COMPASS INITATIVE SERIES: REGIONALIZATION

MANUFACTURING LANDSCAPE ASSESSMENT FOR MATERNAL HEALTH SUPPLIES IN SUB-SAHARAN AFRICA

MARCH 2024

Reproductive Health
SUPPLIES COALITION

USP®

Acknowledgments

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Recommended citation

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Acronyms

API	Active pharmaceutical ingredient
CEP	Certificate of suitability
DMF	Drug master file
DoH	Department of Health
EML	Essential medicines list
EPSA	Ethiopian Pharmaceuticals Supply Agency
FIGO	International Federation of Gynecology and Obstetrics
FPP	Finished pharmaceutical product
GHANEPS	Ghana Electronic Procurement System
GHS	Ghana Health Service
GMP	Good manufacturing practices
HSC	Heat-stable carbetocin
ICM	International Confederation of Midwives
JSI	John Snow, Inc.
KEMSA	Kenya Medical Supplies Authority
LMIC	Low- and middle-income country
$MgSO_4$	Magnesium sulfate
MH	Maternal health
ML3	Maturity level 3
MoH	Ministry of health
MPH	Maternal and prenatal health
NAFDAC	National Agency for Food and Drug Administration and Control

NGO	Non-governmental organization
NMRA	National medicines regulatory authority
NOCOPO	Nigeria Open Contracting Portal
PPA	Public Procurement Authority
PPB	Pharmacy and Poisons Board
PPH	Postpartum hemorrhage
PPIP	Public Procurement Information Portal
PO	Oral
RHSC	Reproductive Health Supplies Coalition
SF	Substandard and falsified
SRA	Stringent regulatory authority
SSA	Sub-Saharan Africa
TXA	Tranexamic acid
UK	United Kingdom
USP	United States Pharmacopeia
WHO	World Health Organization

Executive Summary

The COVID-19 pandemic revealed vulnerabilities in sub-Saharan Africa's (SSA) health supply chains that impact access to critical maternal health (MH) products. The region's reliance on overseas manufacturers and its limited pharmaceutical production capacity have exacerbated these challenges. To address this, there is a growing effort to expand pharmaceutical manufacturing capacity in SSA, including for MH products. A clear understanding of the current state of regional manufacturers is crucial to achieving this expansion. Accordingly, the United States Pharmacopeia (USP) conducted a landscape analysis for the Reproductive Health Supplies Coalition (RHSC) to assess manufacturing capacity and the demand for heat-stable carbetocin (HSC), magnesium sulfate, misoprostol, oxytocin, and tranexamic acid in SSA. The analysis focused on diverse countries that were carefully selected based on specific criteria to serve as a representative sample of the manufacturing base in the region. These countries included Ethiopia, Ghana, Kenya, Nigeria, South Africa, Tanzania, Uganda, and Zimbabwe.

This report provides a detailed analysis of the availability and sources of the above mentioned five MH products in SSA. The data collected offers insights into the sources of the products, the regional manufacturers, and the strength and dosage of each registered MH product within the region.

Overall, the study reveals an overreliance on the importation of the five products and limited manufacturing in SSA. There is limited registration of HSC, which can be attributed to slow progress in updating national guidelines and essential medicines lists (EMLs) in SSA countries.

Magnesium sulfate, a crucial MH product, exhibits potential supply risks due to a lack of diversification—it is primarily sourced from India, China, and the UK. The study identifies four manufacturers of magnesium sulfate in SSA with varying production capacities and distribution channels. These four manufacturers include Humanwell Pharma (Ethiopia), Laboratory and Allied Health (Kenya), Juhel Nigeria Limited (Nigeria), and Adcock Ingram (South Africa).

In the region, misoprostol is primarily sourced from manufacturers in Bangladesh, Canada, China, India, the Netherlands, Nigeria, Spain, the UK, and the USA. The study raises concerns about overreliance on imports. Only Emzor Pharmaceutical Industries Ltd (Emzor), based in Nigeria, is identified as a regional manufacturer of this medicine.

The assessment of the supply of oxytocin revealed India as the predominant source for most of the focus countries, while China also plays a significant role, particularly in Nigeria. Only one Nigeria-based manufacturer, Juhel Nigeria Limited, is currently producing oxytocin in SSA, and it is facing logistical challenges in scaling up production.

The tranexamic acid (TXA) supply in SSA is largely dominated by Indian manufacturers who contribute at least 60 percent of registered products in the focus countries. In SSA, only one Kenyan manufacturer, Tasa Pharma, is actively producing TXA. The company faces challenges in scaling production due to equipment limitations but aims to contribute to strengthening the supply chain.

This report also identifies projects by manufacturers in Ghana, Kenya, and Nigeria to expand or begin production of MH products in the near future.

Overall, the analysis provides a comprehensive understanding of the MH product landscape in SSA, highlighting potential vulnerabilities and opportunities for intervention to strengthen regional manufacturing capacities and ensure a more resilient and diversified supply chain. Additionally, the report highlights the challenges associated with estimating the demand of these MH products in SSA.

Introduction

Background and context

The COVID-19 pandemic presented countless challenges in securing essential health supplies across the African Continent. SSA faced significant hurdles in procuring essential health products, which highlighted the inadequacies of the region's existing health supply chains. There is growing acknowledgment among SSA's leaders that the region's current supply chains and broader health infrastructure require substantial transformation to address the challenges that the pandemic brought to light.

MH in a country or region can be significantly impacted by disruptions to supply chains. In low- and middle-income countries (LMICs), the COVID-19 pandemic led to an estimated 12 million women unable to access family planning services, with supplies and services disrupted for an average of 3.6 months.[1] In SSA, ensuring stable supply chains for quality MH products, such as oxytocin, TXA, and magnesium sulfate, is crucial to improving MH outcomes and reducing maternal mortality.[2 3 4] This requires a comprehensive approach that considers both upstream pharmaceutical production and downstream supply chain logistics as well as market factors such as price. A concerted effort to strengthen supply chains and enhance access to quality MH products is essential to safeguard the health and well-being of women on the Continent.

In early 2021, John Snow, Inc. (JSI) and the RHSC jointly released a comprehensive roadmap report, *Building Resilient Sexual and Reproductive Health Supply Chains During COVID-19 and Beyond: A Community Roadmap for Action and Technical Findings*. This report presents a wide array of recommendations encompassing market dynamics, financing, supply chain strategies, policies, stewardship, and data visibility and access. While the primary focus of the Roadmap is on family planning commodities, the findings and recommendations offered by the authors hold broad relevance for supplies related to maternal and menstrual health.

The authors of the Roadmap are particularly concerned with the potential consequences of SSA relying on a limited number of overseas manufacturers for health supplies, especially during crises. Imports account for over 70 percent of the pharmaceuticals consumed in SSA, while merely three percent of the world's pharmaceutical manufacturing occurs on the Continent.[5] The supply chains for these imported products are often designed and managed to align

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[1] United Nations Population Fund (UNFPA). "Impact of COVID-19 on Family Planning: What we know one year into the pandemic." UNFPA, March 2021, https://www.unfpa.org/resources/impact-covid-19-family-planning-what-we-know-one-year-pandemic.

[2] Anyakora C, Oni Y, Ezedinachi U, Adekoya A, Ali I, Nwachukwu C, Esimone C, Abiola V, Nwokike J. Quality medicines in maternal health: results of oxytocin, misoprostol, magnesium sulfate and calcium gluconate quality audits. BMC Pregnancy Childbirth. 2018 Jan 30;18(1):44. doi: 10.1186/s12884-018-1671-y. PMID: 29382306; PMCID: PMC5791179.

[3] "Poor quality medicines putting the lives of pregnant women at risk." World Health Organization, 10 July 2020, https://www.who.int/news/item/10-07-2020-poor-quality-medicines-putting-lives-of-pregnant-women-at-risk.

[4] Torloni MR, Bonet M, Betrán AP, Ribeiro-do-Valle CC, Widmer M (2020) Quality of medicines for life-threatening pregnancy complications in low- and middle-income countries: A systematic review. PLOS ONE 15(7): e0236060. https://doi.org/10.1371/journal.pone.0236060.

[5] Ejekam CS, Emeje M, Lukulay P, Uche CR, Odibeli O, Sanusi O, Anyakora C. A call to action: securing an uninterrupted supply of Africa's medical products and technologies post COVID-19. J Public Health Policy. 2023 Jun;44(2):276-284. doi: 10.1057/s41271-023-00405-w. Epub 2023 Mar 30. PMID: 36997622; PMCID: PMC10061377.

with global objectives set by organizations based in high-income countries and may not fully optimize the existing supply chain capacity in SSA.

To address challenges such as these and to foster positive health outcomes, there is a growing drive on the Continent to expand SSA's pharmaceutical manufacturing capacity, including for MH products. However, it is essential to first thoroughly understand the current status of regional manufacturers and their capabilities in order to effectively enhance the landscape of MH product manufacturing. In this context, USP conducted a landscape analysis commissioned by RHSC. This analysis aimed to assess the existing demand and manufacturing capacity for five MH commodities: HSC, magnesium sulfate, misoprostol, oxytocin, and TXA.

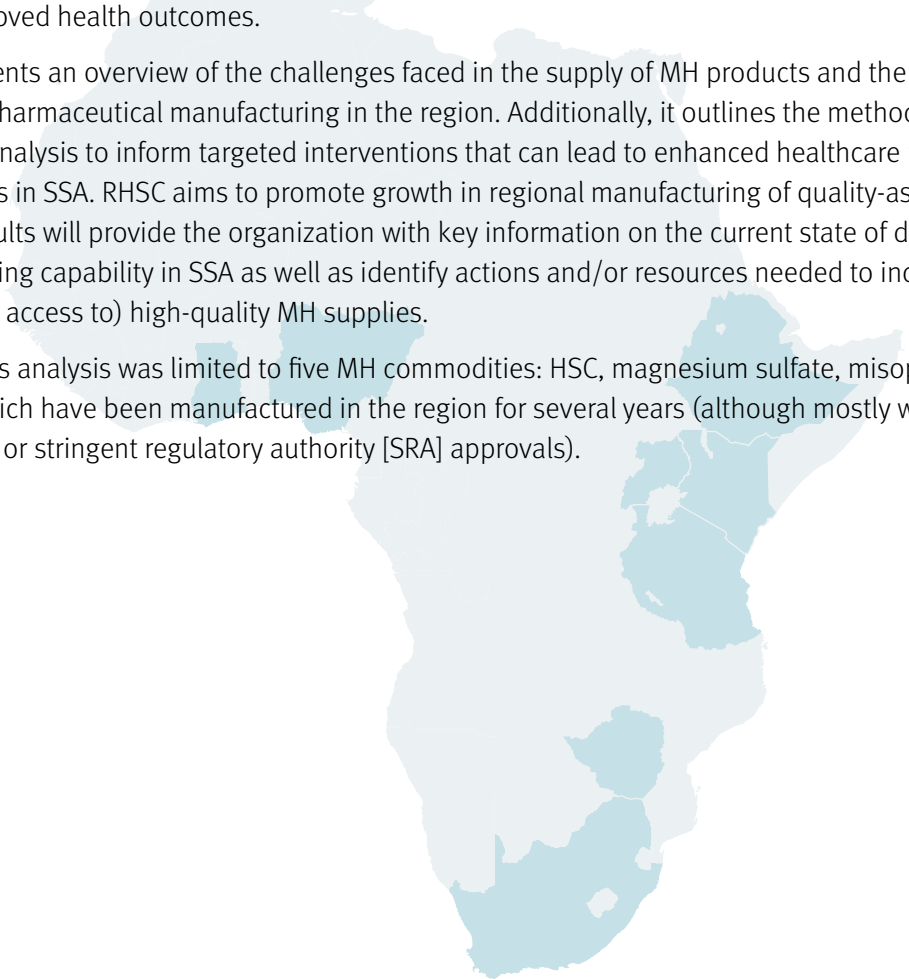
Purpose and objectives of the study

The purpose of this study was to conduct an assessment of focus countries (Ethiopia, Ghana, Kenya, Nigeria, South Africa, Tanzania, Uganda, and Zimbabwe) to determine the current demand, resources, strengths, capacity, and needs of manufacturers in SSA for oxytocin, misoprostol, magnesium sulfate, TXA, and HSC. This included identifying and assessing current and future manufacturers and their capability to meet market demands.

Through this assessment, USP has developed recommendations for strategies to improve manufacturing and supply chain efficiency, interventions for increased access, and collaborative efforts to address MH product supply needs. This work included assessing the technical and economic feasibility for growing manufacturing capacity on the Continent for these products with the overarching goal of promoting healthier markets for MH supplies in SSA in support of improved health outcomes.

The report presents an overview of the challenges faced in the supply of MH products and the imperative for strengthening pharmaceutical manufacturing in the region. Additionally, it outlines the methodology and findings of the landscape analysis to inform targeted interventions that can lead to enhanced healthcare resilience and better health outcomes in SSA. RHSC aims to promote growth in regional manufacturing of quality-assured MH supplies, and the analysis results will provide the organization with key information on the current state of demand for MH supplies and manufacturing capability in SSA as well as identify actions and/or resources needed to increase manufacturing capacity of (and access to) high-quality MH supplies.

The scope of this analysis was limited to five MH commodities: HSC, magnesium sulfate, misoprostol, oxytocin, and TXA, most of which have been manufactured in the region for several years (although mostly without either WHO prequalification or stringent regulatory authority [SRA] approvals).



Maternal health in SSA

MH extends beyond individual well-being; it serves as a cornerstone for public health, social development, and economic progress. MH encompasses the health of women during pregnancy, childbirth, and the postpartum period, including family planning, preconception, and prenatal and postnatal care.[6]

MH plays a significant role in driving socioeconomic development. Healthy mothers are better equipped to actively engage in the workforce, contribute to their communities, and break the cycle of poverty. Additionally, MH is an essential component of public health, serving as an indicator of overall healthcare system performance and the availability of essential services.[7]

Safeguarding the health of expectant mothers is integral to preventing maternal mortality (the death of women during or after pregnancy and childbirth). Maternal deaths not only result in the loss of a mother's life but also significantly impact infant health, as high maternal mortality rates are often accompanied by high rates of infant mortality.[8]

Although global maternal mortality rates decreased by 34 percent from 2000 to 2020,[9] additional effort is required to further improve MH and decrease incidences of preventable maternal deaths. According to the WHO, an estimated 287,000 women lost their lives in 2020 due to preventable causes related to pregnancy and childbirth.[10] The primary complications responsible for nearly 75 percent of these maternal deaths included severe bleeding, infections, preeclampsia, and delivery-related issues.[11]

MH and postpartum hemorrhage

A significant contributor to maternal mortality is postpartum hemorrhage (PPH), a form of severe bleeding after childbirth, defined as the loss of more than 500 ml of blood within the first 24 hours following delivery.[12] PPH is the leading cause of maternal mortality and is responsible for approximately 70,000 maternal deaths annually (nearly a quarter of all maternal deaths worldwide).[13] Many of these deaths could be prevented through timely and appropriate use of prophylactic uterotonics during the third stage of labor. These medications cause the uterus to contract, reducing excessive bleeding.

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[6] "Maternal Health." World Health Organization, https://www.who.int/health-topics/maternal-health#tab=tab_1.

[7] Sajedinejad S, Majdzadeh R, Vedadhir A, Tabatabaei MG, Mohammad K. Maternal mortality: a cross-sectional study in global health. Global Health. 2015 Feb 12;11:4. doi: 10.1186/s12992-015-0087-y. PMID: 25889910; PMCID: PMC4353673.

[8] Moucheraud, C., Worku, A., Molla, M. et al. Consequences of maternal mortality on infant and child survival: a 25-year longitudinal analysis in Butajira Ethiopia (1987-2011). Reprod Health 12 (Suppl 1), S4 (2015). https://doi.org/10.1186/1742-4755-12-S1-S4.

[9] "Maternal Mortality." World Health Organization, 22 February 2023, https://www.who.int/news-room/fact-sheets/detail/maternal-mortality.

[10] "Maternal Health."

[11] Say, Lale et al. "Global causes of maternal death: a WHO systematic analysis," The Lancet, 05 May 2014, https://www.thelancet.com/journals/langlo/article/PIIS2214-109X(14)70227-X/fulltext.

[12] "Lifesaving solution dramatically reduces severe bleeding after childbirth." World Health Organization, 09 May 2023, https://www.who.int/news/item/09-05-2023-lifesaving-solution-dramatically-reduces-severe-bleeding-after-childbirth.

[13] "Postpartum haemorrhage." World Health Organization, https://www.who.int/teams/sexual-and-reproductive-health-and-research-(srh)/areas-of-work/maternal-and-perinatal-health/postpartum-haemorrhage.

PPH in SSA

Maternal mortality is a particularly serious public health issue in SSA, where almost 70 percent of maternal deaths occur, according to the WHO.[14] The risk of maternal mortality in SSA is ten times greater than in high-income countries, underscoring the importance of addressing the root causes of these fatalities and enhancing MH in the region.[15]

PPH is the leading cause of maternal mortality in SSA, accounting for 30-50 percent of maternal deaths.[16] The high incidence of PPH in the region can be attributed to a combination of factors, including underdeveloped healthcare infrastructure, limited access to quality healthcare, inadequately equipped healthcare facilities, and a high incidence of anemia among women.

