SITUATION ANALYSIS STUDY ON

MEDICINES REGISTRATION HARMONISATION IN AFRICA

FINAL REPORT FOR THE EAST AFRICAN COMMUNITY (EAC)

NOVEMBER 2010

NEPAD
TRANSFORMING AFRICA

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ACRONYMS

AIDS	Acquired immunodeficiency syndrome
AMRH	African Medicines Regulatory Harmonisation
API	Active Pharmaceutical Ingredient
ARV	Antiretroviral drug
AU	African Union
BMGF	Bill and Melinda Gates Foundation
COMESA	Common Market for Eastern and Southern Africa
CPP	Certificate of Pharmaceutical Products
CTD	Common Technical Document
DFID	Department for International Development (UK)
DMF	Drug Master File
DPML	Department of Pharmacy, Medicines and Laboratories (Burundi)
EAC	East African Community
EACMFSC	East African Community Medicines and Food Safety Commission
FDA	Food and Drug Administration (USA)
FPMK	Federation of Pharmaceutical Manufacturers of Kenya
GDP	Gross domestic product
GMP	Good Manufacturing Practice
GNP	Gross national product
GTZ	*Deutsche Gesellschaft fur Technische Zusammenarbeit* (German Development Cooperation)
HIV	Human immunodeficiency virus
HRD	Human Resource Development
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
ICM	Integrated Council of Ministers
KAPI	Kenya Association of the Pharmaceutical Industry
M&E	Monitoring and evaluation
MOH	Ministry of Health
NCE	New chemical entity
NDA	National Drug Authority (Uganda)

NEPAD	New Partnership for Africa's Development
NMRA	National Medicines Regulatory Authority
PAP	Pan African Parliament
PIC/S	Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme
PPB	Pharmacy and Poisons Board (Kenya)
REC	Regional economic community
SADC	Southern African Development Community
SIAMED	Model System for Computer-assisted Drug Registration
SRA	Stringent Regulatory Authority
TFDA	Tanzania Food and Drug Authority
TPMA	Tanzania Pharmaceutical Manufacturers Association
UK	United Kingdom
UPMA	Uganda Pharmaceutical Manufacturers Association
USA	United States of America
US$	United States dollar
WHO	World Health Organisation
WHO-PQ	World Health Organisation Prequalification
ZFDB	Zanzibar Food and Drugs Board

FOREWORD

This Situation Analysis Report on Medicines Registration Harmonisation for the East African Community (EAC) has been prepared following rigorous scientific and participatory methods, including the administration of three separate structured questionnaires to the regional economic community (REC), pharmaceutical manufacturers and national medicines regulatory authorities (NMRAs); and a review of documents from the REC and NMRA, including reports by the World Health Organisation (WHO) on medicines regulatory harmonisation in Africa and discussions with key people from the REC and NMRAs.

The purpose of the situation analysis was to establish the status of medicines regulation capacity, harmonisation efforts and challenges in the EAC and member states with a view to enhancing better understanding of the situation in the region, learning from past experiences and developing appropriate interventions to facilitate African Medicines Regulatory Harmonisation (AMRH). The report has been prepared by the consultant with invaluable support received from the EAC Secretariat, heads of national medicines regulatory authorities and pharmaceutical manufacturers and their associations. The report serves among other things as a baseline on the status of medicines regulatory harmonisation in the region, and focuses efforts towards responding to identified gaps, while capitalising on existing strengths.

As part of regional cooperation on health, the EAC partner states have initiated the process of harmonising the regulation of the manufacture, import, trade, sale and export of all medicines and health supplies within the region through the legal mandate of the existing NMRAs in each of the partner states. Nonetheless, there is a need for institutionalisation of the harmonisation of medicines in order to secure and build on the gains that have been made thus far.

This situation analysis report and the data it provides will prove to be a very important source of data to support the efforts to institutionalise and fast-track the harmonisation of medicines regulation in the EAC, which focus on the full realisation of the benefits of the growing pharmaceutical industry in the region as well as ensuring easy access to affordable, safe and quality essential medicines and health supplies for both local use and export to international markets.

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EXECUTIVE SUMMARY

The constant availability of affordable medicines of assured quality, safety and efficacy is an important aspect of any national health system. Providing quality and affordable medicines to the population is a complicated undertaking, ranging from the identification and selection of drugs to the procurement and quality assurance of medicines circulating on the market. National registration of medicines is one way to ensure the quality, safety and efficacy of medicines provided to the population. However, the registration of medicines is cumbersome, requiring considerable technical information from applicants. As a result, it is sometimes difficult to get companies to comply fully with the registration process, as the costs of dossier submission and complying with a gamut of requirements may outweigh the benefits. Over the years, international organisations have been supporting African countries to establish and strengthen their medicines regulatory systems. One such recent effort is the provision of the technical and financial resources needed to progress the African Medicines Regulatory Harmonisation (AMRH) initiative.

Cognisant of the importance of the AMRH initiative, the New Partnership for Africa's Development (NEPAD) commissioned a consultancy to conduct a situation analysis of medicines regulatory harmonisation in the East African Community (EAC). The aim of the study was to establish the status of medicines regulation capacity, harmonisation efforts and challenges in EAC and member states with a view to enhancing better understanding of the situation in Africa, learning from past experience and developing appropriate interventions to facilitate the AMRH initiative. The collection of data involved:

a) the administration of three separate structured questionnaires to the regional economic community (REC), pharmaceutical manufacturers and national medicines regulatory authorities (NMRAs);

b) a review of documents from the REC and NMRAs, including reports of the World Health Organisation (WHO) on medicines regulatory harmonisation in Africa; and

c) discussions with key people from the REC and NMRAs.

The data were analysed to realise the stated objectives. The data presented in this report cover all NMRAs and some pharmaceutical manufacturers in the EAC. The results show that the EAC has provisions in the Treaty for the Establishment of the East African Community as well as the EAC Protocol on Health to cater for the harmonisation of medicines regulation in general, and medicines registration in particular. However, the legislative and regulatory regimes in the EAC do not have provisions for mutual recognition of each partner state's decisions or procedures for medicines registration. Generally, the decision-making process in RECs involves the Heads of State or Government of Member States, the Integrated Council of Ministers (ICM), ministers of health, permanent secretaries, technical subcommittees, national health ministries and stakeholders. The EAC Secretariat coordinates the activities of the Health Section through the senior programme officers for health and pharmaceuticals.

Although the mission of the EAC is clear, few partner states have well-articulated mission statements for their NMRAs. Moreover, some legislation is outdated, and some NMRAs do not have a national medicines policy or implementation strategies for the policies where they exist.

Most of the NMRAs are involved, to varying levels of detail, in regulatory functions such as medicines registration (marketing authorisation); licensing of pharmaceutical manufacturers, importers and retailers; inspection of manufacturers and distribution channels; quality control; control of promotion and advertising; post-marketing quality monitoring surveillance, pharmacovigilance and coordination of medicines regulation. Some are also involved in controlling pharmacy practice, prescribing and dispensing.

Most countries have explicit provisions in their legislation for registering medicines. Countries such as Burundi and Rwanda do not actively register medicines. Registration may be waived under various conditions in some countries. These conditions include investigational medicines for clinical trials, and medicines of public health interest such as medicines for the treatment or control of an epidemic, to mention just a few. Registration guidelines are available and most cover generics, new chemical entities (NCEs) and renewals/retention of registration. The Certificate of Pharmaceutical Product (CPP) is required for registration in most countries, while other countries require registration by at least one Stringent Regulatory Authority (SRA) in order to grant marketing authorisation. In some countries, the legislative frameworks mandate NMRAs to register other products such as vaccines, traditional medicines, pre-packaged food and medical devices. In some cases, information on fast-tracking registrations is made available to the public. The medicines covered by this process generally include those used for the prevention and treatment of HIV/AIDS, malaria and tuberculosis. The average registration times are six months for fast-tracked medicines and 24 months for normal registrations. The final registration decision is made by a board, director general or technical registration committee, depending on the NMRA and its administrative and legislative structure.

The information provided on financial and human resources was scanty, probably because record-keeping is not automated in most NMRAs. The sources of funding include government, donors and industry fees. It is worth noting that government financing is on the decline, while donor support and industry fees are increasing. Human resources are inadequate, and this is particularly acute in Burundi and Rwanda.

The pharmaceutical industry is more developed in Kenya and generally weak in EAC member states. National associations exist in some countries, and the EAC is in the process of launching a regional association. The industry has a moderate to excellent knowledge of what is required to apply for registration. However, respondents considered some aspects of the registration process to be superfluous, including requirements such as the need to include the manufacturing route for the synthesis of the active pharmaceutical ingredient (API) during dossier submissions, and payment of fees in US dollars. The bottlenecks in getting medicines registered include long registration times, unclear guidelines, weak feedback mechanisms, administrative delays and poor record-keeping. These issues notwithstanding, the industry is very supportive of the African Medicines Regulatory Harmonisation (AMRH) initiative.

Sharing information with stakeholders is crucial to the success of the harmonisation process. Although websites do exist, the information is either not updated or uploaded only infrequently. Furthermore, these websites have not been regionally networked. Information is shared through various methods including television, radio and print media. Most NMRAs also share information when they participate in various activities of the AMRH programme.

The REC, NMRAs and the pharmaceutical industry are enthusiastic about, and committed to, the implementation of harmonised medicines regulatory systems. The key stakeholders and partners are aware of and recognise the benefits of drug harmonisation, namely:

a) Communities and patients will enjoy increased availability of safe, effective, quality medicines for neglected and priority diseases. There will be safer, higher-quality medicines circulating on the market in the long term.

b) Harmonisation will help to facilitate the availability of safe and effective essential medicines at affordable prices. In doing so, it will contribute to the achievement of the Millennium Development Goals relating to health (goals 4, 5, 6 and 8).

c) NMRAs will be better equipped to register medicines in a cost-effective and timely manner by improving regulatory processes and making better use of scarce technical skills. They will enjoy

greater technical capacity, improved quality of inspections, and more effective control over registered, unregistered and counterfeit medicines.

d) Pharmaceutical companies and manufacturers will benefit from simplified and standardised regulatory approval processes. It will become possible to submit dossiers for much-needed medicines simultaneously in multiple countries, and evaluation turnaround times will improve.

e) The EAC faces several challenges, however, in taking the medicines regulatory harmonisation agenda forward, the most important of which include:

f) Two countries (Burundi and Rwanda) do not have an NMRA and thus carry out medicines regulatory functions within their national ministries of health.

g) The human capital resources, in terms of both skills and numbers, of the EAC Secretariat and in respective partner states are limited.

h) Physical facilities vary between partner states and require expansion to cater for the full functions of medicines regulation.

i) There is a shortage of quality control laboratories in most NMRAs, and few of them have been pre-qualified by the WHO.

j) Information communication systems vary among the partner states and are generally inadequate.

k) There is inadequate financial support, especially for the smaller medicines regulatory authorities.

l) Regional decisions remain undomesticated by partner/member states, and hence decisions made by individual members are rarely recognised by others.

In view of the above, the following recommendations are made:

Legal framework

The EAC and its partner states should consider the following:

a) Each NMRA should fast-track the enactment of policies and legislation that mutually recognise the persuasive role of regulatory decisions made by the NMRAs of other partner states. These policies and legislation must be consistent with decisions made under the EAC Treaty and the Protocol on Health, and must be passed by the national assemblies of member states.

b) In implementing recommendation (a) above, the laws or statutes passed regarding the registration of medicines must provide for uniform or approximate procedures for approving medicines registration in partner states. This would facilitate the decision of a member state to approve a medicine taking precedence over subsequent applications for similar medicines within the region.

c) Burundi and Rwanda need to enact medicines legislation that clearly provides for medicines regulatory functions and establishes NMRAs as body corporates. These laws should facilitate the platform for implementing medicines registration harmonisation in the region.

d) The EAC Secretariat should take the administrative lead in preparing a roadmap for the implementation of recommendations (a), (b) and (c) and, either alternatively or preferably, draft a protocol to compel each state's legislative machinery to domesticate its national laws timeously so that the decisions made by other member states are mutually recognised, implemented and/or regularised.

e) The EAC should facilitate the development of a framework for mutual recognition based on the Treaty and ensure that there are separate functions for controlling pharmacy practice and

regulating pharmacy professionals, whether government employed or private (namely, those regulating the safety, quality and efficacy of medicines), in order to achieve the comprehensive control of medicines.

f) The lack of mission statements for the national regulation of medicines in some countries is a shortcoming that can readily be addressed. Countries that do not have in place mission statements drawn from existing legislation and policies for regulating medicines should be encouraged to put mission statements in place to set the broad direction for achieving the goal of making safe and quality medicines available. Such mission statements should emphasise the serious intent and commitment of governments to fulfilling the obligation of protecting public health.

Registration of medicines

The EAC and member states' NMRAs should:

a) tighten the conditions guiding waivers in respective NMRAs to avoid abuse;

b) encourage and reward countries adhering to guidelines the for registration of medicines. The scope, frequency of revision of guidelines, and the dissemination of such information using websites and government gazettes, need special attention;

c) shorten registration times no more than 12 to 18 months for most medicines in all NMRAs;

d) develop and implement a framework for joint evaluation of dossiers for the registration of medicines;

e) develop and implement a framework for joint inspection of manufacturing sites for compliance with good manufacturing practice (GMP) requirements;

f) establish a comprehensive information management system for tracking and recording information, including financial data; such information will be important for reference, forecasting and decision-making; and

g) implement pre- and post-marketing surveillance systems.

