BRIEFING NOTES

AFRICA PHARMA CONFERENCE 2018

19TH - 21ST NOVEMBER



High-Level Pan-African Conference on Access to Medicines and Health Commodities: Catalyzing Local Production





















CONCEPT NOTES



AFRICA PHARMA | 19TH - 21ST CONFERENCE 2018 NOVEMBER

HIGH-LEVEL PAN-AFRICAN CONFERENCE ON ACCESS TO MEDICINES AND HEALTH COMMODITIES: CATALYZING LOCAL PRODUCTION

DATE: 19th - 21st November 2018

VENUE: African Union Commission Headquarters, Addis Ababa

WORKING TITLE: Harnessing the Power of the Local Pharmaceutical Industry as a driver of Economic Growth and Universal Access to Quality-Assured essential medicines



African leaders seek to facilitate the creation of an enabling environment where every person has the opportunity to optimize their development potential. As the continent continues to grow such opportunities across several fronts, challenges remain to be fully surmounted in a host of key sectors. Health status of Africans remain suboptimal and

attainable standard of health. The continent bears a significant burden of infectious diseases and non-communicable diseases, with huge unmet needs for Family Planning and other Reproductive Health commodities. Outbreaks of emerging infectious diseases such as the recent Ebola pandemic has further underscored the need, to respond rapidly. Access to medicines for many infectious and non-communicable diseases, nevertheless remains low across Africa in addition to weaknesses in the supply chain systems.

the health care delivery systems at national level are yet to be as efficient and accessible as required to provide for the sustainable delivery of testing, diagnostic, treatment and support services to the highest

This consequently creates an opportunity for pharmaceutical companies (and allied firms) to increase their presence and partnerwithlocalmanufacturing companies to gain access into the market and expand their activities, while national governments reduce their dependency on donors

and facilitate a more secure supply of these essential products.

Africa's pharmaceutical industry is one of the fastest growing in the world. In past ten years the market has exploded to US\$ 21 Billion, with project estimate of US\$60 Billion by the end of 2020. Urbanization, an increase in diseases of lifestyle, increase in discretionary incomes, expansion of healthcare and governments incentives, increase in prescription and generic medicine and medical devices have primarily driven growth in this sector. This growth can be optimized if challenges such as policy and regulation incoherence, shortage of specialists, weak quality regulatory agencies and fragmented markets are addressed.

African leaders have previously established political commitments, including the Pharmaceutical Manufacturing Plan for Africa and its related Business Plan, the African





the operation of potential investors.







Medicines Regulatory Harmonization (AMRH) Programme led by the NEPAD Planning and Coordinating Agency, and the AU Roadmap on Global Solidarity and Shared Responsibility. Furthermore, the continents leaders are firmly committed to industrial development as articulated in the AU Accelerated Industrial Development Plan for Africa (AIDA). These need to be fully developed and implemented.

It is therefore imperative that the continent streamline and harmonize local and regional regulations, integrate markets, incentivise business environment to facilitate

This fits well within the framework of the Action Plan for the Accelerated Industrial Development of Africa (AIDA) which seeks to facilitate an acceleration of industrial development (on the continent) and diversification of the economy to meet the challenges of (sustainable) development.

Experience and knowledge needs to be shared between countries, within industries, and across the range of stakeholders. The challenges and opportunities need to be identified and addressed,

and the political commitment across the continent

harnessed in a structured manner. Private sector actors from the finance institutions, health care service providers and (international and local) pharmaceutical

manufacturers (including medical devices and diagnostics)

must develop mutually beneficial partnerships.

In September 2017, African Union leaders, UN Principals, representatives of international finance institutions and private sector actors reaffirmed their commitment to a broad-based international partnership to industrialize Africa in a socially inclusive and environmentally sustainable manner through the UN General Assembly's declaration of 2016-2025 as the Third Industrial Development Decade for Africa (IDDA III).

Consequently, the NEPAD Agency, African Union Commission (AUC), and key stakeholders including the Consortium of Partners (in support of the PMPA) will convene a high-level, pan-African forum on improving access to essential medicines and facilitating local production. The meeting will focus on establishing clear priorities for specific, coordinated and effective actions as well as Business to Business Platforms with support and commitment of senior policy makers to realize the vision of the African Heads of State and Government. The Africa Pharma Conference will be organized as part of high level activities to commemorate the Africa Industrialization Week (AIW) 2018.

○ OBJECTIVES

The overall aim of the forum is to facilitate concrete action that will improve universal

access to quality assured affordable essential medicines and catalyse local production in Africa by harnessing high-level political commitment and workable solutions.

