

Striking a Balance: Challenges and Strategies for Local Pharmaceutical Manufacturing and Regulation

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About PQM+

The Promoting the Quality of Medicines Plus ([PQM+](#)) program, funded by the U.S. Agency for International Development (USAID) and implemented by the U.S. Pharmacopeial Convention, works to improve systems that assure the quality of essential medical products in low- and middle-income countries (LMICs) to help prevent maternal and child deaths, control the HIV epidemic, and combat infectious diseases through high-performing health systems.



**Promoting the Quality
of Medicines Plus (PQM+)**

COVID-19 disrupted global pharmaceutical supply chains leading to a renewed focus on building resilient supply chains...

- Numerous sources reported the global stockouts and disruptions to pharmaceutical manufacturing caused by COVID-19



- However, outside of vaccine manufacturing, the major headlines have focused on the EU, US and India's response to these challenges

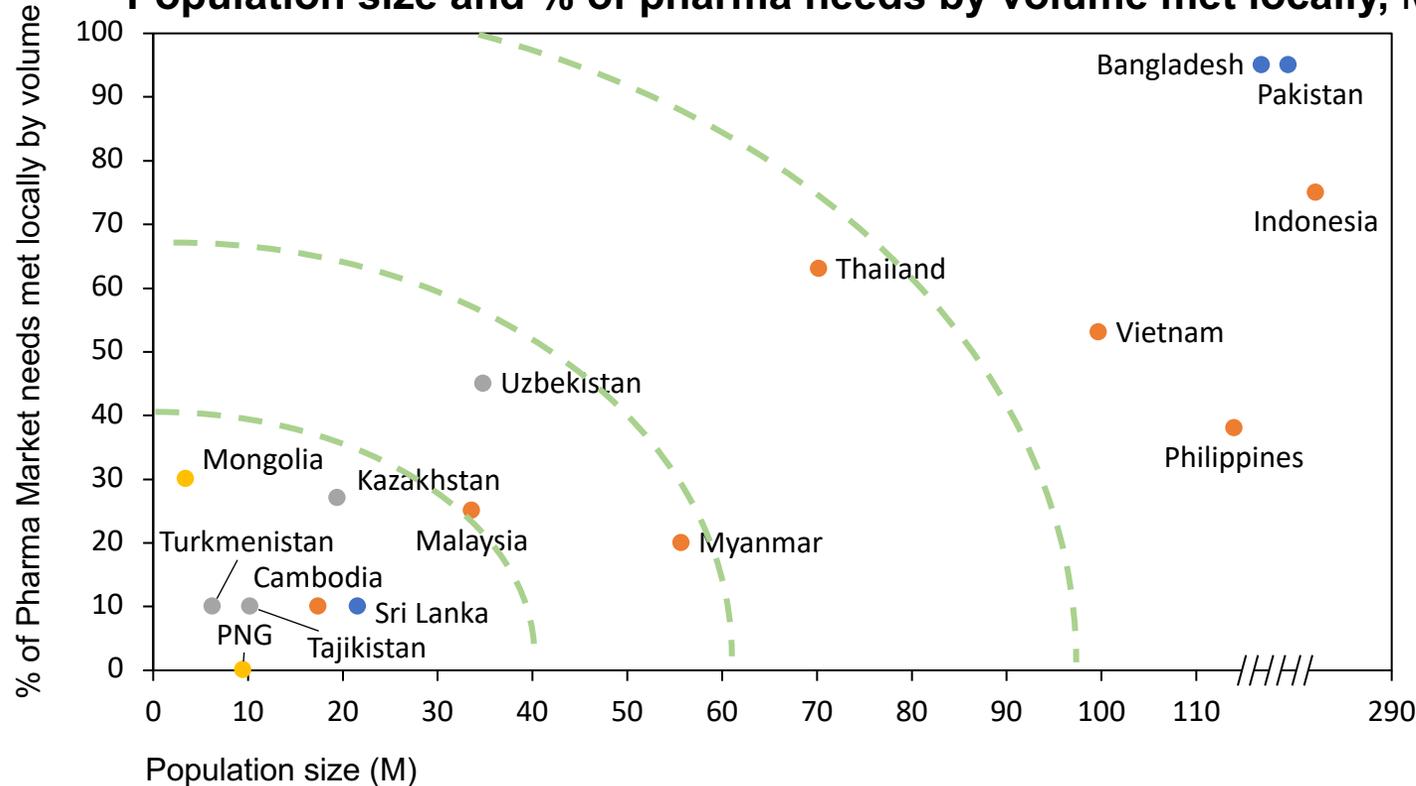


... but would this lead to an increase in local manufacturing of pharmaceutical finished dosage products and ingredients in Africa?



In 2022, PQM+ evaluated 17 LMICs in Asia according to their potential for increased local manufacturing

Population size and % of pharma needs by volume met locally, Mn of people and %



- % of generic demand that is locally manufactured was one of the 9 indicators in the analysis
- For all these countries, the % of value lags behind the % of volume

● South Asia ● Central Asia --- Visual threshold
● ASEAN ● East Asia & Pacific --- threshold

PQM+ will conduct a similar analysis in 2024 for sub-Saharan Africa

We observe similar challenges for countries interested in expanding local manufacturing of pharmaceuticals

Measuring access. Health policy is a driver of investing in local manufacturing. But many countries don't have an objective measurement of which medicines are unavailable or unaffordable in private. If something isn't measured it is harder to define a path to resolving it.