Sharing of information and stakeholder consultation

The EAC and member states' NMRAs should:

a) develop and execute strategies for sensitising regional and national parliaments to the need to fast-track the domestication of decisions on medicines regulatory harmonisation;

b) strengthen the EAC Secretariat for improved coordination and networking;

c) develop and implement a clear roadmap for the harmonisation of medicines registration;

d) create awareness among all stakeholders of the benefits and value of harmonisation;

e) engage the EAC Integrated Council of Ministers to direct and concretise regional pharmaceutical policies;

f) implement a robust roadmap for engaging the pharmaceutical industry;

g) ensure that information-sharing options such as websites are as up to date as possible; and

h) encourage and support regional and national associations.

Capacity building

The EAC and member states' NMRAs should:

a) strengthen the capacity and capability of NMRAs to enable them to fulfil their legal and regulatory functions. This requires implementing the following activities:

   i. utilising pooled regional capacity;

   ii. developing a regional human resource training programme;

   iii. fostering staff exchange programmes;

   iv. establishing regional centres of excellence for training and research; and

   v. introducing incentives for better staff retention in various NMRAs; and

b) mobilise adequate financial resources for regulatory functioning.

It is important for the EAC and NMRAs to take this agenda forward. It is therefore strongly recommended that a medicines regulatory harmonisation strategy for the EAC be developed and that this strategy include clear objectives, measurable indicators, outcomes and a monitoring and evaluation (M&E) framework.

1. BACKGROUND TO THE STUDY

The constant availability of affordable medicines is an important aspect of any national health system. Providing quality, low-priced pharmaceuticals to the population is a complicated undertaking, ranging from the identification and selection of drugs to the procurement and quality assurance of medicines circulating on the market.

The national registration of medicines is one way to assure the quality, safety and efficacy of medicines provided to the population. However, the registration of medicines can be cumbersome, requiring considerable information from applicants. As a result, it is sometimes difficult to get companies to cooperate and comply fully with the registration process, as the costs of submission may outweigh the benefits. In recognition of the challenges of medicines registration, the New Partnership for Africa's Development (NEPAD), the World Health Organisation (WHO), the Pan-African Parliament (PAP), the Bill and Melinda Gates Foundation (BMGF), the UK's Department for International Development (DFID) and the Clinton Foundation have formed a consortium, and together they have developed a strategic approach to mobilising technical and financial resources to advance the African Medicines Regulatory Harmonisation (AMRH) initiative. The overall objective of the AMRH initiative is to improve health of the people in the region by improving access to safe, efficacious and good quality essential medicines for the treatment of neglected and priority diseases. This will be achieved through the harmonisation of medicines regulations and standards, starting with medicines registration, within and across African regional economic communities (RECs) and organisations.

As a means of building upon and strengthening plans that already exist in sub-regional groupings, the consortium has invited RECs to submit project proposals for medicines registration harmonisation. NEPAD and the members of the consortium are working with RECs to ensure complementarities of their efforts; enable continent- wide communication, coordination and technical consistency; and mobilise donor support.

Having a better understanding of ongoing efforts and related barriers to the harmonisation process is an essential ingredient for success with harmonisation. In order for NEPAD, PAP and the WHO to effectively execute their strategic roles in supporting RECs to harmonise their medicine regulations, it is important that the existing information regarding the capacity for medicines regulation in RECs and their national medicines regulatory authorities (NMRAs) is updated to reflect the realities on the ground. For instance, according to the report presented by the WHO at the 1st African Medicines Regulatory Authorities Conference held in Addis Ababa, Ethiopia from 31 October to 3 November 2005, only about 7% of the 46 sub-Saharan African countries had moderately developed medicine regulatory capacity. Of the remaining countries, about 63% had minimal capacities, and 30% did not have an NMRA in place.

Over the years, the WHO and other international organisations and donor countries have been supporting African countries to establish and strengthen their NMRAs. Various assessments of medicines regulatory systems have been undertaken using the WHO Data Collection Tool for the Review of Drug Regulatory Systems. However, information collected by these assessments needs to be updated taking into account various developments over the years and to collect legislative and institutional information that will support the advocacy role of the AMRH initiative. This information is also essential for establishing benchmarks that could be used to assess the efficiency and effectiveness of the harmonisation process.

The need for a situation analysis was reiterated during the 2nd African Medicines Regulatory Authorities Conference held in Maputo, Mozambique from 24–26 November 2009. The conference recommended

among other things that NEPAD should develop a specific tool to obtain information on legislative and institutional frameworks that would assist with advocacy and coordination with respect to medicines regulation harmonisation on the continent.

Against this background, NEPAD commissioned a consultancy to conduct a situation analysis of medicines regulation harmonisation on the African continent. The aim of the assessment was to provide useful information for developing a strategy to support RECs in their ongoing medicines regulation harmonisation initiatives.

1.1 OBJECTIVES

The aim of the study was to establish the status of medicines regulation capacity, harmonisation efforts and challenges in RECs and partner states with a view to enhancing better understanding of the situation in Africa; learning from past experiences and developing appropriate interventions to facilitate the AMRH initiative.

The specific objectives were:

a) critical analysis of legislative and legal frameworks governing the harmonisation of medicines policies and regulations at national, sub-regional and regional levels with a focus on medicines registration harmonisation;

b) evaluation of the status of human capital and infrastructure needs and challenges;

c) evaluation of structures, systems and institutional frameworks as they relate to the harmonisation of medicines regulation at national, sub-regional and regional levels;

d) assessment of funding and financing mechanisms for national medicines agencies and their operations;

e) identification of challenges, barriers and constraints regarding the harmonisation of medicines policies and regulations and exploration of opportunities for effective harmonisation;

f) delineation of views, perceptions and needs for regulatory harmonisation; and

g) establishment of logical steps towards medicines regulation harmonisation in Africa.

1.2 METHODOLOGY

Assessment instruments consisting of three separate structured questionnaires were administered at the levels of the REC, regional/national associations of pharmaceutical manufacturers and NMRAs to gather information, which was analysed to reflect on the situation of medicines registration harmonisation. In addition, checklists were used during focus group discussions, and key informant interviews were conducted in order to collect both qualitative and quantitative data.

The assessment instruments were piloted in the East African Community, taking into account a recent assessment of medicines regulatory capacities in the five partner states, which was conducted using the WHO Assessment Tool. During the second week of May 2010, the assessment team conducted discussions with the EAC Secretariat, industry and heads of NMRAs with a view of identifying gaps in the assessment instruments and gathering inputs from stakeholders. Input from the EAC pre-testing of the assessment instruments was used to review the instrument with a view to replicating the exercise in the remaining RECs. The

assessment team reviewed various documents, including the latest WHO reports on medicines regulatory harmonisation in Africa and other relevant papers, as an input in the assessment exercise.

The assessment team conducted a thorough review of all laws, regulations, forms and instructions pertaining to drug regulatory systems in all partner states; collected new data; analysed processes and systems; evaluated institutional capacity and provided a qualitative and quantitative assessment using the data collected. The team has made recommendations and proposed strategies to address the needs and gaps identified at both national and regional levels.

2. EAST AFRICAN COMMUNITY

2.1 BACKGROUND

The East African Community (EAC) is a regional inter-governmental organisation comprising five partner states, namely the Republic of Kenya, the Republic of Uganda, the Republic of Burundi, the Republic of Rwanda and the United Republic of Tanzania. The EAC has its headquarters in Arusha, Tanzania (www.eac.int). The five EAC countries collectively cover an area of approximately two million square kilometres, with Burundi, Tanzania, Uganda, Kenya and Rwanda accounting for 1.5, 51.7, 13.3, 32.1 and 1.4 per cent of the total surface area respectively. The demographic, social, health and economic data are provided in Table 1. The mid-year population was projected to grow by 3.7% from 122.1 million in 2007 to 126.6 million in 2008. This implies a slight acceleration from the 3% growth recorded in 2007. The life expectancy for the region remained unchanged for most countries except Kenya, where life expectancy declined from 57 years to 53 years. Significant drops in both infant and child mortality rate were recorded in 2008. Overall, the EAC recorded an average GNP per capita of US$506, with Kenya at US$794; Uganda at US$556; Tanzania at US$525; Rwanda at US$494 and Burundi at US$164. In aggregate, total GDP for the region amounted to US$73,338 million in 2008, compared to US$60,258 million in 2007. The average annual underlying inflation rate increased to 13.3% in 2008 from 7.6% in 2007. On average, the EAC fiscal deficit, excluding grants, as a ratio of GDP reduced from 10.5% in 2007 to 9.5% in 2008. The list of respondents to the assessment instruments is shown in Appendix 1.

Table 1: Demographic, social, health and economic data for the EAC (2008)

Country	Burundi	Tanzania	Uganda	Kenya	Rwanda	East Africa (Total)
Area of country (km^2)	27,834	945,087	241,550.7	580,367	26,338	1,821,176.7
Population (million)	8.2	40.7	29.6	38.3	9.8	126.6
Life expectancy (years)	47	50	50	53	52	50.4
Infant mortality rate per 1000 live births	-	84	76	52	62	-
Maternal mortality rate per 100,000	-	577	435	410	750	-
Real GDP growth rates	4.3	7.4	9.2	1.7	11.2	6.76
Gross national product (GNP million US$)	837	12,395	10,875	19,668	3682	9491.4
Gross national product per capita (GNP million US$)	163.5	524.8	555.7	793.5	493.6	506.2

Source: EAC website (www.eac.int)

The people of the East African region share a common history, language, culture and infrastructure. These advantages provide the partner states with a unique framework for regional cooperation and integration in various political, economic, social and cultural areas of common interest. Consequently, the various organs and institutions of the EAC are currently engaged in the promotion and development of priority areas for regional cooperation as diverse as the following: health, customs and trade, agriculture, transport and communications, monetary and

fiscal affairs, environment and natural resources, legal, judicial and parliamentary affairs, and peace and security, among others. As part of regional cooperation on health, the EAC partner states have initiated a process of harmonising the regulation of the manufacture, import, trade, sale and export of all medicines and health supplies within the region through the legal mandate of the existing NMRAs in each of the partner states. Within the five EAC partner states, there are six NMRAs that oversee this process, namely, Burundi, Rwanda, Tanzania Food and Drug Authority (TFDA), Kenyan Pharmacy and Poisons Board (PPB), National Drug Authority (NDA) of Uganda and Zanzibar Food and Drugs Board (ZFDB). However, there is a need to institutionalise and fast-track the regional harmonisation of medicines regulation in order to fully realise the benefits of the growing pharmaceutical industry in the region and also to ensure easy access to affordable, safe and quality essential medicines and health supplies for both local use and export to international markets.

2.2 MEDICINES REGULATION HARMONISATION IN THE EAC

2.2.1 Developments in the harmonisation of medicines regulations

In the provisions of the Treaty for the Establishment of the East African Community (1999) concerning health issues, in Chapter 21 (Article 118), the partner states undertook to:

a) take joint action towards the prevention and control of communicable and non-communicable diseases and to control pandemics and epidemics of communicable and vector-borne diseases such as HIV/AIDS, cholera, malaria, hepatitis and yellow fever that might endanger the health and welfare of the residents of the partner states, and to cooperate in facilitating mass immunisation and other public health community campaigns;

b) promote the management of health delivery systems and better planning mechanisms to enhance the efficiency of health care services within the community;

c) develop a common drug policy which would include establishing quality control capacities and good procurement practices;

d) harmonise drug registration procedures so as to achieve good control of pharmaceutical standards without impeding or obstructing the movement of pharmaceutical products within the community;

e) harmonise national health policies and regulations and promote the exchange of information on health issues in order to achieve quality health within the community;

f) cooperate in promoting research and the development of traditional, alternate or herbal medicines;

g) cooperate in the development of specialised health training, health research, reproductive health, pharmaceutical products and preventive medicine;

h) promote the development of good nutritional standards and the popularisation of indigenous foods, and

i) develop a common approach through the education of the general public and their law enforcement agencies for the control and eradication of the trafficking and consumption of illicit or banned drugs.

In 2000, the EAC Integrated Council of Ministers asked the Research, Policy and Health Systems Working Group to draft a common drug policy and harmonised drug regulation procedures. At their meeting held in Ethiopia in 2005, the African drug regulators recommended

the promotion of medicines regulation harmonisation using existing RECs such as the EAC. Consequently, in the same year, the NMRAs of the EAC partner states prepared an action plan for the harmonisation of drug registration. The plan was not executed, because there was no focal person at the EAC Secretariat to oversee its implementation, and also due to a lack of funds. It is clear that the mandate has been provided for the process of medicines regulatory harmonisation, but that this process has thus far stalled because of inadequate human and financial resources and a lack of effective coordination at the EAC Secretariat. The recent efforts and future plans aimed at implementing the directives of the Integrated Council of Ministers on this initiative have been summarised in Table 2. To this end, the EAC Secretariat has submitted a five-year comprehensive proposal to the Bill and Melinda Gates Foundation with the goal of putting in place a harmonised and functioning medicines registration system in accordance with national and international standards. The implementation will be coordinated through the proposed EAC Medicines and Food Safety Commission.

