The local manufacturing initiative is implemented by WHO and its partners, with the support of the European Commission (EC). It has been developed in the context of the *Global Strategy and Plan of Action on Public Health Innovation and Intellectual Property (GSPA-PHI)* and it explores and supports the feasibility of quality local production of medical products in developing countries with a particular focus on Africa.

The overall goal of the initiative is to increase access to essential medicines, vaccines, medical devices, in-vitro diagnostics and blood products.

### THE CONTEXT

Access to medicines and health technologies remains a challenge in developing countries. Strengthening access will be an important part of achieving universal health coverage and other cross-cutting health targets embedded in the Sustainable Development Goals (SDGs).

India and China are well known suppliers of generic medicines and active pharmaceutical ingredients (APIs). Many middle-income countries have established sizable pharmaceutical industries, built vaccine production capacity and are diversifying into other areas of health technologies. This trend is also growing in low-income countries. However, the success stories of industrial development in India and China are not easy to emulate due to the size of their economies and their strategic policies, including those that relate to intellectual property. Nevertheless, local production is being actively pursued in many developing countries. The *Pharmaceutical Manufacturing Plan Africa – Business Plan (PMPA-BP)*, for example, is being implemented with the assistance of international and bilateral agencies, and related discussions about transfer of technology continue to resonate in multilateral fora. There are underlying concerns, in view of growing demand, about the security of supply of essential medicines and other health commodities in the future if the supply-side is not expanded and diversified. Despite the challenges for local producers to achieve economic feasibility, good manufacturing practice (GMP) compliance and provision of quality assured, affordable medical products, new manufacturing units are increasingly being set up in many African countries.

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*a* See: http://www.who.int/phi/publications/gspa-phi/en/
PHASE I OF THE PROJECT (2009–2012)

Identified the main challenges and obstacles to local production of medical products relevant to public health needs of developing countries and related transfer of technology, and provided evidence-based recommendations for supporting local production that is feasible and leads to improved access.

Outputs

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

- **Trends in Local Production of Medicines and Related Technology Transfer**

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

- **Increasing Access to Vaccines through Technology Transfer and Local Production**

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

- **Increasing Access to Diagnostics through Technology Transfer and Local Production**

- **Pharmaceutical Production and Related Technology Transfer**

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

The publications from Phase I can be downloaded from [http://www.who.int/phi/publications/local_production/en/](http://www.who.int/phi/publications/local_production/en/)
The framework developed during Phase I highlights the objectives of a typical national health policy/national medicines policy and national industrial policy. Further it shows how these objectives can be combined to develop shared national development goals which can be pursued through government support for developing local manufacturing to improve access.

**Industrial policy**

**Main objective:** To develop a viable local industry that is competitive, reliable, innovative, productive and responsible.

**Key factors from medical products development perspective:**
- **Competitive:** offers better prices.
- **Reliable:** complies with quality standards; ensures steady supply.
- **Innovative:** aims for technological change and invests in research and development.
- **Productive:** contributes to national economy through employment generation; human resource development; and supporting associated industries and suppliers.
- **Responsible:** shows corporate responsibility towards social conditions and environment.
- **Strategic:** balances current and future demands.

**Health policy**

**Main objective:** To promote health for all through universal health coverage in terms of prevention, treatment and rehabilitation.

**Key factors from access to medical products perspective:**
- **Universal access to medical products:** through public sector supply system and/or social protection programmes.
- **Availability of essential medicines and diagnostics:** in appropriate formulations suitable for local use.
- **Affordable prices:** for government procurement agencies and for out-of-pocket expenditures by people.
- **Quality assurance:** through effective regulation.
- **Uninterrupted supply:** of essential medical products.
- **Rational selection and use:** by health managers and clinicians.

**Shared goals of health and industrial policies relating to local production for improvement in access to medical products**

- Strategic selection of essential medical products for local production.
- Pricing of locally-produced products that governments and people can afford.
- Strict compliance to quality standards by the manufacturers and effective national regulatory authorities.
- Health security – an uninterrupted supply of essential medicines.
- Innovation for development of products that are more suitable for local conditions.