The forum will;

Examine the evidence as it relates to constraints and how to overcome them, opportunities and propose a number of concrete steps that can be implemented by governments to develop LPP;

Consider a broad range of related issues including those of harmonization of regulatory protocols, research and development, production, quality control, distribution, testing and diagnosis and health care capacity development, as well as incentives that can boost local production on the African continent such as the African Medicines Agency and other health systems initiatives;

- · Facilitate and forge business to business partnerships;
- Articulate a set of recommended actions;

The outcomes of the forum will be presented to the African Union Organs, such as the Assembly of Heads of State and Government for consideration.



These will include:

- 1. Unified African leadership, working with pharmaceutical companies, business leaders and other stakeholders towards establishing a viable African pharmaceutical industry.
- 2. Enhanced understanding of short- and longer-term opportunities for cost reductions, through procurement practices in order to ensure affordable and sustainable supplies of essential medicines.
- 3. Identification of opportunities to expand national and regional capacity to scale up pharmaceutical manufacturing across Africa through
- a. Improved procurement,
- b. Innovative service delivery,
- c. Expanded research and development, and
- d. Streamlined, coordinated and cooperative regulatory capabilities'
- e. Appropriate financial incentives and tax options;
- 4. Strengthened platforms for Triangular collaboration (North-South and South-South) as well as Business to Business partnerships.















PARTICIPATION

Participants and delegates to the Conference will include;

- Heads of State
- ii. Senior Government Officials such as Line Ministers; (Health, Industry, Trade, Finance etc)
- iii. Regional Economic Communities (RECs) i.e. ECOWAS, SADC, COMESA, AMU, EAC, **ECCAS**
- iv. Private Sector Pharmaceutical trade association (e.g. FAPMA, IFPMA) and companies, Medical Device and Diagnostics manufacturers; Investment and Finance Institutions; Logistics firms; etc.
- USP / USAID
- vi. Global Public Health institutions (Global Fund, PEPFAR, UNITAID, MPP etc)
- vii. National Medicines Regulatory Authorities
- viii. United Nations Agencies
- ix. (African) Academic and Research Institutions
- Civil Society
- xi. Donors and Development partners
- xii. Regional and International Finance Institutions

AGENDA

The high level conference will run for three (3) days and the agenda will address amongst others;

- 1. Policy coherence (across sectors),
- 2. Health Sector Imperatives such as Universal Health Coverage (UHC), Maternal and Child Health,
- 3. African Medicines Agency (AMA) and Regulation,
- 4. Market Integration,
- 5. Volume guarantees and Incentives,
- 6. Good Manufacturing Practices (GMP),
- 7. Medical Devices and allied products,
- 8. Leveraging technology and artificial intelligence,
- 9. Pharmaceutical Financing Strategy,
- 10. Catalyzing Research and Development (R&D),
- 11. Strengthening Market Intelligence and Evidence Base,
- 12. Supply Chain Management System (SCMS),



13. Business facilitation and Investment Promotion,

- 14. TRIPS Flexibilities,
- 15. Africa CDC and Humanitarian context
- 16. Leveraging the African Diaspora,
- 17. South-South and Triangular Cooperation,
- 18. Infrastructure and multi-sectoral factors, including human resources development;
- 19. Furthermore, specific sessions will be organized
- 1. Focus on access to products (and devices) such as; Anti-retroviral (ARVs), anti-TB and Anti-Malaria medication; Reproductive Health and Family Planning Commodities (such as Condoms);
- 2. Presentation and dissemination of relevant strategic information;
- 3. Launch of strategic initiatives;

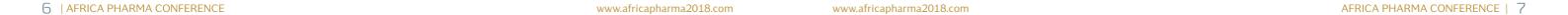


The Conference will be organized to include didactic technical sessions; high level plenary sessions as well as focused thematic events.

DOCUMENTATION

Reference documents – will include but not limited to;

- 1. Situational analysis of current practices in ensuring affordable and sustainable drug supply across Africa, focusing on challenges and best practices, including incentive package to boost private sector investment;
- 2. Policy briefs on selected interventions that promote local production;
- 3. Synopsis on the Business Plan of the PMPA Summary reports of related research and generated evidence;
- 4. Business Plan for the operationalization of the Pharmaceutical Manufacturing Plan
- 5. Background document on Establishment of Fund for African Pharmaceutical Development;
- 6. Action Plan for the Accelerated Industrial Development of Africa (AIDA);
- 7. Declaration of UN General Assembly on Third Industrial Development Decade for Africa (IDDA III);





















DATE AND VENUE

Date; November 19th – 21st; 2018.

Venue: African Union Commission (AUC); Addis Ababa, Ethiopia.

WORKING LANGUAGES

English and French will be the working languages of the conference.