Table 2: EAC efforts towards the harmonisation of medicines regulations

Scope of medicines regulatory harmonisation	Year started	Progress to date	Future plans
Capacity building	2007	Joint training of regulatory staff in dossier assessment done in 2007, 2008 and 2009	To develop a capacity building programme for technical, financial and management staff in project management, including contributing to the establishment of the East African Community Medicines and Food Safety Commission (EACMFSC)
Joint evaluation of dossiers and inspections of medicine manufacturing sites	2010	Joint evaluations piloted in March 2010	To establish a framework for joint evaluations of dossiers and inspections of medicine manufacturing sites and to ensure that these assessments are integrated into national decision-making processes by 2010
Technical requirements for registration	Included in the EAC proposal submitted to donors for funding	Proposal for its development written and submitted to donors	To implement an agreed common document (format and content) of technical requirements and procedures for medicines registration by December 2011
Information management system	Included in the EAC proposal submitted to donors for funding	Proposal	To implement a common information management system for drug registration by December 2012
Quality management system	Included in the EAC proposal submitted to donors for funding	Proposal	To implement a quality management system in each of the EAC partner states' NMRAs
Information sharing	Included in the EAC proposal submitted to donors for funding	Proposal	To establish a mechanism for using regulatory information from partner states' NMRAs (assessments/decisions) and for making information available to the public (legislation, guidelines and lists of registered products etc.) by December 2011
Advocacy	Included in the EAC proposal submitted to donors for funding	Proposal	To develop and implement an advocacy strategy to sensitise key stakeholders at regional and national levels and to build ongoing stakeholder commitment (including political commitment for developing legislative amendments)

2.2.2 Overview of legal issues affecting medicines regulation in the region

This section contains eight subsections that provide an overview of the legal framework for medicines regulations in the region. The subsections hinge on the medicine policies, legal instruments, comprehensiveness of the legislation, synchrony of partner states' legislation and regulations, missions statements and functions of NMRAs, decision-making process, organisation and management of regulatory functions, as well as recommendations on how the regulatory framework could be strengthened and harmonised.

2.2.2.1 National medicines policy

In order for EAC member countries to have in place a comprehensive legal framework for the regulation of safe, quality and efficacious medicines, they need medicine policies both at regional and national levels. The aim of these policies is to set up the broad objectives, the commitment and the roadmap for the region and partner state government regimes on the implementation of regional or national obligations to regulate medicines. It has therefore become essential, at this point in the study report, to determine whether each country has a national medicines policy, as well as the scope of the policy in line with WHO recommendations for medicines policies. National laws on the enforcement of regulatory functions related to safe, quality and efficacious medicines derive their legitimacy to be enacted and implemented from such policies.

All five EAC partner states have national medicines policies, but Burundi's national medicines policy differs from the WHO recommendations. The medicines policies for Kenya, Tanzania (Zanzibar and Mainland), Uganda and Rwanda are very similar to the medicines policy recommended by the WHO, and each country has an implementation plan for concretising the objectives of the policy. The policies of all five partner states vest the responsibility for regulating medicines with the government. Important common elements in these policies include controlling the quality, safety and efficacy of medicines.

The laws in the four partner states (excluding Burundi) have specific provisions for the registration of medicines. All five partner states provide for the broad obligation and commitment of the government to regulate medicines in their national medicines policies, which form the platform for implementing government objectives.

2.2.2.2 Legal instruments and provisions

As indicated in section 2.2.1, the EAC is governed by a legal instrument that provides for the harmonisation of medicines regulation among the partner states; this allows for communication, collaboration and standardisation, leading ultimately to mutual recognition and/or centralised registration procedures. Specifically, Article 118 (c), (d) and (e) of the Treaty commits partner states to: a) develop a common drug policy, which would include establishing quality control capacities and good procurement practices; b) harmonising drug registration procedures so as to achieve sound control of pharmaceutical standards without impeding or obstructing the movement of pharmaceutical products within the community; and c) harmonising national health policies and regulations and promoting the exchange of information on health issues in order to achieve quality health within the community. These provisions are backed by the decision of the EAC Integrated Council of Ministers of 2000, which among other things directed the Research, Policy and Health Systems Working Group to draft a common drug policy and harmonised drug regulation procedures.

2.2.2.3 Comprehensiveness of legislation

An analysis of the comprehensiveness of medicines legislation in EAC partner states was undertaken to determine variations and complementarities.

Despite slight differences in the laws of each EAC partner state that control the quality, safety and efficacy of medicines, Kenya, Tanzania and Uganda have specific laws governing the regulatory functions for the comprehensive control of medicines. The enactment of laws in these three partner states provides for the establishment of a body responsible for medicines regulation. The form and type of body responsible for medicines regulation varies depending on the establishing piece of legislation. Although Rwanda and Burundi do not have specific laws, they derive legitimacy to control medicines from their National Medicine Policies.

The Tanzania Food, Drugs and Cosmetics Act, 2003 established the Tanzania Food and Drugs Authority as a government agency that enjoys semi-autonomy under the Ministry of Health. This law merged the regulatory functions for medicines and foods under the same body. The Zanzibar Food, Drugs and Cosmetics Act, 2006 established the Zanzibar Food and Drugs Authority as a corporate body charged with the duty to regulate medicines and food on the island. The National Drugs Authority in Uganda was established under the National Drug Authority and Policy Act, 1993. The Pharmacy and Poisons Act, Cap 244, established the Pharmacy and Poisons Board of Kenya. These Acts control both the professional practice of pharmacy and the medicines regulatory functions. It is preferable to have separate laws governing professional practice and medicines regulatory functions, as in other EAC countries.

The medicines regulatory laws for Uganda, Kenya and Tanzania (Mainland and Zanzibar) provide for the licensing of manufacturers of pharmaceuticals, while Burundi and Rwanda do not have such laws. Despite the non-existence of specific laws in Rwanda and Burundi, all five partner states issue licences for importing, wholesaling, distribution, retailing and dispensing outlets for pharmaceuticals. The laws of all partner states except Rwanda make provision for marketing authorisation, which involves control of the registration of medicines. Inspections of premises and manufacturing sites, and quality control of medicines are carried out by all five partner states. Other key areas of medicines regulation, such as the control of clinical trials, are unique to the laws of Uganda and Tanzania (Mainland and Zanzibar); other member states do not have explicit legislation on this issue. However, Kenya controls clinical trials under the powers derived from the National Drug Policy. There is no provision for the control of counterfeit medicines in the medicines regulation laws of Kenya and Rwanda, while the medicines legislation of the other partner states provide for the control of counterfeit medicines. Unlike the other member states, medicines regulations in Kenya and Rwanda do not provide for controlling the safety of pharmaceutical products. Burundi and Rwanda do not control the promotion of pharmaceutical products, while medicines laws in the remaining three partner states have specific provisions for the control of pharmaceutical promotion.

These laws for medicines regulation vary in terms of the scope of product controls. Some of these laws control pharmaceutical products as well as the professional practice of pharmacy. Generally, they all have common elements with respect to the control of medicines distribution schedules/categories, narcotics and psychotropic substances, administrative and legal sanctions, such as the suspension or revocation of licences, or fines and imprisonment. With the exception of Rwanda, the pharmaceutical regulatory laws of all the partner states provide a platform to enact subsidiary legislation as a legal instrument to complement the enforcement of the principal law on the regulation of medicines. Table 3 summarises the various laws that are used to regulate medicines in the EAC, while Table 4 shows the countries whose laws do not provide for some key regulatory functions.

Table 3: List of legislation for regulating medicines in EAC partner states

Country	Description/Title and year of enactment
Burundi	*Decret in 100/150 portant organisation de la exercise de la pharmacie au Burundi* (30/09/1980)
Kenya	Pharmacy and Poisons Act, Cap 244 of the laws of Kenya
Rwanda	Pharmacy Law National essential medicine list National treatment guide
Tanzania (Mainland and Zanzibar)	Zanzibar Food, Drug and Cosmetics Act, 2006 and its regulations Traditional and Alternative Medicines Act, 2008 Tanzania Food, Drug and Cosmetics Act, 2003 [Cap 219] of the laws of Tanzania (Supporting regulations includes the Pharmaceutical and Poisons Regulations, 1990;, Fees and Charges Regulations, 2005) Tanzania Food, Drug and Cosmetics (standard and code of ethics for Duka la Dawa Muhimu) Regulations, 2004)
Uganda	National Drug Authority and Policy Act (1993)
EAC	Chapter 21 (Article 118) of the Treaty for the Establishment of the East African Community (1999)

Table 4: Comprehensiveness of legislation for key regulatory functions

Key regulatory function/provision	Country whose legislation does not provide for the key regulatory function/provision	Comments
Establishment of a body responsible for medicines regulation	None	Burundi and Rwanda operate from the Ministry of Health
Licensing of :		
1. Manufacturers	Burundi Rwanda	
2. Importers	None	
3. Wholesalers	None	
4. Distributors	None	
5. Retailers/dispensing outlets	None	
6. Other product licensing	Uganda	
7. Market authorisation/Registration of medicines	Rwanda	
8. Inspection of premises and manufacturing sites	Rwanda	
9. Establishment of Quality Control Laboratory	Rwanda	
10. Control of clinical trials	Kenya Burundi Rwanda	

11. Control of counterfeit medicines	Rwanda	
12. Control of imports and exports	None	
13. Safety monitoring of products	Tanzania Rwanda	
14. Control of product promotion and advertisement	Burundi Rwanda	
15. Control of other products	Uganda Burundi Rwanda	
16. Provision for medicines distribution schedules/categories	None	
17. Control of narcotics and psychotropic substances	None	
18. Administrative and legal sanctions e.g. suspension or revocation of licenses or fines/imprisonment	None	
19. Authority to make regulations	Rwanda	

2.2.2.4 Legislation and regulations of partner states

The legislation and regulations for the registration of medicines enacted by the partner states and the REC form the legal framework for incorporating harmonised procedures for the registration of medicines. These inform the legitimacy and the mission to control the quality, safety and efficacy of medicines within the respective countries.

Currently, each partner state has its own legal framework for the registration of medicines, and these cannot be used to control the requirements of another partner state. However, the East African Community has the EAC Treaty from which legitimacy can be derived to link joint medicines regulation carried out at regional level and within the laws of individual partner states. Chapter 21, Article 118 (d) and (e) of the Treaty gives legitimacy for member states to harmonise drugs registration procedures so as to achieve sound control of pharmaceutical standards without impeding or obstructing the movement of pharmaceutical products within the community, and to develop national health policies and regulations to promote the exchange of information on health issues in order to achieve quality health within the community.

The medicines regulatory regime in each EAC country is implemented by semi-autonomous government agencies such as the TFDA in Tanzania, the NDA in Uganda and the PPB in Kenya, while the setting up of medicines regulatory regimes in Burundi and Rwanda is still in its infancy. The country-specific medicines control legislation is administered by these NMRAs. The status quo of the medicines control laws of EAC member states is explained here. With the exception of Rwanda and Burundi, there are specific laws and regulations that among other things provide for the control of the registration of medicines for the community and for each partner state. However, the legislation of the various partner states is not legally or mutually recognised. Furthermore, the laws do not contain provisions that are in *pari materia* or that impose an obligation on a partner state to harmonise medicines registration procedures with other partner states. Unless there are administrative arrangements to the contrary, the implications of this legal framework are that no partner state is compelled, under any circumstances, to borrow *mutatis mutandis* any decision or procedures for medicines registration applicable in another partner state, even though the diseases for which the medicines are registered occur within the whole region.

This means that a dossier submitted by an applicant for the registration of a medicine in one of the partner states may remain pending for registration in another partner state for several years while awaiting inspection and evaluation reports as well as the approval decision, while the medicine may already be available in a neighbouring partner state. Furthermore, it is possible that each of the five partner states will individually conduct a GMP inspection at the same pharmaceutical manufacturing site with a view to making a regulatory decision on whether or not to register the same medicines. This undertaking is costly and, moreover, delays and adversely affects the distribution and timely availability of safe, quality and efficacious medicines. If regulation systems were harmonised within the EAC, such inspections would be undertaken by a single team of GMP inspectors, whose report could be used by all five partner states to make a regulatory decision.

2.2.2.5 Missions and functions of national medicines regulatory authorities

The mission statements and functions of the NMRA are key indicators of the determination of the government to achieve the objectives of medicines control within its territory. This section reviews and compares the missions of the various NMRAs.

With the exception of Burundi, the five NMRAs (Uganda, Rwanda, Kenya, Tanzania Zanzibar and Tanzania Mainland) have written mission statements derived from the main objective of the national law that provides for the control of medicines. The mission statements cover the accessibility of good quality, safe and efficacious medicines in order to protect and promote public health. The mission statements of the five NMRAs are contained in their strategic plans or are accessible on their websites. They are consistent with the legislation of the specific relevant partner state.

The functions of the NMRAs, as stipulated in their legislation, include but are not restricted to medicines registration; quality control testing; and the regulation of the importation, manufacturing, labelling, marking or identification, storage, marketing and clinical trials of medicines. A summary of specific functions executed by each NMRA is provided in Table 5.

