Making generic and biosimilar manufacturing thrive: a global policy

WHO remarks: improving quality and access

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Supporting Local Production in Developing Countries
improving quality & access

1. Why local production?

2. WHO's approach and work to support local production?

3. Local production for better access
SDG’s

https://sustainabledevelopment.un.org/

- Disease specific targets: HIV/AIDS, TB, malaria, maternal and child health, NCD’s …
- **3.8** Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all
SDGs
https://sustainabledevelopment.un.org/

- **3.b** Support the research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all

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Three Dimensions to Consider When Moving Towards Universal Coverage

Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, WHA 61.21

To increase access, especially for the poor in developing and least developed countries to medicines, vaccines and diagnostics of importance to public health, and especially for neglected diseases of the type II and type III categories as well as the specific needs of developing countries in relation to type I diseases.

Element 4: Promote the transfer of technology and production of health products in developing countries…

What is the link between LP & Access?

- Implicitly yes, but what is the evidence? What does literature tell?
  - Paucity of studies
  - New methods are needed

- e.g. India:
  - > USD 25 billion industry, 10% growth rate
  - > 80% ARVs in Africa are from India
  - > 1 million HIV/AIDS patients in India itself are without treatment access!
WHO's Approach to Supporting Local Production

1. Political commitment of government to develop local industry

2. Clear vision, coherent policy framework, action plan
   - "Health-industry complex" : explicitly linking local industry with local needs
   - What products ? High volume essential medicines ? Niche products ?

3. No compromise on quality – implement global standards
   - Investment in strengthening NRAs
   - Develop and implement national GMP road map
   - Regulatory collaboration/convergence/harmonization

4. (sub) Regional economic free trade area

WHO's Approach to Supporting Local Production

5. Facilitating technology transfer
   - North-south and south-south cooperation
   - Licensing arrangements

6. Building human resource
   - Education, training, retention

7. Supporting management of IP to support local production
   - Use of transitional period under WTO/TRIPS
   - Benefitting from flexibilities

8. Ongoing monitoring and evaluation
   - Reliable and sustainable market data gathering system

9. Working with partners
   - AUC
   - UNIDO, UNAIDS, UNFPA
“Improving access to medical products in developing countries through building capacity for local production and related technology transfer”

- **Phase I** - Identified main trends and barriers to local production of pharmaceuticals, vaccines and diagnostics. Published 8 reports. (2009-2011)

- **Phase II** - Activities to promote greater policy coherence between government policies that affect the local production in order to improve access. (2012-2014)

**Framework for Local Production for Improving Access**

**INDUSTRIAL POLICY**
- Competitive
- Reliable
- Innovative
- Productive
- Responsible
- Strategic

**HEALTH POLICY**
- Access (Availability Affordable)
- Quality
- Supply
- Rational Use

**SHARE GOALS HEALTH + INDUSTRY**
- Strategic selection of essential medical products
- Pricing of local products that governments & people can afford.
- Strict compliance to quality standards
- Effective NRAs.
- Health security
- Innovation.

**Government Support**
- Incentives to reduce the cost of manufacture
- Indirect support of local production for improving access

“To transform the Ethiopian pharmaceutical manufacturing sector into a fully GMP-compliant, competitive and innovative industry that meets the national needs of essential medicines through local production by 2025”

A strategy based on the value chain approach
Is local Production developing countries a good idea?

Advantages and goals

- Design to improve access to medicines
- Local capacity building, HR development
- Industrial and economic development
  - Each job in Pharmaceutical industry creates 7 jobs in associated industries (South African Study)
- Can help security of supply
- Strengthened regulation
- Knowledge economy

Commodities for better health in Africa – time to invest locally

Michel Sidibé, Li Yong & Margaret Chan

WHO Bulletin, June 2014

- “We welcome the surge of interest in the manufacturing of essential health technologies in Africa.”

- “UNAIDS, UNIDO and WHO are working closely with the AUC to better coordinate inter-agency efforts to support African governments.”

- “Africa’s development partners, especially the BRICS countries (Brazil, the Russian Federation, India, China and South Africa), have a special role in supporting this critical phase of African development.”