"TRANSFORMING PHARMACEUTICAL REGULATORY LANDSCAPE FOR INCREASED INVESTMENT IN AFRICA"

Overview and Draft Programme

3rd May 2017, Durban, South Africa

Southern Sun Elengeni - Suite 3 to 5

20:00-22:00hrs

Background

The following delineation of observations and activities constitute the background leading to the concept of this session:

1. The World Economic Forum on Africa forecasts a mixed outlook for economic growth on the continent over the coming years. It aims to refocus Africa's attention to accelerate economic diversification, revitalize manufacturing and harness innovation in order to mitigate the impact of this outlook. Challenges include a growing unemployed young population, climate change, the high burden of disease in general and the increased burden of non-communicable diseases.

2. Sub-optimal investments in health systems and the proliferation of substandard and falsified medical products estimated at 25-30% prevalence rates in Africa, are major threats to public health and negatively impact Africa's pharmaceutical sector growth and its overall contribution to economic development. Estimates indicate that medical products are a major component of total government health expenditure in many African countries, accounting for as high as 67% in some Low and Middle-Income Countries (LMICs). Investment in strengthening regulatory systems and harmonization of regulatory standards will spur pharmaceutical sector growth, expand markets, create employment and contribute to economic growth.

3. The World Economic Forum on Africa will serve as a platform to build on existing efforts to address challenges in public health and renew commitments that address gaps in regulatory capacity at national and regional levels. These include lack of comprehensive legal frameworks to regulate medical products; human and institutional capacity challenges; inconsistent regulatory processes and variable technical standards and guidelines that do not meet international standards.

4. In January 2005, the African Union (AU) Assembly resolved to take all necessary measures to facilitate pharmaceutical sector growth and requested the African Union Commission (AUC), within the framework of NEPAD, to lead the development of a Pharmaceutical Manufacturing Plan for Africa (PMPA). One of the key factors for successful implementation of PMPA is the sub-optimal environment for investment including; i) disparate regulatory standards, requirements, and processes resulting in inefficiencies and barriers to market access by industry; ii) limited regulatory capacity, yet often deployed on non-value adding activities; iii) lengthy review timelines resulting in delayed access by patients to life-saving medical products; and so on. It is within the PMPA Framework that the African Medicines Regulatory Harmonization (AMRH) Programme was initiated in 2009 to provide an enabling regulatory environment for investment in the pharmaceutical industry.

5. In January 2015, the AU Executive Council through Decision {EX.CL/Dec.857 (XXVI))}, endorsed the Milestones for setting up a single medicines regulatory agency in Africa within the context of the AMRH Initiative and as part of the PMPA framework. The council requested the AUC, NEPAD Agency and World Health Organization (WHO) to compose a joint Secretariat for the establishment of the African Medicines Agency (AMA) and to coordinate the work of the AMA Task Team.

6. In January 2016, the AU Assembly, through Decision Assembly/AU/Dec.1-17(XXVI) and Declaration Assembly/AU/Decl.1-2(XXVI) taken during its 26th Ordinary Session, adopted the AU Model Law on Medical Products Regulation as an instrument to guide AU Member States in the enactment or review of national medicines laws, and called on Member States to expeditiously utilise it.

7. AU Agenda 2063 aspires to improving standards of living, quality of life and wellbeing of Africans and making health services accessible to all through sustainable social policies and

support. The United Nations Sustainable Development Goal (SDG) 3 also seeks to ensure health and well-being for all, at every stage of life.

The African Medicines Regulatory (AMRH) Initiative

The AMRH Initiative is a partnership comprised of the NEPAD Agency, AUC, Pan African Parliament (PAP), the World Health Organization (WHO), World Bank (WB), Bill and Melinda Gates Foundation (BMGF) and UK Department for International Development (DFID). The goal of AMRH is to strengthen the capacity for regulation of medical products in Africa and to promote harmonization of medicines regulatory systems, by working through Regional Economic Communities (RECs) and National Medicines Regulatory Authorities (NMRAs) of AU Member States. The Initiative is implemented through regional Medicines Regulatory Harmonization (MRH) Projects.

The World Economic Forum on Africa provides a platform for leaders from business, governments, civil society and development partners to deliberate on potential gains for investment in regulatory systems strengthening and harmonization, and for pharmaceutical sector growth toward economic development of the African continent.

Overall Goal of the Session

To mobilise political, technical and financial support from governments, the private sector and partners, so as to enable the strengthening of medical products regulatory systems and to support the growth of the pharmaceutical sector in Africa.

Specific Objectives:

1. To showcase progress made by the African Medicines Regulatory Harmonisation Initiative as a foundation for establishment of the African Medicines Agency (AMA) and enabler to pharmaceutical sector development in Africa.
2. To advocate for establishment of the AMRH Partnership Platform as a new mechanism for galvanising partners and resources, foster mutual and collective responsibility, alignment and harmonisation of efforts.
3. To consider options for financing medicines regulatory systems strengthening at national level and harmonization at regional and continental levels.
4. To deliberate on investing in Africa's pharmaceutical sector, as a contribution to public health and economic growth.

Date, Time and Venue

Dinner working session on 03 May 2017, 20:00-22:00hrs at *Southern Sun Elengeni - Suite 3 to 5,* Durban, South Africa.