Table 5: Summary of functions executed by each NMRA

Function	Country				
	Burundi	Kenya	Rwanda	Tanzania (Mainland and Zanzibar)	Uganda
Licensing of pharmaceutical manufacturers	✗	✓	✗	✓	✓
Licensing of pharmaceutical imports	✓	✓	✓	✓	✓
Licensing of pharmaceutical wholesale trade	✓	✓	✓	✓	✓
Licensing of medicine retail/dispensing outlets	✓	✓	✓	✓	✓
Product assessment and registration/marketing authorisation	✓	✓	✗	✓	✓
Good manufacturing practice (GMP) inspection	✓	✓	✗	✓	✓
Inspection of distribution channels	✓	✓	✓	✓	✓
Performing medicine quality tests/quality control laboratory	✓	✓	✗	✓	✓
Control prescribing	✓	✓	✓	✓	✓
Coordination of medicines regulation centrally at national level	✓	✓	✓	✓	✓

2.2.2.6 Decision-making process

The procedure used for making regional decisions that ultimately compel countries to abide by the agreed obligations is backed by the Treaty for the Establishment of the East African Community (1999). The Integrated Council of Ministers, which is the policy organ of the community, may establish Sectoral Councils to deal with matters that arise under the Treaty. The decisions of such Sectoral Councils are deemed to be decisions of the Council. Matters of health fall within the realm of the Sectoral Council of Ministers of Health. The regulations, directives and decisions of the Council, taken or given in pursuance of the provisions of the Treaty, are therefore binding on the partner states. Partner states are compelled to implement these decisions through their national legal frameworks and legislative systems.

This study revealed that the Treaty is non-self-executing and therefore requires implementing legislation, namely, a change in the domestic legislation of a partner state that will direct or enable it to fulfil its Treaty obligations. For each obligation made under the Treaty to apply within a partner state, the state is bound to make it part of its domestic law through the national legislative framework. Since a non-self-executing treaty cannot be acted upon without the necessary changes in domestic law, it follows therefore that if a treaty requires implementing legislation, a partner state may be in default of its obligations through the failure of its legislature to pass the necessary domestic laws.

It is therefore important to clarify the timeframe within which partner states are required to commence the application of the legislative framework to domesticate decisions or directives under the Treaty and render these applicable in their own country. The domestication of laws and policies by partner states would allow similar laws and policies to be implemented in the various countries at the same time. For partner states to be effectively bound by obligations such as those relating to the harmonisation of medicines registration, the national policies and laws need to incorporate the respective obligations. While the partner states are part of the decision-making process at regional level, they retain their legal sovereignty as provided in their national constitutions, which confer power on their national parliaments to make legislation. These constitutions are the supreme law of each country, such that the constitution of a partner state cannot override the jurisdiction of another partner state.

It is difficult to impose sanctions on defaulting partner states for non-compliance with obligations such as initiatives for the harmonisation of medicines registration. This is because there are variable commitments and priorities, which change over time, for each partner state to speed up the domestication of obligations made under the Treaty. For example, not all partner states have yet complied with the resolution passed by the Integrated Council of Ministers in 2000 that partner states should, among other things, establish autonomous NMRAs and merge the control of medicines and food products under a single regulatory body. Some partner states, such as Tanzania, started implementing the directive in 2003, while others have not yet done so. At the time of this study, only three of the established NMRAs had merged the regulatory functions for medicines and food, namely, those in Uganda, and Tanzania (Mainland and Zanzibar). Kenya, Rwanda and Burundi have not yet done so, but cannot be declared defaulters or said to have failed to implement the obligations, as they may be working on their infrastructure and legal frameworks.

For the harmonisation of medicines registration to succeed, it is important for each partner state to ensure that obligations made at regional level under the provisions of the Treaty or directives of Sectoral Councils on the harmonisation of medicines registration are indeed integrated into their national laws and policies. These have to be passed by their parliaments timeously, without diminishing national jurisdiction or without fear of losing national legitimacy within the community. This obligation is indeed primary and may require the EAC Secretariat

to develop a roadmap that may be adopted by the Sectoral Council of Ministers of Health to guide the partner states to fast-track the obligations under the Treaty so that the harmonisation of medicines registration is domesticated in the legislative framework of each partner state. Another legal option would be to draft a protocol under the Treaty with a view to compelling partner states to amend their domestic legislation within a specified time. It is also imperative to sensitise parliamentarians to the importance of harmonised procedures for medicines registration and therefore the need to fast-track the processes.

2.2.2.7 Organisation and management of regulatory functions

It is important for the REC as well as NMRAs to have proper organisational structures for managing regulatory functions. At national level, this should be through NMRAs. Rwanda and Burundi do not have corporate bodies for regulating the safety and quality of medicines as in the other three partner states; and neither do they have specific legislation for this purpose. Their operations are through their ministries of health. Burundi carries out medicines regulatory functions from the Department of Pharmacy, Medicines and Laboratories in the Ministry of Health (DPML/MOH), while Rwanda performs these functions through a Pharmacy Task Force in the Ministry of Health. The NMRAs in the other three partner states are corporate bodies with differing levels of autonomy, depending on the laws by which they were established, but they are all government agencies.

Regulatory bodies in the partner states generally exercise similar licensing functions with respect to pharmaceutical manufacturers, imports, and the wholesale and retail pharmaceutical trade. Additional functions carried out by NMRAs include the registration of medicines, product assessment, marketing authorisation, inspection of manufacturers for good manufacturing practice (GMP), control of distribution channels, conducting medicines quality tests and the functions of the quality control laboratory, regulating generic substitution, and the control of prescriptions under specific laws.

The non-establishment of medicines regulatory bodies in Burundi and Rwanda may have weakened the medicines regulatory system. For example, the Pharmacy Task Force in Rwanda has not yet started licensing pharmaceutical manufacturers, and the DPML/MOH in Burundi has not started the registration of medicines, inspection of distribution channels or conducting of medicines quality control tests. Like the DPML/MOH in Burundi, the Tanzania Food and Drug Authority (TFDA) and Kenyan Pharmacy and Poisons Board (PPB) do not regulate generic substitution, and Rwanda is the only member state that regulates medicines prescription.

Kenya, Tanzania and Burundi have an organisational structure that charts out medicine regulatory systems from central to local government. Uganda's National Drug Authority (NDA) has a central office in Kampala and seven regional offices spread geographically across the country. These offices have full-time staff but also employ part-time Ministry of Health local government district assistant inspectors of drugs. The TFDA has an official organisational structure up to the level of zone offices.

The NMRAs in Kenya, Tanzania and Uganda also use external experts and various committees for regulatory functions. The role of these experts is to give opinion on medicines regulatory inspection; medical devices; drug reactions; safety monitoring of drugs; access to medicines; inspection and licensing; evaluation of human medicine and clinical trial protocols; and support services such as training and financing. Uganda, Kenya and Tanzania have written terms of reference, procedures and accepted codes of conduct for the external committees.

The institutional framework for the management and coordination of medicines regulation in the EAC is attached in Appendix 2.

2.2.2.8 Recommendations

To enable the NMRAs to fulfil their obligations with respect to effective medicines regulation and monitoring of the safety and efficacy of products, it is recommended that:

a) Each East African partner state should fast-track the enactment of policies and legislation that mutually recognise the persuasive role of regulatory decisions made by the NMRAs of other partner states. These policies and legislation must be passed by the national assemblies of partner states in order to recognise and implement decisions made under the East African Treaty.

b) For partner states to be able to implement recommendation (a) above, the laws or statutes passed regarding the registration of medicines must include provisions with common objectives.

c) Burundi and Rwanda need to enact medicines laws that will clearly provide for medicines control and establish NMRAs as body corporates, charged with medicines regulatory functions. Such legislation will provide the basis for the regulation of medicines in the two countries and will facilitate a platform for implementing medicines registration harmonisation in the region by establishing similar legal frameworks with other EAC member countries.

d) The EAC Secretariat should take the administrative lead in preparing a roadmap for the implementation of recommendation (a), (b) and (c) above, or alternatively and preferably by drafting a protocol to compel the legislative machinery of partner states to domesticate their national laws timeously so that the mutual recognition of decisions made by other partner states is implemented and/or regularised. The recommended protocol should state, among others things, the objectives, scope and institutional framework with a view to establishing:

   i. the application of common medicines legislation to provide a platform for the uniform application of medicines registration and documentation in the region;

   ii. implementation of common procedures for the approval of medicines registration for subsequent applications for registration to the NMRA of any other partner state;

   iii. elimination of internal registration barriers that impede the availability of medicines to all partner states;

   iv. harmonised registration charges of equivalent effect and discriminatory treatment with respect to medicines registered among partner states; and

   v. export promotion and competitiveness through various incentive schemes for medicines.

e) Medicines regulatory laws should be reviewed to provide separately for the comprehensive control of medicines with respect to regulating their safety, quality and efficacy, and for controlling pharmacy practice with respect to moulding professionals, whether employed by the government or private sector.

f) Development and implementation strategies are required to sensitise regional and national parliaments to the need to fast-track the domestication of decisions on the harmonisation of medicines regulations.

g) Since not all NMRAs have guidelines (and even where guidelines exist, they are not sufficiently comprehensive and vary in their content and format), it is necessary that EAC

partner states develop harmonised guidelines for the registration of medicines and adopt the Common Technical Document (CTD) format for the submission of dossiers to apply for medicines registration.

2.3 MEDICINES REGULATORY HARMONISATION AND REGISTRATION SYSTEM

This section deals with the following aspects of harmonisation: legal and regulatory requirements; guidelines for the registration of medicines; registration times and processes; assessment of applications of pharmaceutical products; factory inspections; and testing of medicine samples for registration.

2.3.1 Legal and regulatory requirements

Data from the responding countries regarding the legal and regulatory requirements for the harmonisation of medicines registration were reviewed and analysed. Following this analysis, it has been established that the EAC uses the following two instruments for undertaking various initiatives towards medicines registration harmonisation, namely:

a) the Treaty for the Establishment of the East African Community (1999), Article 118 (d): "harmonisation of drug registration procedures so as to achieve good control of pharmaceutical standards without impeding or obstructing the movement of pharmaceutical products within the community";

b) the directive of the EAC Integrated Council of Ministers (2000), which established the Research, Policy and Health Systems Working Group tasked with drafting a common drug policy and harmonised drug regulation procedures.

In the EAC region, the legal requirements for medicines registration vary from country to country. Uganda, Zanzibar, Tanzania, Kenya and Rwanda have legislation that provides the legal mandate for their NMRAs to actively register medicines. Burundi is the only EAC country that does not have provision for the registration of medicines. Uganda, Tanzania-Mainland and Rwanda have provision to waive registration requirements under certain conditions, while Tanzania-Zanzibar and Kenya do not have provision for waivers. The conditions for waivers among the three countries vary. In Uganda, a waiver is done under section 8(4) of the National Drug Authority (NDA) Act to meet emergency and extraordinary circumstances. In Tanzania-Mainland, a waiver is considered only when a product has no registered alternative that is therapeutically equivalent, or there is an inadequate supply of a registered medicine, which occurs mainly with orphan drugs such as anti-cancer medicines. In Rwanda, waivers are given for medicines that are WHO pre-qualified.

2.3.2 Guidelines for registration of medicines

The relevant guidelines and reference standards for the registration of medicines in the EAC were reviewed and analysed.

Four countries, namely Uganda, Kenya and Tanzania (Mainland and Zanzibar), have guidelines for the registration of medicines, while Burundi and Rwanda do not. These guidelines are for pharmaceutical products in the four NMRAs, while processes also exist for the registration of human biological products in Tanzania-Mainland and Uganda.

The scope of the guidelines, frequency of revision and reference guides vary in the different

countries. The scope of the guidelines covers renewals and NCEs in Tanzania, Uganda and Kenya; generics in Zanzibar, Tanzania and Uganda; variations in Uganda; and new applicants for the four NMRAs. The frequency of revision of the guidelines is not defined in Uganda and Tanzania. Currently the guidelines are under review in Zanzibar, while in Kenya the guidelines are reviewed as the need arises. The main reference guides used for reviews by Uganda and Tanzania include the WHO Quality Assurance of Pharmaceuticals (a compendium of guidelines and related materials). In addition, Tanzania-Mainland also uses the Ugandan NDA and WHO-PQ as reference guides, while in Tanzania-Zanzibar, the Zanzibar Food and Drugs Board (ZFDB) refers to the Tanzania Food and Drug Authority (TFDA). The NMRAs in Uganda, Kenya and Tanzania use their websites to make all existing regulations and guidelines publicly available. In Kenya, guidelines are also made available to applicants on request at the offices of the Pharmacy and Poisons Board (PPB), while Uganda and Tanzania also sell the guidelines on request. In Rwanda, the documents are kept inhouse and are available to applicants only through the approval of the Pharmacy Task Force of Rwanda.