A significant factor contributing to PPH in the region is the lack of access to quality healthcare products and services, including skilled birth attendants, essential maternal healthcare (MHC) products such as therapeutic oxytocin, and proper healthcare facilities, which are crucial for improving maternal health.[17] [18] Barriers to accessing quality care not only delay women's decisions to seek help but also frequently prevent them from receiving timely and high-quality healthcare when they do seek treatment, further exacerbating the risk of PPH.

Additionally, SSA has high rates of anemia, a condition characterized by low levels of red blood cells, with an estimated 190 million cases.[19] Elevated anemia rates among SSA women of reproductive age, or those currently pregnant, contribute to their susceptibility to PPH due to impaired blood clotting. When facilities are well-resourced with skilled birth attendants and supplies of medications vital to controlling bleeding after childbirth, MH services can reduce fatalities in anemic women through prompt diagnosis and effective management of complications.

PPH-related deaths are preventable under certain conditions, and it is essential to prioritize MH with a focus on reducing PPH-related maternal fatalities. The WHO has outlined recommendations for the prevention and treatment of PPH that include the active management of the third stage of labor using uterotonic medications. These recommendations underscore the importance of ensuring a reliable supply of these medications.[20]

Treatment and prevention of PPH

The WHO has continuously published and revised guidelines for the prevention and management of PPH after publishing its first recommendations in 2012. In 2016, the WHO initiated a living guidelines approach to prioritizing, updating, and developing individual WHO and maternal and prenatal health (MPH) recommendations on PPH, leading to updated guidelines. In response to new evidence in 2017 (from the WOMAN Trial reviewing the effect of early TXA administration), the WHO updated its recommendation on TXA for PPH treatment. Subsequently in 2018,

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[14] "Maternal Mortality." World Health Organization, 22 February, 2023, https://www.who.int/news-room/fact-sheets/detail/maternal-mortality.

[15] "Maternal Mortality." UNICEF, https://data.unicef.org/topic/maternal-health/maternal-mortality/.

[16] Musarandega R, Nyakura M, Machekano R, Pattinson R, Munjanja SP. Causes of maternal mortality in Sub-Saharan Africa: A systematic review of studies published from 2015 to 2020. J Glob Health. 2021 Oct 9;11:04048. doi: 10.7189/jogh.11.04048. PMID: 34737857; PMCID: PMC8542378.

[17] Knight HE, Self A, Kennedy SH (2013) Why Are Women Dying When They Reach Hospital on Time? A Systematic Review of the 'Third Delay'. PLoS ONE 8(5): e63846. https://doi.org/10.1371/journal.pone.0063846.

[18] Combs Thorsen V, Sundby J, Malata A (2012) Piecing Together the Maternal Death Puzzle through Narratives: The Three Delays Model Revisited. PLoS ONE 7(12): e52090. https://doi.org/10.1371/journal.pone.0052090.

[19] Correa-Agudelo, E., Kim, HY., Musuka, G.N. et al. The epidemiological landscape of anemia in women of reproductive age in sub-Saharan Africa. Sci Rep 11, 11955 (2021). https://doi.org/10.1038/s41598-021-91198-z.

[20] "WHO recommendations for the prevention and treatment of postpartum haemorrhage." World Health Organization, 2018, https://www.who.int/publications/i/item/9789241548502.

after considering additional evidence (from the WHO CHAMPION trial which demonstrated HSC to be as safe and effective as oxytocin), it updated its recommendations on the use of **uterotonics**.[21]

The International Federation of Gynecology and Obstetrics (FIGO) and the International Confederation of Midwives (ICM) strongly recommend the use of uterotonics during the active management of third stage labor to prevent PPH during vaginal birth and caesarean section.[22]

These recommendations are aligned with the WHO 2018 uterotonics recommendations. Uterotonics are chemical compounds that increase the tone and contraction of the smooth uterine muscles at the beginning of and during labor and during the postpartum period. Uterotonics are used to induce labor as well as for abortion-related services. They play an important role in the prevention and treatment of PPH.

1 Uterotonics[23]

Oxytocin 10IU, IM/IV

Oxytocin is relatively inexpensive and widely available. However, it requires refrigerated transportation and storage (2–8°C). In settings where this cannot be guaranteed, the quality and effectiveness of the medication may be adversely affected. In these situations, alternative effective uterotonics may be considered.

HSC 100mcg, IM/IV

HSC does not require refrigeration, eliminating the costs and logistics associated with refrigerated storage and transportation. In March 2023, FIGO and ICM issued guidance on the use of this medication as an alternative to oxytocin in the prevention of PPH. HSC is an uterotonic recommended only for PPH prevention and was added by WHO to the core list of reproductive health medicines in the 2019 Model List of Essential Medicines. However, HSC has different pharmacokinetic properties and is not considered to be an equivalent of oxytocin in terms of its pharmacological behaviors or clinical indications.

Misoprostol 200mcg, 400mcg PO

Misoprostol can be used in both hospital and community settings if no other injectable uterotonics are available. Its acceptability may be limited where providers have concerns regarding potential use for other indications or where they need greater understanding of its effectiveness, implementation, and the management of side effects.

Ergometrine/methylergometrine 200mcg, IM/IV OR oxytocin and ergometrine fixed-dose combination 5IU/500mcg, IM

Context specific recommendations for the use of ergometrine can be made where hypertensive disorders can be safely excluded.

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[21] WHO recommendation on routes of oxytocin administration for the prevention of postpartum hemorrhage after vaginal birth. Geneva: World Health Organization; 2020. License: CC BY-NC-SA 3.0 IGO.

[22] International Federation of Gynecology and Obstetrics, International Confederation of Midwives, Joint statement of recommendation for the use of uterotonics for the prevention of postpartum haemorrhage. 2021. Available from: www.figo.org/joint-statement-recommendation-uterotonics-prevention-pph.

[23] International Federation of Gynecology and Obstetrics, International Confederation of Midwives, Joint statement of recommendation for the use of uterotonics for the prevention of postpartum hemorrhage.

WHO recommendations for the use of uterotonics for the prevention of PPH:

a) The use of an effective uterotonic for the prevention of PPH during the third stage of labor is recommended for all births.

b) In settings where multiple uterotonic options are available, oxytocin (10 IU, IM/IV) is the recommended uterotonic agent for the prevention of PPH for all births.

c) In settings where oxytocin is unavailable (or its quality cannot be guaranteed), the use of other injectable uterotonics (carbetocin or, if appropriate, ergometrine/methylergometrine or oxytocin and ergometrine fixed-dose combination) or oral misoprostol is recommended.

d) In settings where skilled health personnel are not present to administer injectable uterotonics, the administration of misoprostol (either 400 µg or 600 µg PO) by community health workers or lay health workers is recommended for the prevention of PPH.

WHO recommendations for the use of uterotonics for the treatment of PPH:[24]

a) Intravenous oxytocin is the recommended uterotonic drug for the treatment of PPH.

b) If intravenous oxytocin is unavailable, or if the bleeding does not respond to oxytocin, the use of intravenous ergometrine, oxytocin-ergometrine fixed dose, or a prostaglandin drug (including sublingual misoprostol, 800 µg) is recommended.

2 Magnesium Sulfate 100mg/ml IV

Magnesium sulfate is commonly used for the treatment of eclampsia and as a prophylaxis for eclampsia in patients with severe preeclampsia. It is usually given intramuscularly or intravenously.[25] FIGO recommends the use of magnesium sulfate in women at risk of early preterm imminent birth, from viability to 30 weeks of gestation, for neuroprotection of the fetus. Magnesium sulfate should be administered regardless of the cause of preterm birth or the number of babies in utero.[26]

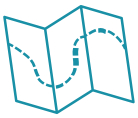
3 TXA 100mg/ml, IV

Early use of intravenous TXA (within three hours of birth) in addition to standard care is recommended for women with clinically diagnosed PPH following vaginal delivery or caesarean section. The use of TXA is recommended for the treatment of all cases of PPH, whether the hemorrhaging is due to trauma or other causes. TXA should be recognized as a lifesaving intervention and be made readily available for the management of PPH in settings where emergency obstetric care is provided.

[24] "WHO recommendations: Uterotonics for the prevention of postpartum hemorrhage." World Health Organization, 2018, https://apps.who.int/iris/bitstream/handle/10665/277276/9789241550420-eng.pdf.

[25] Lu JF, Nightingale CH. Magnesium sulfate in eclampsia and pre-eclampsia: pharmacokinetic principles. Clin Pharmacokinet. 2000 Apr;38(4):305-14. doi: 10.2165/00003088-200038040-00002. PMID: 10803454.

[26] Geary, Michael, ed. Special section: FIGO Working Group for Preterm Birth – Good Practice Recommendations, International Journal of Gynecology and Obstetrics, Volume 155, Issue 1, October 2021, https://obgyn.onlinelibrary.wiley.com/toc/18793479/2021/155/1.



Knowledge gaps in PPH strategies

Gaps in understanding the most effective strategies for the prevention, detection, and treatment of PPH still exist in SSA largely because the PPH innovation landscape has remained stagnant over the last few decades. These gaps can pose challenges to policymakers and healthcare professionals in LMICs regarding which guidance to adopt. As a result, the WHO led the development of *A Roadmap to combat postpartum haemorrhage between 2023 and 2030* which outlines global-level research and advocacy goals (among other goals) from 2023 to 2030.[27]

Barriers to the access of treatment of PPH in SSA

Multiple barriers contribute to the challenge of effectively treating PPH in SSA. Recent studies[28] [29] [30] have identified the following barriers to the access of timely treatment of PPH:

- **Lack of essential medications and supplies:** Many healthcare facilities suffer from stockouts of essential medications like oxytocin, misoprostol, and other uterotonics. The absence of these supplies is a barrier to the timely management of PPH.
- **Financial barriers:** The cost of healthcare, including maternal services, can be a significant barrier, preventing many women from seeking professional care for PPH. The cost of managing a birth involving PPH is as much as 4.1 times that of a birth without PPH.[31] This financial burden is increased because PPH management and treatment requires a range of medical, surgical, and other human interventions. However, uterotonics remain the central component of PPH management.
- **Limited trained and skilled healthcare providers:** Many parts of SSA have a shortage of skilled healthcare providers, including midwives and obstetricians, who are trained in PPH treatment protocols.
- **Inadequate health systems:** Weak health systems in some SSA countries result in substandard care and inconsistent quality of MH products and services.
- **Inadequate antenatal care:** Inadequate or infrequent antenatal care visits result in missed opportunities to identify and manage risk factors for PPH, such as anemia or placental abnormalities.
- **Home births and unattended deliveries:** Many births in SSA occur at home, often without skilled attendants. This makes it difficult to respond promptly to PPH and administer treatments in good time.
- **Inadequate infrastructure and transportation:** Poor road networks, lack of ambulances, and challenges in accessing healthcare facilities contribute to delays in receiving treatment for PPH.
- **Cultural and societal norms:** Cultural practices and societal norms can hinder women from seeking timely

[27] A Roadmap to combat postpartum haemorrhage between 2023 and 2030. Geneva: WorldHealth Organization; 2023. Licence: CC BY-NC-SA 3.0 IGO. https://cdn.who.int/media/docs/default-source/reproductive-health/maternal-health/pph-roadmap.pdf.

[28] Akter, Shahinoor et al. "Detection and management of postpartum hemorrhage: Qualitative evidence on healthcare providers' knowledge and practices in Kenya, Nigeria, and South Africa." Frontiers in Global Women's Health, Vol 3, 18 November 2022. https://www.frontiersin.org/articles/10.3389/fgwh.2022.1020163.

[29] Montagu D, Yamey G, Visconti A, Harding A, Yoong J. Where do poor women in developing countries give birth? A multi-country analysis of demographic and health survey data. PLoS One. 2011 Feb 28;6(2):e17155. doi: 10.1371/journal.pone.0017155. PMID: 21386886; PMCID: PMC3046115.

[30] Bewket, T., Ensieh, F., Virginia, P. et al. Barriers to effective management of primary postpartum haemorrhage following in-hospital births in northwest Ethiopia: healthcare providers' views using a qualitative approach. BMC Pregnancy Childbirth 22, 755 (2022). https://doi.org/10.1186/s12884-022-05071-6.

[31] Theunissen, F., Cleps, I., Goudar, S. et al. Cost of hospital care of women with postpartum haemorrhage in India, Kenya, Nigeria and Uganda: a financial case for improved prevention. Reprod Health 18, 18 (2021). https://doi.org/10.1186/s12978-020-01063-x.

medical care, especially when they experience heavy bleeding after childbirth.

- **Low health literacy:** Limited health literacy among women and their families can result in a lack of awareness regarding the signs and dangers of PPH, leading to delayed intervention.

- **Stigma and fear of hospitalization:** Some women may avoid healthcare facilities due to fear of being hospitalized or stigmatized, which can hinder timely intervention for PPH. For example, among adolescents, stigma of early pregnancy may lead to fear of disclosing pregnancy, non-use of services as a result of feeling shame,[32] or non-use of health care facilities for delivery.[33]

Addressing these barriers to the treatment of PPH in SSA requires a multi-faceted approach. This includes improving healthcare infrastructure, increasing access to skilled birth attendants, enhancing health education and literacy, ensuring the availability of essential medications and supplies, and addressing cultural and societal factors that influence healthcare-seeking behaviors.

[32] Mbiza CR, Kazembe A, Simwaka A. Barriers to health-seeking practices during pregnancy among adolescents in rural Blantyre, Malawi. Afr J Midwifery Womens Health. 2014;8(2):59–65. 57p.

[33] Kyei-Nimakoh, M., Carolan-Olah, M. & McCann, T.V. Access barriers to obstetric care at health facilities in sub-Saharan Africa—a systematic review. Syst Rev 6, 110 (2017). https://doi.org/10.1186/s13643-017-0503-x.

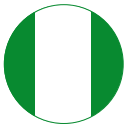
Methodology

Supply assessment

This study used the following criteria to select focus countries in SSA:

- Countries with a diverse range of pharmaceutical companies producing a wide array of products
- Countries whose national regulatory agencies are listed by the World Health Organization (WHO) as Maturity Level 3 (ML3)
- Countries where there is at least one manufacturer with at least one product prequalified by the WHO

Applying the selection criteria, we identified eight focus countries in SSA. These countries are:

Ethiopia  Ghana  Kenya  Nigeria  South Africa  Tanzania  Uganda  Zimbabwe 

To better understand the manufacturing landscape of MH products in SSA, we used multiple data collection methods including an extensive desk and literature review. We began by identifying the existing source(s) of MH products in the eight focus countries. We used product registration information obtained from the databases of national medicines regulatory authorities (NMRAs). Subsequently, we conducted additional research leveraging internal databases and field offices in coordination with NMRAs. **These findings led us to focus our additional analysis of current and future manufacturing on Ethiopia, Kenya, Nigeria, Ghana, and South Africa as they are the only countries in the region where there is a current or future plan(s) to produce any of the MH products of interest**. Our research excluded manufacturers who have discontinued their production lines or are producing any of the products for veterinary use only.

We developed and distributed a survey tool to the identified manufacturers of the MH products. This tool is described in **Table 1**. The study population included the existing and potential manufacturers of HSC, magnesium sulfate, misoprostol, oxytocin, and TXA. The survey was self-administered, and we followed up if necessary for further clarification. We distributed a survey to the six identified current manufacturers, garnering responses from all but one (an 83 percent response rate). It is important to note that the research team did not travel to manufacturing sites for any additional inspection to ascertain the quality of production or good manufacturing practices (GMPs) compliance. We relied on the information provided by the manufacturers.

Table 1 **Manufacturing landscape survey description**

Demand assessment

In addition to assessing supply, the study aimed to determine the level of demand for the selected products in the eight focus countries (Ethiopia, Ghana, Kenya, Nigeria, South Africa, Tanzania, Uganda, and Zimbabwe). We started by conducting a desktop review on medicine stockouts and quantification and demand forecasting challenges in public health systems in SSA. The purpose of this review was to identify any of the focus countries with documented challenges that could have a bearing on the assumed accuracy and reliability of published tender award data. This was followed by a search for tender award information from 2017/2018 to 2022/2023 from procurement portals and websites of ministries of health (MoHs), public procurement authorities, and central procuring entities. Data were assessed and captured into Excel spreadsheets according to the following variables:

- **Product description/specification: generic name, dosage strength, and dosage form**
- **Pack size**
- **Awarded quantities**
- **Unit price**
- **Name of awarded supplier**
- **Contract start and end date**
- **Country of manufacture or importation**

Carbetocin injection (heat-stable) 100mcg/ml is included in the EMLs of Kenya and Nigeria only, while the other four MH products—magnesium sulfate, misoprostol, oxytocin, and TXA—are in the EMLs of all the countries of focus. Therefore, they are predominantly procured and supplied by the public sector for use in the national health systems and are either free to patients or heavily subsidized. In some of the countries, these medicines are procured by donors and donated to national maternal health programs. Donor-funded medicines are also procured by funded and independently run programs and by faith-based institutions that operate their own hospitals in the recipient countries. Additionally, there is a very limited private sector provision of certain products of focus. Even when the private sector does offer these products, there are virtually no data on consumption patterns due to the absence of reliable market intelligence in most African countries.

