

## The Local Production of Essential Drugs: A Roadmap for Sustainable Health in Low- and Middle-Income Countries

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### Abstract

Access to essential medicines is a critical issue in low- and middle-income countries (LMICs), where billions of people face difficulties obtaining medication. Limited local drug production and unclear regulatory processes contribute to this problem. Local drug manufacturing offers a solution by decreasing reliance on imports, thus lowering costs, and improving safety and availability. However, a critical part of increasing access to locally manufactured essential medications is establishing comprehensive manufacturing guidelines and regulatory procedures. Encouraging local drug production and ensuring medications are streamlined through regulatory channels will significantly contribute to global health equity and sustainable development goals (SDG) 1 and 17.

Ending poverty and achieving SDG 1: end poverty in all its forms everywhere requires tackling the root causes of poverty. One of those causes is poor healthcare or limited access to healthcare. More than 2 billion people do not have access to essential medications, most of whom live in low- and middle- income countries (LMICs) (Chattu et al., 2023). LMICs account for 70% of global healthcare expenditure, and rising prices, often paid out of pocket by individuals in these countries who also lack access to insurance, can lead to “illness induced poverty” (Chow et al., 2020).

Increasing access to essential medications will contribute to the reduction of poverty in these nations. Global partnerships will also be fostered by increasing access to medications contributing to SDG 17: Strengthen the means of implementation and revitalize the Global Partnership for Sustainable Development, benefiting local drug manufacturers, and supporting the development of LMICs. Lastly, the World Health Organization (WHO) has a goal of Universal Health Coverage (Universal Health Coverage, 2023) which would also advance with increased access to essential medications in LMICs. Currently, the Local Production & Assistance (LPA) Unit of the WHO is working to “strengthen sustainable local production” of essential medications (Local Production & Assistance, 2023). The WHO also developed the National Essential Medicines List (NEML) which details which medications are essential to treat certain populations. Additionally, each country has its own National Drug Registry (NDR) where all medications manufactured in or imported into a country, ideally, should be registered. However, although local drug production has been offered as a solution and a framework is provided with assistance from the LPA, the issue still arises of countries’ abilities to adhere to these guidelines and effectively provide

essential medications based on the needs of their populations.

### Current State of Local Production of Essential Medications

In a case study evaluating local manufacturers in Kenya, Tanzania, and Uganda, these countries were only producing 21%, 5%, and 10% of the medications on their respective NEMLs (Baldeh et al., 2023). Furthermore, a substantial portion of essential medications produced in these countries were not officially registered to their country’s NDR. Specifically, in Kenya 24% of essential medications produced were not registered, and much more alarmingly, in Tanzania, 47% were not registered, and in Uganda 40% were not registered (Baldeh et al., 2023).

A second case study in Pakistan found that 26% of essential medications are not registered to Pakistan’s NDR (Rafi et al., 2021). This absence of registration impedes the accessibility and quality assurance of medications, which poses a risk to patient safety and public health. An additional case study in Mongolia discovered that the prevalence of unregistered medications was higher in rural areas than city areas (Khurelbat et al., 2020). This disparity highlights another access issue, where individuals living in Mongolia’s rural regions have a greater challenge in obtaining essential, quality medications. The lack of registered drugs in these areas further harms the populations and promotes existing health inequities, leaving the rural populations more vulnerable to adverse health outcomes.

### Reliance on Imports

Local production of essential medications was first initiated as an idea due to the strong reliance on imports

LMICs have for essential medications. One issue that lies with importing medication is falsified, substandard, and counterfeit medications. According to the WHO, substandard medicines, also referred to as “out of specification,” are authorized medical products that fail to meet quality standards or specifications, or both. Falsified and counterfeit medical products deliberately and fraudulently misrepresent their identity, composition, or source (Khurelbat et al., 2020). These problems relate to the need for registration of medications in LMICs. Even imported medications must be registered if they are to be made safely available to the public.