2.3.3 Registration times and processes

2.3.3.1 Requirements for registration and marketing authorisation

There are a number of similarities in the requirements for registration among the NMRAs, which is conducive for the harmonisation process. A WHO-type Certificate of Pharmaceutical Product (CPP) is required at the time of dossier submission for the registration of all medicines and pharmaceutical products in Uganda and Tanzania and generic medicines in Rwanda. The countries that require WHO prequalification (WHO-PQ) or Stringent Regulatory Authority (SRA) approval for generic medicines and all pharmaceutical products, and NCEs from less regulated markets, are as follows: the Ugandan NDA requires WHO-PQ for market authorisation, while the ZFDB and TFDA require both WHO-PQ and SRA approval. As far as importation approval is concerned, the Ugandan NDA requires information from an SRA as a reference for approval, while the ZFDB and Rwanda require both WHO-PQ and SRA approval.

Decisions made by other regulatory authorities are taken into account when NMRAs register medicines. The NMRA references that are used include TFDA for Zanzibar; the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and the Food and Drug Administration (FDA) for Rwanda; ICH and WHO-PQ for Tanzania; and products jointly evaluated by the EAC/WHO and prequalified by the WHO and SRA for Kenya. The authorities that constitute an SRA are countries in the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme (PIC/S), ICH countries, or countries or authorities on the defined list (Malaysia, South Africa, WHO-PQ, Israel, South Korea, NDA, PPB and TFDA). Uganda, Zanzibar and Tanzania-Mainland do not require a factory inspection if such references are provided. An evaluation decision is accepted without the need to perform a separate review by Zanzibar, Kenya and Rwanda ,and an abbreviated evaluation is performed by Tanzania-Mainland for those aspects that might differ.

The NRMAs normally recognise market authorisations granted elsewhere if the following conditions are fulfilled:

a) The NDA requires marketing authorisation from another SRA to support applications for NCEs from less regulated markets.

b) Medicines registered by the TFDA are allowed on to the market in Zanzibar.

c) The TFDA requires the existence of documentary evidence showing that assessment has been done to its satisfaction.

d) The PBB recognises products that have been jointly evaluated in EAC countries.

e) Rwanda recognises market authorisations from countries with a well-established NMRA.

The NMRAs in Uganda, Zanzibar, Tanzania-Mainland and Kenya allow a generic manufacturer to register its products even when the innovator product is not registered in the country. However, this is only permitted if the manufacturer submits the following data:

a) a bio-equivalence study using an innovator product approved by an SRA as the reference product in Uganda, Tanzania (Mainland and Zanzibar) and Kenya;

b) the right to reference the clinical data used in the innovators' SRA filing in Zanzibar; and

c) published clinical data on the innovator product that is sufficient to demonstrate safety and efficacy in Zanzibar and Kenya.

The legislation in all EAC countries with the exception of Rwanda provides for the registration of other products, ranging from vaccines to traditional medicines, medical devices, cosmetics and packaged food.

2.3.3.2 Assessment of applications for the registration of pharmaceutical products

The NMRAs use various ways to assess applications for the registration of pharmaceutical products. The NDA (Uganda), TFDA (Tanzania) and PPB (Kenya) have technical committees that assess applications for the registration of pharmaceutical products, namely, the Drug Registration Department (Uganda), the NDA Technical Committee (Uganda), the Technical Committee for Registration of Human Medical Products (Tanzania), and the Technical Committee for Generics and NCEs (Kenya). At the NDA and PPB, the board makes the final decision following the recommendations of the technical committee. At the TFDA, the final decision is made by the director-general on the advice given by the technical committee.

With the exception of Tanzania-Zanzibar, the NMRAs have fast-track policies for considering applications for medicines for treating high-priority diseases such as HIV/AIDS, tuberculosis and malaria, and for NCEs and medicines for neglected diseases for which treatment has been almost absent. A fast-track policy is available to applicants in Tanzania-Mainland, Kenya and Burundi. The relevant information is attached to registration guidelines, is included on the websites, and is available in some health units. In Uganda, there is an unwritten internal policy to prioritise applications for antiretroviral drugs (ARVs) irrespective of when such applications are received. To ensure transparency and accountability, applicants are appropriately informed if they qualify for a fast-track review process in Kenya. The fast-track standard review target time in Tanzania for the above-mentioned diseases varies from 6 to 12 months.

2.3.3.3 Average registration time

This section reviews the registration times for applications for medicines for the treatment of certain priority diseases in the EAC. During the three-year reporting period (2007–2009), complete data on applications for the registration of medicines for treating high-priority diseases were available only from Tanzania. For HIV/AIDS drugs, 122 applications were received, 97 products were approved for registration, there were no backlogs, and the average registration time was 18 months. Seven applications were received for anti-tuberculosis medicines, three

were approved, no backlogs were recorded, and the average registration time was 18 months. For anti-malarial medicines, 65 applications were received, 38 products were approved, no backlogs were recorded, and the average registration time was 18 months. Twenty-nine applications for NCEs were received, 23 products were approved, no backlogs were recorded, and the average registration time was 24 months. A total of 1835 applications were received for generic products, 1071 products were approved, there were 217 backlogs, and the average registration time was 18 months. In the case of Kenya, the average registration times were nine months in 2010, six months in 2008 and four months in 2009 for all application types.

The problems of providing data are due to the limitations of the various information management systems in the NMRAs. Uganda and Kenya use SIAMED, which is not user friendly and is difficult to integrate with other platforms. Burundi and Tanzania-Zanzibar use manual systems, and Rwanda's electronic system is not integrated. Tanzania-Mainland uses an integrated information management system, but the system faces several operational challenges. It is therefore necessary to implement a common regionally linked information management system for an effective harmonised medicines registration system.

2.3.4.4 Factory inspection

With the exception of Zanzibar and Rwanda, the other EAC countries have factory inspection policies that are available to applicants in the four NMRAs. The information is published on the website in Uganda and Kenya, while in Tanzania and Burundi it is included in the guideline/ policy document. Uganda, Tanzania, Kenya and Burundi inspect factories outside their borders as part of the registration process.

In Tanzania and Burundi, approval of a manufacturers' track record by another competent authority and WHO-PQ determine whether a factory inspection is required. In Kenya, all manufacturers of products on the market have to be inspected, while in Uganda, all factories that are not exempted from inspection are inspected once every three years. In addition to the factors that are considered in other countries, Tanzania considers product risk and SRA approval with respect to factory inspections.

It was noted that the NMRAs waive inspections for some factories. A waiver is applicable in Uganda when inspection needs to be done in North America, and in Burundi, a waiver applies for applications for medicines registration from a country known to have GMP approval from the NMRA of the country where the factory is located. In Tanzania, an inspection waiver is granted if the facility is in a country with an NMRA that applies stringent standards with respect to the documentation to support GMP submitted by the applicant. Kenya does not grant a waiver under any circumstance. If joint inspections were carried out through a harmonised initiative, these waivers would be streamlined. These differences emphasise the need to implement a Common Technical Document (CTD).

2.3.4.5 Medicine samples testing for medicines registration

Only two NMRAs (Zanzibar and Kenya) test medicine samples for medicines registration. However, samples are tested for post-marketing surveillance in all the NMRAs apart from Rwanda. In respect of the number of samples required, Zanzibar requires six samples, while the number required by Uganda and Rwanda is unknown, and the number required by Kenya depends on the formulation. The national quality control laboratory is responsible for testing in Uganda, Tanzania and Kenya, while the government analyst conducts tests in Tanzania. The NMRAs of Burundi and Tanzania sometimes use quality control laboratories abroad. In Tanzania and Zanzibar, there are also mini-laboratories at district and regional level that test samples.

2.3.4.6 Recommendations

The legal and regulatory policies guiding medicines registration harmonisation in EAC countries are plagued by lack of uniformity and sometimes lack of adherence to laid-down procedures. To counteract these deficiencies, the following recommendations are made:

a) Legal provisions for the recognition of regulatory decisions made by other partner states need to be clearly spelt out.

b) The capacity of NMRAs needs to be improved to enable them to fulfil their legal and regulatory functions. Short-term technical assistance should be provided to Burundi and Rwanda to improve their regulatory capacity. Countries where regulatory policies are in place need to adhere strictly to agreed guidelines.

c) The conditions guiding waivers in the respective NMRAs need to be tightened to avoid abuse.

d) Countries that do not adhere to guidelines for the registration of medicines should be encouraged to do so.

e) The scope and frequency of revision of guidelines, and the dissemination of such information using websites and government gazettes, need special attention.

f) The average registration times of 18 months for most medicines in all the NMRAs should be shortened, and record-keeping needs to be improved through the implementation of an information management system.

g) The lack of factory inspections in some NMRAs (Zanzibar and Rwanda) should be corrected. A framework for joint evaluation of dossiers and inspection of manufacturing sites for compliance with GMP requirements should be implemented.

2.4 BENEFITS AND CHALLENGES OF REGIONAL MEDICINES REGULATORY HARMONISATION IN THE EAC

The NMRAs believe that the development and implementation of a regionally harmonised medicines regulatory system will have benefits, but will also face some challenges.

2.4.1 Benefits

The NMRAs consider that they will derive the following benefits from a regionally harmonised medicines regulatory system:

a) Governments, communities and patients in East Africa will enjoy increased availability of safe, effective, quality medicines for neglected and priority diseases.

b) Safer and higher-quality medicines will be readily available on the market.

c) The increased availability of safe and effective essential medicines at affordable prices will contribute to the achievement of the Millennium Development Goals related to health (goals 4, 5, 6 and 8).

d) Governments and NMRAs will be better equipped to register medicines in a cost-effective and timely manner through improved regulatory processes and better use of technical skills.

e) There will be greater technical capacity for improved quality of inspections, and more effective control over registered, unregistered and counterfeit medicines.

f) Pharmaceutical companies will benefit from simplified and standardised regulatory approval processes. It will become possible to submit dossiers for much-needed medicines simultaneously in multiple countries, and evaluation turnaround times will improve.

g) Human capital will be enhanced, and other limited resources will be pooled and thus utilised more efficiently in the region.

h) NMRAs will share the outcomes of regulatory decisions more efficiently and effectively.

i) The existence of common technical documents across the REC will catalyse greater efficiency in processing applications.

j) The NMRAs will experience reduced and minimal flouting of pharmaceutical regulations.

k) Access to larger and wider regional markets will increase.

2.4.2 Challenges

The EAC and its NMRAs have experienced some challenges to medicines registration harmonisation, namely:

a) Due to differences in laws among partner states, decisions made by one NMRA are not recognised by another.

b) Only three EAC partner states (Kenya, Uganda and Tanzania) have NMRAs that are operational and autonomous, while the other two countries (Burundi and Rwanda) carry out national medicines regulatory functions within their national ministries of health. This means that partner states are at different levels in terms of harmonisation of medicines regulatory processes.

c) The human resource capacity of the EAC Secretariat and in respective partner states is limited in terms of both numbers and skills. For example, the EAC Secretariat does not have anyone to coordinate pharmaceutical activities related to the harmonisation of medicines regulation. Moreover, there are no evaluators, inspectors or other regulatory staff.

d) The quality and robustness of physical facilities vary among partner states. Two of the partner states (Rwanda and Burundi) have very limited physical infrastructure to enable them to carry out the full range of medicines regulatory activities.

e) There are insufficient quality control laboratories for drugs in the EAC. The laboratory in Kenya is the only one that is prequalified by the WHO. The process of prequalification and accreditation to meet international standards is under way for the laboratories in Uganda and Tanzania.

f) Information and communication systems to support regional and national networking and exchange of information across the region are weak and erratic.

g) NMRAs are over-reliant on government subvention, which continues to decline

h) Partner countries have varying requirements for medicines registration

i) The coordination systems among partner states are weak and ineffective.

j) The delays in the approval of the regional pharmaceutical policy by the Integrated Council of Ministers have resulted in delayed implementation.

2.4.3 Recommendations

In order to achieve greater harmonisation of medicines registration, the EAC and its partner states should address the following:

a) The EAC and NMRAs should undertake reviews of the regulatory and legislative provisions for medicines registration harmonisation.

b) The EAC Secretariat should be strengthened for improved coordination and leadership.

c) A clear roadmap should be established for the harmonisation of medicines registration.

d) Adequate allocations of financial resources should be made for harmonisation activities.

e) All stakeholders should be engaged and sensitised with respect to the benefits and value of harmonisation.