**Government support of local production for access to medical products**

**Direct support to reduce the cost of manufacture:** Grants, subsidies, soft loans, provision of land, tax and duty exemptions for imported inputs for local production of essential medical products.

**Indirect support of local production for improving access:**
- Invest in strengthening regulation of national medical products; develop national priority lists of medical products; improve the financing of health services for expanding the domestic market; facilitate access to foreign markets; facilitate development of regional pooled procurement mechanisms; encourage regulatory harmonization; introduce appropriate pricing policies; facilitate relevant transfer of technology; support incremental innovation and production; develop appropriate intellectual property regimes; develop appropriate investment policies and facilitate joint ventures; facilitate international cooperation for local production.

1. Policy analysis: National policies administered by different ministries are often at cross-purposes in terms of their vision or impact on local manufacturing of health commodities.
   - Regional report on Africa;
   - Generic-capacity building manual;
   - Capacity-building workshops in Ethiopia, Ghana, Kenya and the United Republic of Tanzania.

2. Development of global resources to support local manufacturing.
   - Web-based information and knowledge repository on local production and technology transfer;
   - Report on patent protection of medicines and local production in LMICs;
   - WHO Model List of Essential Medicines risk analysis for local production;
   - Development of methodology to measure the impact of local production on access to medicines;
   - Comprehensive technical assistance for local production of blood-derived products to blood establishments in Indonesia, which would also positively impact access to plasma fractionation products in the neighboring countries.

   - Support to manufacturing of essential medicines and preparing for WHO prequalification in Ethiopia, Ghana, Nigeria and the United Republic of Tanzania;
   - Technology transfer assistance to vaccine producers in Egypt (Vacsera), Senegal (Institute Pasteur in Dakar) and in South Africa (Biovac Institute);
   - Technical assistance to selecting and supporting a technology transfer centre at Utrecht University (Netherlands) for the manufacture of prohibitively expensive biotherapeutics, such as palivizumab;
   - Developing a policy framework and strategy for local production of in-vitro diagnostics (IVDs) in Africa;
   - Workshops in Ethiopia, Nigeria, South Africa and the United Republic of Tanzania to stimulate innovation and appropriate technical transfer for local production of medical devices;
   - Developing a policy framework and strategy for local production of blood-derived products to blood establishments in Indonesia, which would also positively impact access to plasma fractionation products in the neighboring countries.

4. Advocacy for quality local production for improving access in developing countries.
   - Strategic opportunities have been sought to advocate for the local production framework for improving access. A group of senior experts in the pharmaceutical field have been engaged to develop six state-of-the-art briefing papers, focusing on:
     - (i) The pharmaceutical value chain and the vision for manufacturing in Africa;
     - (ii) Government incentives, economic tools and support for local production;
     - (iii) The potential for API manufacturing in Africa;
     - (v) The role of national regulatory authorities in ensuring quality local production;
     - and (vi) Modelling to predict the future demand for pharmaceuticals as a tool for local production planning.

A partnership has been established between UNAIDS, UNIDO and WHO to undertake a strategically important joint study on forecasting future demands or health technologies (ARVs and insulin) in Africa, and the role of local manufacturing to ensure future commodity security.

An influential editorial has been jointly published by Dr Margaret Chan (Director General, WHO), Mr Michele Sidibé (Executive Director, UNAIDS) and Mr Ll Young (Director General, UNIDO) entitled *Commodities for better health in Africa – time to invest locally* (1).

**Partners**

[Logos of United Nations agencies and partners]

b As the project has a specific Africa focus, agencies actively working on the PMPA and the related Business plan (PMPA-BP) have formed a consortium in support of African Union Commission and include: NEPAD, UNIDO, WHO, UNAIDS, UNDP, UNFPA, UNECA, FAPMA, ANDI, AfDB and USP.
THE FUTURE PLAN
A POSSIBLE PHASE III

Africa is growing economically, its consumer market is expanding and foreign direct investment is rising. African governments are showing political commitment for strengthening pharmaceutical manufacturing as an important sector for economic development and health policies.

Local manufacturing of health commodities is a complex undertaking and it requires a clear, holistic and long-term vision. WHO is looked upon for supporting governments in these endeavours, in collaboration with other agencies.