Expected participants

The session will be open to all accredited participants in the World Economic Forum on Africa, Government representatives, civil society, AMRH partners, potential AMRH partners, representatives of regulators, RECs, representatives of the African pharmaceutical industry and other stakeholders.

Structure for the Session

The Co-Chairs will set the stage by giving opening remarks followed by a key note address from the main speaker and a selected panel of four (5) speakers. The key note speaker will make a 15 minute presentation while each of the other panellists will be given 8 minutes to address one of the topics. The moderator of the session will subsequently open the floor for questions, discussions and contributions.

Proposed Agenda and Topics

1. Investing in Africa's pharmaceutical sector – the benefits and role of regulation.
2. Africa's Pharmaceutical agenda and the AMRH – vision, strategy, and progress
3. Partnership, mutual and collective responsibility, alignment for regulatory systems strengthening and harmonisation in Africa.
4. Sustainable financing options for regulatory systems strengthening.
5. AMRH contribution to AU Agenda 2063 and Sustainable Development Goals (SDGs)

Expected outcomes

- Definition of issues and factors impacting sustainable funding of medical products regulation in Africa.
- Identification of potential creative mechanisms and approaches to financing growth in the African pharmaceutical sector.
- Agreement on a need to hold further dialogue to build on conversations started at this forum.

Draft Programme

Title: **"**Transforming Pharmaceutical Regulatory Landscape for Increased Investment in Africa"

Time: 20:00 – 22:00hrs

Venue: *Southern Sun Elengeni - Suite 3 to 5,* Durban, South Africa.

AMRH Current Partnership: NEPAD Agency, African Union Commission (AUC), Pan African Parliament (PAP), Regional Economic Communities (RECs), World Health Organization (WHO), World Bank (WB), Bill and Melinda Gates Foundation (BMGF), and UK Department for International Development (DFID).

20.00 – 20:10 hrs	**Opening Remarks, Statements and introduction of discussion topics** ***Dr Ibrahim A. Mayaki****, CEO, NEPAD Agency – Co-Chair (Confirmed)* ***Dr Ayo Ajayi****, Bill and Melinda Gate Foundation Director for Africa – Co-chair - (Confirmed)* ***Statement by H.E. Amira El Fadil,*** Commissioner for Social Affairs, African Union Commission
20.10 – 20:25 hrs	**Key Note Address** ***Precious Matsotso****, Director General, South Africa Dept. of Health – Key Note Address (Confirmed)* How is medical products regulation and harmonisation contributing to Agenda 2063 and Sustainable Development Goals?
20:25 – 22:00 hrs	**Moderated Session by Mike Ward,** *Coordinator, Regulatory Systems Strengthening (RSS), WHO-HQ*
20:25 – 20:35 hrs	**Investing in Africa's pharmaceutical sector** ***Dr Paul Lartey,*** *Former Chairperson, Federation of the African Pharmaceutical Manufacturers' Association (FAPMA)* What are the opportunities, challenges and benefits of investing in pharmaceutical production in Africa; the AU commitment through the Pharmaceutical Manufacturing Plan for Africa (PMPA), what needs to be done to address the identified challenges, what contribution does regulation bring in advancement of pharmaceutical industry.
20:35 – 20:43 hrs	**Regulatory Harmonization in Africa: The Journey and the Future outlook** ***Gugu Mahlangu,*** *Chairperson, African Medicines Agency (AMA) Task Team*

Regulators perspective on harmonisation initiative in Africa – what has been done and what remains to be done? What are the priority areas in the new strategy and what does this mean for the future of medicines regulatory strengthening and harmonization in Africa? What are the efforts being made towards alignment with organizations doing similar work? How is AMRH contributing to establishment of African Medicines Agency (AMA)?

20:43 – 20:51 hrs **Partnership, mutual and collective responsibility**

Margareth Ndomondo-Sigonda, *Head, Health Programme, NEPAD Agency*

At the recently held AMRH strategic planning meeting in Johannesburg, South Africa in 2017, partners and stakeholders agreed to adopt a lean governance structure. What role will the AMRH Partnership Platform play in the new strategy and how will it be used effectively? What role can other interested partners/stakeholders play in this platform? What role will the partnership platform occupy in resource mobilization?

20:51 – 21:07 hrs **"Why 'Medicines Regulatory Harmonization and local production' from a global and regional partner perspective, and how we can sustain the progress made"**

David Mukanga, *Senior Program Officer Regulatory Affairs, Africa Systems, Bill and Melinda Gates Foundation*

Hon . Christophe Bazivamo, Deputy Secretary General, Productive and Social Sectors, East African Community

Justification of medicines regulatory harmonisation efforts and how they facilitate promotion of local production of pharmaceutical. Definition of issues and factors impacting sustainable funding of medical products regulation in Africa. How can we make regulation and harmonisation sustainable? What financing mechanisms can be put in place to ensure sufficient and stable funding from national governments, private sector investment, development loans/grants, private/public partnerships?

21:07 – 21:45 hrs **Interactive discussions – questions and clarifications**

Participants will include High Level delegates from Africa and across the World including public sector, private sector, accredited participants to the WEF on Africa, AMRH current and potential partners, industry players and other key development stakeholders and academicians.

21:45 – 22:00 hrs **Concluding remarks by Mike Ward,** *Coordinator, Regulatory Systems Strengthening (RSS), WHO-HQ*