Leveraging and Cultivating Enabling Factors for Local Production

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Sustainable Development Goals and WHO’s 13th General Programme of Work

MISSION

Promote Health – Keep the World Safe – Serve the Vulnerable

3 billion targets:

Local production of quality-assured medical products can contribute to achieving the 3 billion targets and SDG health-related targets
Promoting sustainable quality local production needs government commitment

To achieve policy coherence and effective multi-sectoral collaboration

The sectors should work in concert to enable the business & regulatory environment

Health Policy
- Access (Availability, Affordable)
- Quality
- Supply
- Rational Use

Industrial Policy
- Competitive
- Reliable
- Innovative
- Productive
- Responsible
- Strategic

Shared 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

There are also key elements necessary for sustainable quality local production

Some challenges include:

- Higher cost to maintain GMP & quality production
- Price competition from imported products
- Local and/or regional markets unable to help manufacturers achieve economies of scale

A holistic and collaborative approach could help to overcome challenges in achieving quality and sustainability
WHO supports Member States in strengthening local production with assured quality, safety and efficacy

**NURTURING STRATEGIC PARTNERSHIPS**
- Interagency statement on promoting local production
- Interagency consultations on local production
- Secretariat for IPC Sub-committee on Local Production

**STRATEGY SETTING**
- Conducting holistic situational analyses for sustainable quality local production
- Supporting the development & implementation of national strategies and roadmaps

**SUPPORT IN THE STRATEGIC SELECTION OF PRODUCTS**
- Tool for risk-based selection of medicines for local production with assured quality

**CAPACITY BUILDING AND TECHNICAL SUPPORT OF STAKEHOLDERS**
- Holistic training workshops
- Specialized technical assistance for specific projects or products
- Compliance with quality assurance standards

*In collaboration with WHO technical units & disease programs and external partners*
https://www.who.int/phi/implementation/tech_transfer/en/

Training workshop on Key Enabling Factors for Successful Local Production and Supply of Quality-Assured Medicines

WHO, in collaboration with USP-PQM and AUDA-NEPAD, organized a training workshop from 17-19 December 2018 in Addis Ababa for African manufacturers. The workshop built manufacturers’ capacity to cultivate and leverage upon key enabling factors to strengthen quality local production and be sustainable.

Training workshop on Key Enabling Factors for Successful Local Production and Supply of Quality-Assured Medicines

News: Advancing local production and supply of quality assured medicines to improve access in the Africa region

Local production & technology transfer for access to quality medical products

Local production has been discussed in World Health Assemblies since the 1970s. The adoption of Resolution WHA51.21 for the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GS-PA PHI) brought a renewed focus on local production and related technology transfer as a strategy to promote innovation, build capacity and improve access to quality-assured medical products. The Local Production Programme has since been supporting Member States in strengthening sustainable local production and technology transfer in a holistic and strategic manner in collaboration with governments, partners and other stakeholders.

Local production | Technology transfer

Low- and middle-income countries (LMICs) are becoming increasingly interested in developing the local production of quality-assured medical products. LMICs view local production as a strategy to improve access to quality medical products, achieve universal health coverage, strengthen health security and reach the health-related targets and broader developmental goals of the SDGs.

Read more

News & Events | Press releases | Contact
Resources on local production and tech transfer within reach

https://www.who.int/phi/implementation/tech_transfer/local_productionOverview/en/
Interagency Statement on Promoting Local Production of Medicines and Other Health Technologies

- Signed by the top leadership of 6 international organizations
- Official launch at 72nd WHA Technical Briefing on Local Production in May 2019
- It signals the commitment of the 6 organizations aiming to work in a holistic, strategic and collaborative manner in partnership with governments and other relevant stakeholders

Within the context of the public health agenda, promoting local production requires a holistic approach to enable manufacturers to comply with international quality standards, be competitive and engage in sustainable manufacturing.”
A holistic approach is taken to promote local production for sustainability and quality

Holistic situational analyses are conducted to identify gaps and provide evidence-based recommendations towards sustainable quality local production

➤ A tool has been developed to assist with the analysis in key areas

Capacity building has been conducted on key enabling factors for successful and sustainable quality local production

➤ Including holistic range of topics
Product selection should be based on a holistic approach

Various factors should be assessed individually and holistically

Product selection should include whether the candidate can be produced with assured quality.
Risk-based assessment tool for product selection for quality local production

- A tool has been developed to assist manufacturers in selecting a candidate for production that is commensurate with existing capabilities to ensure quality using a risk-based approach.

- The tool considers aspects related to production that could impact the quality of the finished product:
  - Aspects related to the manufacturing site
    - GMP compliance status, quality systems, contracting steps to external 3rd parties, existing capabilities, personnel
  - Aspects related to manufacturing the candidate
    - API characteristics, formulation, product development, manufacturing process

- The tool is being piloted by manufacturers, regulators and other stakeholders to further refine the tool.
Product selection should undergo a standard process and be evidence-based

Rationale:

- The same set of data is collected for each candidate and analyzed in the same manner
- Different candidates are compared on an equal level
- Selection of the candidate becomes objective

Documentation is a key aspect towards standardizing the selection process

- Turning the process into an SOP makes the process systematic and consistent
- By documenting the results during the selection process, these results can be re-visited at a later date
Sustainable quality local production and WHO prequalification

Local Production could support PQ

- Building capacity towards and achieving production with assured quality are steps towards product prequalification
- Building an enabling policy & business environment to enable PQ to be achieved and sustainable, e.g. incentive package
- Using the WHO risk-based assessment tool to select products from the PQ EOI to ensure quality
- Strengthening the NRA to support local production for PQ of vaccines

PQ could catalyse Local Production

- Increase capacity in QMS and GMP compliance
- Increase capacity in manufacturing products with assured quality
- Enable access to donor-sponsored, international tenders and Medicine Patent Pool licences
- Create brand recognition for manufacturing prequalified products
- Strengthening the NRA to support quality local production

Locally-produced PQ products could bring the supply of quality assured essential medicines closer to the need
Thank you

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WHO Local Production Programme website:
https://www.who.int/phi/implementation/tech_transfer/en/