and create favorable conditions for implementation of the proposed AMRH grant by the EAC. For example, the EU is processing a follow-up grant for WHO allowing continuation of the capacity building program and Germany is in the process of extending its grants for industry support. The Bank team is in regular contact with the other development partners active in this field to ensure effective coordination and collaboration.

With its strong convening power and effective fiduciary oversight the World Bank is uniquely placed to support AMRH. The Bank#s 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, makes it a natural choice to coordinate the AMRH initiative. 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 Health Nutrition and Population (HNP) Anchor.

In consultation with its Partner States and with technical support from NEPAD and WHO, the 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. Some other regional economic communities with support from NEPAD Agency and WHO are also preparing grant proposals which will be subsequently considered for support under the MDTF based on experiences of EAC and additional financing received from partners committed to promote medicine regulatory harmonization.

III. Project Development Objectives

To harmonize medicines registration systems and to improve efficiency and enhance transparency in medicines registration among the East African Community Partner States.

IV. Project Description

Component Name
Regional Coordination and Capacity Building for Medicines Regulatory Harmonization
Institutional Development and Strengthening of National Medicines Regulatory Authorities (NMRAs)

V. Financing (in USD Million)

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VI. Implementation

Institutional and Implementation Arrangements

Over the past two years, the NEPAD Agency and the WHO were engaged in substantive policy dialogue with EAC and its member states on the AMRH initiative and have undertaken comprehensive assessment of the NMRAs. In addition, the Bank has undertaken fiduciary risk assessment of the EAC. The proposed institutional and implementation arrangements are informed by these assessments. Also the overall program in the EAC region has already been endorsed by the Council of Ministers which is expected to ensure sustained political commitment for this initiative.

The recently constituted Project Steering Committee will be responsible for approvals of annual work plans, budgets and will provide technical oversight for the project implementation. The steering committee will have representation of the NMRAs as well as a pharmaceutical policy maker from the participating country in addition to one technical officer responsible for medicine registration and will meet at least twice in a year. The EAC Sectoral Committee on Health and the Sectoral Council of Ministers will provide policy direction and overall oversight of the project including formal approvals for the budgets and fiduciary oversight.

At the regional level, the EAC Secretariat will have the responsibility for implementing the project and will have a dedicated Project Coordination Team consisting of a project coordinator (senior health officer # Medicine Regulation) supported by a dedicated accountant and e-health and informatics officer. The NMRAs will be responsible for project implementation in their respective member states. They will prepare annual work plans, budgets and procurement plans which will be approved by the Project Steering Committee. The NMRAs in turn will report quarterly performance to the project coordination team which in turn consolidates these reports and presents to the Project Steering Committee which meets semi-annually.

Each lead NMRA will constitute the Regional Technical Working Group for which it is responsible. These working groups will develop harmonized guidelines and supporting standard operating procedures. WHO will be providing sustained technical assistance to the working groups through its National Professional Officers (NPOs) and consultants based on the requests received from the working group chair persons. The NEPAD Agency will continue its advocacy role engaging with EAC senior policy makers and ministers, and will facilitate coordination across the regional economic blocks.

VII. Safeguard Policies (including public consultation)

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