Tender award information on essential medicines is generally published by national procurement agencies. However, detailed information on the products procured, shipped, and consumed are generally not made public, and, in most cases, procuring agencies are hesitant to share this kind of data with external parties. For this reason, our multiple efforts to secure this information were not successful. Consequently, we relied on publicly available tender award information for our study. Our preliminary review of this information revealed no published data on donor-procured MH products. Furthermore, our multiple attempts to acquire procurement data and market share information from the international procurement organizations proved unsuccessful. Given the delay resulting from the unavailability of such data, we decided to narrow the scope of our review exclusively to government tender awards. As such, the study does not include MH products supplied through the private sector and donor channels.

An aim of this study was to compare regional demand with regional production capacity to determine existing supply gaps and identify opportunities to invigorate regional manufacturing capacity to meet regional demand.

Unfortunately, in many cases, we could not access sufficient demand data to conduct this analysis. Frequently, the data received were either insufficient or lacking critical details. Many attempts to clarify critical information were unsuccessful due to a lack of responsiveness. Nevertheless, this study unveiled critical opportunities to strengthen the supply of MH products in SSA.

Data sources

We consulted key data sources, including national public procurement e-tender portals and websites of the departments of health, central medical stores, and procuring entities.

Table 2 Tender award sources reviewed

Ethiopia 	Ethiopian Pharmaceuticals Supply Agency (EPSA), https://epss.gov.et/
Ghana 	Ghana Electronic Procurement System (GHANEPS), https://www.ghaneps.gov.gh/epps/home.do Ghana Public Procurement Authority, https://ppa.gov.gh/
Kenya 	Kenya Medical Supplies Authority (KEMSA), https://www.kemsa.co.ke Public Procurement Information Portal (PPIP), https://tenders.go.ke/
Nigeria 	Nigeria Open Contracting Portal (NOCOPO), http://nocopo.bpp.gov.ng/
South Africa 	National Department of Health, https://www.health.gov.za/tenders/ Government E-Tender Publications Portal, https://www.etenders.gov.za/

Data gaps and limitations

Some of the main challenges we faced during this research included:

- **Inconsistencies in regulatory registers:** There are numerous inconsistencies in the data provided in the NMRA register of each focus country. For example, the same product from different manufacturers could be included in the same register under different generic names without identifying the API. Additionally, some registers did not include key data such as the manufacturers of the listed products.

- **Lack of data regarding the demand for these products:** In some focus countries, the procurement of these products is decentralized and carried out by various agencies under different jurisdictions. Attempts to obtain the procurement data from the public sector to understand the market were unsuccessful. Also, the private sector demand in these countries is highly fragmented, and there is a lack of certainty regarding the quality of the collected data.

- **Unreachable contact persons:** Multiple attempts to reach various points of contact of one manufacturer and multiple procurement organizations were unsuccessful. Although initial contact may have been made, the contact persons did not respond even after being contacted directly by phone once the requests for specific data were made.

Additionally, we used the following review criteria (**Table 3**) to assess whether the demand data was sufficient for estimating the countries' demand for MH products.

Table 3

Assessing quality of tender award data

No.	Data review criteria	Ethiopia	Ghana	Kenya	Nigeria	South Africa
1	Pharmaceutical or essential medicines tenders are published on the website or procurement portal of the procuring entity (e.g., MoH, Medical Supplies Authority).	✓	✓	✓	✗	✓
2	Pharmaceutical or essential medicines contract award lists are available from the national public procurement portal and/or procuring entity's website.	✗	✓	✓	✗	✗
3	Contract award lists can be downloaded in a table format that is editable.	✗	✗	✓	N/A	✗
4	Contract award information is easy to locate on the websites or procurement portals.	✓	✓	✗	✗	✓
5	**The following information is provided in the contract award lists:**					
5.1	Product description/specification	✓	✗	✗	N/A	✓
5.2	Unit/pack size	✗	✗	✗	N/A	✓
5.3	Awarded quantities	✗	✗	✗	N/A	✓
5.4	Price	✗	✗	✗	N/A	✓
5.5	Name of awarded supplier	✗	✗	✗	N/A	✓
5.6	Contract start and end date	✓	✗	✗	N/A	✓
5.7	Country of manufacture or importation	✓	✗	✗	N/A	✗
6	All of the above tender award information is in documents that are easily identifiable and can be collated quickly.	✗	✗	✗	N/A	✓
7	All of the above tender award information is in various documents that are not easily identifiable, and it takes time to collate.	✓	✗	✗	N/A	✗
8	Some of the above tender award information is in various documents and can be collated, but it takes time.	N/A	✗	✓	N/A	N/A

In the end, contrary to the common belief that government tender award data are published and easily available, we could find no data for Nigeria and Ghana and only scattered or incomplete data for Ethiopia and Kenya. The findings for each country are discussed in detail in the following sections.

Current supply of maternal health products in SSA

Overview of the supply of maternal health products in SSA

To determine the availability and sources of HSC, magnesium sulfate, misoprostol, oxytocin, and TXA, we searched the registration records of each of the NMRAs in the countries under consideration. Current guidelines stipulate that every health product distributed in a country must be evaluated, approved, and registered by the country's NMRA. Consequently, an NMRA drug registration implies that the product has undergone a rigorous evaluation for safety, efficacy, and quality as specified by the manufacturer, and that it has been granted the license to be made available to patients.

However, this approval and registration does not guarantee that the manufacturers actively supply the specified products in a given country, nor does it provide information on the volume of the product entering the country. Therefore, certain companies may have products registered in a country without actually supplying those products to the country's markets. At a minimum, though, the registration data indicate the authorized sources of a product in a given country.

During our research, we encountered many repetitions of the same products from the same manufacturers in the registration records of various study countries. We removed those repetitions and counted the product, strength, and manufacturer just once per country since the repetitions account for the same source. (Some of the registrations are likely from previous years or products that have expired but have not been removed from the database.)

Overall, the data collected allowed us to determine the manufacturers and their country of origin as well as the strength and dosage of each registered MH product. In the context of this report, "brand" means a specific MH product produced from a manufacturer at a specific strength. We identified the number of brands of MH products registered by NMRAs in the focus countries. For example, a manufacturer that registered two strengths of the same products is counted as two brands of the products in our analysis.

Our inquiry deliberately omitted manufacturers involved in veterinary production or those that may have halted their product lines. For example, our data omitted a major manufacturer in South Africa that halted the production of TXA a couple of years ago due to the loss of tender.

While we observed that some countries rely on a handful of manufacturers (three to seven) for these products, others have many more products—up to 24—registered from several manufacturers. This could be due to the fact that some registrations have expired and have not been removed from the records. Overall, other than HSC, all the products are widely registered in all the countries. The products are supplied by various companies from different countries.

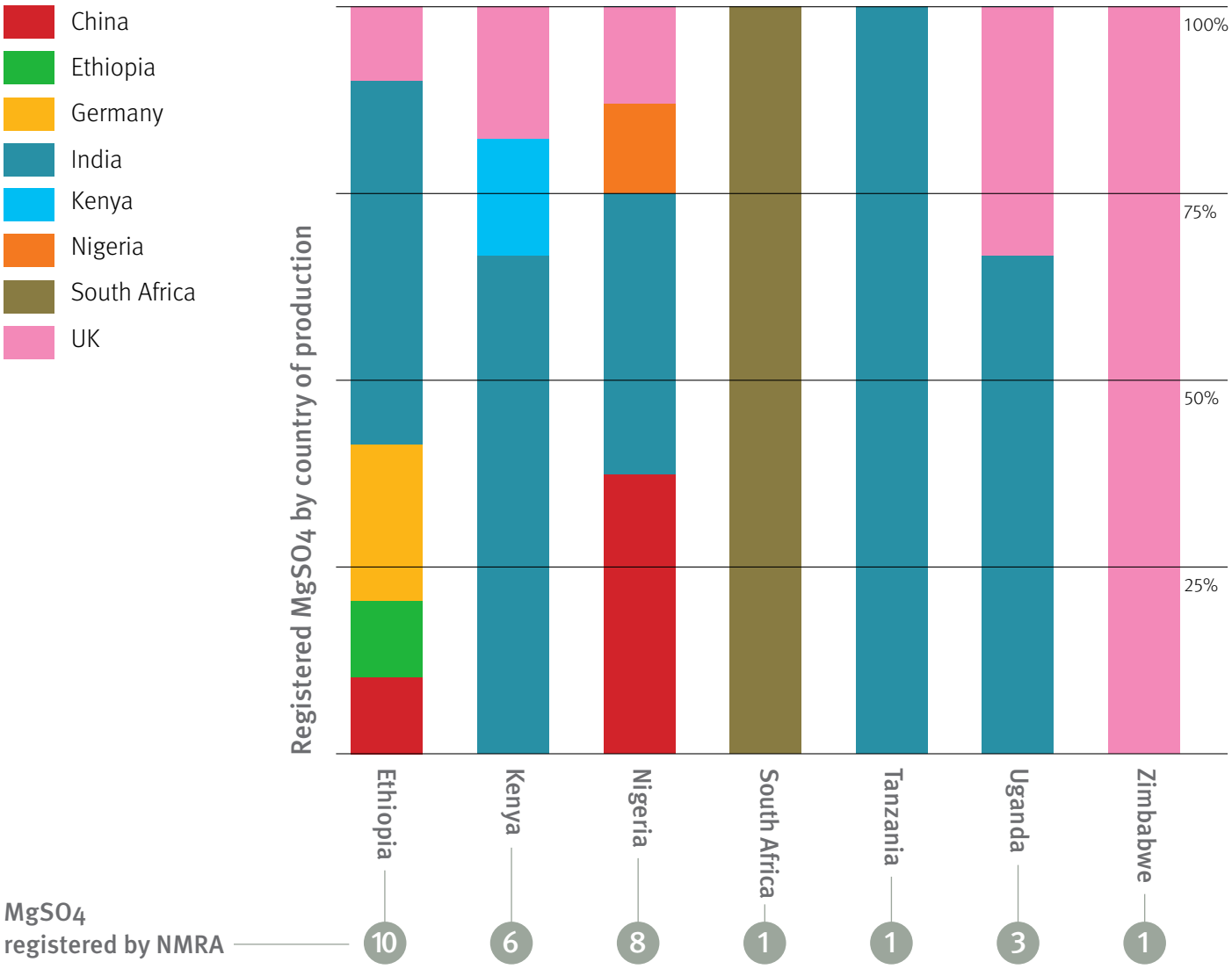
Sources of HSC

HSC is registered in Ethiopia, Ghana, Kenya, Nigeria, Tanzania, and Uganda; the products registered are from companies based in Germany and China. The registered strength of the injectable form is 100 mcg/ml. The limited registration of the product is largely due to the slow progress toward updating the national PPH guidelines and EMLs since policy updates precede regulatory approval of HSC in most SSA countries.[34] Targeted interventions leading to updates of PPH guidelines and EMLs may lead to increased registration of HSC in more countries.

[34] Ng'ang'a J, Chitimbe T, Mburu R, et al. Challenges in updating national guidelines and essential medicines lists in Sub- Saharan African countries to include WHO-recommended postpartum hemorrhage medicines. Int J Gynecol Obstet. 2022;158(Suppl. 1):11- 13. doi:10.1002/ ijgo.14269.

Sources of magnesium sulfate

Figure 1 **Sources of magnesium sulfate**



Supply of magnesium sulfate

The strength of injectable magnesium sulfate available in SSA is 50% w/v (500 mg magnesium sulfate heptahydrate per mL). NMRAs in Ethiopia, Kenya, Nigeria, and Uganda have registered multiple brands, with ten, six, eight, and three registrations respectively, in each country (**Figure 1**). In contrast, South Africa, Tanzania, and Zimbabwe have the product registered with just one manufacturer, although the registered manufacturer differs by country. Indian manufacturers have the most registered magnesium sulfate in Ethiopia, Kenya, Tanzania, and Uganda, accounting for 67 to 100 percent of the registrations. One company from the United Kingdom (UK), one from China, and two from India appear to dominate the market across various countries. This suggests a lack of diversification in the supply of magnesium sulfate, posing a potential risk in the event of a disruption in the producing countries.

The NMRAs of Ethiopia, Kenya, Nigeria, and South Africa have each registered a product from a manufacturer operating in their respective countries. None of these manufacturers has their product registered in any other SSA country we investigated.

Manufacturing of magnesium sulfate in SSA

We identified four manufacturers of magnesium sulfate in SSA: Humanwell Pharma in Ethiopia, Laboratory and Allied Health in Kenya, Juhel Nigeria Ltd in Nigeria, and Adcock Ingram in South Africa. Three of the four companies responded to our survey (**Table 4**). All three responding manufacturers produce FPPs and package the products themselves. Two of the manufacturers independently developed their products, while one relied on technology transfer for product processing. A summary of key information about the manufacturers is provided in **Table 5**.

Table 4

Identified magnesium sulfate manufacturers in SSA and their participation in our survey

Manufacturers	Responded
Humanwell Pharma (Ethiopia)	☑
Laboratory and Allied Health Ltd	☑
Juhel Nigeria Ltd (Nigeria)	☑
Adcock Ingram (South Africa)	☐

3 out of 4 manufacturers participated

Table 5

Magnesium sulfate production factsheet of participating manufacturers in SSA

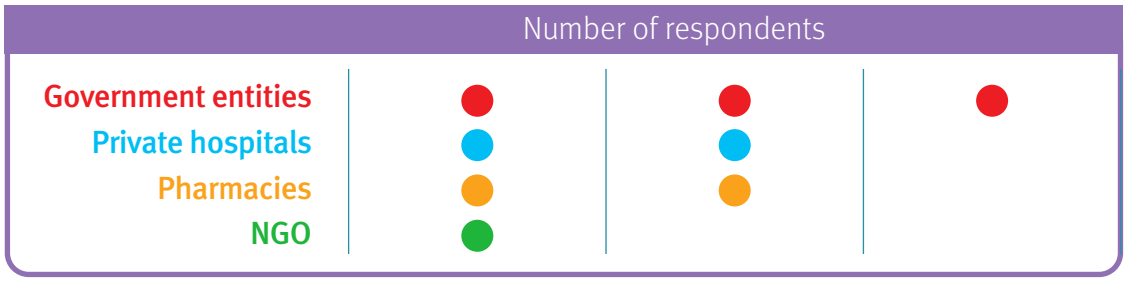
Number of participants and their countries of origin	Three; Ethiopia, Kenya, Nigeria
Sources of APIs	India, China, and the Czech Republic
Drug master files (DMFs) of APIs	API DMF, certificate of suitability (CEP)
Sources of product development information	In-house (2); technology transfer (1)
Strength produced	50% w/v
Shelf life	24 months (2), 36 months (1)
Full stability data to support shelf life	Available (100 percent)
Combined annual production	Approximately 150 million ampules/year
Leading buyer of magnesium sulfate	Government sector, private hospitals, pharmacies

Supply chain overview

The participating manufacturers source their APIs from India, China, or the Czech Republic. The FPP produced across all three manufacturers is the 50 w/v sterile solution form of magnesium sulfate. Two companies produce magnesium sulfate with a shelf life of 24 months, while one produces the MH product with a shelf life of 36 months. Each of the three manufacturers possesses comprehensive stability data to substantiate its specified shelf life.

The public sector is the primary channel for the distribution of finished products. All three manufacturers supply their products to the national health systems of their respective countries. Notably, government entities, including MoHs and national procurement agencies, are reported by the manufacturers as the primary purchasers of magnesium sulfate, accounting for more than 50 percent of sales. Interestingly, one manufacturer exclusively sells its products to the country's MoH agencies, while the other two have a diversified clientele that encompasses both public and private sectors as well as non-governmental organizations (NGOs). Private hospitals and pharmacies also constitute significant buyers for two manufacturers, as outlined in **Figure 2**. Overall, this data suggests that, at this stage, manufacturing capacity of magnesium sulfate in these countries depends highly on demand from local governments.

Figure 2 **Distribution channels of magnesium sulfate for regional manufacturers**



Manufacturing capacity

The reported annual production volumes of the manufacturers vary from 20 million to 80 million ampules with a combined annual volume of approximately 150 million ampules. It is worth noting that one manufacturer reported that its annual production levels fluctuate depending on market demand.