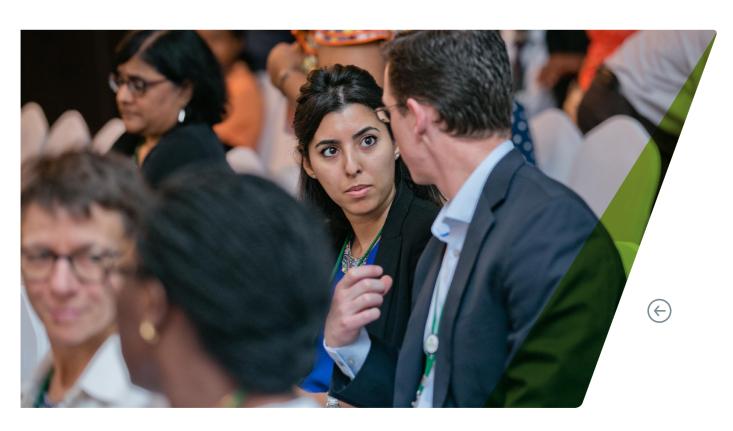


FOR FURTHER INFORMATION, PLEASE CONTACT

- Dr Janet Byaruhanga; Senior Program Officer; NEPAD; JanetB@nepad.org
- Mrs Ron Osman Omar; Senior Policy Officer; Industry Division; AUC OmarR@africa-union.org
- 3. Mr Bankole Eniola; Executive Director, DFS Africa; bankole@developmentfinancesummit.com



PROGRAMME



TOPICAL COVERAGE AREA





Devices

Pharma & Healthcare



Financing







CONFIRMED SPEAKERS



President Paul Kagame

President of Rwanda Chairperson - African Union



Li YongDirector General - United Nations Industrial

Development Organization (UNIDO)



Michel Sidibé
Executive Director - UNAIDS



Akinwumi Ayodeji Adesina
President - African Development Bank Group



H.E. Moussa Faki Mahamat

Chairperson - African Union Commission (AUC)



Dr Tedros Ghebreyesus
Director-General - WHO



Vera Songwe

Executive Secretary - Economic Commission for Africa (ECA)



Ambassador. Albert M. Muchanga

Commissioner for Trade and Industry



Mrs Amira Mohamed El Fadil
Commissioner for Social Affairs - AUC



Nelson Torto

Executive Director - The African Academy of Sciences (AAS)



Bience Gawanas

Special Adviser on Africa (UN SAA)



Dr. Ibrahim Assane Mayaki
Chief Executive Officer - New Partnership for Africa's
Development (NEPAD) Agency



Francisca Mutapi
Tackling Infections to Benefit Africa (TIBA)



EMMANUEL MUJURU
Chairman - FAPMA













CONFERENCE AGENDA



PROGRAMME FOR THE AFRICA INDUSTRIALIZATION WEEK AND AFRICA PHARMA CONFERENCE

	DAY 1
09:00 – 12:00	Official Opening - Launch of the Africa Industrialization Week
	Welcome Remarks - Commissioner Industry High Level Statements — Private Sector UNECA — Executive Secretary UNIDO — Director General WHO — Director General NPCA — Chief Executive Officer AUC Chairperson AU Chair
10:00 – 10:10	Short video Africa Industrialization - 5 Mins Local Production – 5 Mins
10.15 – 12.00	Moderated Panel Discussion and Questions from the Audience (High Level) Panelists: 1. H.E President (tbc) 2. H.E President (tbc) 3. Dr Akinwumi Adesina (AfDB) 4. Private Pharma Sector 5. H.E Michel Sidibe
	 6. H.E Bience Gawanas (UN-SAA) Issues Political Will, National Vision and Strategies National Policy coherence and Inter-governmental coordination for seamless execution National Champions to drive Infant industry development Commitment of resourcing and incentive framework
12.00 – 1.00	Highlights of relevant continental policy and programmes Commissioner of Trade and Industry Commissioner for Social Affairs Continental Private Sector (Bank)
14.00 – 15.15	Leadership in Local Production in Africa - USP The next frontiers in the delivery of essential medicines, from QA to production close to the area of need (J Nwokike / E Kane) General Discussions
15.15 – 16.00	 Universal Access to Quality Assured Essential Medicines Malaria Futures for Africa at a Glance – Novartis Mylan – a global leader in ART provision: The Case for Dedicating Capacity to the production of ARV (H Bresch) Novartis – A history of game changing engagement in Africa (P Matchaba) Bangladesh Pharma – From 80% reliance on imports to 97% production of all essential medicines the next phase taking on India and China in the world (BAPI Rep)

