



World Health
Organization

Promoting Local Production of Quality Medical Products to Improve Access: WHO Perspective

Global Pharmaceutical Regulation 2017

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Relevance of Local Production to WHO



Increasing access to medical products

We will continue to improve access to safe, quality, affordable and effective medicines. We will support innovation for affordable health technology, **local production**, and national regulatory authorities.

Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property



World Health Organization

Element 4 Transfer of technology

Promote transfer of technology for production of health products in developing countries

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Why Local Production

Local production can contribute to long-term socio-economic development by:

- *improving access* to and providing *uninterrupted supply* of quality-assured medical products
- *saving resources* through less expensive, locally produced medical products, if the production scale is sufficiently large
- *creating employment*, increasing purchasing power and stimulating investments
- *stimulating increased local innovation capacity and improving health workforce capacities & technical skills*

“Improving access to medical products in developing countries through building capacity for local production and related technology transfer”

- EC Project (Phase 1)
 - Laid down groundwork about local production and technology transfer
 - Studied landscape & trends surrounding local production (LP) & technology transfer (TT)
 - Identified related challenges & obstacles
 - Provided evidence-based recommendations for supporting/strengthening LP

“Improving access to medical products in developing countries through building capacity for local production and related technology transfer”

EC Project (Phase 1)



Local Production and Access to Medicines in Low- and Middle-Income Countries
A literature review and critical analysis



Increasing Access to Vaccines Through Technology Transfer and Local Production



Pharmaceutical Production and Related Technology Transfer



Trends in Local Production of Medicines and Related Technology Transfer



Local Production and Technology Transfer to Increase Access to Medical Devices
Addressing the barriers and challenges in low- and middle-income countries



Improving Access to Safe Blood Products through Local Production and Technology Transfer in Blood Establishments



Local Production of Pharmaceuticals and Related Technology Transfer in Developing Countries
A series of case studies conducted by UNCTAD



Increasing Access to Diagnostics Through Technology Transfer and Local Production

The publications from Phase I can be downloaded from http://www.who.int/phi/publications/local_production/en/

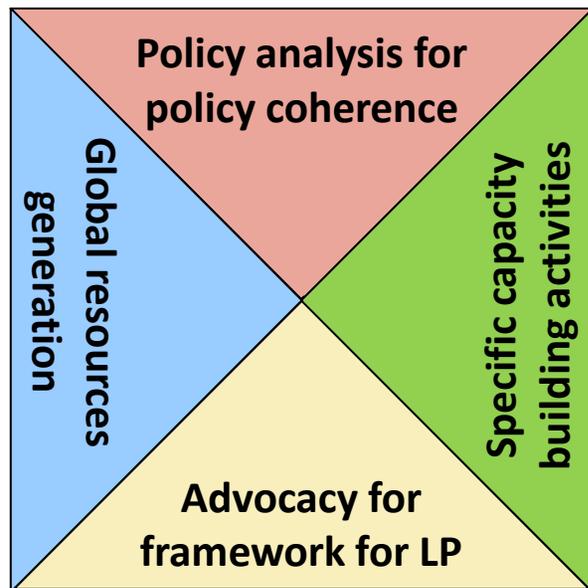
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Framework for Local Production to Improve Quality and Access



“Improving access to medical products in developing countries through building capacity for local production and related technology transfer”

EC Project (Phase 2)



Some examples:

- Development of resources
 - WHO Model List of Essential Medicines risk analysis for local production
 - Country experiences with strengthening local production & technology transfer
 - Report on the role of IP in local production and its challenges/obstacles
- Policy analyses for policy coherence
- Technical assistance for manufacturers

“Improving access to medical products in developing countries through building capacity for local production and related technology transfer”

- EC Project (Phase 2)
 - Country experiences in promoting local production to improve access & public health
 - Cuba, China and India
 - Look into different government policies that contributed to promoting LP
 - e.g. for Cuba, education policies were put in place for necessary knowledge & skills to support biopharmaceutical industry

