Pharma Connect Africa Conference

2019

Presentation by

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NEPAD BUSINESS FOUNDATION

Who is the NEPAD Business Foundation?

The NEPAD Business Foundation (NBF) is a non-profit organisation that co-ordinates private sector efforts aimed at Africa's economic growth and development in alignment with the NEPAD thematic areas

African Union

In 2001, the **African Union** set out an economic development program for the African continent

NEPAD TRANSFORMING AFRICA

In 2001, the **NEPAD Agency** was formed as the implementing arm of AU's continental development Agenda

South Africa | Senegal | Nigeria | Algeria | Egypt

Founding African Member States of NEPAD Agency

NEPAD BUSINESS FOUNDATION

In 2002, the **NEPAD Business Foundation** was formed to facilitate linkages between **business** and **government** to support implementation of the AU's continental development Agenda

Our Genesis: Former RSA President Thabo Mbeki

Our Founding Chairman: Dr Ruel Khoza

NEPAD FOCUS AREAS

Through signed MoU's with the African Union, NEPAD Agency and the SADC Secretariat, among others, the NBF and its private sector stakeholders are able to implement interventions that complement the development efforts by governments across the continent.

The NBF operates as a pan-African institution with interventions and operations in over 36 African countries.

REGIONAL INTEGRATION, INFRASTRUCTURE

NORTH-SOUTH RAIL CORRIDOR (NSC)

The NSC Rail Project is being implemented to reduce the cost of trade in the SADC region

SADC REGIONAL GAS TASK FORCE

The SADC Regional Gas Task Force is a multi-stakeholder platform for public-private sector dialogue designed to enable and support the monetization of the natural gas resources within the SADC region

LOCAL ECONOMIC DEVELOPMENT (LED) PROJECT

The development of an enabling environment for delivering LED in the planning, procurement and implementation of infrastructure projects

NATURAL RESOURCES GOVERNANCE AND FOOD SECURITY

STRATEGIC WATER PARTNERS NETWORK (SWPN)

A partnership between the public and private sectors and civil society to close a 17% gap between water supply and demand (2030) in South Africa

MINE WATER COORDINATING BODY (MWCB)

Collaborative public-private platform to address environmental, social and economic challenges that arise from mine closure including long-term mine water management and regional mine closure

INDUSTRIALISATION, SCIENCE, TECHNOLOGY AND INNOVATION

SADC BUSINESS COUNCIL

Inclusive business platform for public-private engagement within the SADC region in alignment with the SADC Secretariat's Regional Indicative Strategic Development Programme and SADC Industrialisation Strategy

SADC PHARMACEUTICAL WORKING GROUP

Collaborative platform to increase pharmaceutical value chain investments by identifying pharmaceutical investment barriers and solutions to identified challenges

HUMAN CAPITAL DEVELOPMENT

CP3P PPP TRAINING

NBF is an accredited institution to provide training for the internationally recognised APMG Public-Private Partnership Certification

PROJECT FINANCE ADVISORY

Long-term financial consultant to Stockholm International Water Institute (SIWI) supporting the roll out of the Africa-EU Water Partnership Project (AEWPP)

AFRICAN CORPORATE GOVERNANCE NETWORK (ACGN)

Collaborative network of director membership organisations that promote effective corporate governance and ethical leadership on the African continent

SADC Pharmaceutical Working Group

OBJECTIVE

To increase pharmaceutical value chain investments by identifying pharmaceutical policy and operational barriers hindering pharmaceutical investments and finding solutions to these

Specific objectives of the working group

- Harmonisation of medicine registration requirements
- Improved reciprocity between regulatory agencies
- Improved transparency of medicine registration
- Reduced delays in the medicine registration process
- Increase regional sales of pharmaceutical products
- Increase local participation in pharmaceutical value chains
- Positive public health impacts

Pharmaceutical Working Group Sector Challenges

- Lack of policy harmonisation in the registration of new medicines in the region
- Delays in new product approvals
- Inconsistent enforcement of pharmaceutical regulations in SADC
- Outdated medicine laws and Intellectual Property laws that are not TRIPS compliant
- Uncertainty about the effectiveness of Zazibona
- Weak exchange rate which increases the cost of imported active pharmaceutical ingredients
- Limited Pharmaceutical manufacturing in the region and in the continent
- Sub-standard and counterfeit drugs entering the local market
- Lack of funding for R&D
- Uncoordinated efforts from governments to develop the region as an attractive site for clinical trials

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Local Pharmaceutical Manufacturing Challenges in SADC

Pharmaceuticals Working Group

Current Initiatives

- Policy/ operational matrix for the pharmaceutical industry outlining the various policy and implementation barriers experienced by private sector companies when doing business in the region
- Study on Regulatory variance in the pharmaceutical value chain in SADC. The aim of the study was to understand industry gaps across the pharmaceuticals value chain
- Completed a study assessing human resource capacity to effectively implement pharmaceutical policies and regulations in SADC in Jan 2018
- Promoting the expansion of the ZAZIBONA process, an initiative to collaborate on assessment and inspections for medicines registrations with objectives to: reduce workload, reduce timelines to registrations, develop mutual trust and confidence in regulatory collaboration, platform for training and collaboration in other regulatory fields

