'The Pharmaceutical Manufacturing Plan for African - pathway to Local Production of Generic Medicines in Africa??

IP FORUM – Gallagher Estate, Midrand
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Deputy CEO: Cipla Medpro
26th February 2013
Outline

- Overview of Africa’s healthcare challenges
- Overview of African pharma industry
- The Pharmaceutical Manufacturing Plan for Africa (PMPA) – the Road Ahead
  - History, Objectives, Vision
  - PMPA Solutions to Grow Africa-based Industry
- Conclusion
Overview of state of Africa’s Healthcare systems
High Disease Burden (current)

- 25% of the global disease burden
  - 75% of the global HIV/AIDS pandemic
  - 90% of the malaria cases and deaths
  - 9 countries (excluding North Africa) among the 15 countries with the highest TB burden in the world.
  - MDR-TB and XDR-TB rated among the highest in the world.
  - Significant child mortality – diarrhoeal, measles, URTI etc
# High Disease Burden (2030 Projections)

<table>
<thead>
<tr>
<th>Diseases</th>
<th>Number</th>
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<tbody>
<tr>
<td>Hypertension</td>
<td>60 mil</td>
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<tr>
<td>Diabetes</td>
<td>18.6 mil</td>
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<tr>
<td>Cancer</td>
<td>1 mil (new cases annually)</td>
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<tr>
<td>Other (CNS, CVS, Resp.)</td>
<td>Will surpass HIV / AIDS as leading cause of death</td>
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Significant Healthcare challenges

- Poor healthcare infrastructure
  - Software – Shortage of healthcare HR
  - Hard ware – clinics, hospitals, labs, supply chains inadequate
  - Inadequate quality systems -- limited access

- Limited healthcare funding
  - Limited National budgets
  - Donor dependence (? fatigue)
State of African Pharma - Challenges and Opportunities
Pharmaceutical Production Process

RAW MATERIALS
- Plants
- Animal tissue
- Chemical

INTERMEDIATES
- Extraction
- Synthesis
- Fermentation

API
- Isolation
- Purification

FINISHED FORMULATION
- Formulation & packaging

Source: Metanoia Consulting Pty Ltd (SA)
State of African Pharma

- Africa imports more than 95 percent of API and roughly 75 percent of finished formulations.
- ~38 countries have pharmaceutical manufacturing
- Only 2 with limited API production
  - API Production is the source of Security of Supply
- Various global players active through agencies / distributorships etc
- Big pharma moving plants to centres of excellence globally
African Pharma Challenges

- **Policy Incoherence**
  - Health vs. Industrial vs. Finance / Treasury priorities: Technocrats in key support ministries have limited knowledge of the pharma sector

- **Lack of Regulatory capacity**
  - Lack of resources
  - Lack of autonomy, financial independence & frequent incidences of political interference

- **Lack of Regulatory Harmonization**
  - Varying legal and regulatory frameworks
  - Delayed registrations
  - Increased costs due to need to customise regulatory processes
African Pharma Challenges

- **Counterfeit and Substandard medicines**
  - USP (2011) - 30 to 50 percent of malaria medicines in some markets are counterfeit and as many as 84 percent in countries sampled on the continent were substandard.
  - WHO (2011) - 28.5 percent of the medicines sampled failed to comply with specifications (anti-malarials)
  - Direct consequence of the lack of adequate regulatory capacity and proper enforcement

- **Lack of Specialised Pharmaceutical Skills**
  - Unresponsive training – institutions mostly offer generalist science and retail oriented Pharmacy degrees
  - Challenges with external recruitment – e.g. permits
**African Pharma Challenges**

- **Access to technology**
  - Absence of home grown - and difficulty in accessing foreign technologies
  - Lack of academia / R&D institute & industry interface
  - *The Indian experience – government’s catalytic role!!!!!*

- **The Pandemic blindside**
  - Priority given *LARGELY* to the three pandemics
  - Local production prejudiced by the perceived ease with which African countries can access affordable quality medicines from low cost producers in the east – albeit only for the epidemics
African Pharma Challenges