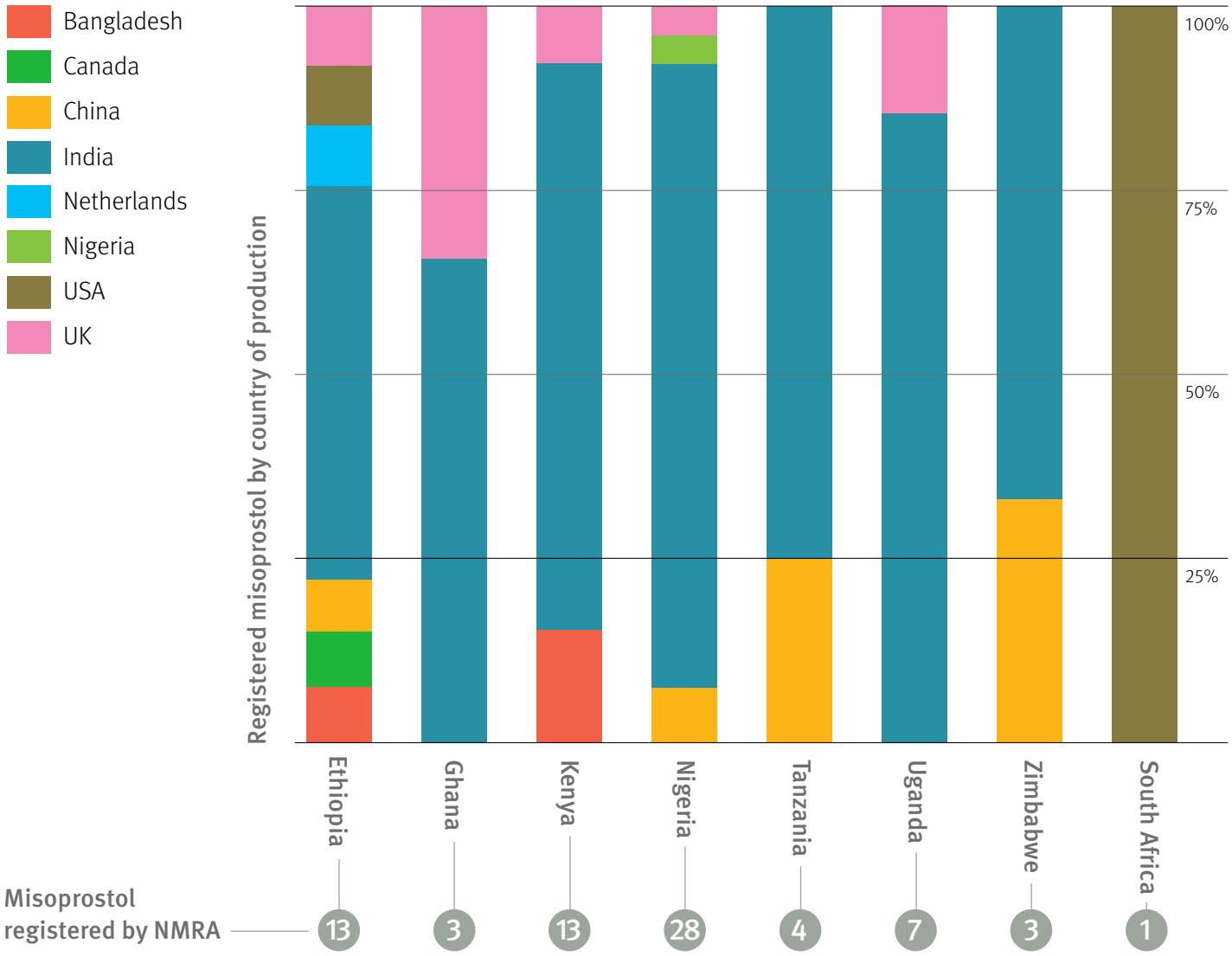
The manufacturing operations are organized either for maintaining stock inventory or in response to specific customer orders. Only one manufacturer caters to both scenarios. Each surveyed company holds its required market authorization for local distribution. However, none of the manufacturers reported supplying their products to neighboring countries or other regions in Africa. Common challenges hindering distribution across borders include the unpredictable nature of regulatory frameworks, registration delays, inadequate transportation infrastructure, and the lack of a regional procurement mechanism.

Specific quality information

All the manufacturers possess the API DMF or CEP developed by their API suppliers. They all possess the market authorization for their respective market and indicated they are compliant with NMRA guidelines. They all have available a site master file, review of complaints and recalls due to product defects, and annual product quality review. While none of the products from the manufacturers surveyed have achieved WHO prequalification, two manufacturers are actively pursuing prequalification. One company indicated that its production line was inspected in June 2023. The other has already submitted its dossier for evaluation.

Sources of misoprostol

Figure 3 **Sources of misoprostol**



Supply of misoprostol

Misoprostol registered with the NMRAs in the eight countries considered is primarily sourced from manufacturers based in Bangladesh, Canada, China, India, the Netherlands, Nigeria, Spain, the UK, and the United States of America (**Figure 3**). Specifically, three suppliers from India, two from China, one from Bangladesh, and one from the UK seem to be the primary sources of misoprostol for the countries we reviewed. The standard registered strength across these countries is 200 mcg in an oral solid dosage. However, Nigeria and Kenya also have authorized the supply of a 25-mcg tablet.

The MoHs in the focus countries in SSA procure misoprostol from at least three different companies based in at least two countries (according to data from their respective NMRAs). Generally, India-based manufacturers supply misoprostol to all these countries except South Africa (Figure 3). Some countries, such as Ghana, Tanzania, and Zimbabwe, rely on three or four manufacturers from two different countries, including China, India, or the UK.

Meanwhile, Ethiopia, Kenya, and Nigeria have misoprostol registered from more than a dozen manufacturers. Nigeria's National Agency for Food and Drug Administration and Control (NAFDAC) has registered 24 brands from manufacturers based in four different countries, although the majority of the products are from India. It is unclear whether all these brands of misoprostol are currently available in Nigeria. Conversely, one US-based company seems to be the sole source of misoprostol in South Africa. This could be the result of a tender awarded to the manufacturer in 2017, ensuring its exclusive supply to the South African MoH.

An interesting observation is that only one Nigerian manufacturing company, Emzor, has successfully registered its misoprostol product in Nigeria, making it the only misoprostol manufacturer in the country and in the region. Notably, none of the focus countries considered have registered misoprostol produced in any other African nation, including the Nigerian manufacturer. This highlights the significant reliance on imports for this crucial medication.

Manufacturing of misoprostol in SSA

The sole identified regional misoprostol manufacturer agreed to participate in the survey, and it supplied the information requested. A summary of its key information is provided in **Table 6**.

Table 6

Misoprostol production factsheet of participating manufacturers in SSA

Number of participants and their countries of origin	One; Nigeria
Sources of APIs	China
Drug master files of APIs	API DMF
Sources of product development information	Technology transfer followed by in-house R&D
Strength produced	200 mcg and 25 mg tablets
Shelf life	24 months
Full stability data to support shelf life	Available
Combined annual production	Approximately 800 kg per year
Leading buyer of misoprostol	Government, university, and private hospitals; pharmacies

Overview of the supply chain

Emzor specializes in the formulation and distribution of 25 mcg and 200 mcg tablets. This manufacturer relies on imports from China for its APIs, and it sources excipients from India and China. Notably, this company stands out as one of the two local producers identified in this study that procures packaging materials from the local market.

The manufacturer distributes misoprostol only in Nigeria. Batches are typically produced on a per order basis from local entities or, in some instances, for stock inventory. The most frequent customers include government, university, and private hospitals as well as pharmacies. Interestingly, NGOs, donors, and regional procurement organizations do not currently procure misoprostol from this manufacturer.

In the event of a substantial surge in demand, the manufacturer may find it necessary to expand its existing facility or even consider constructing a new plant. Given the potency of the product, it is imperative that this manufacturing facility remains dedicated and rigorously controlled to prevent any risk of cross contamination with other production units and personnel. The manufacturer exhibits some reluctance to commit to additional investments without a firm guarantee of additional purchase orders of the MH product and the required technical support.

Manufacturing capacity

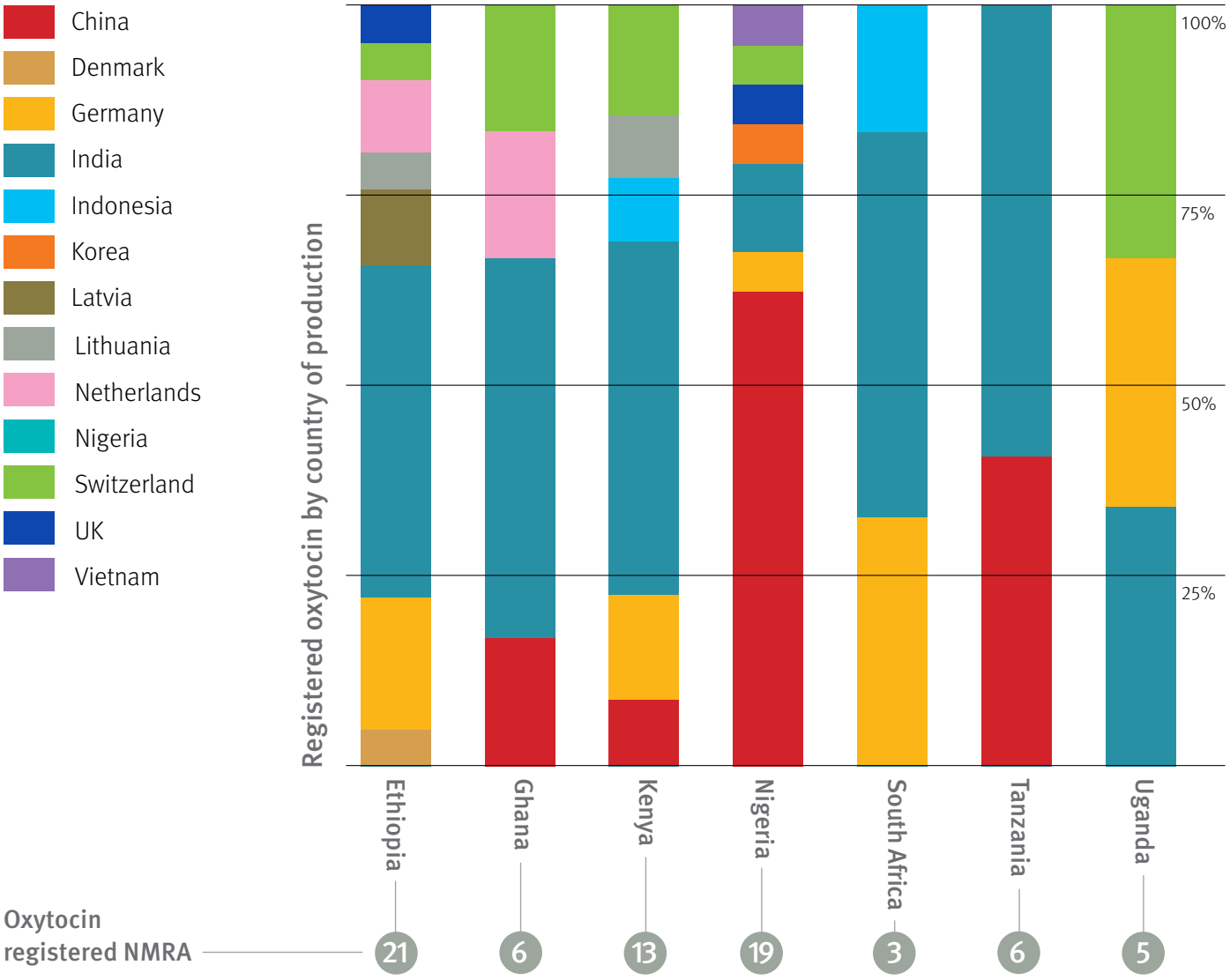
While the manufacturer possesses the capacity to produce a higher volume of misoprostol, its annual production falls well below potential with an output of less than 800 kg per year. This low production output is primarily attributed to the fact that the annual demand for misoprostol received by the company is estimated at approximately 500 kg.

Specific quality information

The manufacturer possesses the API DMF developed by the API producer. However, no answer was provided as to whether the API itself holds WHO prequalification status. Moreover, the company possesses the necessary market authorization for its host country and is fully compliant with all GMP requirements stipulated by its NMRA, ensuring the safety and quality of the product in its intended market.

Sources of oxytocin

Figure 4 **Sources of oxytocin**



Supply of oxytocin

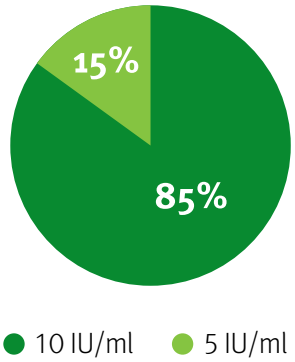
We reviewed the registration records of the NMRAs of Ethiopia, Ghana, Kenya, Nigeria, South Africa, Tanzania, and Uganda to evaluate the supply of oxytocin. Our findings revealed that some countries have a higher number of brands registered than others (**Figure 4**). For example, while Ethiopia and Nigeria have 21 and 19 brands of oxytocin registered respectively, South Africa has only three brands of the products registered. Overall, the data suggests that the product is widely registered in the countries surveyed.

The prevailing strength of oxytocin in the region is 10 IU/ml in the injectable form (**Figure 5**). This is the only strength registered in Nigeria and Uganda. Other countries also appear to have the 5 IU/ml available, accounting for 15 percent of the registered oxytocin from various manufacturers in the region.

As seen across SSA, most countries rely heavily on manufacturers from India to source oxytocin. In Ethiopia, Ghana, Kenya, South Africa, Tanzania, and Uganda, 43 to 60 percent of the registered oxytocin is produced in India (**Figure 5**). However, Chinese manufacturers also play a significant role in the sourcing of oxytocin, especially for Nigeria (63 percent of the country's registered oxytocin). Oxytocin brands produced in countries such as Germany, Indonesia, and Switzerland also contribute to the supply diversification of the product in countries such as Ethiopia, Kenya, South Africa, and Uganda.

In SSA, only one Nigeria-based manufacturer, Juhel Nigeria Limited, currently registers oxytocin in the same country. This manufacturer's product is not registered in any other country.

Figure 5 **Strength of oxytocin available in focus countries**



Manufacturing of oxytocin in SSA

Juhel Nigeria Limited specializes in the local production and distribution of oxytocin in Nigeria. It is the only manufacturer currently producing this MH product in SSA. The company agreed to participate in the survey, and it supplied the information requested. A summary of key information is provided in **Table 7**.

Table 7

Oxytocin production factsheet of participating manufacturers in SSA

Number of participants and their countries of origin	One; Nigeria
Sources of APIs	India
Drug master files of APIs	CEP
Sources of product development information	In-house
Strength produced	Sterile injectable; 10IU/2ml
Shelf life	36 months
Full stability data to support shelf life	Available
Combined annual production	Annual production not provided; or according to customer order
Leading buyer of oxytocin	Government sector, private hospitals, pharmacies, NGOs

Supply chain overview

The strength of the sterile injectable produced is 10 IU/2ml. The manufacturer's production process relies on importing essential inputs from India, China, and the European Union (EU). In common with other manufacturers in the region, this company procures some of its packaging materials locally. Specifically, primary packaging materials are sourced from the EU, while secondary packaging materials are obtained from local vendors and manufacturers.

These batches are exclusively manufactured based on customer orders, with a small reserve produced for stock inventory. The product is distributed to government, university, and private hospitals as well as to pharmacies and NGOs.

Manufacturing capacity

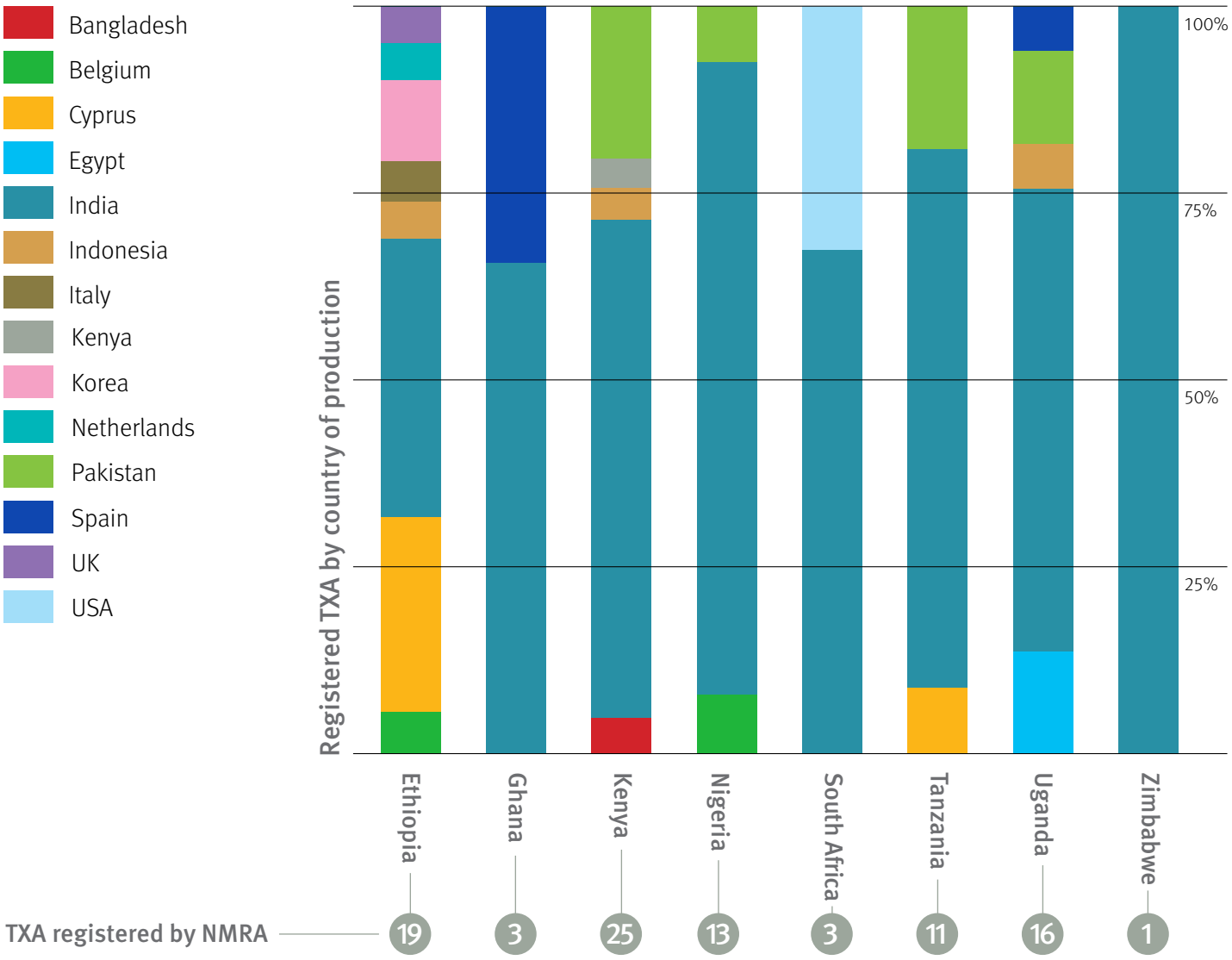
This manufacturer's annual production volume fluctuates significantly, presenting a challenge to accurately estimate it. This fluctuation is primarily driven by the unpredictability of orders and the need to utilize the same equipment for the manufacturing of other products, which significantly affects the consistency of oxytocin's yearly output. The overall market demand exceeds the company's production capacity to such an extent that it remains unquantified. Nevertheless, the manufacturer ensures the production of at least 600 kg of oxytocin per year. It is important to note that the manufacturer faces significant logistical challenges to scaling up its oxytocin supply, particularly related to technical expertise in maintaining and repairing cold chain equipment.