Another issue would be the unaffordable prices associated with importing medications. Almost 79% of medications in Africa are imported (Yenet, Nibret and Tegegne, 2023). This means that many of the medications available in LMICs are going through multiple “middlemen” which likely drive up the cost when they are finally put on the shelves. In the private sector, wholesale mark-ups ranged from 2% to 380%, retail mark-ups ranged from 10% to 552%. In countries where tax was applied, the amount charged varied from 4% to 15% of product cost (Cameron et al., 2009). Multiple studies have found that in countries where local production is viable, costs were lowered due to shorter supply chains and fewer markups (Baldeh et al., 2023).

## Registration of Medication

Registration of medication is a process that involves medication being reviewed by the regulatory agency for the market that medication is being distributed in (Substandard and falsified medical products, 2018).

This means that highly skilled personnel and time are required to register medications. When medication is not registered, this causes severe issues for drug markets and decreases the availability of medications to those who need to purchase them. Unregistered medications can be imported based on special circumstances. However, the process is usually slow and only designed for emergency situations.

Alternatively, individuals who are desperate could turn to an unsafe source for medication, simply because they need it. In recent years there have been instances where unregistered medications were found in private pharmacies and drug stores. This poses a health risk to the public, offering potentially dangerous medication that has not been through the proper regulatory channels and quality checks due to market demand (Brhlikova et al., 2020).

Reviewing the previous case studies, in Kenya, Tanzania, and Uganda only 33%, 40%, and 54% of their registered medicines respectively were essential medications (Baldeh et al., 2023). This data connects to a concerning trend where essential medications are not only underproduced but also under registered compared to their non-essential counterparts. When non-essential medications are registered more often, this diverts regulatory resources such as the specialized personnel and time mentioned previously away from the most needed and important essential medications. Currently, LMICs are facing both problems: Essential medications have limited production, and they are under registered.

## Private Public Partnerships

During the LPA’s 2nd annual World Local Production Forum, a recommendation was made titled “Supporting Ecosystem Creation” by Dr. Jicui Dong. She details that part of this recommendation is ensuring that countries provide an enabling environment for manufacturers and ensure market access for manufacturers (Reflections from the second World Local Production Forum, 2023). Additionally, Dr. Tedros Adhanom Ghebreyesus, Director-General of WHO outlined that to provide an enabling environment the LPA should be enacting policies and regulations ensuring coherence among manufacturers and implementing incentives to make sure manufacturers have access to local markets. Supporting an ecosystem will aid in improving the number of medications registered in LMICs. These incentives could range from tax breaks and subsidies to streamlined regulatory approvals for drugs manufactured locally and support in reaching compliance standards.

These approaches align with the more comprehensive goals of the United Nations SDG 17. Fostering global partnerships between nations, manufacturers, and the United Nations will create a more cohesive and equitable global healthcare economy.

## Policy Recommendations

Moving forwards, for the United Nations to achieve their 2030 goals, the United Nations and WHO should continue working with the LPA to promote local production of essential medicines. Additionally, to ensure this is done effectively and populations can access the medicines manufactured, the LPA should conduct yearly audits of local manufacturing facilities of member nations and set an expectation of a proportion of essential medications these facilities should be developing. This proportion should be close to 80% of

all medications produced and should reflect the essential medications listed on the country's NEML, following the WHO's benchmark (Yenet, Nibret and Tegegne, 2023). Local manufacturers could be incentivized to produce essential medications through partnerships between themselves and governments of the country they manufacture in, fostered by the United Nations. The United Nations could start the conversation between private manufacturers and public governments for incentives. These partnerships could allow for tax exemptions on materials for essential medications, subsidies, or other programs designed to encourage the production of medications on NEMLs instead of non-essential medications. This way, the mostly unnecessary production of non-essential medications will be second to essential.

