Trends in local production of medical products in developing countries: integrating public health and industrial development

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Intellectual Property and Trade

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World Health Organization

Key lessons of phase 1

- Assessment of local production requires *holistic approach*
  - This holistic approach is reflected in the Framework for Public Health developed in Phase 1
  - Production facilities do not operate in isolation from society or surrounding environment
  - Strong relationship with education, training, science and technology community
    - Existence of job market influences decision-making during education
  - Economic effects not limited to pricing of specific therapies
    - Employment effects
    - Required providers of inputs and ancillary services
    - Effects on tax and financial base
    - Balance of payments effects

Key lessons of phase 1

- Build up of production-related regulatory capacity generally improves public health environment
  - Better control over of quality of products
  - Better control over distribution chains
- Security of supply important
  - Spectrum of interests range from pandemic vaccines and treatments, to long-term chronic conditions (e.g., HIV-AIDS), to conditions widely affecting society (e.g., diabetes, cancer, coronary disease)
- Local production may be needed to address specific unmet public health needs

Key lessons of phase 1

- Success requires political, legislative, technical and financial groundwork
  - Particularly for developing countries, government incentives and support are necessary for production efforts to succeed
    - Infrastructure development necessarily entails public expenditure
    - Financial and tax incentives are needed to create economically viable operations
    - Medium to long-term contracts for procurement assist with economic security necessary for investment
    - Governments must identify and remedy policies that may disfavor local producers (e.g., tariff structures that favor finished product imports over input imports)

Key lessons of phase 1

- Structured analysis and plan must be developed among government agencies
  - Public health, science, industry and finance needed for successful collaboration
- Long-term commitment by technical staff is required
  - Initiating local production project involves multiyear time horizon
  - Maintaining continuity at political level is difficult
- At present, meaningful international public financial support for local production is limited

Key lessons of phase 1

- Public health assessment of medical product needs an essential condition of planning
  - Public and private demand for vaccines, drugs and diagnostics is determined by disease patterns
    - Public health demand and “access” involve different variables
- WHO expertise is relied upon for identifying incidence of disease, preferred methods of treatment and term of requirements
    - HIV-AIDS treatment requirements, for example, change over time and must be anticipated
    - WHO plays important role in identifying gaps in availability of treatments

Key lessons of phase 1

- Best practices planning for local production requires integration of demand assessment, procurement requirements and potential benefits of local sourcing
  - Estimates of likely economic externalities are important to promoting public health policy objectives
- Expertise of collaborating organizations -- UNCTAD, UNIDO, academic institutions, IGOs and NGOs -- necessary for designing appropriate complementary industrial policies and recommendations, as well as carrying out in-depth research on public health and industrial development circumstances

Key lessons of phase 1

- Economies of scale and avoidance of regulatory inefficiencies strongly favor regional approaches to distribution of manufacturing capacity, procurement, regulations and enforcement
- Pharmaceutical Manufacturing Plan for Africa (PMPA) is intended to develop and implement a regional approach, with significant government political support
  - From a historical standpoint, political and interested party obstacles to regional approaches are persistent. There are limited internal political constituencies for “regionalism”
  - Mechanisms to overcome obstacles relating to distribution of benefits an important part of design
- Governments assess industrial policy projects and expenditures on a competitive basis. Question is not necessarily “do we want local production of medicines”, but “as compared to alternatives”

Key lessons of phase 1

- Technology, equipment and infrastructure requirements for local production of most essential medicines are available for purchase on international markets
- The issue is not whether local production is conceptually feasible, but whether there is sufficient motivation and financing to bring the necessary factors of production together in specific environments
- This is not intended to discount obstacles to the use of certain technologies, such as patented technologies on newer medicines (including biologics)
  - Development and implementation of appropriate transfer of technology policies remains essential
  - Highlights role of collaborating institutions

Implementation in Phase 2

- Role of WHO in supporting local production
  - Assessment of local and regional medical product needs based on medium and long-term demand
  - Participation in formulation of best practices government planning for local production and distribution
    - Public health aspects of industrial policy
    - Identify existing policies and practices generating successful outcomes (e.g., country case studies)
  - Involvement in strengthening regulatory frameworks essential for entire chain of medical product development and supply
    - Encourage regional solutions where feasible

Identifying "best practices"

- Example of holistic approach to planning for local production is study by Industrial Development Division (IDD) of South Africa Department of Trade and Industry (DTI)

  "Procuring locally made pharmaceuticals provides clear benefits for the Department of Health through improved security of supply, better enforcement of quality and responsiveness to fluctuating demand. It also provides considerable and measurable benefits to the country's economy, healthcare, science and tertiary education."

