

Local Production for Access to Medical Products

Developing a Framework to Improve Public Health

This briefing paper provides an overview of activities undertaken by WHO and its partners during the first phase of a project on the local production of medical products¹ for improved access in developing and least developed countries (LDCs). This is an action supported with funding from the European Union.² The project is in the context of the Global Strategy and Plan of Action on Public Health Innovation and Intellectual Property. The aim of phase 1 was to develop a framework and shared goals that could bring together and guide policy-makers and others from the fields of public health, trade, industrial policy and other relevant sectors (1).

Summary: a coherent, long-term policy approach is needed

- Ensuring access to medical products is a complex undertaking requiring governments, through their relevant policies, to balance the availability of quality assured medical products (supply side) with meeting priority public health needs with products that are acceptable and affordable (demand side).
- Supporting local production is one means by which governments in the developing world may seek to maintain this balance, and this project has reviewed many of these activities in a number of countries – with some demonstrating a real potential to make a difference in the area of improving access.
- Developing countries aspire to build and strengthen their domestic medical product industry. Trends show that local production is growing and diversifying in these countries through national efforts and with support from regional and international initiatives.
- However, the evidence for local production resulting in an improvement in access to medical products is inconclusive. In order to ensure a strong linkage between what is produced locally and what improves access, a comprehensive and system-wide approach is needed. This has to bring coherence between industrial, trade and health policies. From a public health perspective, support for local production should have the explicit intention of improving access to medical products.
- The framework paper and the related reports from phase 1 of this project contribute to the process of identifying the appropriate policy areas and actions that are needed so that governments can ensure that local production of medical products can contribute to the economic development of a country while also meeting its public health needs.
- WHO, working in collaboration with key partners, plans to promote and seek to implement this framework in phase 2 of the project globally, regionally and in a selected number of countries.

Outputs from phase 1 of the project

Phase 1 of the current project concentrated on identifying the main challenges and obstacles to local production of medical products and related technology transfer in developing countries. This work has been presented as a series of reports that are available for free download from the WHO website and includes the framework document.

1. *Local production and access to medicine in low- and middle-income countries: A literature review and critical analysis.*
2. *Trends in local production of medicines and related technology transfer.*
3. *Pharmaceutical production and related technology transfer: Landscape report.*
4. *Local production of pharmaceuticals and related technology transfer: A series of case studies.*
5. *Increasing access to vaccines through technology transfer and local production.*
6. *Increasing access to diagnostics through technology transfer and local production.*
7. *Local production for access to medical products: Developing a framework to improve public health.*

Background and context

Access to medicines remains a challenge in developing countries and it is an important part of the Millennium Development Goals (MDGs).³ Surveys of medicine prices and availability have shown that public sector availability of a selection of generic⁴ medicines is less than 60% across WHO regions (2).

- 1 In this phase, 'medical products' includes pharmaceuticals, vaccines and diagnostics.
- 2 This is an action under a European Parliament resolution to support pharmaceutical-related transfer of technology and capacity building for local production of medicines in developing countries, especially in least developed countries. *European Parliament Resolution on the TRIPS Agreement and access to medicines* (B6-0288/2007/P6_TA (2007)0353).
- 3 MDG Target 8.e: In cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries. See: <http://www.un.org/millenniumgoals/global.shtml>
- 4 WHO defines generic medicines as: "Pharmaceutically equivalent or pharmaceutically alternative products that may or may not be therapeutically equivalent. Multisource pharmaceutical products that are therapeutically equivalent or interchangeable."



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India and China are well known as suppliers of generic medicines and active pharmaceutical ingredients (API). For example, 80% of all donor-funded annual purchase volumes of antiretroviral (ARV) medicines in 2008 were supplied by Indian manufacturers and around 75% of API production from China and India is exported (3,4). Many other middle-income countries have also established a sizable pharmaceutical industry, built vaccine production capacity and are diversifying in other areas of health technologies. This trend is also growing in low-income countries and in some LDCs. 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 in relation to intellectual property (IP) particularly before and after implementation of the Trade Related Aspects of Intellectual Property Rights Agreement (TRIPS).

Local production nevertheless is being actively pursued and supported in many developing countries. *The Pharmaceutical Manufacturing Plan for Africa*, for example, is being implemented with the assistance of international agencies, and related discussions about transfer of technology remain active in international fora. This is coupled with an uncertain future for the global supply of affordable generic medicines from India and China. So, despite the challenge for local producers to achieve economic feasibility and provide quality assured, affordable medical products, at least in the short- to medium-term, new manufacturing units are being set-up.

