The Pharmaceutical Manufacturing Plan for Africa Business Plan (PMPA BP)

Juergen Reinhardt
Project Manager
Business, Investment and Technology Services Branch
UNIDO, Vienna
OUTLINE OF THE PRESENTATION

1. History of the PMPA BP
2. Challenges and Opportunities
3. The Business Plan
4. Next Steps – Towards implementation
5. Conclusions
History of the PMPA and the development of the Business Plan
Abuja 2005: Original Heads of State decision to develop a PMPA
Accra 2007: Initial Pharmaceutical Manufacturing Plan for Africa (PMPA) endorsed by Heads of State

2011 - 2012

- 2011: Proposal for expanded TC and development of Business Plan
- March 2011: CAMI 19 incorporation of sector in AIDA & PMPA as mechanism
- July 2011: Partnership Agreement AUC & UNIDO: Assistance to AUC in preparation of the PMPA BP
- Sept. 2011: Inception Workshop AUC & UNIDO
- Dec 2011: Inception Report for TC
- April 2012: presentation of draft PMPA BP to expanded TC
- May 2012: approval of draft PMPA BP by CAMH
- July 2012: Endorsement of PMPA BP by Heads of State at AU Summit
Challenges and Opportunities
ACCESS SITUATION IN AFRICA: TODAY AND TOMORROW

11% of world population, bears 25 percent of the global disease burden

>68% of the global HIV/AIDS burden

Malaria is killing more than 1500 African children every day!

Top 7 causes of death in LICs (48%) include CD (3) and NCD (4) which are soon to become major cause of death in DCs

Pneumonia = leading cause of death in children (est. 1.6bn die p.a.); only 20% receive treatment

>68% of the global HIV/AIDS burden

50% w/o regular access to medicines

11% of world population and 1% of global healthcare expenditure

Future situation:
Distinct increase of non-communicable diseases (NCDs) will add to overall disease burden, resulting from
- Ageing population
- Urbanization
- Lifestyle (diet, alcohol, tobacco consumption)

By 2020: 1 m cancer cases p.a.

By 2020: approx. 60m cases of hypertension

By 2030: 18.6 m will suffer from diabetes

Source: WHO Global Infobase
LOCAL MANUFACTURING IN AFRICA IS A REALITY

Recent headlines regarding African pharma

- New Tanzanian plant to produce its first ARV
  - 6 March 2012
- Swiss firm Lonza in $211 mln South Africa API Joint Venture
  - 10 February 2012
- Egyptian delegation explores opportunities in South Sudan
  - 22 February 2012
- UNAIDS Executive Director calls for greater production of HIV medicines in Ghana
  - 24 February 2012
- Cadila Joint Venture to set up plant in Rwanda
  - 7 March 2011

Drug supply in SSA:
Ca. 30% from LP (volume), 70% imports

- Ghana: ~ 40 manuf.
- Nigeria: ~ 100 manuf.
- South Africa: ~ 70% of African supply
- Kenya: ~ 40 manuf.
| OUTREACH | • 38 (est.) countries with manufacturing sites  
  • Very diverse in terms of number and size of companies  
  • S. Africa: 70% of total; a further 20% combined from GHA, KEN & NIG  
  • APIs: 95% imported (largely India & China) |
| PRODUCTION FOCUS | • Near exclusive focus on finished formulations  
  • Mostly old & highly commoditized products, e.g. nutra-ceuticals, cough & cold preparations, simple analgesics & sedatives, anti-malarials, older generation antibiotics, anti-helminthics, 1st generation anti-hypertensives, anti-diabetics  
  • API production only in South Africa, Egypt & Ghana (small, internal consumption) |
| FACILITIES | • Often obsolete equipment & machinery  
  • Capacity utilization <50% in some cases |
| QUALITY | • Variable: majority of firms not (international) c-GMP compliant  
  • Drivers progressing (GMP, WHO PQ, upgrading, etc.) |
| R&D | • Few companies with reverse engineering units  
  • Essentially no involvement in original R&D |
# AFRICAN PHARMA: PROMISING MACRO DRIVERS

## Economic
- Population to hit 1.3 billion (2020)
- Combined GDP of USD 2.9 trillion
- 600 million people to live in urban areas (megacities & transport corridors)
- >50% of households with disposable income of >20 USD/day
- Healthcare expenditure of around USD 200 billion
- Pharmaceutical market valued at USD 23 billion (est.)