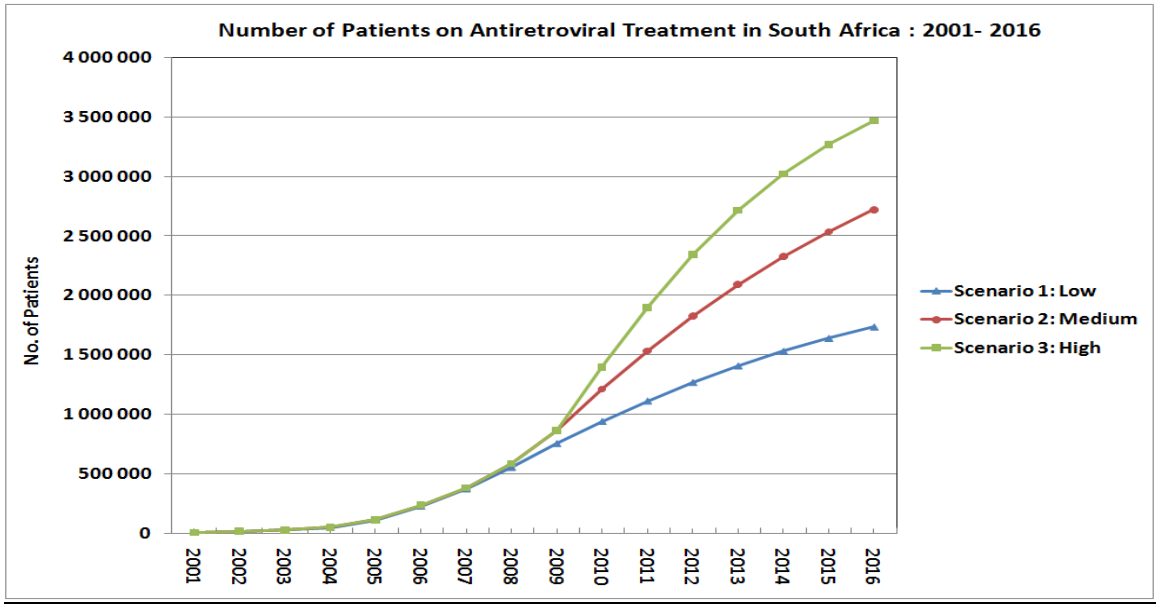
  – The South African Pharmaceutical Sector, Profile for the Consideration of Designation of Pharmaceutical Products In Terms of the PPPFA, (Final Version, 9 Nov. 2011) (Executive Summary)

Excerpts from SA DTI Study

"The country's pharmaceutical manufacturing base has been eroded, with 37 plants closing down between 1995 and 2010 and 6,500 jobs lost. The medical products sector, which includes pharmaceuticals, medical diagnostics and medical devices, became the fifth largest contributor to South Africa's imports burden. Imports of pharmaceuticals (excluding active pharmaceutical ingredients, APIs) have grown from R 6.2 billion in 2002 to R 15.1 billion in 2010. Pharmaceuticals in finished-dosage form account for 80% of the sector's total imports, growing at 12.5% per annum over the past four years, from 7.3 billion Rands in 2006 to 11.6 billion in 2010. South Africa imports 95% of APIs, including all APIs for ARVs and antibiotics; a precarious situation, considering the concentration of generic API manufacture in just two countries, China and India, and the level of AIDS and TB epidemics in South Africa."

Excerpts from SA DTI Study

- **Graph 2: The SA ART estimates 2001 – 2016 (ASSA AIDS Committee)**



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Excerpts from SA DTI Study

"This document identifies tenders and individual pharmaceutical products recommended by the DTI for procurement exclusively from domestic manufacturers. It also recommends the percentage of tender volumes to be set-aside for domestic manufacturers and indicates the level of price premiums needed vis-à-vis imports from the lowest-cost producers."

"The recommended price premiums, on average 15%, are far below the level of neutral return to the State calculated in IDC's cost-benefit analysis (32.5%) and the protection awarded to domestic manufacturers by customs duties in most developing countries. The set-aside tender volumes and price premiums in this document are indicative and should be fine-tuned through discussions, first with the Health Department and the National Teasury and subsequently with the manufacturers. The rules of designation must guarantee satisfying both the Health Department's priorities (competitive prices, security of supply etc.) and reasonable financial expectations of manufacturers (return on investment, profit margins etc)."

Implementation in Phase 2

- Develop centralized portal for various elements relevant for local production
  - Human resources
    - WHO departments
    - External technical experts
    - Facilities design and construction specialists
  - Material resources
    - Sources of machinery and equipment
    - Sources of production inputs
    - Sources of computer and software controls
  - Legal and regulatory resources
  - Generally address question of WHO affiliation/non-affiliation with identified resources

Implementation in Phase 2

- Integrating expertise of collaborating institutions -- UNCTAD, UNIDO, academic institutions, IGOs and NGOs -- essential to successful implementation of the Framework
- Seek to broaden potential financial support for specific local production projects
  - For example, pursue deeper cooperation with World Bank International Finance Corporation
  - Work to assure that new projects meet criteria for international procurement
  - Consider role of regional development banks
- Work to improve access to technologies
  - Identify potential partnerships/collaborations with technology holders
  - Provide legal guidance regarding appropriate use of international intellectual property flexibilities
  - Support extension of LDC TRIPS transition exemption

Policy Support

- Stakeholders seeking to promote local production within developing countries face obstacles, particularly from competing budget demands
  - Short-term benefits in terms of specific product pricing may not be demonstrable
- WHO is the most respected international advocate for public health and should be prepared to provide well-grounded support for plans built on best practices
- Collaborating institutions with industrial policy focus should be prepared to provide well-grounded support from a developmental perspective
- It is important to present the “holistic” case that ties together the various elements involved in the supply chain, including education, innovation capacity, employment, security and access