But an important link is still missing: it remains unclear whether and how increasing local production in developing countries is improving access to essential medical products for those who need them the most. The degree to which existing local production for medical products, and new investments in this area, can be aligned with public health needs is an important and unanswered question that forms the basis for this project.

Key findings from phase 1

Evidence from phase 1 suggests that some activity has taken place to transfer technology and enable local production of medicines within the context of private business transactions. However, major technology transfer initiatives have concentrated on medicines used to treat a limited number of diseases, namely tuberculosis (TB), malaria, pandemic flu, human immunodeficiency virus (HIV) infection and conditions associated with acquired immunodeficiency syndrome (AIDS). There is an evident need to explore technology transfer for local production of medicines in other therapeutic areas, such as noncommunicable and neglected tropical diseases.⁵

Vaccine production is concentrated in a few countries. But the mechanisms for technology transfer for vaccines appear to be better established and more utilized than those for other medical products, with a more active role of the public sector in this area.

In the area of diagnostics there is a familiar set of barriers to establishing local production with regard to the establishment of local capacity and infrastructure. These obstacles are

compounded further by a market that has very little regulation and a consequent proliferation of poor-quality diagnostics tests.

Evidence from countries that have developed a viable local manufacturing industry shows that a long-term vision and coherence across national policies are the key factors for success. A mutually supportive, complementary and coherent combination of policies is required to ensure long-term sustainability. Alignment between medical regulation, industrial and investment policies, science, technology and innovation policies, intellectual property policies, health insurance policies, procurement policies, and technology transfer policies appears to be particularly important.

The literature search and other activities in phase 1 have shown that the presumed link between local production of medical products and improved access remains inconclusive and success of local production is not generally determined by measured improvement in access. But as this project seeks to demonstrate a growing understanding about the factors and policies that can strengthen production as a means to improve access to locally-produced medical products. These are set out below.

The need for a policy framework for local production for access to medical products

The need for such a policy framework is essential for the following reasons:

- Industrial development alone is insufficient to leverage the potential benefits of greater access to medical products in developing countries;
- In order to help develop and foster a common understanding for policy coherence for both industrial and health development;
- To help ensure that public investments in national regulatory bodies are made to ensure locally-produced medical products comply with quality standards;
- To assist governments to identify and justify incentives to local manufacturers;
- To address a possible future scenario where the global supply of affordable generic medicines may be uncertain.
- To better coordinate international support for complementary industrial and health development policies.

A diverse range of policies may be deployed to better ensure that local manufacturers of medical products in developing countries are encouraged to meet access needs in their own and other developing countries.

The framework diagram depicted in Figure 1 outlines the main relevant factors from both industrial (Box A) and public health (Box B) policy perspectives. This indicates that common or shared goals exist between these two perspectives, such that the objectives of industrial policy can also help to meet those of public health (Box C). In order to help achieve these shared goals the government role is to provide a range of direct and indirect financial incentives in various combinations, and to help ensure coherence across the entire policy arena (Box D).

⁵ Noncommunicable diseases (NCDs) are diseases of long duration and generally slow progression. NCDs such as heart disease, stroke, cancer, chronic respiratory diseases and diabetes, are by far the leading cause of mortality in the world, representing 63% of all deaths.

(A) 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.

(B) 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.

(C) Shared goals of industrial and health policies for 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.

(D) 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.

Figure 1. Local production and access to essential medical products: A framework for improving public health

The industrial policy perspective: factors of relevance for local production

The main objective, from the industrial policy perspective, is to support the development of a viable local industry that is:

1. Competitive: offers better priced products than other sources e.g. imports.
2. Reliable: products comply with quality standards; ensures steady supply.
3. Innovative: aims for technological change and invests in research and development (R&D).
4. Productive: contributes to national economy through employment generation; human resource development; and supporting associated industries and suppliers.
5. Responsible: shows corporate responsibility towards social conditions and the environment.
6. Strategic: balances supply with current and future demands.

The health policy perspective: key factors to ensure access to medical products

The main objective of an effective health policy is to promote health for all through universal health coverage in terms of prevention, treatment and rehabilitation. There are key objectives to be met if a medical product, regardless of its origin of manufacture, is to be accessible. These include:

1. Universal access: is ensured through the public sector supply system and/or social protection programmes.
2. Availability of essential medicines and diagnostics: in appropriate formulations suitable for local use.
3. Affordable prices: for government procurement agencies and for out-of-pocket expenditures by people.
4. Quality assurance: through effective regulation.
5. Uninterrupted supply: of essential medical products.