## Health
- Patent expiries of many leading medicines
- Growth of pandemics and increasing numbers of people on treatment
- Ageing population & increase in life-style diseases – projections:
  - 60 million people with hypertension
  - 1 million cases of cancer annually
  - 18.6 million people with diabetes
- Improved health insurance & coverage environment
OPERATING CONDITIONS OF LPP: CHALLENGES AND DISCONNECTS

Market environment

Plant level challenges

Industrial policy

Health policy

Limited distribution capacities
Import of raw materials
Access to capital
Reliability & costs of utilities
Intellectual property rights regime
Small market size & fragmented regional markets

Infrastructure
Capacity at medicines regulatory authorities
Human resources
Access to technical know-how/technology

Regulatory landscape
Sector representation
Limited access to medicine
Health funding
Limited access to medicine

Public

Private

Poverty Reduction through Productive Activities • Trade Capacity Building • Environment and Energy
The Business Plan
PMPA BUSINESS PLAN

PHARMACEUTICAL MANUFACTURING PLAN FOR AFRICA

Business Plan

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Prepared as part of the AUC-UNIDO Partnership

Poverty Reduction through Productive Activity
PMPA BUSINESS PLAN: BASICS

- Philosophy:
  - Access to quality healthcare is a *fundamental* human right
  - Promotion of industrial development and safeguarding & protection of public health *are not* mutually exclusive priorities
  - Production of quality medicines and development of an international GMP-compliant industry in Africa are possible, desirable and eminently doable

- Vision:
  - To develop a competitive and enduring integrated manufacturing pharmaceutical 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.

- Approach:
  - Holistic, pragmatic, consultative
  - Augment, not supplant – recognition of ongoing efforts (RECs, country level): e.g. regulatory harmonization, skills development, technology transfer
  - Avoid duplication & wasted effort: coordination and integration of related activities critical
  - Not prescriptive
Fundamental objective of PMPA BP is to develop sustainable high quality manufacturing of essential drugs

- In general, this requires raising the standard of manufacturing on the continent
- However, to be sustainable the cost structure of the industry needs to evolve
- Steps are being taken to mitigate risk to public health whilst quality standards develop
- These and others will also support/protect the leading companies during the transition period
- The approach will benefit both the economic development and the public health of the continent
- But will require shared action from industry and health portfolios, as well as many other players
- Initial focus on small molecules formulations will be coordinated with development of strategies for e.g. biologicals, vaccines, API production, associated services and industries....
- Established R&D capacity on the continent will be incorporated in the approach (e.g. through involvement of ANDI)
Pharmaceutical manufacturing involves a complex interplay of different actors that determine the operating environment.
KEY PMPA SUCCESS FACTORS

Achieving the ambition requires a firm foundation be established and maintained and for coordinated action on key dimensions.
PMPA BP: DEVELOPING SOLUTIONS & RELATIONSHIPS FOR COORDINATED IMPLEMENTATION

Owing lead entity:

African Union Commission

Consortium of possible core partners:

Indicative Solution Packages:
- Guidance on legislative & policy considerations
- HR development
- Guidance on industry incentives
- Generic GMP road map, in conj. w. risk assessment of EML
- Guidance on production efficiency
- CoE: Dev. new formulations for GMP manufacturers
- Access to affordable finance
- Technical assistance to NMRAs
- Partnership & Bus Linkages Platform

Coordinated, tailored implementation as requested

Region A:
- Country A
- Country B
- Country C

Region B:
- Country D
- Country E
- Country F

Region C:
- Country G
- Country H
- Country I

Poverty Reduction through Productive Activities • Trade Capacity Building • Environment and Energy
PMPA BUSINESS PLAN: IMPLEMENTATION PRINCIPLES

- Implementation largely at country level (upon request), some at REC and continental level
- Interconnectedness of key dimensions and requirements of manufacturing system
- Breadth of expertise needed for delivery of full solution package requires inputs from many players (50+ service providers listed in BP)
- Vertical stand-alone solutions not enough – need for systemic approach
- Partnership & collaboration
  - Alignment & coordination of various interventions critical, but
  - Need for central depository of expertise, knowledge, skills and capacity for deployment where required (generic solutions, to be tailored to specific contexts)
Next Steps – towards implementation
Three main phases envisaged – set up phase has begun

**Set up Phase – The details**

- The AUC has invited UNIDO to coordinate the formation of the consortium.
- UNIDO will work closely with the AUC to mobilize the resources required (estimated at $54m in first 5 years) which would be disbursed to partners according to a mutually agreed work plan.
- An initial meeting of potential core partners took place on the 27th & 28th Nov 2012 in Vienna.
- UNIDO following up to develop detailed concept for review at a 2nd meeting scheduled for Q1/2013 (tent.)
- We have set aside some initial resources for moving forward with partners on developing the solutions (e.g. EML risk assessment by WHO).
- The concept will propose a governance structure for the long term oversight of this initiative which will need to remain vibrant over an extended period of time.
- A side event co-hosted by the AUC and UNIDO is planned for the AU Heads of State and Government Summit in January 2013.
Conclusions
TO CONCLUDE

- Through a collaboration between the AUC and UNIDO (est. July 2011) the PMPA BP has been developed
- It is approved by CAMH5 and endorsed by Heads of State
- The objective is for WHO GMP to be the standard to which all manufacturing is conducted
- This will require a coordinated response across many partners
- The business plan proposes a package of solutions and an approach for implementation that will enable coordinated action across the array of issues that need to be addressed
- The start up phase is underway and momentum will be built with a high level event in January 2013
TO CONCLUDE

“No Indian company can make an API that meets our specifications.”

Global R&D company in letter to an Indian pharma company in 1984
Thank you!

j.reinhardt@unido.org
www.unido.org/pharmaceuticals
Pharma system: Inter-dependence