Furthermore, assistance with registering these medications must be provided and a recommendation for registration must be made for the manufacturers. This ensures the locally produced medication will be available for larger public use. Both recommendations could be encouraged by offering more assistance to countries that choose to follow the guidelines. A merit system could be employed. For example, if a manufacturer is continuously hitting their targets recommended by the WHO, then their respective government could reward them with either exemptions, subsidies, or any other appropriate reward as decided through conversation facilitated by the UN between member nations and private manufacturers.

The LPA could potentially authorize a subcommittee dedicated to promoting local drug manufacturing while focusing specifically on the regulatory process of each member nation and providing expectations and assistance for local manufacturers and their respective countries. This committee would be comprised of policy experts from each country as well as scientists and professionals well versed in drug manufacturing. This committee could be modeled after the "SWAT" teams developed for the COVID-19 vaccine distribution. The Covid-19 Vaccines Global Access (COVAX) was established by the WHO and many subcommittees under COVAX were created. The SWAT teams offered workshops to vaccine developers, government agencies, and non-governmental organizations. The workshops covered issues that were common to all developers big or small (King, 2024). The United Nations should consider this framework for LPA subcommittees.

The United Nations must take these steps to improve access to essential medications in LMICs. The effects of

this improvement will lead to a more sustainable model for LMICs to distribute safe and effective medications to local populations. Which, in turn, will reduce poverty and foster global partnerships between nations and drug manufacturers leading to the further development of LMICs and propelling the world closer to achieving the 2030 SDGs.

## References

- Baldeh, A.-O. et al. (2023) 'Bridging the gap? Local production of medicines on the national essential medicine lists of Kenya, Tanzania and Uganda', *Journal of Pharmaceutical Policy and Practice*, 16, p. 18. Available at: <https://doi.org/10.1186/s40545-022-00497-x>.
- Bhrlikova, P. et al. (2020) 'Registration and local production of essential medicines in Uganda', *Journal of Pharmaceutical Policy and Practice*, 13, p. 31. Available at: <https://doi.org/10.1186/s40545-020-00234-2>.
- Cameron, A. et al. (2009) 'Medicine prices, availability, and affordability in 36 developing and middle-income countries: a secondary analysis', *Lancet* (London, England), 373(9659), pp. 240–249. Available at: [https://doi.org/10.1016/S0140-6736\(08\)61762-6](https://doi.org/10.1016/S0140-6736(08)61762-6).
- Chattu, V.K. et al. (2023) 'Access to medicines through global health diplomacy', *Health Promotion Perspectives*, 13(1), pp. 40–46. Available at: <https://doi.org/10.34172/hpp.2023.05>.
- Chow, C.K. et al. (2020) 'Availability and affordability of medicines and cardiovascular outcomes in 21 high-income, middle-income and low-income countries', *BMJ Global Health*, 5(11), p. e002640. Available at: <https://doi.org/10.1136/bmjgh-2020-002640>.
- Khurelbat, D. et al. (2020) 'A cross-sectional analysis of falsified, counterfeit and substandard medicines in a low-middle income country', *BMC Public Health*, 20(1), p. 743. Available at: <https://doi.org/10.1186/s12889-020-08897-x>.
- King, M.L. (2024) 'How manufacturing won or lost the COVID-19 vaccine race', *Vaccine*, 42(5), pp. 1004–1012. Available at: <https://doi.org/10.1016/j.vaccine.2023.12.031>.
- Local Production & Assistance (no date). Available at: <https://www.who.int/teams/regulation-prequalification/lpa> (Accessed: 29 February 2024).
- Rafi, S. et al. (2021) 'Availability of essential medicines in Pakistan-A comprehensive document analysis', *PloS One*, 16(7), p. e0253880. Available at: <https://doi.org/10.1371/journal.pone.0253880>.

Reflections from the second World Local Production Forum, November 2023 (no date). Available at: <https://www.who.int/news/item/05-12-2023-reflections-from-the-second-world-local-production-forum--november-2023> (Accessed: 1 March 2024).

Substandard and falsified medical products (no date). Available at: <https://www.who.int/news-room/fact-sheets/detail/substandard-and-falsified-medical-products> (Accessed: 1 March 2024).