6. Rational selection and use: by health managers and clinicians.

The shared goals of industrial and health policies for local production and improvement in access to medical technology

1. **Strategic selection of essential medical products for local production**
Focusing on the medical products that are important for local public health needs, are in short supply and that can be produced locally with some support.
2. **Pricing of locally-produced medical products that governments and people can afford**
Striking a correct balance between affordability and economic feasibility of production is a challenge. Government support to help local producers of selected essential medicines through appropriate pricing policies can be very important.
3. **Strict compliance to quality standards by manufacturers and effective national regulatory authorities**
No local production of medical products is desirable without quality assurance, and any government incentives have to ensure strict compliance with required quality control systems in accordance with acceptable quality standards.
4. **Ensure health security – an uninterrupted supply of essential medical products**
To ensure health security there must be continuous availability of essential medicines at various levels of the health system. Taking a longer-term strategic perspective, local production is one area that could contribute to greater health security and access.

5. Innovation for development of formulations more suitable for local conditions

Innovation capacity is a critical prerequisite not only for R&D leading to new drug discovery, but also for the development of products that are incremental improvements, such as formulations that are more suitable for local conditions.

Government support to local production for improving access to medical products

Governments support local manufacture of medical products through a wide range of fiscal and non-fiscal policy incentives. From a public health point of view it is important that such support is not just for industrial development but also explicitly aims to improve people's access to locally-produced medical products. To achieve this, it is important that government incentives are aimed at supporting the shared goals of industrial and health policies.

There are a number of interdependencies between these policies. For example, seeking to access foreign markets in order to ensure economic viability, will not be possible without ensuring an effective national regulatory authority to provide quality assurance.

Government support must be based upon a long-term vision for local industry to eventually become competitive in the market place. Such support cannot be unlimited nor static. There is no one fixed formula for the kind of support and combination of incentives that governments should provide to private enterprises. It will vary in accordance with the context and should evolve over time. There are three important considerations for governments, so they can provide and calibrate their support between different potential incentives:

1. Government support should encompass the shared goals of industrial and health policies.
2. Direct government support to manufacturers of essential medical products should be planned for the short- to medium-term in order to help manufacturers to eventually stand on their own feet and compete. Such support can be in the forms of grants, subsidies, soft loans, provision of land, tax and duty exemptions for imported inputs for local production.
3. Indirect government support can be provided by the development of policies to:
 - a) Invest in strengthening national medical product regulation;
 - b) Develop national priority lists of medical products;
 - c) Improve the financing of health services for expanding the domestic market;
 - d) Facilitate access to foreign markets;
 - e) Facilitate development of regional pooled procurement mechanisms;

- f) Encourage regulatory harmonization;
- g) Introduce appropriate pricing policies;
- h) Facilitate relevant transfer of technology;
- i) Support incremental innovation and production;
- j) Develop appropriate intellectual property regimes;
- k) Develop appropriate investment policies and facilitate joint ventures;
- l) Facilitate international cooperation for local production.

The way forward: using the framework to promote local production for improving access to medical products

Along with other partners, WHO plans to promote this framework in phase 2 of the project globally, regionally and in some selected countries especially in Africa in the context of *The Pharmaceutical Manufacturing Plan for Africa*. The activities are planned in the following four major groups:

1. **Analysis for policy coherence**
In selected countries industry, trade and health policies will be mapped with input from the relevant policy-makers and other stakeholders in order to identify measures for improved policy coherence for local production and access to medical products.
2. **Development of global resources on local production, technology transfer and access to medical products**
A web-based global repository of technical materials will be established including a database of relevant literature. The patent status of medical technologies that are considered essential to meet high-priority national public health needs will be assessed. Links will be provided to experts and organizations providing support in this area and to technology transfer initiatives.
3. **Advocacy for the policy framework**
Briefing papers, journal articles and workshops will be used to advocate for the use and improvement of this framework approach to promote local production for improving access to medical products.
4. **Capacity building and technical assistance for local production of selected essential medical products**
The real value of this framework will be in its implementation. In selected countries there is a plan to identify essential medical products that can be produced locally with some assistance and which are not being produced for one reason or the other causing difficulties in access. Areas for specific capacity building will be identified at the policy level, at the national regulatory authority level and at the firm level. Local production of such products will be facilitated in close collaboration with health authorities and manufacturers.

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