Pharmaceuticals Value Chain Matrix

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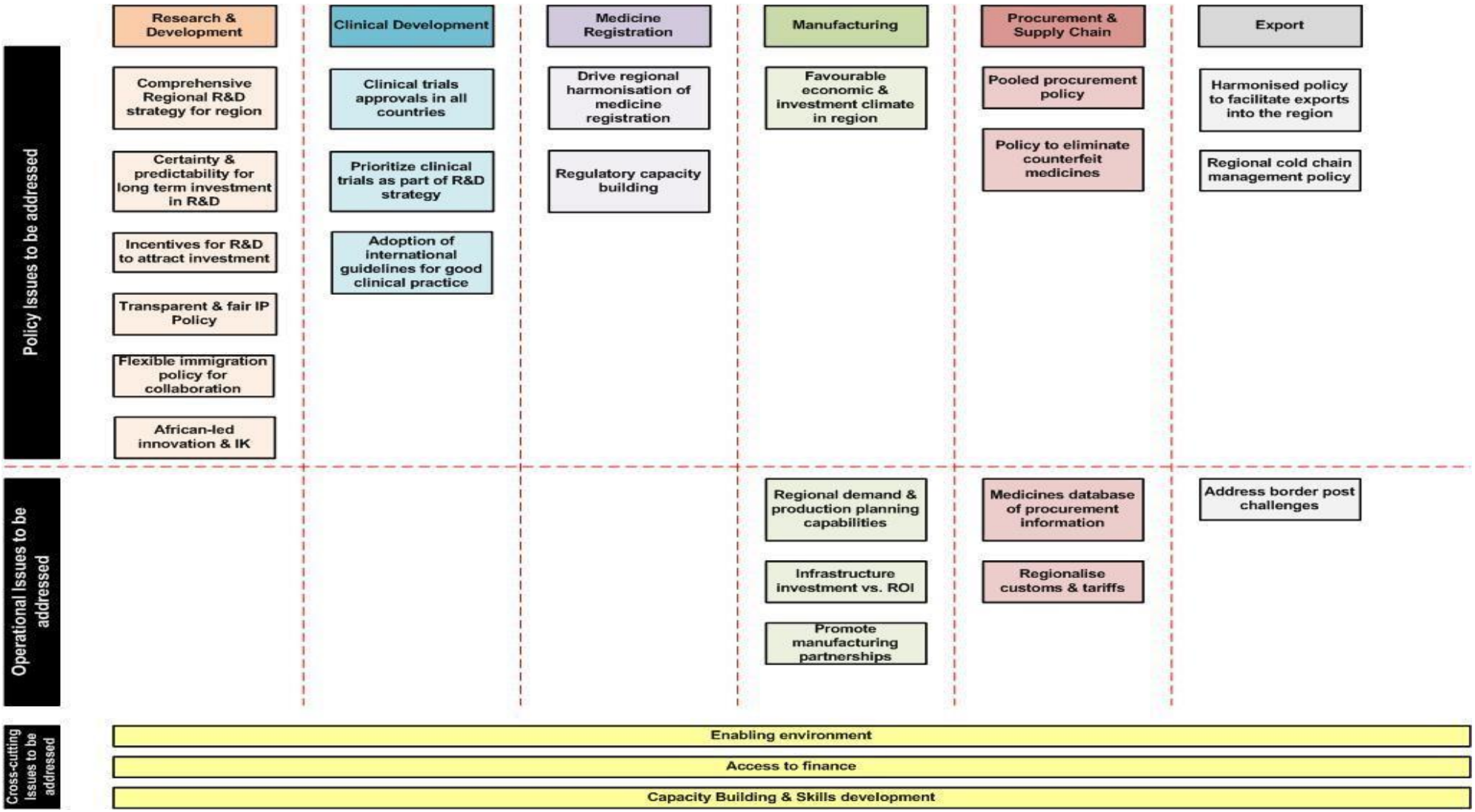

Report: Regulatory Variance in the Pharmaceutical Value Chains in the SADC Region

This study was done to understand industry gaps that exist across the SADC pharmaceutical value chain i.e. in medicine registration, R&D, manufacturing and procurement, and clinical development.

Results

- Varying human resource capacity issues across MS
- Inadequate Research and Development investments by member states in the region
- Lack of transparency of medicine registration requirements in the region.
- Lack of reciprocity between regulatory agencies
- No active coordinated effort from governments to develop SADC as an attractive site for clinical development
- Lack of consistent feedback loop between pharmaceutical companies and regulators
- Discrepancy with documentation required from country to country

Report: Assessing Human resource capacity to effectively implement pharmaceutical policies and regulations in SADC region

Study shows pharmaceutical human resource constraints are the major impediment to the development of the pharmaceutical sector in SADC.

Challenges (medicine registration)

- According to the report, 86% of delays in medicine registration in SADC were primarily caused by diminished human resources capacity, 71% by the submission of incomplete or substandard dossiers, and another 71% by lack of standardized medicine registration requirements per country

Recommendations

- Promote use of the Zazibona process
- Funding Masters, PhDs and other degrees for creating scientific leaders in Africa

Zazibona Project Workplan

- Identify policy and harmonisation gaps that still exist in the Zazibona process
- Assess Zazibona' s achievements on medicines registration in the region
- Find out the markets or countries where Zazibona processes have reduced medicine registration timelines in SADC
- Develop a survey on Zazibona process and outcomes and send it to industry stakeholders to gauge their satisfaction with the Zazibona
- Develop a set of recommendations upon consulting with regional stakeholders
- Develop a policy brief on Zazibona identifying the gaps in the system

Contacts

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