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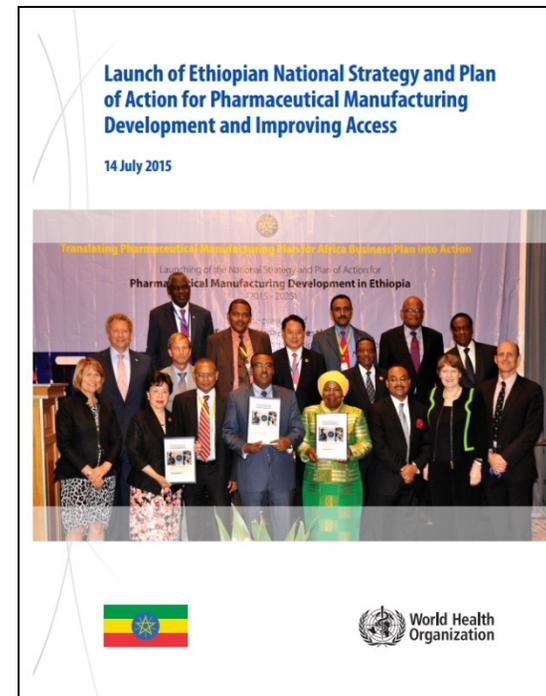
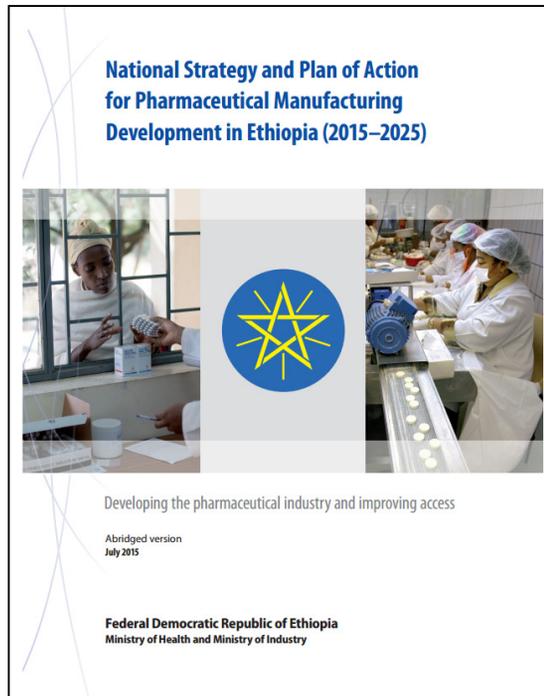
“Improving access to medical products in developing countries through building capacity for local production and related technology transfer”

- EC Project (Phase 2)
 - Report on role of intellectual property (IP) in local production in developing countries
 - Gives guidance to policy-makers on designing an IP system conducive to LP & public health
 - Examples of different situations:
 - LP through agreements
 - Landscape of patents for select medicines in select countries/regions

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NSPA-Pharma



The Ethiopian Deputy Prime Minister, while officially launching the strategy, called it a “flagship programme” for Ethiopia’s next 5-year National Development Plan (GTP-II, 2015-2020). WHO has been working with the government as a development & technical partner, with the launch & implementation supported financially by Gates Foundation. [Click](#)

NSPA-Pharma Implementation

Key achievements in 2016:

WHO supporting the Ethiopian Government

- Set up project governance structures
- Strengthen the national regulatory system
- Revitalize the national GMP road map
- Develop a method to prioritize the local production of essential medicines
- Assess the readiness and feasibility for local API manufacturing
- Assess the feasibility for local production of *entecavir* (anti-Hep B)
- Develop a post graduate curriculum on regulatory affairs
- Provide technical assistance to local and foreign projects (2 local, 4 foreign)
- Exploit Ethiopia's LDC status to locally produce patented products



- Develop the draft national incentive packages for local manufacturers and foreign investors

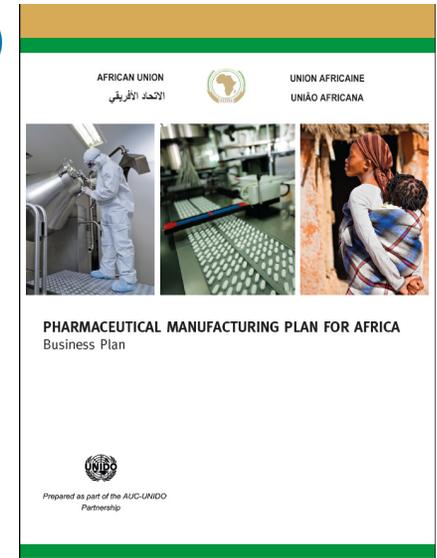


WHO Activities on Local Production

Collaboration with Development Partners

Under the context of the PMPA (endorsed in 2007)

- Development of a collaboration framework for the PMPA-BP Consortium
- Development of Vaccine Manufacturing and Procurement in Africa (VMPA) study (*an inter-agency collaboration*)
 - VPMA White Paper & Case Studies (South Africa, other)
- Revitalization of the PMPA's Technical Committee
 - the 6th TC meeting
- Development of the abridged version of the PMPA-BP



Let's Discuss

1. WHO's roles on Local Production?

Examples: Strengthen quality and the regulatory system; Enable evidence-based decision-making to address priority global challenges

Want to listen to you...

2. How to coordinate the interagency partnerships, and how to collaborate with various stakeholders?