Specific quality information

Recognizing that the oxytocin market in the region hinges on two pivotal factors—quality and price—the manufacturer is committed to adhering to the standards set by the NMRA. The company reported that it has regularly conducted process validation and possesses full stability data of the finished product to support the specified shelf life. Moreover, the production site has undergone inspections by the NMRA over the past three years and has received its approval.

Sources of TXA

Figure 6 **Sources of TXA**



Supply of TXA

India-based manufacturers seem to dominate the TXA market in SSA (**Figure 6**). The registration records in nearly all the countries reviewed indicate that an Indian manufacturer accounts for at least 60 percent of the registered TXA in Ghana, Kenya, Nigeria, South Africa, Tanzania, Uganda, and Zimbabwe. Three Pakistani companies also seem to play a significant role in the supply of TXA in Kenya, Tanzania, Uganda, and in Nigeria.

The registration records of TXA in the region suggest that a nearly even number of injectable and tablets are available throughout SSA (**Figure 7**), although the proportion differs depending on the country. For example, the injectable form of the drug appears to be the most registered in Ethiopia and Tanzania (more than 90 percent), while in Uganda and Zimbabwe there is an even split between tablets and injectables. The most prevalent strength is 500 mg/5ml, accounting for 66 percent of all registered products in SSA (**Figure 8**). The 100 mg/ml and 250 mg/5ml account for 21 percent and 11 percent of the registered products, respectively.

Only one manufacturer in Kenya has registered TXA with the country's NMRA and is currently producing the MH product in SSA.

Figure 7 **Dosage of TXA available in SSA**

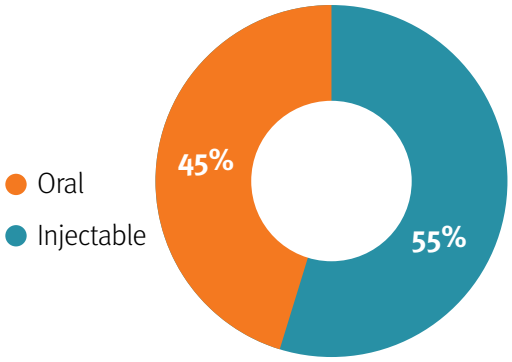
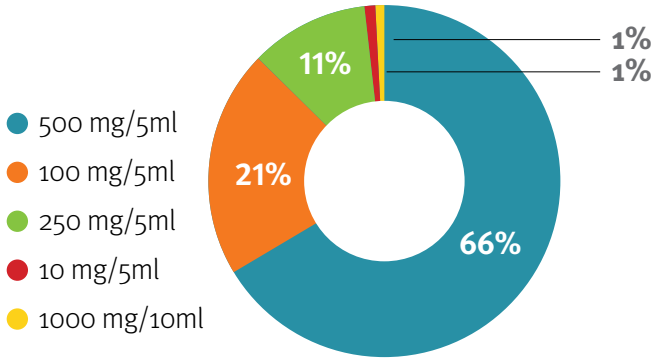


Figure 8 **Strength of TXA available in SSA**



Manufacturing of TXA in SSA

We identified two manufacturers of TXA in SSA, one in Kenya (Tasa Pharma) and another in South Africa. However, the South Africa-based company discontinued its production line due to the loss of tender a couple of years ago. This highlights the fragility of the market for manufacturers due to competition from imports and the need to design policy to boost demand. Our attempts to gather more information from the South African manufacturer were unsuccessful. However, Tasa Pharma agreed to participate in our survey and supplied the information requested. A summary of key information is provided in **Table 8**.

Table 8

TXA production factsheet of participating manufacturers in SSA

Number of participants and their countries of origin	One; Kenya
Sources of APIs	India
Drug master files of APIs	CEP
Sources of product development information	In-house
Strength produced	500 mg/5 ml glass ampules
Shelf life	24 months
Full stability data to support shelf life	Available
Combined annual production	Approximately 1,600,000 ampules/year
Leading buyer of TXA	Public, university, and private hospitals; NGOs

Supply chain overview

Tasa Pharma is a new start-up that aims to produce more MH products. It is currently producing 500 mg/5ml glass ampules of TXA. The company relies on imports from India for its APIs (CEP certified, according to the manufacturer). Its excipients come from the EU, and packaging materials are sourced from India. Nearly all current production is designated for stock inventory. Buyers include government and university hospitals, private pharmacies, and NGOs.

Manufacturing capacity

The company developed its product in-house and has begun producing TXA with an annual production of approximately 800 kg or 1,600,000 ampules. Several batches are currently being produced and packaged in blisters of five or ten 10 ml ampules. Equipment challenges, including the limited size of autoclaves, hinder the possibility of scaling production.

Specific quality information

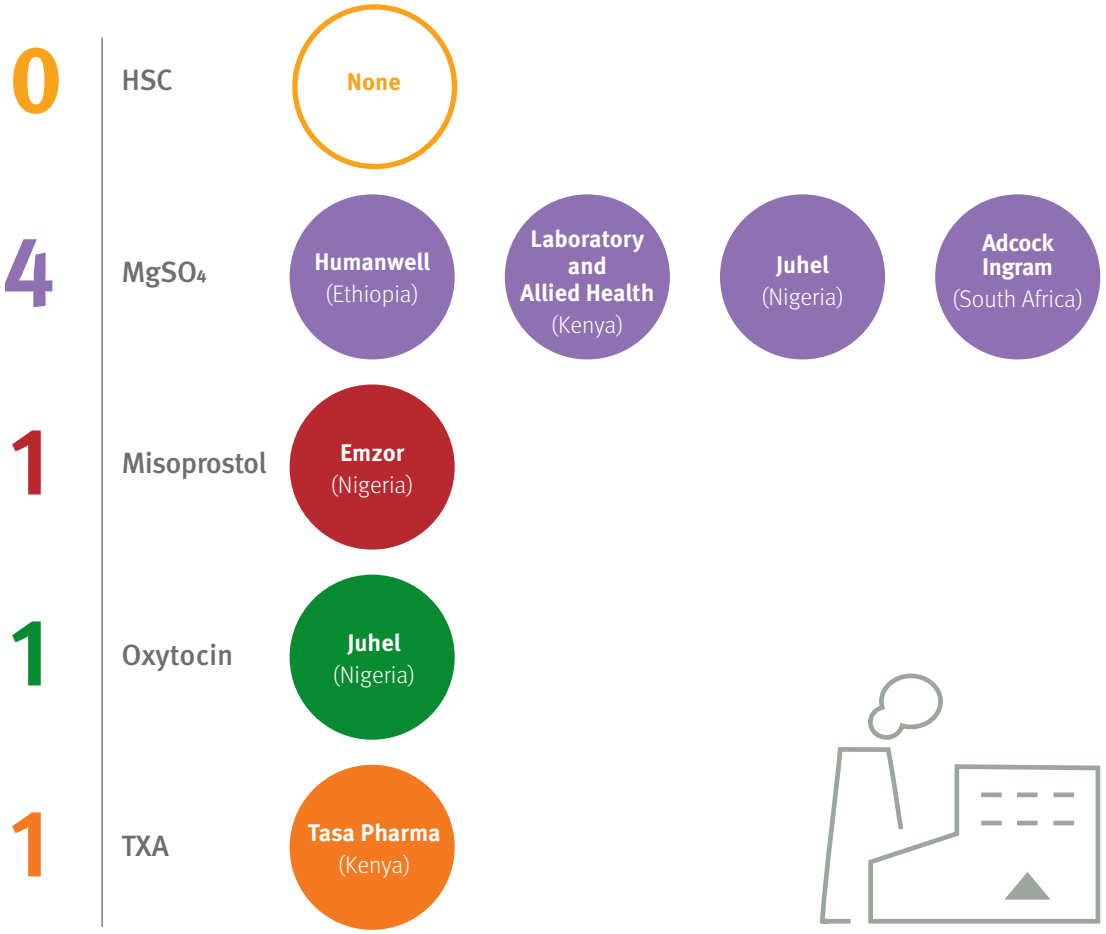
The manufacturer possesses an API CEP developed by the API producer. It possesses the necessary market authorization for its host countries and is fully compliant with all GMP requirements stipulated by its NMRA.

Overview of MH products manufacturing in SSA

In total, we identified six manufacturers spanning four countries (Ethiopia, Kenya, Nigeria, and South Africa) actively involved in the production of MH products (**Figure 9**). Most of these companies have only one MH product in their portfolio. Juhel stands out as the exception, producing two essential MH products: magnesium sulfate and oxytocin.

Overall, magnesium sulfate emerges as the predominant MH product manufactured in the region. It is produced by four manufacturers in four different countries: Nigeria, Ethiopia, Kenya, and South Africa (**Figure 9**). All four manufacturers are engaged in secondary manufacturing—they all formulate and package the FPPs. None of the identified manufacturers are limited to only packaging services, a sign of the growing maturity of the industry in SSA as compared to previous decades.

Figure 9 **Number of current SSA manufacturers of MH products and their countries of production**



Oxytocin, misoprostol, and TXA each have one manufacturer based in SSA. Unsurprisingly, our landscape analysis identified no manufacturers of HSC in the region. Although the primary patent on carbetocin has expired, there are patents or patent applications on the heat-stable formulation in several countries that are current until 2031.[35] Therefore, no manufacturer in SSA can produce HSC without a licensing agreement with the patent holder. Even with a licensing agreement, with the current level of uptake on the Continent, most manufacturers will struggle to make

[35] Medicines Patent Pool. Prioritisation of medicines for in-licensing by the Medicines Patent Pool-2021, July, 2022, https://medicinespatentpool.org/what-we-do/prioritising-medicines-for-licensing.

a business case for the production of HSC within the region because of the small size of the current market and the availability from current manufacturers. Even though all products are not produced in each region of the Continent, there is a balanced distribution of at least one manufacturer of an MH product in each region.

Table 9

Assessment of the five participating manufacturers for key regulatory requirements

Regulatory requirements	Complied	Not Complied	Unsure
Manufacturing license issued by the national authority	5	0	0
GMPs certified by health authority	5	0	0
Site master file current	5	0	0
List of authorized products available	5	0	0
GMPs inspection report issued by local NMRA in the past 3 years	5	0	0
GMPs inspection report issued by a competent regulatory authority in the past 3 years	5	0	0
Most recent annual product quality review	3	2	0
Batch manufacturing instructions, release procedure, and executed records	5	0	0
Review of most recent complaints and any recalls due to product quality defect	3	1	1
Market authorization	5	0	0

Our study did not entail on-site visits for in-depth due diligence of manufacturing practices. We focused on assessing compliance with specific regulatory requirements that ensure the drug products' quality, efficacy, and safety. We concentrated on ten regulatory requirements, such as GMP certification by NMRA, the status of the site master file, and the most recent annual product quality review (**Table 9**). The annual product quality review, for example, is a critical mechanism that serves the purpose of assessing a drug product's quality standards. This involves the verification of process consistency, appropriateness of control procedures, and an overall evaluation of the starting materials and final product. The level of compliance with these specified requirements provides a preliminary insight into the level of adherence to regulatory guidelines, which ultimately influences the quality of FPPs.

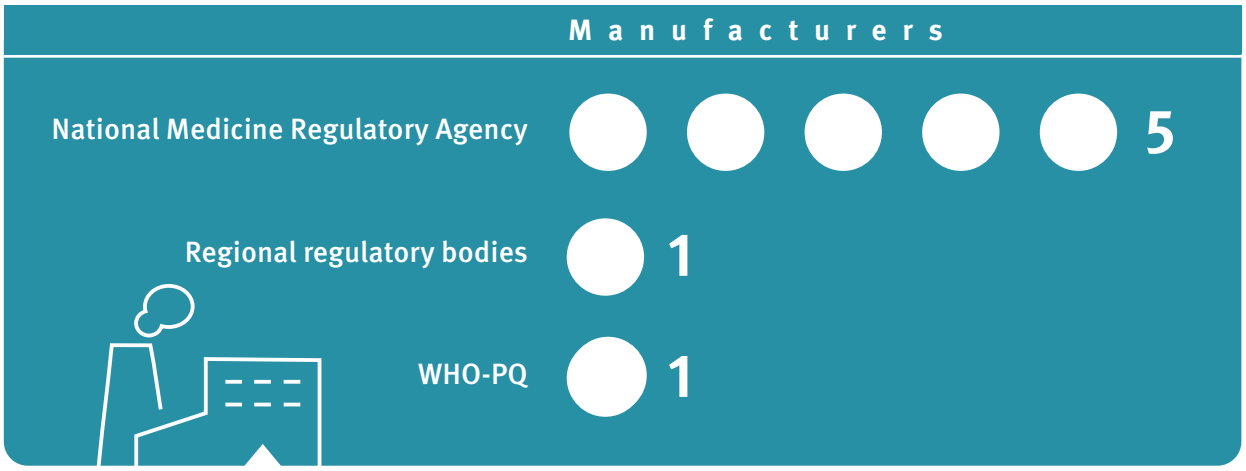
All five of the companies responding to our survey have adhered to the significant majority of the regulatory compliance requirements as outlined in **Table 9**. Each company's production sites have been inspected by its country's NMRA, resulting in approvals for compliance with GMPs within the last three years. While most of the companies have been

diligent in maintaining the most recent annual product quality review and review of most recent complaints and any recalls due to product quality defect, two did not possess one of these specific records. Additionally, three manufacturers underwent inspections by a regulatory body other than their respective NMRA, such as a regional regulatory body or the WHO's prequalification team. This underscores the manufacturers' commitment to the quality assurance of their products (**Figure 10**).

It is crucial to underscore that all the respondents have successfully obtained market authorization from the NMRAs of their respective countries. No manufacturers indicated holding a market authorization beyond the border of the countries of manufacture, although they do possess such authorization for other products in their portfolios.

Figure 10

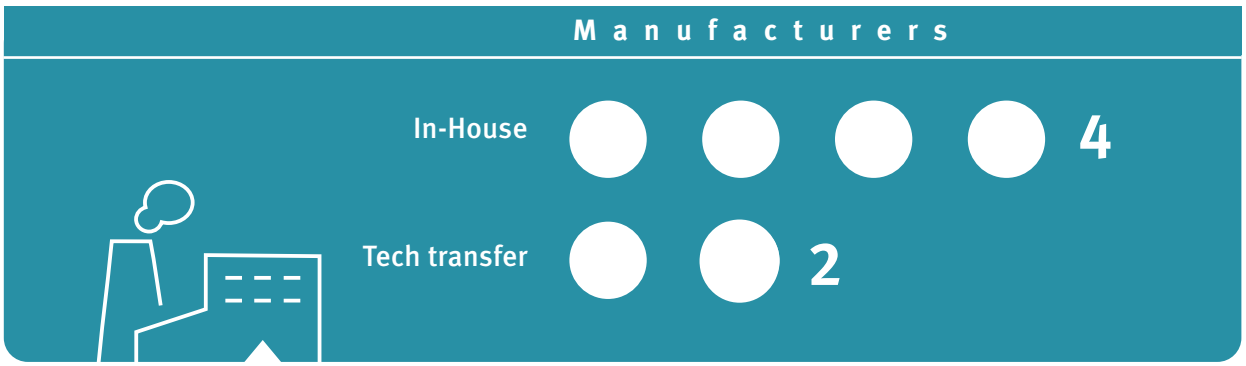
Number of manufacturers inspected by regulatory bodies over the past three years



Most manufacturers reported conducting their product development in-house (**Figure 11**). However, two have relied on technology transfer for product development, with one having conducted further research and development to improve the process in-house. In addition, all manufacturers currently depend heavily on imports, primarily from India, China, and the European Union, for their APIs, excipients, and packaging materials. Interestingly, three manufacturers mentioned sourcing some or all of their packaging materials locally.

