LOCAL PRODUCTION OF PHARMACEUTICAL PRODUCTS IN AFRICA: THE WHO APPROACH

Frederick M. Abbott
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Reinvigorated Attention to Local Production

• New era of industrial development in Africa
• Need for long-term security of supply for HIV-AIDS and other treatments
• Recognition that Africa confronts non-communicable diseases just as other regions
  • Growing "paying" patient market
  • Multinational investor interest increasing
• International programs do not address NCDs
Local Production Efforts Are Not Without Controversy

- African government budgets are limited
- India and China offer supplies at low cost
- Public health procurement realities confront the holistic logic of local production
- Playing fields are not even
  - Asian governments provide substantial incentives to domestic producers to participate in export markets
Obstacles to African local production

- Inadequate infrastructure (e.g., continuous electricity, transport and clean water)
  - Not atypical of developing countries -- can be addressed through "private infrastructure"
- High costs of capital
- Technology (production and product)
  - Specialized technical expertise available from international consultants, including training
  - Major design and construction firms are global
  - New drug technology (e.g. patents) are an issue in some cases
    - Joint venturing is an option
Regulatory Barriers

- Pharmaceutical production benefits from economies of scale
  - Cross-border movement of pharmaceuticals important to achieving scale
- Lack of cooperation and coordination among regulatory authorities hampers cross-border trade
  - Multiyear efforts to improve situation so far unsuccessful
- Regulatory authorities may move slowly in approving introduction of products
- Serious resource constraints in inspection and approval of facilities
- Competition among producing countries (e.g. Nigeria and South Africa) may impede regulatory cooperation
The Case for Local Production

• Sustainability of supply
  • In cases such as HIV-AIDS, reliance on foreign suppliers may be problematic as "business case" may shift
  • Adverse balance of payments effects may be significant, particularly if support from international donors decreases

• Development of advanced technological capacity important to the future of Africa
  • Development of new drug products is related to capacity to move into production
  • It is possible to focus on "pure science" and offshore production, but does not capture value chain

• Basis for addressing counterfeit/substandard drugs on the market
  • Importance of local producer interest
African Political Momentum

- African Union declarations and Commission's Business Plan for Implementing the Pharmaceutical Manufacturing Plan for Africa
  - Business Plan is comprehensive document laying out case for local production and beginnings of roadmap for achieving the objectives
  - Includes cooperation with multilateral organizations, including UNIDO, WHO, UNCTAD, UNAIDS and others
  - African Development Bank interest
- Global Strategy and Plan of Action (GSPA) direct WHO Director General to support local production efforts
  - Division on Public Health, Innovation, Intellectual Property and Trade (PHI), with financial support from European Union, has been working to provide conceptual and practical support
PHI Activities

- Published a number of studies and reports on local production, including framework document
- Organized Global Advisory Committee
  - Oversight and recommendations regarding efforts
- Convened small technical advisory group - Advisory Group on Local Production
  - Briefing papers in progress
  - Include identification of appropriate government incentives, and identification of new production technologies and potential for implementing in Africa
- Various parts of WHO provide direct and indirect support for local production on an ongoing basis
Where This is Going

• Private sector interest in local production is evident, particularly in larger markets like Nigeria
• Some governments taking very active steps to promote local production
• As in other areas of development, there are genuine possibilities for technology leapfrogging
• Multinational investors showing increased interest
• Multilateral institutions will not and should not drive the process, but have key roles to play in promoting appropriate regulatory environments and focus on meeting public health needs
• WHO's focus of attention is on assuring that local production be directed toward satisfying the needs of patients