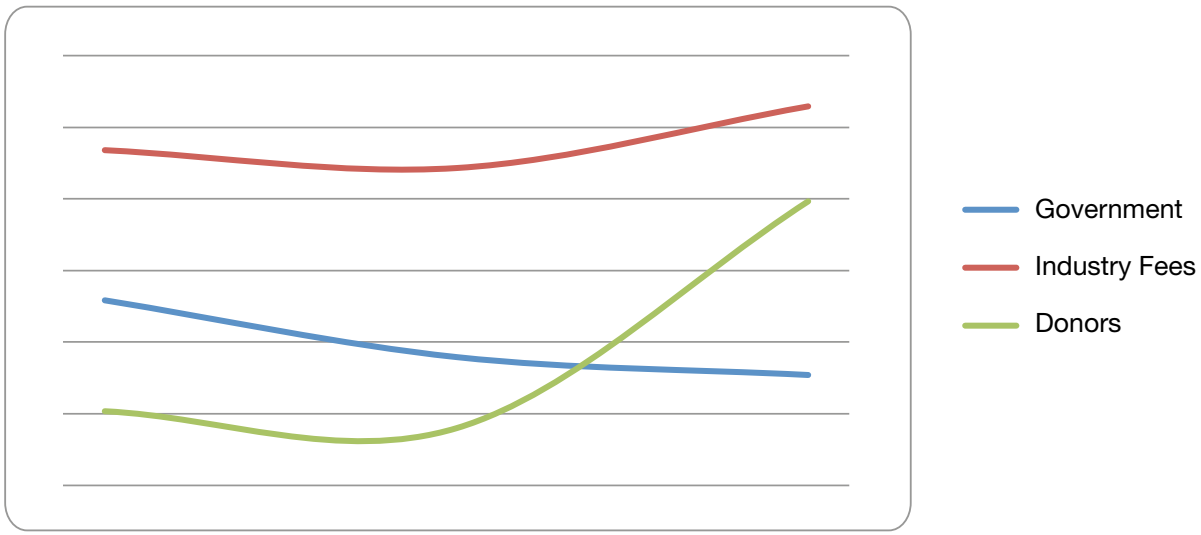
f) The Integrated Council of Ministers of the EAC should agree upon and concretise the regional pharmaceutical policy.

2.5 STATUS OF FINANCIAL AND HUMAN RESOURCES IN NMRAs

2.5.1 Sources and levels of funding

The information on levels of funding from government, industry fees and donors to the NMRAs for 2007, 2008 and 2009 was scanty. The TFDA provided clear and informative data on sources and associated proportions of funding for the NMRA. It is evident that government subvention constitutes 22.65% of the total revenue of the NMRA, donor funding 22.20% and fees 55.15%. While government financing has been decreasing, industry fees and donor support have increased steadily (Figure 1). Unlike other countries, Rwanda does not retain fees for various regulatory functions and operations. Fifty per cent of the subvention from government to the TFDA is used for the institution's wage bill. In Kenya, the staff wage bill is covered by treasury subvention, while operations are fully financed by industry fees. The Ugandan NDA is fully funded by industry fees (90%) and donor support (10%).

Figure 1: TFDA financing trends in US$ (2007–2009)



2.5.1.1 Recommendations

In order to have a clear picture of trends related to financing mechanisms and the total resource base, it is recommended that:

Each NMRA should establish a comprehensive information management system for tracking and recording information, including financial data; this will be important for forecasting and decision-making.

The financial commitment of each member country towards the sustainability of the resource base should be enforced in order to increase local ownership and sustainability of NMRA activities.

A resource mobilisation plan should be developed, properly articulated and implemented by each NMRA and the EAC.

2.5.2 Human capacity in NMRAs and the REC

The human capacity for medicines regulatory activities in the NMRAs is limited and varies between NMRAs (Table 6). Comparisons across the region reveal that Uganda, Kenya and Tanzania are better resourced in this respect than Zanzibar, Rwanda and Burundi. The largest concentration of staff is skewed towards diploma holders, and there are few personnel with a bachelor, masters or doctoral degree. Pooling resources across the region through harmonisation would therefore enhance regional capacity in the four main regulatory functions of NMRAs (namely, the evaluation of dossiers, distribution chain inspection, GMP inspection and quality analysis of the medicines). The two NMRAs in Tanzania (Mainland and Zanzibar) should use the available skills and competencies to complement each other. There is a need to build capacity for effective participation in the harmonisation process. It is worth noting that all the NMRAs have unfilled vacant posts, largely due to the low financial resource base.

Table 6: Relative capacities of NMRAs in the EAC

NMRA/ Country	Regulatory function	Qualified staff				TOTAL	Staff with specialised training
		Diploma	Bachelor degree	Masters degree	Doctorate		
Kenya	Distribution chain inspectors	30	8	1		76 (39)[1]	39
	GMP inspectors		2	1		7 (3)	3
	Laboratory analysts					28	-
	Evaluators	2	2	7	-	28 (11)	11
	quality data					6 (10)*	
	safety data					6 (5)*	
	Efficacy data					6 (5)*	
Rwanda	Distribution chain inspectors						2
	GMP inspectors						-
	Laboratory analysts						-
	Evaluators		1	1		4 (2)	-
	quality data					0 (0)*	
	safety data					0	
	efficacy data					0	

NMRA/ Country	Regulatory function	Qualified staff				TOTAL	Staff with specialised training
		Diploma	Bachelor degree	Masters degree	Doctorate		
Tanzania	Distribution chain inspectors	4	26	5		49 (39)	-
	GMP inspectors		10	13		(23)	20
	Laboratory analysts	1	2	6		17 (9)	9
	Evaluators		6	2		31 (8)	8
	quality data					7 (0)*	
	safety data					2 (5)*	
	efficacy data					2 (5)*	
Uganda	Distribution chain inspectors	6	21	5		32 (32)	-
	GMP inspectors	24	7	1		32 (32)	-
	Laboratory analysts	1	7	2	1	11 (11)	1
	Evaluators	1	7	2		10 (10)	-
	quality					2 (0)*	
	safety data					0	
	efficacy					0	
Zanzibar	Distribution chain inspectors	13	1	1			-
	GMP inspectors						-
	Laboratory analysts	3	1				1
	Evaluators	1			1		1
	quality data					1 (0)*	
	safety data					0	
	efficacy data					0	

Note: 1 Number in brackets indicates total staff in post; * External evaluators or assessors; - no data provided and available.

Human resources in the health and pharmaceutical sectors are also limited, as shown in Table 7. It is worth noting that the numbers of medical and pharmacy schools in the region are also low.

Table 7: Health and pharmaceutical human resources in NMRAs of the EAC

Indicators	Burundi	Tanzania	Uganda	Kenya	Rwanda
Doctors	-	6776	-	6623	578
Dentists	-	-	-	974	-
Pharmacists	-	700	-	2860	247
Pharmacy technologists	-	349	-	1815	-
Registered nurses	-	10,669	-	14,073	6318
Enrolled nurses	-	-	-	31,917	5914
Clinical officers	-	-	-	5035	-
Public health officers	-	-	-	6960	-
Public health technicians	-	-	-	5969	-
No. of medical schools in the country (2010)	3		1	1	3
No. of pharmacy schools in the country (2010)	-	6	1	1	3
No. of other related schools in the country (2010)	1		18	6	

2.5.2.1 Human resource planning in the EAC and NMRAs

The NMRAs in Kenya, Rwanda, Tanzania and Uganda have human resource development (HRD) plans, most of which have not been implemented, partly due to declining funding. In Tanzania, the HRD plan remains unimplemented, although it was expected to be rolled out in July 2010. In Uganda, highly specialised training has not been included in the HRD plan. The EAC developed a regional programme for capacity building of NMRAs in the partner states. This was based on the need for regional training programmes related to the evaluation of dossiers. Twenty participants benefited annually from this programme in 2007, 2008 and 2009. Capacity building initiatives with respect to GMP inspections and laboratory analysis are necessary for the harmonisation of medicines registration and regulations, but have not been implemented.

2.5.3 Recommendations

The development and strengthening of human resources will inform better delivery of the harmonisation of medicines registration in the NMRAs of the EAC. It is recommended that the EAC and NMRAs should therefore:

a) ensure that modalities for utilising pooled regional capacity are developed and implemented;

b) initiate and implement regional human resource development planning; the building and expansion of human capital should target both national and regional needs;

c) develop and promote staff exchange programmes so that the better-capacitated NMRAs support the development of NMRAs in sister countries; and

d) establish regional centres of excellence for training and research; training NMRA staff within the region will reduce the cost of training and increase retention rates.

2.6 PHARMACEUTICAL MANUFACTURING SECTOR IN THE EAC

An analysis of the pharmaceutical industry with reference to pharmaceutical companies in three member states (two from Kenya and one each from Tanzania and Uganda) provided insights into their perceptions about the medicines harmonisation initiative. These partner states have several pharmaceutical associations, namely, the Kenya Association of the Pharmaceutical Industry (KAPI), the Federation of Pharmaceutical Manufacturers of Kenya (FPMK), the Tanzania Pharmaceutical Manufacturers Association (TPMA) and the Uganda Pharmaceutical Manufacturers Association (UPMA). The membership of the FPMK, UPMA and TPMA includes local manufacturers, the membership of KAPI includes both local and innovation-based manufacturers (Appendix 3). The formation of a regional association is still in its infancy. However, the heads of the industry associations in Uganda, Kenya and Tanzania have signed and submitted a letter of intent to work towards establishing a regional association. It is expected that the association will be based in Arusha, Tanzania and that its functionality will be supported by GTZ.

2.6.1 Recommendations

National and regional pharmaceutical associations are important for the EAC. It is therefore recommended that the EAC should put in place systems in order to establish a regional association soon that will mobilise national associations to participate actively in the medicines regulation harmonisation initiative.

2.6.2 Benefits, drawbacks and challenges of medicines regulation harmonisation

Generally, industry considers the process of medicines regulation harmonisation to be an important step in order to create opportunities to expand business within the EAC and beyond; create greater efficiency and optimal reduction of the bureaucracy involved in registering medicines in the different East African nations; and reduce the current volume of administrative paperwork. Industry therefore identified several benefits, drawbacks and challenges of medicines regulation harmonisation. These are summarised in the following sub-sections.

2.6.2.1 Potential benefits

Industry believes that the medicines regulation harmonisation initiative will:

a) result in better medicines regulation in the region;
b) expand business opportunities beyond each country and within the region;
c) reduce the workload of staff in charge of registration;
d) improve communication across the region;
e) enhance the reputation of industries from national to regional levels;
f) lead to faster access and lower costs of development of medicines; and
g) enhance efficiency in the registration process.

2.6.3 Drawbacks and challenges

Despite the potential benefits, industry anticipates drawbacks and challenges, namely:

a) a tendency for regulators to focus on documentation and GMP inspections while failing to focus on post-marketing surveillance;
b) increased competition with more developed manufacturers;
c) higher and increased requirements with respect to standards and quality;
d) unprepared and inadequate capacity of evaluators in the region;
e) unclear formula for sharing income and fees;
f) unscrupulous industries not implementing and adhering to basic quality assurance and monitoring systems;
g) non-adherence to minimum standards and specifications by most industries; and
h) absence of proper training programmes for inspectors and staff of regulatory bodies.

The views of the industry on the harmonisation process are not surprising, because they have not previously been involved in discussions on medicines regulation harmonisation. The industry in the EAC wishes to witness:

a) reduced duplication of resources and more collaboration;
b) a single market;
c) good collaboration and fast registration for price advantages;
d) existing private pharmaceutical companies being well informed about medicines registration; and

e) a clear roadmap for the harmonisation process, with milestones being developed and implemented. Industry is thus very committed to participating in the process.

In the EAC, industry appreciation of what is required to comply with registration requirements ranges from 'good' to 'excellent'. This notwithstanding, Uganda and Kenya consider that some of the requirements are unnecessary, namely: the repetition of information; the need for site inspection by all agencies; supplying Drug Master Files (DMF) for generics; and the analysis of pre-registration samples. Other challenges and bottlenecks in the registration process include that the analysis of samples and file reviews takes too long; lack of evaluators and capacity to evaluate certain products; and administrative delays due to lack of resources in the regulating bodies.

2.6.4 Effectiveness of medicines registration processes and areas requiring improvement

In the EAC region, there are success and impeding factors that influence effective medicines registration processes. The main success factors are the quality of the presented data, strong market surveillance, proper and clear guidelines on requirements for registration, close liaison between industry and registration authorities, and adherence to the application guidelines and processes. The impeding factors across the region are largely the lack of harmonisation, the absence of enforcement mechanisms, the lack of post-approval market surveillance, the use of inappropriate guidelines, administrative bureaucracy, and limited human capital and analytical and financial resources. The factors identified as being required to support efficient and effective registration in the EAC include enhanced harmonisation, the presence of functional registration systems, better and more active dialogue between industry and regulators, adequate human, technical and financial resources, and post-registration surveillance. The specific factors are presented in Table 8.

Table 8: Factors related to medicines registration in the EAC

Country	Factors		
	Success	Impeding	Required
Burundi			Develop and implement a functional registration system Promote local production and related investment Interaction between the pharmaceutical industry and NMRA
Kenya	Quality of data presented GMP inspection Evaluation by trained persons Post-approval market surveillance Proper list of exemptions on requirements Strong market surveillance Proper guidelines on requirements of registration	Lack of enforcement of current laws Lack of post-approval market surveillance Too much focus on documentation Inappropriate guidelines, especially with respect to packaging Repetitions	Post-registration marketing surveillance Better regulation of outlets Risk-based GMP inspection Adherence to timelines of responses Consistency in response to queries
Rwanda			Human resources Legal framework

Country	Factors		
	Success	Impeding	Required
Tanzania	Strength with clear guidelines Process is strictly followed and adhered to	Lack of technical and other requisite resources at regulatory body Time taken too long, especially for local manufacturers Bureaucracy causing unnecessary delays No open channel for communication with the regulatory body for local industry-related issues	Create a separate department for registration of local products Fast track for critical/essential medicines Improve resources at regulatory body level
Uganda	Closer liaison between industry and registration authorities Harmonisation of requirements	Slowness of review of files Lack of harmonisation	Faster review of files Enhance harmonisation

2.6.4.1 Recommendations

In order to achieve effective medicines registration in the EAC and its member NMRAs, it is recommended that the following are undertaken:

a) strengthening and/or establishing medicines regulatory authorities for effective implementation of their functions, which is critical to achieving success;

b) effective harmonisation of medicines registration processes;

c) implementing pre- and post-registration inspection and marketing surveillance across the region using well-trained human capital; and

d) developing and implementing a clear roadmap for engagement with the industry.