Figure 11

Number of manufacturers using each type of MH product development method

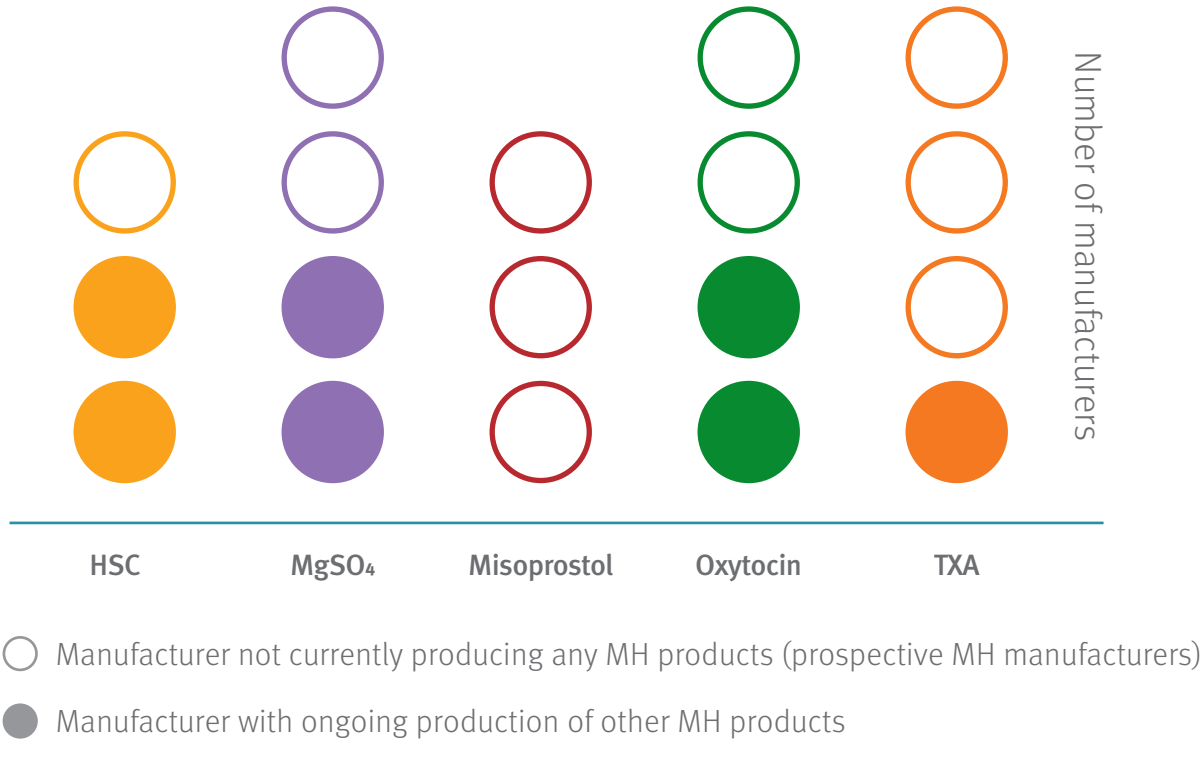


Plans to expand production of MH products in SSA

All the current regional manufacturers we identified have relatively low factory utilization rates, fluctuating between 25 and 60 percent, depending on the company. It is not surprising that all of them, except one, have plans to expand their portfolios of MH products. Figure 12 illustrates the planned additions by each of the manufacturers, with ongoing production of MH supplies, exploring expansion into additional MH products. This expansion would be primarily driven by market demand.

Furthermore, our research sought to identify manufacturers across SSA that are currently not producing any MH products but have plans to initiate production in the near future. For the purpose of this study, we refer to these manufacturers as "prospective MH manufacturers" and our findings indicate that they are primarily located in Nigeria and Ghana. We identified four specific, future MH manufacturers, three situated in Nigeria and one in Ghana (**Figure 12**). Our research did not reveal the existence of similar future manufacturers in regions outside of West Africa.

Figure 12 **Planned production expansion of MH products**



HSC

Two regional manufacturers currently producing other MH supplies intend to expand their portfolio by adding the production of the HSC. Additionally, another prospective manufacturer, has plans to establish a production line for HSC. These endeavors would be significant since there is currently no HSC manufacturer in SSA. Given the limited number of producers worldwide, these initiatives will strengthen the global supply of this critical medicine, assuming these companies can secure the necessary agreements and are able to make a favorable business case. Each company aiming to produce HSC plans to rely on technology transfer for its manufacturing processes.

Magnesium sulfate

One manufacturer in Kenya currently producing another maternal health product is notably advanced in its efforts to begin to also produce magnesium sulfate. This manufacturer has already submitted a dossier for approval with the Kenyan Pharmacy and Poisons Board (PPB) and stands out as the only company with active plans to begin producing magnesium sulfate, which have progressed to the dossier submission stage with an NMRA. Upon approval, this achievement will significantly enhance Kenya's production capacity and will make the manufacturer the second magnesium sulfate producer in the country and the third largest in East Africa. In Nigeria, another MH product manufacturer is actively working to add a production line for magnesium sulfate, potentially increasing the total number of magnesium sulfate producers in Nigeria. Two prospective MH manufacturers located in Ghana and Nigeria also plan to produce magnesium sulfate. They plan to produce 20% w/v and 50% w/v of the drug product.

Misoprostol

Interestingly, other than Emzor (which currently produces misoprostol), none of the other current producers of MH products in SSA intend to add misoprostol to their portfolio in the foreseeable future. However, three prospective manufacturers all based in Nigeria plan to produce misoprostol. One has already secured its market authorization. Each of these companies plans to produce 200 mcg tablets of misoprostol (like the current manufacturer in Nigeria).

Oxytocin

Two current manufacturers, one in Kenya and the other in Nigeria, have also expressed interest in adding oxytocin production to their factories. In addition, two prospective manufacturers, one based in Ghana and the other in Nigeria, are actively planning to begin making the product. The strengths they aim to produce are 5 UI and 10 UI. The Ghanaian manufacturer will achieve a significant milestone as it will become the first company in the country to manufacture MH products. When asked about API sources and the type of API drug master file available, the Ghana-based company distinguished itself from all current and prospective MH product manufacturers. It sources a WHO prequalified API, which is of paramount importance given its aspirations to pursue WHO prequalification for the oxytocin it will produce. While the Ghana-based company is yet to obtain the market authorization to produce oxytocin, the Nigeria-based company has confirmed that it has already obtained authorization. There are currently no oxytocin manufacturers in Kenya or East Africa, while there is one in Nigeria. These potential projects could strengthen the supply chains and markets for oxytocin in the two countries and the region.

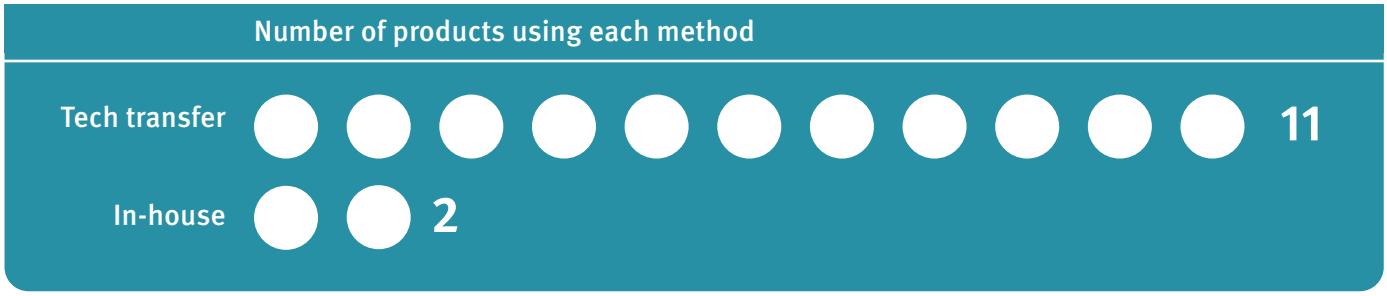
TXA

The only manufacturer of MH products with plans to also start producing TXA is located in Kenya, where there is already a TXA manufacturer. As with other MH products in this study, a demand study needs to be conducted to inform a rigorous business case, which justifies the production of the same MH product by multiple manufacturers in the same country in light of the market size. Given the product's small profit margin, market fragmentation could negatively impact these companies. However, a business case becomes more optimistic when the companies have easier access to regional markets. (This is also the case for the other MH products discussed previously.) Three other prospective manufacturers located in Ghana and Nigeria also intend to add TXA production. Two of the companies are gearing up to produce 250 mg and 500 mg strengths in sterile injectable form, while one intends to produce oral solid dosage forms of this essential drug. If successful, this manufacturer will become the sole producer of oral solid dosage TXA in SSA.

Product development strategies and timelines

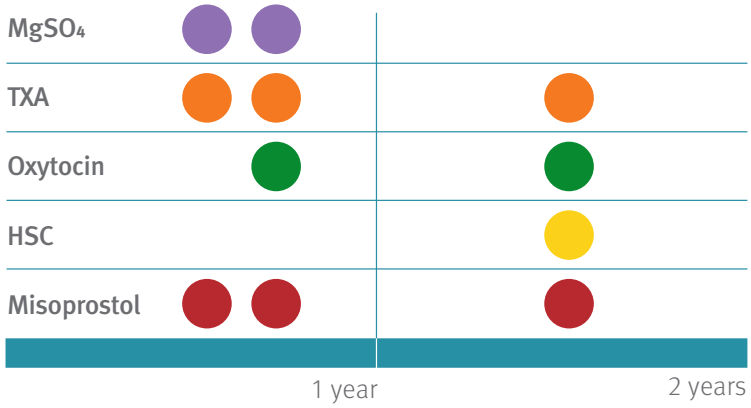
Prospective MH manufacturers plan to rely on technology transfer to produce approximately 85 percent of the MH products they plan to add to their portfolio. As demonstrated in **Figure 13**, prospective MH manufacturers plan to develop 15 percent of these products in-house.

Figure 13 **MH FFP product development strategy**



To our surprise, all the prospective MH manufacturers have active plans to begin production in a maximum of two years (**Figure 14**). Most of the prospective manufacturers plan to begin production of one or more of the products in less than a year. Prospective manufacturers of magnesium sulfate, misoprostol, and TXA plan to begin production of each within a year. Another prospective manufacturer also plans to begin production of oxytocin within a year. Additionally, prospective manufacturers intend to begin production of HSC, misoprostol, oxytocin, and TXA within two years.

Figure 14
Timeline of the prospective numbers of MH manufacturers to begin production



Demand for maternal health products in SSA

Approach and methodology

Part of the scope of this analysis was to assess demand for the five essential MH products in the countries of focus. For the purposes of this study, demand means the quantities of the MH products a country's health ministry procures in a given period of time at various prices. In this section, we present the estimated demand for the analyzed MH products.

An important factor to consider in using tender award data to estimate demand is the accuracy and reliability of that data. Our key assumption about the accuracy and reliability of the published tender award data for the focus countries was that procured quantities of the MH products were informed by rigorous quantification and demand forecasting methods and processes and therefore could be assumed to be a fairly accurate reflection of the actual demand in the public sector, and in turn a reliable proxy for demand. We were also cognizant of the fact that, in many African countries, frequent medicine stockouts are often attributed to poor quantification and demand forecasting, among other reasons. Therefore, we conducted a search to identify and highlight any documented stockout reports or related accounts of supply chain issues in the countries of study. For example, in Tanzania, poor data quality is reported as a key challenge in the medical supply chain management system and as an impediment to forecasting health facilities' supply of and demand for medical commodities.[36]

In this study, we aimed to compare the manufacturing capacity within the region and the demand to determine the local supply gaps and required actions to address these gaps. Unfortunately, the lack of sufficient demand data available within the timeline of the study, especially from the countries of production, precluded conducting such analysis.

Demand estimates

Ethiopia

The Ethiopian Pharmaceuticals Supply Agency (EPSA) is a government agency operating under the MoH that is mandated to procure, store, and distribute quality-assured pharmaceutical products to public health institutions. EPSA publishes pharmaceuticals tender information on its website. However, the published contract awards do not include details such as the names of awarded products, quantities, or contract/tender reference numbers. To find this additional information, we delved into the tender archive list. Through further research using the tender codes, we obtained the necessary data to conduct a demand analysis of the MH products. It is important to note that, since information was extracted from different documents, there is no guarantee we identified all relevant contracts awarded from 2017 to 2022.

[36] Wong J, Mattes M, Min Yi Hou A, Quarcoo A, Warrier A. "Reaching the last mile: Tanzania's medical supply chain." Munk School of Global Affairs & Public Policy, University of Toronto, 2020, https://reachalliance.org/wp-content/uploads/2019/03/REACH2020-Tanzania.pdf.

There are two critical issues related to Ethiopia's supply chain to be considered while examining EPSA's published tender awards:

1. **Quantification and demand forecasting challenges:** An analysis of the public health supply chain and EPSA's internal processes found that quantification error for pharmaceutical products funded through the Revolving Drug Fund is as high as 40 percent, resulting in stockouts and wastage across the supply chain. The major cause of this problem is that the majority of public hospitals are not properly using the Health Commodity Management Information System to monitor their stock.[37] This system has a number of shortfalls, including the lack of a management information system module for forecasting and supply planning. Also, the agency was found to be using semi-automated, fragmented, and non-database tools such as Excel spreadsheets to conduct quantification. An assessment conducted by Results for Development identified numerous weaknesses in the quantification of medicines and other health commodities. Notable among these were ad hoc or fragmented procurement requests, absence of an electronic procurement system, and inaccurate forecasting and supply planning.[38] Therefore, it is likely that the quantities reflected in tender documents were underestimated or overestimated and not a true reflection of the actual demand. EPSA is currently implementing a 10-year (2020/21 – 2029/30) transformational plan to address all identified problem areas with its supply chain and internal processes.[39]

2. **Dollar shortages in 2019:** It is widely reported in the media that Ethiopia has been experiencing challenges with foreign currency shortages since at least 2019. These shortages have affected pharmaceutical imports as there has not been enough foreign currency to procure sufficient quantities to meet demand—the tender award data presented in **Table 10** presents the procurement of four of the five studied MH products from 2017 to 2022.

Table 10 **MH products awarded by EPSA 2017 – 2022**

Year	Product Description	Unit	Quantity
2018	Magnesium sulfate 50% in 20ml injection	100	2,493
2018	Magnesium sulphate 50% inj.	10	238,880
2019	Magnesium sulphate 50% inj.	10	409,005
2020	Magnesium sulphate 50% in10 ml inj.	1x100 Ampules	37,790
2021	Magnesium sulphate 50% in 10ml inj.	10	29,490
2018	Mifepristone + Misoprostol 200mg + 200mcg	kit	377,960
2019	Mifepristone 200 mg + Misoprostol 200 mg	2	1,128,276
2020	Misoprostol 25 mcg tablet	4	174,771
2022	Misoprostol 25mcg tablet	4	25,000
2019	Misoprostol 200µg tablet	28	678,658
2021	Misoprostol 200 mg	28	37,600
2022	Misoprostol 200 mcg Tablet	28	436,790

[37] Ethiopia Pharmaceutical Supply Agency (EPSA). Ethiopia, National Survey of the Integrated Pharmaceutical Logistics System: AIDSFree, and Pharmaceutical Supply Agency (EPSA), 2019. https://www.researchgate.net/profile/Fantaye-Teka-2/publication/335207169_Ethiopia_National_Survey_on_the_Integrated_Pharmaceutical_Logistics_System_IPLS/links/5d56b1dca6fdccb7dc40beob/Ethiopia-National-Survey-on-the-Integrated-Pharmaceutical-Logistics-System-IPLS.pdf

[38] Results for Development. "Progress Brief Ethiopia Market Shaping Capacity Improvement Project (MSCIP)." December 2021, https://r4d.org/wp-content/uploads/R4D-InstitutionalizingMarketShapingCapacityinEthiopia-ProjectProgress.pdf.

[39] Ethiopia Pharmaceutical Supply Agency (EPSA). Ethiopia, National Survey of the Integrated Pharmaceutical Logistics System: AIDSFree, and Pharmaceutical Supply Agency (EPSA)

Table 10 (continued) **MH products awarded by EPSA 2017 – 2022**

Year	Product Description	Unit	Quantity
2017	Oxytocin 10 units/ml in 1ml injection	10x10	83,936
2019	Oxytocin – 10 Units/ml in 1ml Ampoule – Inj.	10	721,580
2021	Oxytocin 10iu inj.	50	132,861
2022	Oxytocin 10iu inj.	ea	4,900,960
2018	TXA 500 mg tablet	10x2	7,500
2019	TXA 500 mg tablet	10x10	5,439
2018	TXA 100mg/ml inj.	10	16,981
2019	TXA 500mg/5ml-Inj.	10	150

The data in the above table demonstrates an abnormal decline in awarded quantities of magnesium sulfate injection, misoprostol 200mg, and oxytocin in 2020 and 2021. For example, magnesium sulfate quantities dropped by about 91 percent—from 400,000 in 2019 to approximately 38,000 in 2020 and 29,000 in 2021. In the absence of any documented explanation or information on quantities put out to tender and given the fact that all awards were granted to foreign suppliers, we assume that small quantities were procured because there was a global supply shortage due to the COVID-19 pandemic. This forced procurers to settle for the limited quantities that suppliers could offer. COVID-19 caused a breakdown in global supply chains and a steep decline in exports from supplying countries. It is well-reported that several countries, including India (a major exporter to Africa), imposed export restrictions on various health commodities during the pandemic. China, the largest API supplier in the world, closed all of its factories for a period of time, a development that was bound to broadly impact the supply of finished products. As a result of these developments, there were shortages of TB drugs, ARVs, and contraceptives, among others. An additional reason for the limited quantities could be the shortage of foreign currency described at the beginning of this section.

