

LOCAL PRODUCTION OF PHARMACEUTICAL PRODUCTS IN AFRICA: THE WHO APPROACH

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Reinvigorated Attention to Local Production

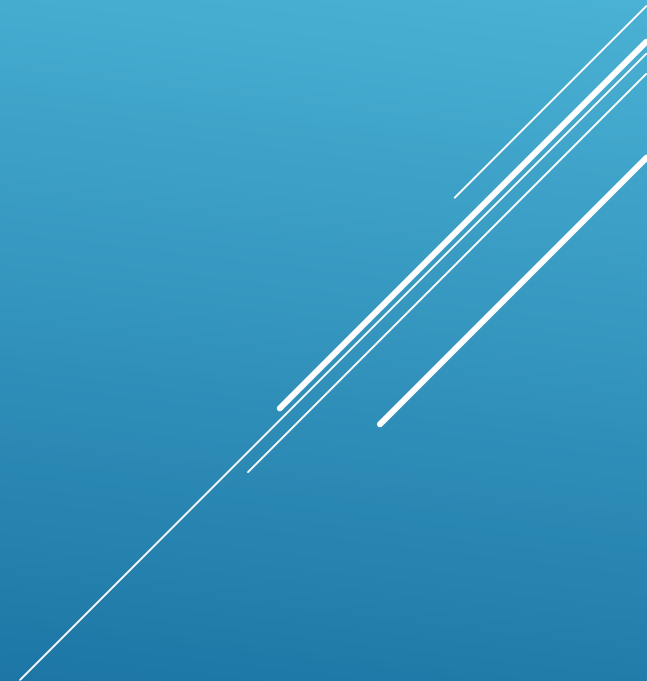
- New era of industrial development in Africa
 - Need for long-term security of supply for HIV-AIDS and other treatments
 - Recognition that Africa confronts non-communicable diseases just as other regions
 - Growing "paying" patient market
 - Multinational investor interest increasing
 - International programs do not address NCDs
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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
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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
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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
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PHI Activities

- Published a number of studies and reports on local production, including framework document
 - http://www.who.int/phi/publications/local_production/en/
 - 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
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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
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