2.6.5 Pharmaceutical production status

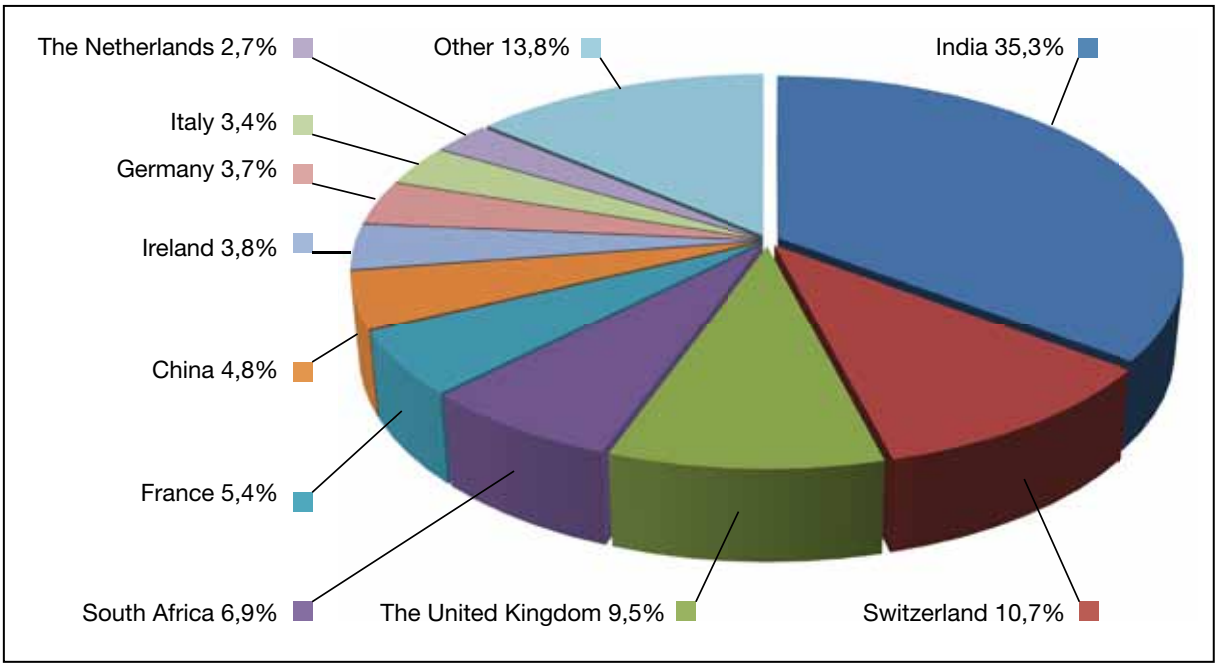
Table 9 depicts the pharmaceutical production status of the five EAC partner states. Sixty-two per cent of pharmaceutical plants are owned by nationals (government or private). Fifty per cent of the manufacturing plants in the EAC are based in Kenya. Almost 87% of the plants manufacture generic products. It was not possible to determine government expenditure on the total value of domestic production, the total value of imports of finished products, or the total value of exports of active ingredients or finished products. According to the Federation of Kenya Pharmaceutical Manufacturers (FKMP), however, the pharmaceutical industry in Kenya is the most developed in the region. The market for locally manufactured pharmaceutical products currently commands 28% of the overall pharmaceutical market in Kenya, valued at US$58.4 million. The worth of the Kenyan pharmaceutical market is expected to increase from US$229 million in 2008 to US$359 million in 2013, representing a compound annual growth rate of 9.34%. The key drivers of market expansion are greater access to health care, increased out-of-pocket spending (in terms of both volume and value) and more government involvement in health-care matters. Poverty levels as well as the international financial downturn may negate the growth. Antibiotics are the most registered products, constituting 30% of registered medicines, followed by analgesics and anti-malarial drugs. India is the leading competitor of Kenyan manufacturers. Kenyan imports of pharmaceutical products in 2007 by country of origin and percentage share are shown in Figure 2.

Table 9: Pharmaceutical production status of EAC partner states (2010)

Country	Burundi	Tanzania	Uganda	Kenya	Rwanda	Total
Total number of pharmaceutical manufacturing plants	1	7	21	42	1	72
Total number of research-based pharmaceutical industries	0	0	0	0	0	0
Total number of generic pharmaceutical product (including branded generics) manufacturers	1	7	12	42	10	72
Total number of pharmaceutical plants owned by nationals (government and private)	0	3	7	40	1	51

Note: The NMRA in Zanzibar did not report any information with respect to the pharmaceutical production status.

Figure 2: Kenyan imports of pharmaceutical products by country of origin (2007)



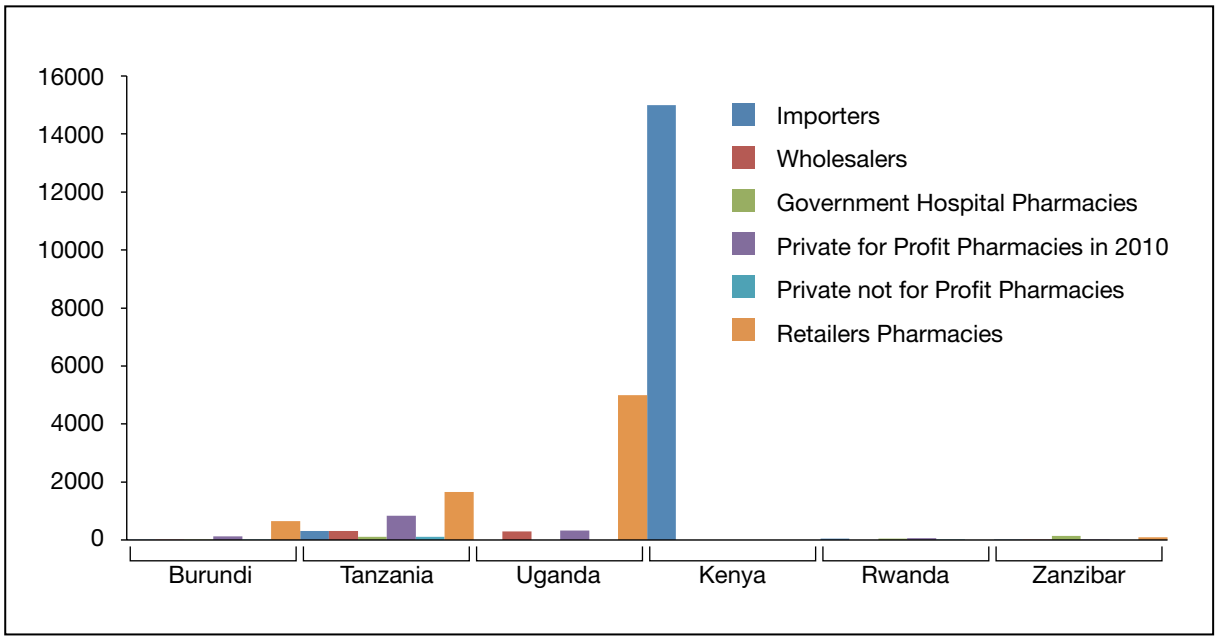
Source: Wanyanga and Weche (2009)

As indicated in Table 10 and Figure 3, Kenya leads with respect to the number of pharmaceutical industries, followed by Uganda, Tanzania, Burundi, Zanzibar and Rwanda, in that order.

Table 10: Distribution of pharmaceutical industries in the EAC (2010)

Country	Burundi	Tanzania	Uganda	Kenya	Rwanda	Zanzibar
Importers	18	310	-	-	41	8
Wholesalers	10	310	298	-	-	7
Government hospital pharmacies	5	111	-	-	44	137
Private for-profit pharmacies	131	830	323	-	70	23
Private not-for-profit pharmacies	1	108	0	-	14	-
Retail pharmacies	643	1652	5000	-	-	87

Figure 3: Distribution of pharmaceutical industries in the EAC (2010)



2.6.5.1 Recommendation

Both pharmaceutical industries and NMRAs should keep records of their various operations. To facilitate this, training in record-keeping and the implementation of an effective information management system should be prioritised.

2.7 INFORMATION SHARING AND STAKEHOLDER INVOLVEMENT/ ENGAGEMENT IN THE EAC AND NMRAs

The EAC has developed mechanisms for sharing information among its member NMRAs. However, there is no specific mechanism for sharing information regarding medicines registration decisions made by NMRAs at the regional level. If any such information sharing mechanisms do exist among members, these are largely informal and occur through joint activities. For example, in March 2010, the NMRAs of EAC partner states and the WHO piloted a joint dossier assessment to facilitate harmonisation and the sharing of information and expertise. More joint activities have been planned and will be extended to facility inspections. It is envisaged that the presence of a regional association in future will enhance information sharing among the various membership categories. The EAC has already initiated a process of engaging various stakeholders such as the pharmaceutical industry, civil society, researchers and academia in medicines regulatory harmonisation decisions. The regional proposal on EAC medicines registration harmonisation includes an annual stakeholders' forum on medicines and drugs regulation, which will provide a platform for stakeholders to solicit and exchange views on the implementation process and report on progress. It is also envisaged that this annual event will bring together both regional and national stakeholders to ensure an inclusive approach as well as effective implementation of medicines registration harmonisation by taking advantage of any identified complementarities. The functions and responsibilities of the forum are to disseminate and share information on progress with project implementation; build political and technical commitment to the harmonisation process; and share experiences from other regional bodies outside the EAC region.

The NMRAs in the EAC use various information sharing systems, the most important and widely used of which are their websites, which provide information on legislation, guidelines, fees, lists of registered products, lists of rejected products, lists of banned products and lists of authorised manufacturers. The NMRAs also use flyers, state-owned newspapers, government gazettes and various publications to disseminate information to the public and potential clients. The medicines regulation guidelines are shared with the public by publishing them on the NMRAs' websites; making them freely available to applicants on request; or selling them.

The NMRAs and the EAC experience limitations with existing information sharing mechanisms. The NDA, TFDA and PPB have their own websites, but these are not regularly updated. In Burundi, Rwanda and Zanzibar, the websites are hosted by the ministries of health, and the management of the websites is at the discretion of the hosts. The WHO shared point at the EAC is inactive due to the lack of a focal person to manage the information.

With the exception of Zanzibar, all the other NMRAs have developed mechanisms for engaging stakeholders in medicines regulatory decisions. The objectives of such engagement are threefold:

a) to update stakeholders on medicines regulation and to solicit and exchange views on the implementation of regulations;

b) to strengthen collaboration in setting up rules and regulations and ultimately promote voluntary compliance; and

c) to involve all stakeholders in monitoring the accessibility of quality drugs.

These objectives are achieved by seeking stakeholder inputs at national workshops to the process of revising the guidelines; holding meeting of stakeholders when regulatory issues are to be shared; and encouraging stakeholders to provide comments on draft documents uploaded on NMRA websites or sent directly to them on request.

Interaction between the pharmaceutical industry and the EAC is important in order to improve the legal framework, facilitate the approval of registration dossiers and implement action plans for inspection. Currently there are modalities of engagement between the industry and NMRAs in Kenya and Uganda. In Rwanda and Tanzania, engagement is achieved through the chief pharmacist and local manufacturing associations and during the quality assurance of pharmacy products. In Burundi, the NMRA does not have mechanisms for consultation with stakeholders. Important consultation mechanisms include public meetings when policies and regulations are developed, invitations to stakeholder meetings to discuss policies and regulations, stakeholder representation on board committees (at the NDA, for example) and the constitution of a national establishment committee during the development of the essential medicines list.

2.7.1 Recommendations

To achieve greater communication and sharing of information in the EAC and within NMRAs, it is essential that:

a) an information sharing and exchange framework or strategy be developed, agreed and implemented for the EAC;

b) The websites of the NMRAs and the EAC be reviewed and updated regularly; and

c) the health desk at the EAC Secretariat be made functional.

2.8 CONCLUSIONS AND RECOMMENDATIONS

2.8.1 Conclusions

The EAC has made important strides towards implementing a harmonised medicines regulatory system, as provided for by Chapter 21 (Article 118) of the Treaty for the Establishment of the East African Community (1999). Some of these include capacity building programmes; providing legal instruments for NMRAs in some partner states, including Kenya, Tanzania and Uganda; preparing a proposal on the medicines registration harmonisation initiative for funding by the Bill and Melinda Gates Foundation; and engaging various stakeholders to facilitate the implementation of the initiative.

Evidently the EAC, NMRAs and the pharmaceutical industry are enthusiastic about and committed to implementing a harmonised medicines regulatory system. The key stakeholders and partners are aware of and recognise the benefits of drug harmonisation, namely:

Increased availability of safe, effective, quality medicines for neglected and priority diseases. There will be safer, more affordable and higher-quality medicines circulating on the market in the long term. This will contribute to the achievement of the Millennium Development Goals relating to health (goals 4, 5, 6 and 8).

