

**1<sup>ST</sup> International High Level Multi-Stakeholders  
Meeting on Promoting Pharmaceutical Sector  
Investments in the East African Community (EAC)  
Region**

**OPENING STATEMENT BY**

**Hon. Phyllis J. Kandie, EGH. Cabinet Secretary, East  
African Community, Labour and Social Protection**

**WEDNESDAY , 2<sup>ND</sup> NOVEMBER ,2016**

**THE LAICO REGENCY HOTEL, NAIROBI, KENYA**

- **Hon. Dr Nijimbere Josiane, Minister of Public Health and Fight against AIDS, Burundi**
- **Permanent Secretaries**
- **The Chief Executive Officer, AU NEPAD Agency, Dr Ibrahim Mayaki**
- **The Chairman of the Federation of East African Pharmaceutical Manufacturers, Mr Nazeem Mohammed**
- **Heads of Delegations**
- **Representatives from the International Collaborating Development Partners**
- **Invited Guests,**
- **Ladies and Gentlemen,**

Let me take this opportunity to welcome you all to the Republic of Kenya and welcome those among us who are visiting the region for the first time to East Africa. Let me too, on behalf of the Ministers responsible for EAC in the Partner States welcome you all to this 1<sup>st</sup> International High Level Multi-stakeholders meeting on promoting Pharmaceutical Sector Investments in the EAC region.

For us in EAC, the pharmaceutical sector is a critical area of our cooperation in health and this meeting is therefore significant as it provides a platform for us to have a conversation among the policy makers, industry players, the civil society; and our social and development partners on how to deepen cooperation in the sector.

As you may be aware, the EAC which was established sixteen (16) years ago has registered meaningful progress in terms of trade in goods and services, in movement of people and also in the integration of financial markets, to mention but a few. During this period of her existence, the EAC registered an average growth rate of 6.2%, making it the top one-fifth in the distribution of ten-year growth-rate episodes experienced by all countries worldwide.

This growth was manifest in all sectors. For instance in 2014, the pharmaceutical market of the EAC was valued at **USD1.9bn** and is forecast to grow at a compound annual rate of 8.3% to reach **USD4.2bn** in 2024. However, Kenya which is the leading pharmaceutical producer in the region, with approximately 50% production and rising exports, supplies just 25% of the Kenyan market. And Tanzania supplies a declining share of its own domestic medicines market, down from 35% in 2009 to less than 10%-20% today.

In terms of market size, the EAC population has risen to **162 million** people with the accession of South Sudan to the Community. And with the ongoing negotiations in the EAC- SADC- COMESA Free Trade, EAC will progressively be able to access an integrated market of 26 countries in Africa: - with a population of about 600 million people, and a combined GDP of about USD 1.0 trillion which is more than half of AU membership, and 57 per cent

of the total population of the African Continent. Whereas this growth in population gives good market signals, it does pose concerns from the health perspective where common disease burden profile of the Community remain a concern.

Both communicable and non-communicable diseases continue to cause high morbidity, mortality and disability among our citizens; private healthcare expenditure accounts for as staggering 62% of the healthcare market with much of the population not covered by health insurance schemes; out-of-pocket payments at private facilities are still commonplace; and access to safe, affordable and quality Medicines for the treatment of diseases, especially HIV and AIDS, Malaria, Tuberculosis, Respiratory Infections, Diarrhea and various non-communicable diseases such as Diabetes, Cardiovascular diseases and Cancers remain out of reach to many people.

Barriers such as: high prices; anti-competitive restrictions; reliance on importation; limited local pharmaceutical production capacity; limited public financing; and constraints in health service delivery; medicine quality; health system capacity; and lack of research and development especially on vaccines for prevention of childhood diseases also continue to hinder access to essential medicines.

These significant unmet medical needs provide a real sustainable investment opportunity in pharmaceuticals.

Recognizing the strategic importance of the pharmaceutical sector in promoting access to affordable quality essential medicines as well as in promoting industrial development, the EAC Secretariat and the Partner States have put in place the EAC Regional Pharmaceutical Manufacturing Plan of Action (EAC-RPMPOA): 2012- 2016; included the pharmaceutical sector among the six priority intervention areas in the EAC Industrialization Policy and Strategy (2012-2017); and are implementing the on-going EAC Medicines Registration Harmonization Project that seeks to address challenges of different sets of requirements to applicants in to a single set of requirements for the region.

I am therefore pleased to note that through joint assessments 30 applications for medicines evaluation have been received and 4 products registered and that over 3000 applications have been received at national level since the start of the domestication of harmonized guidelines. Four hundred and twenty (420) products have also been registered across the six National Medicines Regulatory Agencies in the region. In addition, 10 joint inspections have been conducted within and outside the EAC region.

In order to strengthen the Post-market surveillance system in the region, the EAC with the support of German Government through PTB (German Metrology Institute) has procured **8 minilabs** for Rwanda and plans are at advanced stages to supply a similar

number to Burundi and Tanzania (Zanzibar) Medicines Regulatory Authorities respectively.

Despite these developments, the Pharmaceutical manufacturers operating from within the EAC region generally produce at a cost disadvantage to larger generic product manufacturers internationally due to a variety of reasons including scale, expensive asset base coupled with older technology, higher financing costs plus a lack of integration with active pharmaceutical ingredients suppliers. This situation makes domestically manufactured medicines uncompetitive compared to imports and the regional pharmaceutical market is therefore dominated by imports with domestic manufacturers only meeting less than **30%** of the medicines demand.

Similarly, although notable progress has been made on the harmonization of medicines regulation in the EAC Partner States, there remain challenges in the harmonization and enforcement of the regulation of medical devices, cosmetics, herbal medicines, veterinary medicines, nutritional supplements and food safety and quality.

There is therefore need to support the growth of the sector by engaging and addressing the concerns of the domestic pharmaceutical manufacturers and potential investors.

I am therefore pleased that we are gathered here today to deliberate and propose viable and practical options for promoting growth and investment in the domestic pharmaceutical manufacturing industry.

I am informed that the overall objective of the workshop is to develop a common and shared vision for promoting investment in the regional pharmaceutical manufacturing sector. In particular, the Pharmaceutical manufacturers will be sensitized on the EAC Regional Harmonized Medicines Registration Procedures/guidelines and the delegates are expected to discuss and propose the most viable incentive schemes for promoting domestic pharmaceutical manufacturing.

I therefore thank the International Development Partners who have been and continue to support the EAC regional pharmaceutical sector. In particular, I would like to thank the following partners; African Medicines Regulatory Harmonization Consortium of partners (namely The Bill and Melinda Gates Foundation, The United Kingdom Development Agency (DfiD), World Bank, World Health Organization (WHO), AU NEPAD Agency); UNCTAD; UNIDO; GIZ and PTB.

As I conclude, distinguished delegates, I wish to thank all you for finding time in your busy schedule to attend this conference and wish to reiterate that the EAC Secretariat and the Partner States

will accord due consideration to the recommendations of this meeting.

I wish you all very successful deliberations and an enjoyable stay in Nairobi, Kenya.

**Delegates**, it is now my pleasure to declare this **1<sup>st</sup> International High Level Multi-Stakeholders Meeting on Promoting Pharmaceutical Sector Investments in the EAC Region** officially open.

**Thank You!**