16.00 – 16.30	TEA BREAK
16.30 – 18.00	 Technology Transfer as a Catalyst for Local Production of Medicines and other Technologies Setting up a Condom Manufacturing Facility in Africa – Lessons from Nulatex SA (K Tloubatla) Quality Chemicals and Cipla – WHO prequalification and quality production of essential medicines (G Baguma) Juhel Pharma and Oxytocin Production in Nigeria (Dr I Okoye) IFPMA and Technology Transfer to Africa based manufacturers (G Perry)

	DAY 2
8.30 – 10.00	Creating the Right Financial instruments for LPP, Financing initiatives: Origination, Structuring and Execution Fund for Africa's Pharmaceutical Sector Development (FAP-D) AfDB IFC AFRIEXIM Bank Abraaj Group The Indian Pharmaceutical Industry – government incentives for global competitiveness (S Chaudri) Video from a continental bank
10.00 - 10.30	TEA BREAK
10.30 – 11.45	 Research and Development and Harnessing the Diaspora Capacity Leveraging Africa based research competencies (S Nwaka) An Africa developed blockbuster in the horizon? (K Chibale) Policy incentives to attract Diaspora investment and develop local talent (Dr C Niyikiza) Harnessing Diaspora scientific talent (P Lartey) Accelerating Excellence in Science in Africa (AESA) – Tom Kariuki (ASS) and Prof Ambali (NEPAD) Tackling Infections to Benefit Africa (TIBA) – Francisca Mutapi
11.45 - 13.00	 API Production in Africa – From Dream to Reality The Lagray Experience with Azithromycin (P Lartey) Competing in an Uneven Playing Field (Fine Chemicals) Egypt and the March to self-sufficiency (S Helmy) Is Leap-frogging possible for Africa: Adopting Faster, Cleaner, Greener Technologies and Process (J Fortunak)
13.00 – 14.00	LUNCH BREAK
14.00 - 15.30	 Developing LPP – What is the Evidence from Around the World Leveraging government Procurement as a financial asset for local companies (G. Banda) TRIPS Flexibilities and other Patent Mechanisms Bangladesh Speaker (BAPI Rep) Medicines Patent Pool (Sandeep Juneja) Voluntary Licenses and Technology Transfer – from a local African company to global leader: the case of Aspen (Stavros Nicolaou)
15.30 – 16.30	Towards Policy Coherence for LPP – Selected Country Experiences The Ethiopia Case Study (M Wolde - Miriam) Ghana Algeria Bangladesh Case Study
16.30 - 17.00	TEA BREAK
17.00 - 18.30	Leveraging International Development Support for Local Pharmaceutical Production: - Inclusive procurement practices - Carve-outs and set-asides for local manufacturers







- WHO pre-qualification (R Kuwana) IFPAM (G Perry)
- Global Fund (A Pratt)
- UNFPA (CSB)
- UNDP (T Avafia)
 UNIDO (Alastair West)
- **UNAIDS**

	DAY 3
8.30 – 10.30	 Health and Human Rights – No one left behind Access to Essential Medicines in Africa Reproductive Health Commodities and Family Planning – Making Universal Healthcare a reality – (BMGF) (PPP and) Universal Health Care - Non - Communicable diseases and Local production - Falsified and Substandard Drugs – Africa's silent Pandemic - WHO Anti-microbial resistance in Africa – the evidence and newer treatment options Neglected Tropical Diseases; "Neglected Human Beings" – John H. Amuasi (ARNTD)
10.30 - 11.00	TEA BREAK
11.00 – 12.00	 Growing Sustainable Supportive/Allied Industries and Services Technology and artificial intelligence Supply Chain Management Legal and Intellectual property related services Multi-sectoral infrastructure and services 5 Minutes video of commercial bank or related business
12.00 – 13.00	 Strategic Continental Initiatives Regulatory systems and harmonization: Foundation for establishment of the African Medicine Agency and AMRH Africa CDC Africa Continental Free Trade Area (AfCFTA)
13.00 – 14.00	LUNCH BREAK
14.00 – 15.30	Replicating and Scale Up of Good Practices, Successful Approaches, Methodologies and Interventions for Universal Access/Local Production UNIDO GMP Roadmap and Lean Manufacturing: The Real-World Experience Medicines Regulatory Systems strengthening and harmonization The ZAZIBONA Experience EAC WHO Collaborative Procedure Technology Transfer experiences USAID and the Bioequivalence study assistance Expedited registrations – The Ghana Experience Bangladesh and the API Brokerage
15.30 – 17.00	Africa Beyond Condom Donations/Local Manufacturing
17.00 – 17.30	COFFEE BREAK
17.30 – 18.30	 Closing Ceremony FAPMA United Nations NEPAD CEO Commissioner for Social Affairs Commissioner for Trade and Industry Govt of Rwanda – (Minister/Amb)



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- Merger & Acquisitions Advisory Services
- Valuations and Fairness Opinions

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