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INDUSTRY, INNOVATION AND INFRASTRUCTURE

Formulating National Strategies for Pharmaceutical Sector Development

UNIDO's Approach

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Outline

- Introduction
- Key role of Government & relevant stakeholders
- Steps in Strategy formulation
- Summary





Introduction

- Generation of sector development strategies for the national pharmaceutical industry has been a cornerstone of the UNIDO global project
- Approach developed and optimized over the course of the project through application in successive countries in varying contexts:
Ghana, Kenya, Viet Nam, Zimbabwe
- Approach in an individual country involves tailoring common, core elements to the country-specific dynamic and requirements
- In the process, some key insights realized, which has led to the development of a methodology





Key consideration : Government has a major role to play, so political will and public-private cooperation are vital

Government assistance essential, at a minimum, to:

- Develop infrastructure to increase visibility of market opportunities through better market information
- Implement time-limited incentives to enhance market access and local industry competitiveness, thereby boosting market share of domestic companies
- Direct required financial resources for development of pharmaceutical sector

Regular, sustained involvement of key stakeholders critical in strategy formulation process

Key stakeholders (at a minimum):

- **Ministry of Industry**
- **Ministry of Health**
- **Ministry of Finance**
- **National Medicines Regulatory Authority**
- **Industry trade association**
- **National Revenue Authority**

For strategy formulation, 2-tier governance structure found to be effective ...

Steering Committee

- comprises institutional Heads
- monitoring of progress, assistance in removal of any roadblocks



Working Group

- consists of Managers of key Departments
- Data collection and review, joint decision-making on Strategy components



LPP DEVELOPMENT : CORE COMPONENTS OF A HOLISTIC STRATEGY

GMP Roadmap

Application of GMP roadmap for industry upgrading

Incentives

Guidance on time-limited incentives to support the transition of the pharmaceutical industry

Regulatory strengthening

Assistance to improve regulatory capacity

Policy coherence

Support to adjust policy framework for the industry across govt. actors

Market opportunities

Supporting defragmentation (reg.harmonization) & enhanced pharma market data transparency

Key guiding criteria:

- Quality
- Commercial viability

Governance

Functional, sustainable governance structures including Government and key stakeholders

Know-how/technology transfer

Supporting partnerships and business linkages to access know-how and technology

Human resources

Strengthening and upgrading human resources

Product portfolios

Helping GMP-compliant companies to expand their portfolios with generics of particular importance to public health

Investment

Facilitating access to affordable long term finance to enable upgrading





Strategy Formulation:

1. Do Diagnostic of National Market

- **Baseline: establish shares per market component**
 - commercially imported medicines
 - donated medicines
 - locally-produced medicines
 - (re)exported medicines
- If trend data not available, then at least one year's "snapshot"
- Ideal to examine consumption by product category, if data available

Strategy Formulation:

2. Assess reasons for low (or declining) market share of local production

Typical factors seen in African markets:

- **Lack of competitiveness** compared to imported product
 - inimical tariff structure of import vs. local production
 - market access / penetration problem
 - low capacity utilization
 - reduced operational efficiency
- **Perceived low quality** of locally-manufactured product
- **Limited product offerings**
 - technological / financial capacity issues
 - regulatory barriers to new product development



Strategy Formulation:

3. Consider remedies as possible Strategy components

Example: Lack of competitiveness

- Some form of short-term market protection (restriction of imports)
- Rationalization of tariffs for imports vs. locally-manufactured product
- Use of public procurement as an available tool to boost Local Pharmaceutical Production
- Any of a range of other demand-side, supply-side, or production cost-reducing incentives



Strategy Formulation:

3. Consider remedies as possible Strategy components ...

Example: Product quality improvement

- Assess manufacturing quality status of domestic companies, using **UNIDO's GMP Roadmap concept**, that entails a multi-year, stepwise path for manufacturers to attain WHO-level GMP (Good Manufacturing Practice)
- Develop and implement quality upgrading plans in local companies
- Effect awareness of QA/QC, and skills training / capacity building in local company personnel

Strategy Formulation:

4. Consider and include measures to improve enabling environment or ecosystem to promote local production

- Principal among these would be enhancement of systems / capacity of regulator
 - Training for GMP inspectors / registration personnel
 - Support for regional regulatory harmonization
 - Implementation of appropriate IT systems for tracking of imports / exports / local production / registrations
- Development of related infrastructure, e.g. tracking public-sector expenditure on medicines



Strategy Formulation:

5. Prioritize and combine Strategy components into consistent whole

- Strategy components are necessarily interlinked; therefore, proposed measures have to be internally consistent
- Strategy has to be holistic in addressing critical factors influencing the operating environment of local pharmaceutical companies
- UNIDO experience indicates that Strategy components cannot be implemented piecemeal; minimum subset of closely-linked Strategy components need to be implemented simultaneously

Strategy Formulation:

5. Estimate costs of implementation of Strategy

- Strategy formulation is not complete without estimation of costs of implementation. Costs are important to know what magnitude of financial resources will need to be mobilized
- 3 major parts to costs:
 - costs for GMP upgrading
 - costs for revamping product portfolios / new product development
 - costs for improvement of required systems / infrastructure

Mobilization of resources for Strategy implementation has to be a joint public / private sector effort



Summary

- UNIDO's approach to pharma industry development encompasses formulation of holistic national Strategies for sector development
- Strong political will, and the sustained, regular involvement of the range of relevant stakeholders is recognized to be critical to the process of Strategy formulation
- There are a number of common components which have been found to be central to a national Pharmaceutical Sector Development Strategy; others have to be tailored on a case by case basis in each country into a consistent whole
- Costing of implementation is an essential feature of a Strategy, to determine the level of resources required, and to aid joint public / private sector effort to mobilize needed financial resources



Thank you

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