- Lack of affordable Finance and Incentive Schemes
  - Commercial banks reluctant to offer loans to the industry - interest rates ~ 25-30%
  - Absence of well developed stock markets
  - Investors have little appetite for the pharmaceutical industry - amounts made available often insufficient for pharmaceutical upgrades (counterfeits / weak regulation / Asian tigers / uncompetitive against local non-GMP firms)
  - Unreasonable lending requirements e.g. IFC demands WHO PQ before they can advance a loan – yet loan necessary to assist companies to upgrade for international GMP (? agenda)
African Pharma Challenges

- Governance and business culture
  - Founders reluctant to give up control or dilute their influence.
  - Poor record keeping – challenges with business evaluations
  - Poor governance

- Lack of market data / intelligence and information
  - Lack of proper market data - multiple and poorly regulated channels through which products enter and leave the market & unofficial/unlicensed dispensing points
  - Public procurement data non existent
Supporting industries & associated infrastructure
African Pharma Challenges

- Weak or non-existent related and supporting Industries
  - Raw materials, tooling and machine spare parts
  - CRO’s and BE centers
  - Unregulated, fragmented and grossly inefficient pharmaceutical distribution chains
  - Utilities unreliable
  - Underdeveloped and unresponsive financial and legal infrastructure
About the PMPA
## PMPA Background & Key Milestones

<table>
<thead>
<tr>
<th>Year</th>
<th>Place</th>
<th>Milestone</th>
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<tbody>
<tr>
<td>2005, July</td>
<td>Abuja</td>
<td>Original decision to develop a PMPA</td>
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<td>2007, July</td>
<td>Accra</td>
<td>Initial Plan endorsed by Heads of State</td>
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<td>2011, March</td>
<td>Algiers</td>
<td>CAMI Roundtable on local production and incorporation of sector in AIDA</td>
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<td>2011, Sep to 2012, April</td>
<td>Vienna</td>
<td>Inception workshop, data gathering, country visits &amp; strategic plan development</td>
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<tr>
<td>2012, May</td>
<td>Geneva</td>
<td>Adopted by the Conference of African Minister’s of Health (CAMH) – wide support from stakeholders, UN Agencies, other potential partners</td>
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<td>2012, July</td>
<td>Addis</td>
<td>Endorsed by Heads of State of State and Government</td>
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<tr>
<td>2012, Oct /Dec</td>
<td>Vienna / CT</td>
<td>High level meeting with Heads of Agency, AUC, Donors, Political leadership, FAPMA etc</td>
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Core objectives

- Support local pharmaceutical manufacturing to:
  - increase access to affordable quality medicines
  - ensure sustainable supply of essential medicines
  - improve public health outcomes
  - promote industrial and economic development
To develop a competitive and enduring integrated pharmaceutical manufacturing industry in Africa, able to respond to the continent’s need for a secure and reliable supply of quality, affordable, accessible, safe and efficacious medicines.
PMPA Package of Solutions for Growing the Africa based Industry
National Medicines Regulatory Authorities

- e.g. oversight of clinical trials and GLP
- e.g. dossier review, plant inspection, GMP certification & monitoring
- e.g. oversight and enforcement of GDP and GWP
- e.g. Pharmacovigilance and adverse events reporting system

Inputs
- Business partners - access to formulations and know how
- Business partners - supply agreements etc.
- Material inputs (e.g. API, excipients)
- Utilities
- Other supporting industries e.g. Maintenance and repair of equipment
- Clinical research for BA/BE
- National Standards Board e.g. calibration of equipment

Local Manufacturing
- Manufacturers
- Formulation development
- Final formulation

Distribution
- Distribution - array of public & private systems
- Distribution - range of mechanisms including national systems and donor operated supply chains

Market
- National Markets
- Public procurement
- Private market
- NGO procurement
- Sub-regional exports
  - Public procurement
  - Private market
  - NGO procurement
- Donor funded market for pandemics (both national and export), e.g.
  - Global Fund
  - PEPFAR
  - PMI
- Prequalified products from other countries largely from India

External Players
- Products from other countries particularly India as well as intra African Trade
- Other NMRAs
- Other MoF
- Other MoH

Trade Associations*
- Various National Ministries including Health, Finance, Industry, Trade
- * - Note trade associations can perform a range of functions on behalf of their members to influence the business environment, such as dissemination of best practice, partnership brokering, lobbying

Key:
- Material flows
- - - - = supply of services/access to knowledge
- - - - = influence, including through regulatory oversight, policy, lobbying etc.
PMPA Package of Solutions