There is no information in the table for magnesium sulfate for 2022, misoprostol for 2020, oxytocin for 2018, and TXA for 2020-2022. This could be an unintended data omission by EPSA, or there may have been no procurement of these products during this period.

Accurately estimating Ethiopia's demand for the five MH products it procures is made difficult by the observations and findings outlined above, including the absence of published lists of awards with essential information (such as names of products and quantities), the potential inaccuracies with the EPSA's quantification and demand forecasting processes, and the unexplained huge declines in procurement quantities in 2020 and 2021. We recommend that the highest quantity awarded for each product be considered as a guideline to what the potential demand could be and be increased by 30-40 percent, which is the assumed under-quantification error according to EPSA's 2018 analysis. Gaps and shortcomings discussed above should also be taken into consideration. The estimated annual demand is presented in **Table 11**. TXA is not included because the quantities procured appear to be very small for Ethiopia, given its demographic profile and maternal mortality rate.

Table 11 **Ethiopia's estimated demand for MH products**

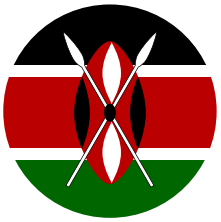
Product	Highest awarded qty/year	40% of highest awarded qty	Estimated annual demand
Magnesium sulfate 50% in 10 ml injection	409,005	163,602	572,607
Mifepristone 200 mg + misoprostol 200 mg	1,128,276	451,310	1,579,586
Misoprostol 200 mg	678,658	271,463	950,121
Oxytocin 10 iu inj.	4,900,960	1,960,384	6,861,344

Ghana

The key actors in the Ghana public health sector supply chain are the Ghana Health Service (GHS), the MoH, and the central and regional medical stores. Awarded contracts data listed on the Public Procurement Authority's (PPA) website and in the Ghana Electronic Procurement System (GHANEPS) show that the GHS procures the majority of public sector essential medicines; additionally, there are a few tenders awarded by government, district, and teaching hospitals. Essential medicines contracts are listed on the PPA website and in the GHANEPS portal. It was not clear to us if the two systems are linked. The PPA lists 450 awarded contracts running from 2012 to 2024, but this list could only be viewed and not downloaded or copied. The information provided for the listed contracts is limited to the name of the awarding agency, tender number, description ("essential medicine, various quantities"), contract dates, value, and awarded supplier. The same applies to contracts listed on GHANEPS. The import data is summarized in **Table 12**. Although there is no regional producer currently supplying the market, we deemed it necessary to correlate this import data with procurement data to fully capture the demand in Ghana, due to potential re-exports to neighboring countries. Because we were not able to correlate import and procurement data from these sources, we were not able to conduct the demand assessment in Ghana.

Table 12 **Ghana: Imported MH products 2020 – 2023**

Year	Product Description	Imported Quantity
2020	Carbetocin 100 mcg/1ml injection	3,750
2021	Carbetocin 100 mcg/1ml injection	10,000
2022	Carbetocin 100 mcg/1ml injection	15,200
2023	Carbetocin 100 mcg/1ml injection	6,500
2020	Magnesium sulfate injection 50%	4,700
2021	Magnesium sulfate injection 50%	13,400
2022	Magnesium sulfate injection 50%	13,000
2023	Magnesium sulfate injection 50%	-
2020	Misoprostol tablets 200 mg (6x10 blister)	18,105
2021	Misoprostol tablets 200 mg (6x10 blister)	25,098
2022	Misoprostol tablets 200 mg (6x10 blister)	25,496
2023	Misoprostol tablets 200 mg	15,952
2020	Oxytocin inj. 10iu/ml	27,522
2021	Oxytocin inj. 10iu/ml	44,966
2022	Oxytocin inj. 10iu/ml	264,043
2023	Oxytocin inj. 10iu/ml	175,700
2020	TXA inj. 100 mg/ml	119,012
2021	TXA inj. 100 mg/ml	149,792
2022	TXA inj. 100 mg/ml	86,256
2023	TXA inj. 100 mg/ml	61,601
2020	TXA tablets 500 mg	1,000
2021	TXA tablets 500 mg	14,296
2022	TXA tablets 500 mg	2,531
2023	TXA tablets 500 mg	6,700



Kenya

Kenya Medical Supplies Authority (KEMSA) is a state corporation responsible for procuring, warehousing, and distributing drugs and medical supplies for prescribed public health programs, the national strategic stock reserve, prescribed essential health packages, and national referral hospitals.[40] We assessed and reviewed a list of 128 pharmaceutical contracts awarded from 2017 to January 2023. The list does not include names of products and quantities awarded, and so we were not able to identify which awards were for the relevant MH products. Using contract reference numbers, we conducted further research and determined the names and quantity estimates which were advertised for the relevant MH products. However, we still could not match this information with the contracts awarded. An example of a tender for the supply of pharmaceuticals advertised in 2021 is provided in **Table 13** below. A total of 22 lots are listed in this tender, including two lots for magnesium sulfate and oxytocin injections. The second section of the table lists the tender award information as downloaded from the public procurement information portal (PPIP). The only information that is common in the two sections is the tender/contract number.

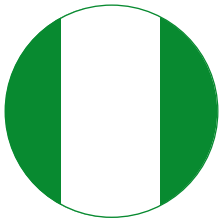
Table 13 Example of a tender for the supply of pharmaceuticals

KEMSA/OIT01/2021-2023		SUPPLY OF HEALTH PRODUCTS (PHARMACEUTICALS)		
Lot No.	**Item code**	**Item description**	**Pack size**	**Initial quantity**
15a	PM06MAG001	$MgSO_4$ Injection 50%, 10ml		105,493
15b	PM06MAG001	$MgSO_4$ Injection 50%, 10ml		70,328
17a	PM10XYT001	Oxytocin injection 10IU/ml	Ampoule	1,259,678
17b	PM10XYT001	Oxytocin injection 10IU/ml	Ampoule	839,786

Supplier	Contract No.	Value	Start date	End date
Laboratory and Allied Limited	KEMSA/OIT01/2021-23	137,061,659	16/11/2021	15/11/2023
Harley's Limited	KEMSA/OIT01/2021-23	112,542,476	11/11/2021	10/11/2023
Crown Solutions Limited	KEMSA/OIT01/2021-23	256,090,903	16/12/2021	15/12/2023
Zan Global Limited	KEMSA/OIT01/2021-23	163,574,275	02/12/2021	01/12/2023
Regal Pharmaceuticals Limited	KEMSA/OIT01/2021-23	40,386,463	11/11/2021	20/12/2023
Reddys Pharma Limited	KEMSA/OIT01/2021-23	12,934,396	15/12/2021	10/11/2023
Surgilinks Limited	KEMSA/OIT01/2021-23	131,062,558	23/11/2021	22/11/2023

Based on the findings of the data review exercise coupled with our unfruitful attempts to secure additional data, we concluded that there is insufficient published tender award information on MH products to effectively estimate the demand for the relevant MH products in Kenya.

[40] Kenya Medical Supplies Authority (KEMSA). Vision & Mission Statements. https://www.kemsa.go.ke/vision-mission-statements-2/.



Nigeria

The Nigerian public procurement system is complex and highly fragmented. It works through several actors at the federal and state government levels. The country's federal public procurement is overseen by the Bureau of Public Procurement, while state governments manage their own public procurement portals. In most of the country's 36 states, medicines are procured mainly through the Drug Revolving Fund system (designed as a profit-based parastatal entity), the Central Medical Stores, public procurement agencies, and health supplies management agencies. Secondary and tertiary hospitals also conduct their own procurement directly through hospital pharmacies. In some states, procurement of medicines for public health facilities is driven by donors and international NGOs. Nigeria Open Contracting Portal (NOCOPO), the official contracting portal for the federal government, lists 23,690 projects. We filtered the list by several criteria—MoH, hospitals, health centers, and status and stage of project—but could not find a single project/contract for the procurement of medicines or pharmaceutical products.

In the absence of tender award information in the public domain, we sourced import data of the MH products of interest from 2019 to 2023. This data is shown in the **table 14** below.

Emzor Pharmaceutical Industries, which is based in Nigeria, manufactures misoprostol, and Juhel Nigeria Limited manufactures magnesium sulfate and oxytocin. These manufacturers have indicated through our survey that they supply significant quantities to public health systems. Consequently, the import data in Table 14 does not give an accurate reflection of Nigeria's approximate demand for magnesium sulfate, misoprostol, and oxytocin. Relying solely on import data to determine Nigeria's demand becomes problematic, especially given the fluctuation in quantity from year to year. As a result, the uncertainty surrounding the data prevented us from conducting a thorough gap analysis to inform the level of regional production required to meet the demand.

Table 14 **Nigeria: Imported MH products 2019 – 2023**

Year	Product Description	Quantity
2022	Carbetocin ferring 100 mcg/1ml inj.	4,322
2023	Carbetocin 100 micrograms/ML 1ML INJ, 10 AMP	2,401
2019	Magnesium sulfate injection 50%	5,000
2020	Magnesium sulfate injection 50%	1,000
2021	Magnesium sulfate injection 50%	729
2022	Magnesium sulfate injection 50%	63,264
2023	Magnesium sulfate injection 50%	6,030
2021	Misoprostol tablets 200 mg	100,000
2022	Misoprostol tablets 200 mg	721,348
2019	Oxytocin inj. 10iu/ml	1,759,200
2020	Oxytocin inj. 10iu/ml	283,758
2021	Oxytocin inj. 10iu/ml	2,000
2022	Oxytocin inj. 10iu/ml	232,500
2023	Oxytocin inj. 10iu/ml	2,000
2019	TXA inj. 100 mg/ml	182,192
2020	TXA inj. 100 mg/ml	1,530
2022	TXA inj. 100 mg/ml	40,566
2023	TXA inj. 100 mg/ml	1,066
2020	TXA tablets 500 mg	980
2021	TXA tablets 500 mg	1,126,661
2022	TXA tablets 500 mg	134,114
2023	TXA tablets 500 mg	96,320

[41] A Brief Report on Nigeria's Procurement System for Maternal Health Medicines." Nigeria Health Watch, October 2022, https://www.nigeriahealthwatch.com/reports/download/7#:~:text=The%20state's%20procurement%20of%20maternal,the%20last%20quarter%20of%202021.

South Africa

In South Africa, the national Department of Health's (DoH) procurement unit is responsible for the forecasting, quantification, and administration of all tenders and for the procurement of all health commodities. The provinces have limited autonomy and can elect to order products independently of and outside the national government tender. However, the DoH works with the provinces to quantify usage in the preceding tender and adjusts the volumes accordingly for new tenders. During the course of a tender, the DoH and the provinces share information on utilization, supplier performance, etc. Because most of this is dependent on the accurate reporting or completing of the necessary information capture forms (paper-based or electronic), it is prone to error. Significantly, a lot of off-tender procurement is driven by the provincial drug depots or the hospitals. Hospitals have small discretionary budgets (allocated to the Hospital Chief Pharmacist) for cases of emergency or medicines not yet on tender, but which are required for specialized care for some patients. In most cases, contracted suppliers have reported that they supplied more quantities than those awarded. As a result, it is generally assumed that awarded quantities are approximately 30 percent less than the actual demand. However, significant improvements have been reported in recent years. Since approximately 2019, the DoH has been working with USAID's Global Health Supply Chain Program to develop the Medicine Master Data System. This system will provide a centralized, uniform set of master data related to medicines and will ensure that medicines master data can be exchanged and processed across different networks in the public health medicine supply chain.[42] Once fully operational, the system is expected to improve medicine availability, enhance data analysis for better planning, and support cost-effective budgeting.

Table 15 below presents tender award information compiled from published DoH documents. Magnesium sulfate, oxytocin, and TXA injections are procured under tender 'HP06 – SVP' (small volume parentals) every three years. Prior to 2021, procurement was conducted every two years by the National Treasury on behalf of the DoH. The same applies to misoprostol tablets, which are procured under tender 'HP03-CHM' (contraceptives and hormones modulating agents) and TXA tablets procured under tender 'HP09-SD' (solid dosage forms).

The data presented in Table 15 show a trend in quantities procured, with increases from one procurement cycle to the next, except for misoprostol and TXA tablets, whose quantities dropped by more than 30 percent from the previous to the latest procurement cycle.

Table 15 South Africa - annual quantities of MH products awarded on tender

Start date	End date	Item specification	3-year qty.	1-year qty.*
5/1/2019	4/30/2021	Magnesium sulfate, 50%, Injection, 2ml Ampoule	2,896,910	1,448,455
5/21/2021	4/30/2024	Magnesium sulfate, 50%, Injection, 2ml	5,111,040	1,703,680
5/1/2024	4/30/2024	Magnesium sulfate, 50%, Injection, 2ml	5,272,098	1,757,366
10/1/2017	9/30/2020	Misoprostol 200mcg tablet, 60 tablets	59,180	19,727
10/1/2020	9/30/2023	Misoprostol 200mcg tablet, 60 tablets	64,678	21,559
10/1/2023	9/30/2026	Misoprostol 200mcg tablet, 60 tablets	43,120	14,373
5/1/2019	4/30/2021	Oxytocin 10 IU injection, 1ml	2,154,740	1,077,370
5/1/2021	4/30/2024	Oxytocin 10 IU injection, 1ml	6,406,260	2,135,420
5/1/2024	4/30/2027	Oxytocin 10 IU injection, 1ml	5,925,760	1,975,253

*Estimate

[42] USAID. Technical Brief: Medicine Master Data System Global Health Supply Chain Program – Technical Assistance, https://www.ghsupplychain.org/sites/default/files/2020-12/GHSC-TA%20Technical%20Brief_MMDS_2019.09.16%20V.F_508%20compliant.pdf

Table 15 (continued) **South Africa - annual quantities of MH products awarded on tender**

Start date	End date	Item specification	3-year qty.	1-year qty.*
5/1/2019	4/30/2021	Magnesium sulfate, 50%, Injection, 2ml Ampoule	2,896,910	1,448,455
5/21/2021	4/30/2024	Magnesium sulfate, 50%, Injection, 2ml	5,111,040	1,703,680
5/1/2024	4/30/2024	Magnesium sulfate, 50%, Injection, 2ml	5,272,098	1,757,366
10/1/2017	9/30/2020	Misoprostol 200mcg tablet, 60 tablets	59,180	19,727
10/1/2020	9/30/2023	Misoprostol 200mcg tablet, 60 tablets	64,678	21,559
10/1/2023	9/30/2026	Misoprostol 200mcg tablet, 60 tablets	43,120	14,373
5/1/2019	4/30/2021	Oxytocin 10 IU injection, 1ml	2,154,740	1,077,370
5/1/2021	4/30/2024	Oxytocin 10 IU injection, 1ml	6,406,260	2,135,420
5/1/2024	4/30/2027	Oxytocin 10 IU injection, 1ml	5,925,760	1,975,253
5/1/2019	4/30/2021	Oxytocin 5 IU injection, 1ml	468,585	234,293
5/1/2021	4/30/2024	Oxytocin 5 IU injection, 1ml	1,031,980	343,993
5/1/2024	4/30/2027	Oxytocin 5 IU injection, 1ml	1,394,530	464,843
5/1/2019	4/30/2021	Oxytocin 5 IU Ergometrine 0.5mg, injection, 1ml	150,980	75,490
5/1/2021	4/30/2024	Oxytocin 5 IU Ergometrine 0.5mg, injection, 1ml	538,290	179,430
5/1/2019	4/30/2021	Tranexamic acid 100mg/ml, injection, 5ml	907,200	453,600
5/1/2021	4/30/2024	Tranexamic acid 100mg/ml, injection, 5ml	1,734,980	578,327
5/1/2024	4/30/2027	Tranexamic acid 100mg/ml, injection, 5ml	2,090,666	696,889
5/1/2019	4/30/2021	Tranexamic acid 500mg tablets (30)	17,140	8,570
5/1/2021	4/30/2023	Tranexamic acid 500mg tablets (30)	351,281	117,094
5/1/2023	4/30/2026	Tranexamic acid 500mg tablets (30)	221,410	73,803

*Estimate

We relied on tender award data to determine annual demand, assuming that the latest awards reflected the current forecast for these products. In estimating annual demand, we increased the annual quantities for each product by 30 percent, the general assumed quantification error. The results for South Africa are summarized in **Table 16**.