Maintaining quality. As the number of manufacturing facilities expands it can be challenging for regulators to maintain pace with facility inspection, dossier review, pharmacovigilance and post marketing surveillance. These gaps can lead to poor medicine quality and / or the perception of poor medicine quality.

Cultivating trust among consumers. Patients and medical professionals are frequently skeptical of locally manufactured products. It is common to hear of consumers choosing the 'brand' or foreign made product over the local option.

We refined the original framework by assessing available indicators and limits of secondary research and then simplifying to most relevant indicators

Composite Indicators

Sub-Indicators

Criticality of unmet needs

- % of local pharma needs met through domestic production
- Population size
- % Out of pocket spend of total health exp.
- Pharma market growth
- Universal Health Coverage

Enabling environment

- Ease of doing business ranking
- Evaluation of regulatory environment
- Assessment of health/industrial policies focused on local pharma mfg.

Manufacturing and potential export capability

- Economic Complexity Outlook Index (improvement since 2009-2019)
- Productive Capacities Index (improvement 2014-2018)
- UNIDO Industrial Competitiveness (CIP Improvement 2010-2020)
- LMIC vs LDC classification as it pertains to IP sharing

Indicators for the criticality of unmet need

Composite Indicators

Sub-Indicators (total potential points)

Criticality of unmet needs

- % of local pharma needs met through domestic production & Population size (3)
- % Out of pocket spend of total health exp. (2)
- Pharma market growth (3)
- Universal Health Coverage (2)

Enabling environment

- Ease of doing business ranking
- Evaluation of regulatory environment
- Assessment of health/industrial policies focused on local pharma mfg.

Manufacturing and potential export capability

- Economic Complexity Outlook Index (improvement since 2009-2019)
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The current local manufacturing contribution (% domestic production) and population (pop. size) are used to evaluate whether the need is something that is ideally addressed through local manufacturing.

Pharma market growth (%) is used to assess whether that need / demand is projected to increase.

These indicators compare countries need based on access to health services (UHC) and how much of medicine costs consumers are responsible for (OOP%).

Indicators for the enabling environment take the perspective of the manufacturer

Composite Indicators

Sub-Indicators (total potential points)

Criticality of unmet needs

- % of local pharma needs met through domestic production
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- Pharma market growth
- Universal Health Coverage

Enabling environment

- Ease of doing business ranking (3)
- Evaluation of regulatory environment (3)
- Assessment of health/industrial policies focused on local pharma mfg. (3)

Manufacturing and potential export capability

- Economic Complexity Outlook Index (improvement since 2009-2019)
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- LMIC vs LDC classification as it pertains to IP sharing

These indicators focus on the structures that support a local pharmaceutical manufacturing sector:

What obstacles do manufacturers face in running a business (ease of doing business)?

How effectively does the regulator support timely product registration, and ensure safety, efficacy, quality of drugs and restricts SF products?

What policies, if any, are in place to support the sector's growth?

Indicators for manufacturing and potential export capability

Composite Indicators

Sub-Indicators (Total potential points)

<p>Criticality of unmet needs</p>	<ul style="list-style-type: none"> - % of local pharma needs met through domestic production - Population size - % Out of pocket spend of total health exp. - Pharma market growth - Universal Health Coverage
<p>Enabling environment</p>	<ul style="list-style-type: none"> - Ease of doing business ranking - Evaluation of regulatory environment - Assessment of health/industrial policies focused on local pharma mfg.
<p>Manufacturing and potential export capability</p>	<ul style="list-style-type: none"> - Economic Complexity Outlook Index (improvement since 2009-2019) (2) - Productive Capacities Index (improvement 2014-2018) (3) - UNIDO Industrial Competitiveness (CIP Improvement 2010-2020) (2) - LMIC vs LDC classification as it pertains to IP sharing (1)

These indicators attempt to measure the change or level of effort in improving a country's ability to manufacture or export medicines not current ability.

Specifically, they look at improvement in the capacity for production, competitiveness of a country's production (CIP), position to diversify its product offerings (COI).

Separately they evaluate whether a country has special access to IP. This is not a measure of which country has the most advanced manufacturing technologies or complex export basket.

PQM+ developed a guide that can help plan for some of these challenges through the following approach

Guidance for Developing a Strategy for Local Production of Essential Medical Products (PQM+, 2023)

Stages

1. Align on process with stakeholders

2. Analyze the situation

3. Define key elements

4. Set the path

Steps

1. Define governance
2. Define scope and problem statement

1. Collect manufacturer baseline data
2. Evaluate local regulatory capacity
3. Assess the current policy framework
4. Consolidate findings into a situational analysis

1. Invest in quality manufacturing
2. Address gaps in the National Medicine Regulatory System
3. Develop targeted incentives for manufacturers
4. Build a sector wide workforce development plan

1. Define and communicate ambitious, achievable goals
2. Finalize action plan
3. Mobilize resources

Thank you!



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of Medicines Plus (POM+)**