NMRAs will be better equipped to register medicines in a more cost-effective and timely manner by improving regulatory processes and making better use of technical skills. There will be greater technical capacity, improved quality of inspections, and more effective control over registered, unregistered and counterfeit medicines.

Pharmaceutical companies will benefit from simplified and standardised regulatory approval processes. It will become possible to submit dossiers for much-needed medicines simultaneously in multiple countries, and evaluation turnaround times will improve.

However, the region faces several challenges in taking the medicines regulation harmonisation agenda forward, the most important of which are:

a) Currently, only three EAC partner states (Kenya, Uganda and Tanzania) have NMRAs that are operational and autonomous. The other two countries (Burundi and Rwanda) carry out national medicines regulatory functions within their national ministries of health, but these two countries are currently in the process of establishing NMRAs.

b) Human capital resources, in terms of both skills and numbers, at the EAC Secretariat and in respective partner states are limited. For example, at the EAC Secretariat there are no staff to coordinate pharmaceutical activities, particularly activities related to the harmonisation of medicines regulation.

c) Physical facilities vary between partner states and require expansion to cater for the full functions of medicines regulation. Two of the partner states (Rwanda and Burundi) have very limited physical infrastructure to carry out the full range of medicines regulatory activities.

d) Three drug quality control laboratories exist in the EAC. The only WHO pre-qualified laboratory in the EAC is in Kenya, and the other two quality control laboratories in the region have not yet been prequalified.

e) Information communication systems vary among the partner states and require improvement.

f) There is inadequate financial support, especially for small medicines regulatory authorities.

g) EAC decisions remains undomesticated by partner states, and hence decisions made by individual members are not recognised by others.

2.8.2 Recommendations

For greater consolidation of medicines harmonisation, the following recommendations are made:

2.8.2.1 Legal framework

The EAC and its member countries should:

a) fast-track the enactment of policies and legislation that mutually recognise the persuasive role of regulatory decisions made by other partner state NMRAs. These policies and legislation must be consistent with decisions made under the EAC Treaty and must be passed by the national assemblies of partner states;

b) ensure that the laws or statutes passed regarding the registration of medicines include provision for common objectives among EAC partner states;

c) assist Burundi and Rwanda to enact medicines registration control laws that clearly provide for medicines regulatory functions and the establishment of NMRAs as body corporates;

d) support the EAC Secretariat in preparing an administrative framework for the implementation of points (a), (b) and (c), and developing a protocol to compel the legislative machinery of partner states to domesticate their national laws timeously so that the mutual recognition of decisions made by other partner states is implemented and/or regularised; and

e) ensure that separate functions exist for controlling pharmacy practice and moulding professional pharmacists (whether government employed or private), and for regulating the safety, quality and efficacy of medicines in order to attain comprehensive control of medicines.

2.8.2.2 Registration of medicines

The EAC and its member countries should:

a) tighten the conditions guiding waivers in NMRAs to avoid abuse;

b) encourage and reward countries that adhere to guidelines for the registration of medicines. (The scope, frequency of revision of guidelines and dissemination of such information using websites and government gazettes need special attention.);

c) shorten the registration time to a maximum of 12 to 18 months for most medicines in all the NMRAs of the region;

d) develop a framework for joint evaluation of dossiers and implement the inspection of manufacturing sites for compliance with GMP requirements;

a) establish a comprehensive information management system for each NMRA for tracking and recording information, including financial data that are important for forecasting and decision-making; and

b) implement pre- and post-marketing surveillance systems.

2.8.2.3 Sharing of information and stakeholder consultation

The EAC and its member states should:

a) develop and execute strategies for sensitising regional and national parliaments to the need for fast-tracking the domestication of decisions on medicines registration harmonisation;

b) strengthen the EAC Secretariat for improved coordination and networking;

c) develop an implementation plan for the harmonisation of medicines registration;

d) create awareness among all stakeholders of the benefits and value of harmonisation using various forums and information dissemination tools;

e) ensure that the EAC Integrated Council of Ministers directs and concretises the regional pharmaceutical policy;

f) engage industry with respect to the medicines harmonisation programme; and

g) endeavour to use a variety of information sharing options, including websites which should be kept updated.

2.8.2.4 Capacity building

The EAC and its member states should:

a) build capacity and capability among NMRAs to enable them to fulfil their legal and regulatory functions; and

b) mobilise and efficiently utilise financial resources for the sustainability of NMRA activities.

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APPENDICES

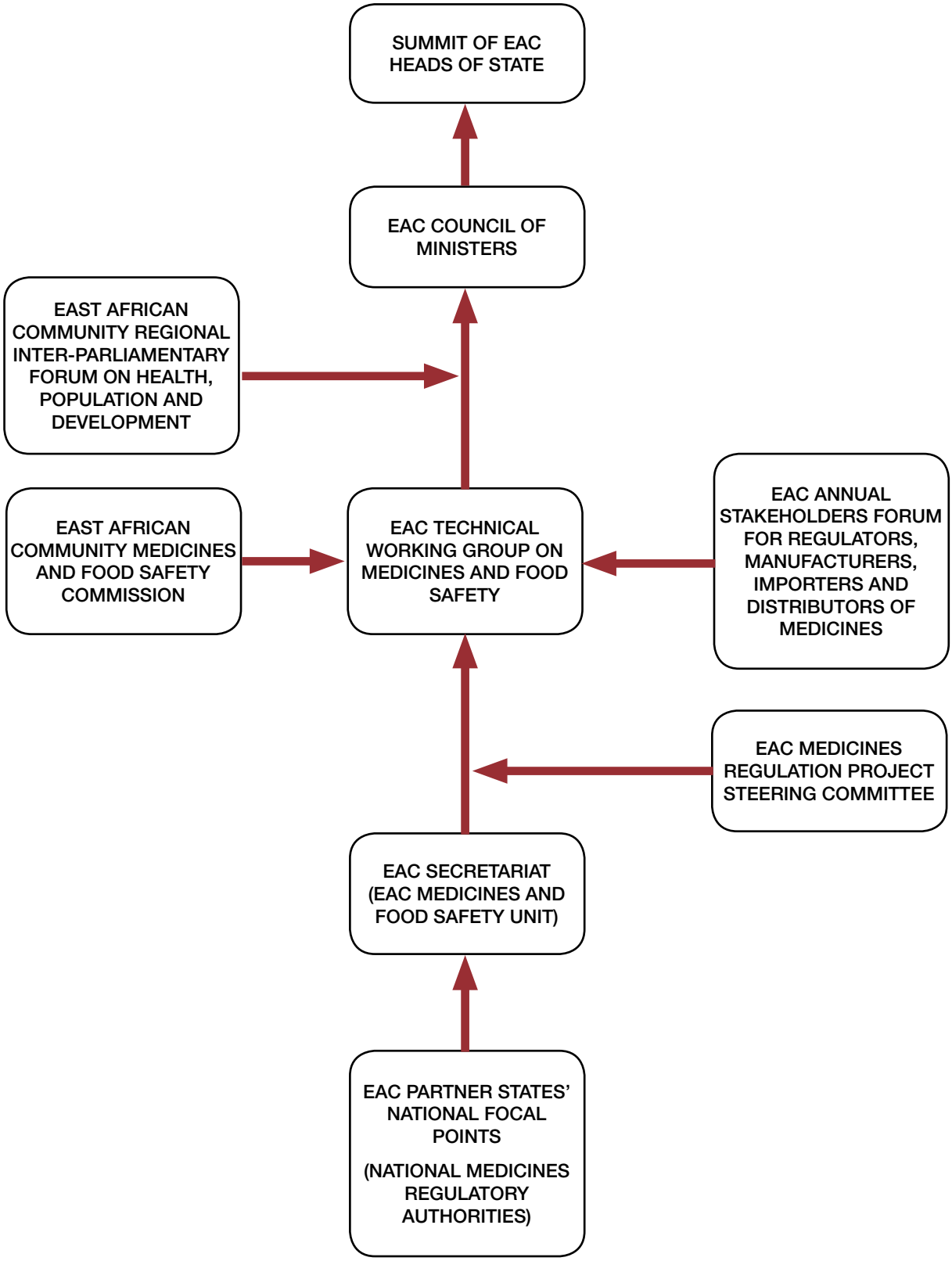
APPENDIX 1

CONTACT DETAILS OF RESPONDENTS TO THE ASSESSMENT INSTRUMENT FROM THE EAST AFRICAN COMMUNITY

Country/ Region	Affiliation	Name of institution	Head of the institution	Position	Contact details			
					Address	Telephone/Cell	Email	Website
Burundi	NMRA	DPML	Deogratias Niyozima	Director	Avenue de l' amite, C/O BP 1820 Bujumbura	+25722273255 +25779936201	Niyoga2007@yahoo.fr	
	Pharmaceutical manufacturers	SIPHAR	Pierre Claver Niyonizigiye	Director of Administration and Legal Affairs	Airport road, 36, Industrial Area, P.O. Box 2024, Bujumbura	+25722242226 +25778856588	Claver_000@yahoo.com	
Kenya	NMRA	PPB	Fred Moin Siyoi	Deputy Chief Pharmacist/ Deputy Registrar	Lenana Road,, Kenya	+254203562107 +254720608811 +254733884411	admin@pharmacyboardkenya.org	www.pharmacyboardkenya.org
	Pharmaceutical manufacturers	FKPMA	Dr Dhirendra Shah	Chairman	Lunga Lunga Road Box 234, Nairobi, Kenya	+254204180991 +2544180694 +2540733709614	info@fkpm.co.ke	
		KAPI	Dr William Mwatu	Vice Chairperson	78392-0057 Viwandani Road, Kenya	+254206933327 +254722774053	William.mwatu@gsk.com	
Rwanda	NMRA	PTF	John Patrick Mwesigye	Acting Coordinator	Pharmacy Task Force Box 84, Kigali Rwanda	+250788652910	mwesigyejp@yahoo.co.uk	
	Pharmaceutical manufacturers	PTF	John Patrick Mwesigye	Acting Coordinator	Pharmacy Task Force Box 84, Kigali Rwanda	+250788652910	mwesigyejp@yahoo.co.uk	
Tanzania	NMRA	TFDA	Hiiti B. Sillo	Acting Director General	External Mabibo, Along Mandela Road, P.O Box 77150, Dar es Salaam	+255222450512 +255754307179	info@tfda.or.tz/hiiti.sillo@tfda.or.tz	www.tfda.or.tz
		Zanzibar (ZFDB)	Simai Dr Burhani Othman	Registrar	Zanzibar, Tanzania, Kaunda Road, Mnazi Mmoja Area	+255242233959 +255777414455	bsimai@yahoo.com	www.zanhealth.info/zdfb
	Pharmaceutical manufacturers	TPMA	Mr Dipen Shah	Secretary	368 Msasani Road, Oysterbay, Dar es Salaam, Tanzania	+255222165100 +255784800999	dipen@sumaria.biz	
Uganda	NMRA	NDA	Apollo E. Muhairwe	Executive Secretary/ Registrar	Plot 46-48 Lumumba Avenue, Kampala, P.O. Box 23096, Kampala, Uganda	+256 414255665 +256772573027	apollo5000x@yahoo.com ndaug@nda.or.ug	www.nda.or.og
	Pharmaceutical manufacturers	UPMA	Nazeem Mohamed	Chairman	Stretcher Road, Ntinda, Kampala	+256752785773	nazeem@kpi.co.ug	
EAC (REC)		East African Community	Dr Stanley Sonoiya	Principal Health Officer	Arusha International Conference Centre, 5th Floor Kilimanjaro Wing, P.O. Box 1096 Arusha, Tanzania	+255272504253/8 +254727332460	ssonoiya@eachq.org	

APPENDIX 2

INSTITUTIONAL FRAMEWORK FOR MANAGING AND COORDINATING MEDICINES REGULATION IN THE EAC



APPENDIX 3

COMPOSITION OF PHARMACEUTICAL ASSOCIATIONS IN SOME NMRAS OF THE EAST AFRICAN COMMUNITY

Association	Membership
TPMA	Shelys Pharmaceuticals Ltd Zenufa Laboratories Ltd Mansoor Daya Chemicals Ltd Tanzania Pharmaceutical Industries Ltd Keko Pharmaceutical Industries Ltd Tanzansino United Pharmaceuticals Ltd
UPMA	KPI BIN UPL Q61C Abacos MAVIN Medipham
FPMK	Aesthetics Ltd Biodeal Laboratories Ltd Beta Healthcare International Ltd Cosmos Ltd Dawa Ltd Elys Chemical Industries Ltd GlaxoSmithKline (GSK) Laboratory and Allied Ltd Medivet Products Ltd Nerix Pharma Ltd Novelty Manufacturing Ltd Oss-Chemie (K) Ltd Pharmaceutical Manufacturing Company (PMC) Regal Pharmaceuticals Ltd Skylite Chemicals Ltd Universal Corporation Ltd
KAPI	Kenya Association of the Pharmaceutical Industry

For more information on African Medicines
Regulatory Harmonisation (AMRH):
Email: amrh@nepad.org
Website: www.amrh.org