Quality, Access, Availability, Affordability

Competitiveness, Sustainability & Self Reliance

- HR Development
- Access to Product & Technology
- Access to Affordable Finance & Time Limited Incentives
- Regulatory Systems Strengthening & Enforcement
- Partnerships, Collaborations & Fostering Business Linkages
- Enhancing Market Data Collection & Facilitating Market Access

Sound Sector Strategy

Policy Coherence

Political Commitment
## HR Development

### Key Interventions:

- **Training of:**
  - NMRA (all aspects of Quality - GMP, GDP, GLP, GWP, policy etc.)
  - Pharmaceutical companies (e.g., formulation, GMP, Lean manufacturing, business management, plant operations)
  - Govt policy makers (e.g., policy development & coherence)

- Facilitate the review & reorientation of science/pharmacy/engineering curricular at institution of higher learning

### Key objective:
To build capacity to meet skills requirements for local production of affordable and safe quality medicines.
HR Development

- **Professional & short courses (< 1 year)**
  - Who - Industry experts, International organisations (e.g. USP, WHO, SRAs)
  - How - Trade associations & NMRA’s
  - Where - Centres of excellence

- **Long term courses (> 1 year)**
  - Specialised tertiary institutions (e.g. St Lukes, University of Ibadan, UZ, UCT etc)
  - Centers of Excellence (e.g. ANDI)
## Access to Products & Technology

<table>
<thead>
<tr>
<th>Key objective:</th>
<th>Key interventions:</th>
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<tr>
<td>Assist African companies to access and acquire best in class technology &amp; improve product portfolios</td>
<td>Working with CoEs, develop formulations and diffuse technology to GMP compliant companies</td>
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<td>Working with UNDP/UNCTAD/ARIPO etc., exploit TRIPS flexibilities to supply donor funded markets in LDC’s</td>
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<td>Negotiate directly with patent holders for voluntary licences</td>
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<td>Facilitate access to technology through partnerships; e.g. WHO/EGA/KEMRI/NIPRD etc.</td>
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## Access to funding & incentives

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<td>Assist African companies to access affordable capital, and advise governments on conducive incentives</td>
<td>- Advisory and technical assistance to governments on development of policies including incentive programmes that are supportive of the growth of the pharma industry</td>
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<td>- Mobilise enthusiasm for pharma sector and lobby for review of funding/investment criteria (e.g. local banks and international finance organisations)</td>
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## Regulatory systems strengthening

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<tr>
<td>Assist NMRA to develop the capacity to fulfil their mandate – ensuring that the products on the market are safe, efficacious and of good quality</td>
<td>Offer technical assistance to</td>
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<tr>
<td></td>
<td>▪ Develop legislative framework for the NMRA</td>
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<td>▪ produce organisational development plans, policies and procedures</td>
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<td>▪ NMRA’s and partnership with AMRH for regulatory harmonisation</td>
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<td>Establish a “GMP road map” &amp; an audit tool to establish baseline for industry &amp; Enhance capacity of NMRA’s to enforce</td>
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Facilitating partnerships & business linkages

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<th>Key interventions:</th>
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<tr>
<td>Promote business linkages and partnerships to facilitate access to products, finance, and skills &amp; know how</td>
<td>Create a web portal with corporate profiles and a B2B facilitation platform</td>
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<td>Facilitate bi-annual matchmaking meetings and fairs with global counterparts</td>
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<td>Strengthen linkages with ANDI and other CoE’s</td>
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<td>Strengthen industry associations &amp; partner with them to foster internal partnerships (e.g. Pooled procurement of products and services)</td>
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<td>Monitor and track deal flow &amp; and the aspirations of global and African pharma</td>
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## Enhancing market data collection & access

<table>
<thead>
<tr>
<th>Key objective: facilitate the collection of market data</th>
<th>Key interventions:</th>
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<td></td>
<td>Identify &amp; partner with reputable research organisations to collect market data and intelligence</td>
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<td>TA to government procurement agencies to develop forecasting and data collection abilities</td>
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## Facilitating access to market

<table>
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<th>Key interventions:</th>
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</table>
| Assist companies to improve product quality & portfolio thereby strengthening their access to local & funded markets | ☐ Facilitate acquisition of international GMP standards, product and technology to supply funded markets  
☐ Promote regulatory harmonization and intra-regional trade  
☐ Exploit TRIPS flexibilities |
Conclusion
End

thank you...

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