Our strategic partnerships in implementing various Phase II activities, most importantly with governments, are being appreciated and valued. There is now an increasing number of high-level government requests to WHO for technical assistance in strengthening local production e.g. 15 Member States from Western Africa are exploring collaboration with WHO through the Economic Community of West African States (ECOWAS) and the West African Health Organization (WAHO). The policy coherence agenda is having an incremental impact. It is part of the PMPA-BP, where WHO has been identified to take the lead on related policy analysis.

WHO brings a special added value by methodically linking local production to improvements in access to essential medicines and health technologies.

However, strengthening local production is a long-term effort. Project-bound and time-limited efforts can show some results but in order to be sustainable, continuity of effort needs to be ensured. Based upon Phases I and II of this project, the proposed Phase III will comprise of six priority strategic directions for the continuity of work for enhancing local production of essential medicines and other health products in developing countries from 2016 onwards:

1. Based on the situation analysis, including policy analysis, assisting governments in developing long-term, coherent national policies and national pharmaceutical development strategies for progressive pharmaceutical manufacturing along the value chain, with clear action plans for improving access to essential medicines and other health technologies.
2. Assisting governments in developing and implementing time-bound national GMP roadmaps for upgrading national pharmaceutical and health technology industries to ensure quality manufacturing and avoid harm caused by sub-standard medical products. This builds upon ongoing work on strengthening national regulatory authorities and regulatory harmonization.

3. Assisting governments in developing time-bound incentives for local pharmaceutical companies to develop and compete, and meet the local medicine needs.

4. Facilitating north–south and south–south transfer of technology between companies for important essential medicines and other health products that address priority public health needs in developing countries. This strand of work builds upon the ongoing work on transfer of technology to 14 vaccine manufacturers in developing countries.

5. Supporting governments in their efforts to develop appropriately educated, trained and skilled human resources for pharmaceutical and health technology manufacturing, including in the area of regulatory sciences.

6. Supporting reliable collation of market data and monitoring through standard methodologies the impact of local production on access to medicines and other health technologies.

REFERENCES

Africa is economically growing, its consumer market is expanding and foreign direct investments are rising. African governments now want their manufacturing sectors to be strengthened. They see development of pharmaceutical manufacturing as an important area for their economies as well as for their health policy. Since the beginning of this project, local manufacturing of medicines and other health commodities have gained much more political attention. Heads of State in Africa have signed-off business plan for PMPA in 2012 and African countries are now requesting technical support for enhancing local manufacturing from international organizations more than ever before. Partly, this project can also take credit for growing attention to local production agenda.

Local manufacturing of health commodities is a complex undertaking and it requires a clear, holistic and long term vision. It requires simultaneous action on many fronts. Governments have to show political commitment, ensure sustainability of effort and most importantly develop policy cohesion across the government policies. They have to demonstrate their strong ownership and willingness to invest in creating supportive environment by investing in strengthening of regulatory systems, human resource development and by providing well calculated and tailored incentives to local manufacturers. Some governments in Africa have started showing readiness for such course of action. International agencies have a definite role to play in assisting governments that hold the initiative. WHO is looked upon for supporting governments in these endeavours in concert with other agencies.

Through this project WHO is establishing itself as a willing partner with the governments. Our strategic partnerships in implementing various activities in Phase II, most importantly with governments themselves, are being appreciated and valued. Policy coherence agenda that we are promoting is gradually having its impact. It is already taken up by PMPA-BP where WHO has been identified to take lead on policy analysis for policy coherence. Global resources generation on local production would promote and facilitate access to relevant knowledge and information. The work on WHO MLEM from the perspective of local production and partnership with UNIDO on risk-assessment in the production of essential medicines and GMP compliance assessment can go a long way in changing the approach to local manufacturing in developing countries. Likewise, strategic work on development of manufacturing plan for vaccines in Africa, brokering establishment of technology transfer hub for production of bio-therapeutics in developing countries, strategy development for local production of IVDs, exploratory and capacity building work for local production of medical devices in sub-Saharan Africa, and technical assistance for quality production of blood products – all these activities in Phase II have a generic and extrapolative value for developing countries.

WHO brings a special value by linking local production to improvement in access and our investment in this area through this project would be a great contribution in this field.