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Maternal health supplies in sub-Saharan Africa

A regional manufacturing landscape assessment – Report Summary

Overview

In sub-Saharan Africa (SSA), disruptions in health supply chains, limited regional pharmaceutical production, and excessive reliance on foreign imports combine to impede availability of essential maternal health (MH) products.

Why it matters

In 2020, WHO estimated that 287,000 women died due to preventable causes related to pregnancy and childbirth. Nearly 75 percent of those deaths were due to postpartum hemorrhage (PPH), a form of severe bleeding; other causes of maternal mortality included infections, preeclampsia, and delivery-related issues. Nearly 70 percent of all maternal deaths occur in SSA. Across the globe and specifically in SSA, stable and resilient supply chains for qualityassured MH products are crucial to reducing maternal mortality.

About the study

USP and the Reproductive Health Supplies Coalition (RHSC) conducted a landscape analysis to assess the demand for and manufacturing capacity of the following five essential MH commodities: heat-stable carbetocin (HSC), magnesium sulfate, misoprostol, oxytocin, and tranexamic acid (TXA). The study analyzed supply and demand across eight focus countries in SSA: Ethiopia, Ghana, Kenya, Nigeria, South Africa, Tanzania, Uganda, and Zimbabwe.

Key findings

Our analysis of the availability and sources of MH products, regional manufacturers, and strength and dosage of registered products across SSA found the following:

Lack of diversified, regional suppliers. The vast majority of oxytocin, one of the most inexpensive, widely available, and effective medicines to prevent and treat PPH, and TXA which also helps to treat PPH, is manufactured in India. Only one manufacturer located in Nigeria and another manufacturer in Kenya produce oxytocin and TXA respectively in SSA, and they are both facing logistical challenges in scaling up production.

Limited registration. HSC also helps to prevent PPH, and, unlike oxytocin, it does not require refrigeration. Yet, HSC is not registered in many countries across SSA. Outdated national guidelines and essential medicines lists may contribute to relatively low rates of national registration and availability of this critical product.

Overreliance on foreign imports. Misoprostol can be used to prevent and treat PPH in hospital and community settings. However, this medicine, oxytocin, and TXA are each currently manufactured by only one producer based in SSA. The region relies heavily on foreign imported brands of these essential medicines.

Varying capacity and distribution of regional manufacturers. Magnesium sulfate, which aids in treating eclampsia or seizures due to high blood pressure that occur during pregnancy or after birth, is produced by four manufacturers in four countries in SSA, including Ethiopia, Kenya, Nigeria, and South Africa. Despite this comparatively higher number of regional manufacturers, magnesium sulfate is still at risk of supply chain disruptions, in part due to limited production capacity and a need for greater diversification in product distribution.



Recommendations

To promote increased availability, access, and affordability of essential MH medicines and to ensure a more stable supply of these products, we recommend the following regulatory, manufacturing, and procurement actions:

- Maintain an up-to-date national medicines regulatory authority (NMRA) registration database and foster information sharing among national regulatory bodies.
- Increase harmonization and convergence among NMRAs and regional regulatory authorities to streamline product registration and align fees, approvals, and processes.
- Strategically diversify the manufacturing footprint of MH commodities across the region, while ensuring that new production lines don't exceed regional demand or dilute the market.
- Build capacity for regional manufacturers to more efficiently navigate regulatory processes, improve good manufacturing practices (GMP), and absorb new technologies and skills.
- Support manufacturers through technical assistance in achieving WHO prequalification and stringent regulatory authority approvals.
- Create knowledge-sharing platforms among manufacturers to exchange best practices, regulatory insights, and market information.
- Establish comprehensive market sizing for MH products to facilitate accurate demand estimates and increase transparency of market data.
- Prioritize procurement from regional manufacturers and track procurement volumes of regionally manufactured products as a supply chain disruption mitigation strategy.
- Consider market shaping interventions such as guaranteed procurement volumes and pooled procurement mechanisms.

Moving forward

Despite challenges related to imports, regulatory barriers, equipment limitations, and skilled labor shortages, manufacturers across SSA are committed to increasing the production of essential MH commodities and to addressing critical gaps in ensuring a stable and diverse supply.

Collaboration between local governments, regional bodies, and international organizations will be essential in overcoming challenges and fostering a more robust MH product manufacturing industry. Strengthening business and regulatory environments and improving access to regional and continental markets will be crucial to ensuring the availability and affordability of these lifesaving MH products across the region.