

# Local Production and Access to Medicine

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# Capacities Pharmaceutical Industry

- Development and marketing of new molecule
- Innovative abilities in the existing molecules
- Abilities to produce API
- Abilities to produce formulation
- Abilities only in package

# Status of Local Production

- Out of 46 Member States within WHO AFRO 37 are having local production
- 1 MS has primary production
- 34 MS have secondary production
- 25 MS have tertiary production
- Studies shows that 80% of ARV drugs are imported

# Reasons for Local Production

- Saves foreign exchange,
- creates jobs, thus alleviating poverty and promoting social development
- Facilitates technology transfer
- Stimulate exports,
- Raw materials produced locally will be readily available and cheaper,
- Improves/ enhance self-sufficiency in drug supply
- Optimise the use of TRIPS Flexibilities

# Primary Requirements

- Capital
- Technology
- Raw materials
- Human resources
- Market
- Supporting legal and regulatory system

# Tension between Local Production and A2M

- Quality
- Price
- Industrial policy v health objectives
- Long Term v Short Term

# International Funding for Medicines and Local Production

- Policies of international funders can hamper local production Eg. Global Fund insistence on prequalification excludes local producers from supplying to the local market
- An Assessment of PQ reveals
  - Share of developing country manufacturers has been flat since start of program for FPPs and APIs
  - Share of DCVMs relatively constant, with majority coming from HI countries
  - Share of DCMs has moderately increased from zero since start of program for Dx

# Impact of Regulatory Regime on Local Production

- In many countries, essential drugs required for the prevention and treatment of locally endemic conditions are not supplied by the major multinationals, but by local industry or by generic manufacturers. If these suppliers are unable to meet what may be unsubstantiated quality standards, the adverse impact of the withdrawal of these drugs on the health of the population might well be far more dramatic than that of any hypothetical risk posed by failing to achieve the ICH standards.

*(WHO Report: The Impact of ICH Guidelines in Non-ICH Countries)*



# IP Protection and Local Production

- Patent protection impacts the local production
  - Eg. India, Bangladesh
- Use of flexibilities are critical for the local production

# Trade and Investment Policies

- Low cost imports
- 100% FDI

# Role of State in Local Production

- Need an Entrepreneurial State
  - Market creation
  - Technology facilitation
  - Favourable trade and investment policies
  - Financing/Credit
- N

# Doha Declaration

- We recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

# Doha Declaration

- We reaffirm the commitment of developed-country members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country members pursuant to Article 66.2. We also agree that the least-developed country members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement

# AU Initiative 2012

The screenshot shows a web browser window with the following elements:

- Browser Tabs:** WHO, Concerns, Kenya, EU dir, Local, Local, s164, Supp, Microsoft, OM12, Assen, ACFrOgDi, WTO.
- Address Bar:** [https://au.int/sites/default/files/pages/32895-file-pmpa\\_business\\_plan.pdf](https://au.int/sites/default/files/pages/32895-file-pmpa_business_plan.pdf)
- Page Header:** الاتحاد الأفريقي (Arabic) and UNIÃO AFRICANA (Portuguese), with the AU logo in the center.
- Image Row:** Three images: a person in a white lab coat working with pharmaceutical machinery; a close-up of a conveyor belt with white pills; a woman carrying a child on her back.
- Section Title:** **PHARMACEUTICAL MANUFACTURING PLAN FOR AFRICA**  
Business Plan

# Further reading