Table 16 **South Africa's estimated demand for MH products**

Item specification	3-year qty.	1-year qty.*	Annual demand*
Magnesium sulfate 50% injection, 2ml	5,272,098	1,757,366	2,284,576
Misoprostol 200mcg tablet, 60 tablets	43,120	14,373	18,685
Oxytocin 10 IU injection	5,925,760	1,975,253	2,567,829
Oxytocin 5 IU, Ergometrine 0.5mg, injection 1 mg	1,394,530	464,843	604,296
TXA 100 mg/ml injection	2,090,666	686,889	905,955
TXA 500 mg tablets (30)	221,410	73,803	95,944

*Estimate

Challenges and opportunities

Challenges to regional manufacturing and access for MH products in SSA

SSA relies on imports for nearly 70 percent of its medicines.[43] The reliance on imported MH products considered in this study is much greater than this percentage. Only magnesium sulfate is manufactured by four regional manufacturers, who are based in four separate countries. Oxytocin, misoprostol, and TXA are each currently manufactured by only one regional producer. These manufacturers are not remotely satisfying the demand in their countries of production. The lack of regional manufacturing contributes to the fragility of public health supply chains in SSA. Investments and interventions are needed to minimize the risk of disruption. This study clearly identifies opportunities to expand the manufacturing base of MH products, thereby strengthening the supply chains and potentially bringing other benefits, as well.

For the manufacturers in this study, plant utilization rates range from 10 to 60 percent, with a median of 40 percent, which presents an opportunity for increased regional production and supply. The factors most influencing the utilization rates include reliance on imports for raw materials, lack of readily available equipment and parts, limited access to affordable financing, and intense competition from imported goods (**Table 17**). Collectively, these factors discourage growth in regional manufacturers' operations and in their readiness to respond to market needs. Generic manufacturing is a relatively low-margin business in which manufacturers must compete globally to survive and thrive. In resource-scarce settings, governments tend to procure from suppliers offering competitively lower prices.

Increased access to markets outside of their own country can greatly benefit regional manufacturers, to improve their economies of scale, reduce the conversion cost, and expand their capability to improve quality and cost to meet international norms and to become more competitive in SSA, where there is constant and relentless pressure on suppliers to reduce prices.

Table 17

Factors impacting utilization rates of manufacturing plants in decreasing order of importance

Access to affordable finance	High impact
Competition from imports	
Equipment and spares limited	Medium impact
Access to raw materials	
Lack of diversified portfolio	Low impact
Shortage of skilled labor	

[43] Di Caelers. Drug manufacture-tech transfer compact holds promise for replication across Africa. Highly efficient, cost-effective reactor produces significant quantities in just hours. Nature Africa, 2023.

Another critical barrier to access to MH products involves the lack of regulatory harmonization in SSA, the slow and opaque national regulatory systems hindering access to regional markets, and the requirement for companies to incur considerable costs to achieve and maintain product registrations in multiple jurisdictions with no assurance of speedy approvals or access to markets. Historically, it has taken manufacturers four to seven years to obtain the final approval for market authorization in some SSA countries.[44] Recent efforts by regional and continental regulatory bodies to implement various strategies to significantly improve the lag time are paying dividends. For example, in 2013, countries in the Southern African Development Community implemented the Zazibona initiative to reduce the approval time to eight months through the adoption of the collaborative registration procedure or CRP. Since then, steady progress has been made. From 2019 to 2020, for example, the average range of approval time was reduced from 218-890 days to 158-696 days.[45] Similarly, in the East Africa Community, the joint assessment procedure established in 2015 helped to reduce the market authorization timeline from 24 months to 8-14 months. In 2021, in West Africa, the ECOWAS regulatory harmonization framework was adopted, allowing a joint assessment procedure to also reduce the timeline of the market authorization.

At the continental level, the establishment of the African Medicines Agency (AMA) represents an important milestone. The AMA aims to develop common standards and regulations, coordinate reviews of clinical trial applications, coordinate the review of dossiers, and share information about market authorizations. The functionalization of the AMA may significantly streamline the regulation of medical products in Africa. These efforts will need to be sustained and expanded, to improve efficiency and to facilitate more cost-effective product registrations across SSA.

Most national departments of health and procurement units operate in silos; forecasting and quantification is inaccurate in part because clinics and hospitals, as well as central medical stores, historically keep poor records of usage patterns. The lack of access to market data, especially transparency around demand patterns and utilization, further discourages potential suppliers from entering selected markets as they encounter low volumes on public procurement portals or a total lack of clarity about the market potential for individual products.

A further impediment to access comes from the widespread prevalence of substandard and falsified (SF) medicines, which enter the supply chain irregularly and find their way into clinics, hospitals, and other types of outlets. When SF medicines are found and enforcement action taken, drug shortages can ensue.

Stigma and cultural and religious practices can also impact the adoption and utilization of products such as misoprostol, which has multiple applications for gastric ulcers, PPH, and post-abortion care, but is often viewed only through the medical abortion lens. This can lead to resistance to use or even procurement of suboptimal quantities for fear of the drug being “abused.”

[44] Ahonkhai V, Martins SF, Portet A, Lumpkin M, Hartman D. Speeding access to vaccines and medicines in low- and middle-income countries: a case for change and a framework for optimized product market authorization. PLoS One. 2016;11(11):e0166515. doi: 10.1371/journal.pone.0166515.

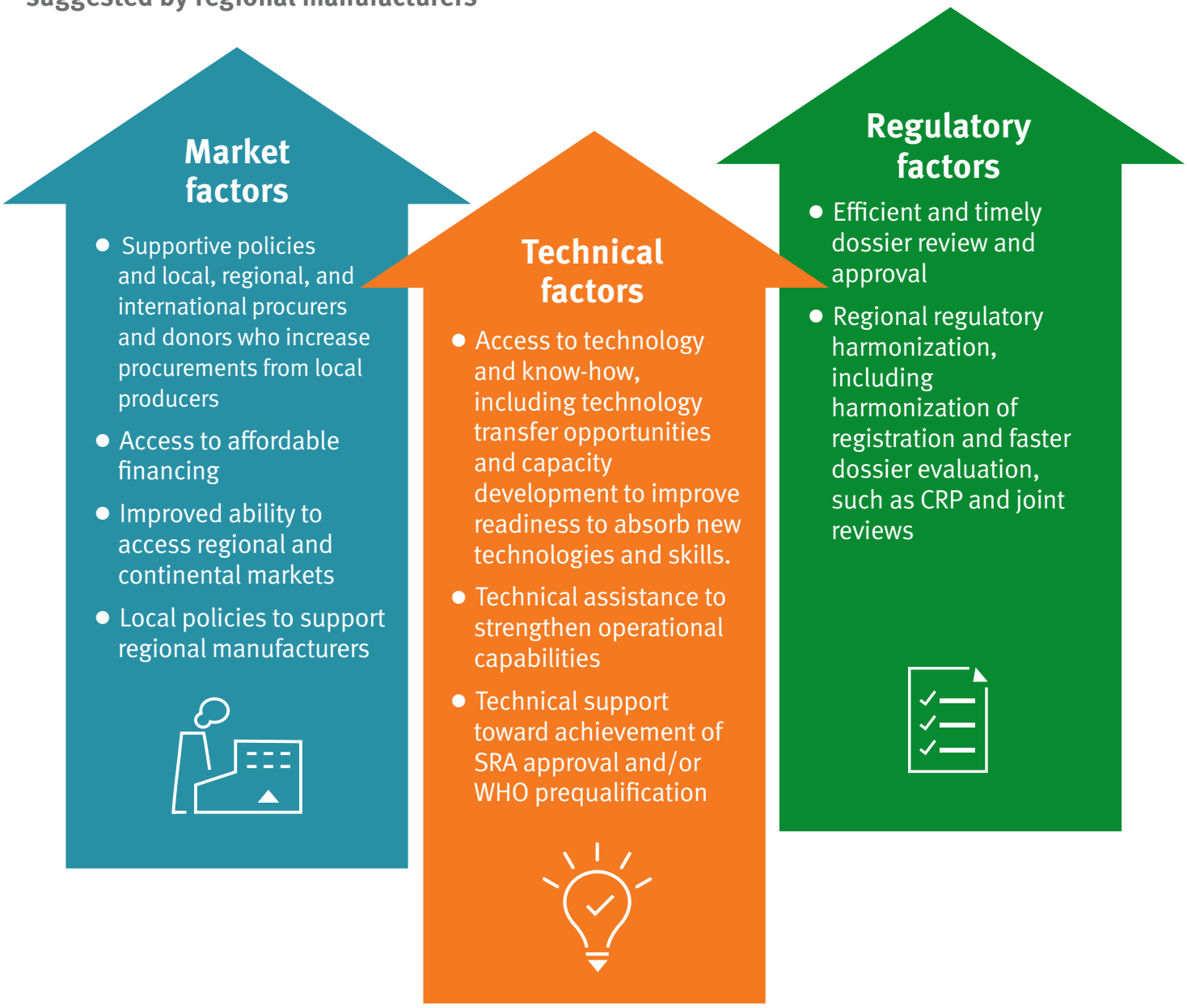
[45] Sithole T, Mahlangu G, Capote V, Sitoie T, Shifotoka S, Gaeseb J, Danks L, Nkambule P, Juma A, Fimbo A, Munkombwe Z, Mwale B, Salek S, Walker S. Evaluation of the Review Models and Approval Timelines of Countries Participating in the Southern African Development Community: Alignment and Strategies for Moving Forward. Front Med (Lausanne). 2021 Aug 27;8:742200. doi: 10.3389/fmed.2021.742200. PMID: 34513894; PMCID: PMC8429484.

Interventions to increase access and affordability

Simplifying regulatory processes and approvals is a critical step in improving access and building more resilient supply chains in SSA. A predictable, reliable, cost-effective, and harmonized regulatory regime will entice more regional and international companies to register their products in the markets of interest, increasing competition and alternative sources of supply, and exerting a downward pressure on market prices. Providing technical support to interested companies in negotiating in-country or regional regulatory processes, to support early product introduction or the entry of multiple suppliers, might also help to a lesser extent to broaden access and supply. In cases where donor-supported markets require WHO-prequalified products, assistance to regional manufacturers would be critical in helping them to qualify as suppliers.

Table 18

Interventions that will increase the production of MH products in SSA, suggested by regional manufacturers



Procurers' choice of product is also very important to improving access. Products such as oxytocin that require a cold chain are problematic for many developing health systems and in rural hospitals and clinics that may not have a reliable power supply. Working with MoHs and funding and procurement agencies to diversify product choice in light of local conditions is key to increasing access. Offering guaranteed offtakes (agreement to buy in advance) as a tool can encourage pharmaceutical manufacturers to invest in research and development, in order to develop new formulations that are more adapted to regional needs, and it would also improve access. In addition, where national governments have not included certain products in their EMLs (e.g., heat-stable carbetocin), it is important to collaborate with key opinion leaders, MoHs, procurement agencies, and healthcare providers (via continuing professional education) to increase product awareness.

Interventions to respond to the lack of market data and information asymmetry are critical to improve market visibility and increase the interest of new manufacturers. Access to market data is crucial to increase the understanding of consumption patterns in both the public and private sectors, as well as for funded programs. Procurement reforms, including adopting central master data and electronic procurement systems, simplifying procurement patterns, and increasing robustness in forecasting and quantification are also important steps that give manufacturers greater certainty of volumes and enable them to plan and price properly.

The share of the healthcare budget allocated to maternal and child health is often woefully inadequate for the size of the population, the birth cohort, and maternal mortality statistics. This often leads to product shortages. Countries should continue to consider designing healthcare interventions to effectively meet the local needs.

Recommendations

Supporting regional production is an important intervention that can promote availability, access, and affordability of these essential medicines in the long run. These recommendations aim to address the challenges and opportunities identified in the course of our research. Their implementation will contribute to the growth and improvement of the MH product manufacturing industry in SSA and help to address the access barriers that currently exist.

Regulatory

Maintain up to date NMRA data on registered products. The supply of quality-assured medicines in a given country relies on the efficiency of its NMRA to effectively provide oversight for the importation and production of pharmaceutical products. Therefore, it is essential that NMRAs in each of the countries surveyed and in SSA more broadly maintain and regularly update a database with accurate records of licensed MH products. This will help to ensure that the information reflects the current availability of drugs in the market and does not contain unnecessary repetition or omissions. For example, this (and other) research has revealed companies that may be manufacturing products for a country, which are not in the NMRA registers. Further investigations need to be conducted to understand the root causes of lack of maintenance of regulatory registers and to formulate adequate solutions.

Improve the consistency of NMRA reporting of data variables. There is a wide discrepancy in the data variables reported by NMRAs across the region. A few are well-detailed, but many are not. In some cases, there may be similarities in the variables' content, although the variable names may differ. Consistent information reporting among NMRAs has the potential to support the functionalization of the AMA and improve transparency and access. This transparency and accessibility can help healthcare providers, policymakers, and global health partners to make informed decisions regarding drug procurement and supply chain management.

Sustain efforts toward regulatory harmonization or convergence. It is notable that many steps have been taken at the regional level toward regulatory harmonization. However, efforts to simplify and harmonize the regulatory processes for the registration, approval, information sharing, and determination of the cost of registration should be further increased. Equally, regional regulatory bodies working with global health partners should raise awareness and offer guidance and support to regional manufacturers to effectively navigate regulatory processes. This will encourage early product introduction and could lead to more efficient and effective processes. One of the consistent complaints of regional (and international) producers has been the difficulties encountered in registering their products across borders. National and regional regulatory authorities should streamline and expedite the registration process for MH products across borders and reduce registration fees and expenses. Simplified registration procedures will encourage manufacturers to expand their market reach, benefiting both regional producers and regional health systems. NMRAs should continue to prioritize rigorous evaluation of drug safety, efficacy, and quality during the registration process to ensure that only high-quality MH medicines are made available to patients.

Regional manufacturing

Strategically diversify the manufacturing footprint across the region. It was a positive outcome of this study to learn that there is at least one manufacturer producing oxytocin, magnesium sulfate, misoprostol, and TXA in SSA. While existing and prospective manufacturers express intentions to scale up production of these medicines, it is crucial to ensure that the establishment of new production capacities does not surpass the regional demand and lead to market fragmentation. Expanding production to additional countries in SSA will enhance the resilience of the supply chains of MH products in the region and improve the sustainability of regional manufacturing of these products. However, achieving this goal requires the establishment of regional or continental coordination platforms that involve regulatory bodies, manufacturers or manufacturers associations, and procurement agencies. Such coordination is essential to prevent the fragmentation of the sector, while fostering competition for high quality products.

Support technical assistance to build capacity. Global stakeholders should consider supporting the provision of technical assistance for regional manufacturers. This assistance could include support for regulatory filings such as the Common Technical Document, assistance to continue to improve GMPs, and increase capacity to efficiently and effectively adopt new technologies and skills. Many surveyed manufacturers expressed the necessity for technical support to navigate various regional regulatory guidelines as well as the WHO prequalification process. Obtaining the WHO PQ demonstrates the manufacturer's adherence to international guidelines and assures that the medical product meets international standards of quality, safety, and efficacy. Supporting the regional manufacturers in obtaining the prequalification of their products is critical not only to ensure public access to quality-assured medicines but also to enable manufacturers to expand their customer base to international procurement agencies and increase their credibility in the global market.

Create knowledge-sharing platforms. Knowledge-sharing platforms would enable manufacturers to exchange best practices, regulatory insights, and market information, and would help to strengthen the region's MH product manufacturing landscape. This sharing could foster collaboration between manufacturers, regulatory authorities, and international organizations to address common challenges in SSA's MH product manufacturing industry. For example, technology transfer and collaborative research and development in the region with global health partners will improve product development capabilities and reduce dependency on foreign technologies, thus lowering associated costs.

Procurement

Establish comprehensive market sizing for MH products. In the course of this study, it was challenging to effectively determine the demand for MH products in many countries. Many regional manufacturers face the same challenge, making it difficult to develop a business case and to determine the level of investment and production required to meet demand. Governments and procurement agencies should consider increasing transparency by publishing detailed tender awards, including products, names, and quantities, to facilitate accurate demand estimates. Additionally, a more comprehensive market sizing study that includes off-tender procurement is warranted in the SSA region to fully estimate the market and effectively determine existing supply gaps.

Prioritize procurement from regional manufacturers as a disruption mitigation strategy. National ministries and global health partners should consider diversifying their supplier bases for critical medicines. Overreliance on a limited number of international manufacturers, as seen with oxytocin and TXA in some countries, can pose risks to supply chains. Prioritizing procurement from regional manufacturers can mitigate these risks. To avoid potential shortages in and disruptions to the supply chains, countries should establish more rigorous mechanisms to monitor the reliability of manufacturers in supplying registered drugs. These mechanisms may include tracking the volume of products procured and assessing the consistency of supply.

Guarantee volume through pooled procurement to support regional manufacturing. The adoption of regional, pooled procurement of MH products could improve price negotiation and support growth in regional manufacturing. Given that the main buyers of MH products from regional manufacturers are public health systems, a pooled public sector procurement of these products will increase the sustainability of regional production. Market shaping interventions, such as price and volume guarantees, might further incentivize manufacturers to make additional investments to expand the production of MH products; however, market shaping initiatives such as volume guarantees often have unintended consequences, and they should only be entered into after careful consideration. Developing and implementing policies that promote regional procurement of MH products by regional and national health systems will strengthen the domestic markets and create a more stable demand for regional manufacturers.

Conclusion

Efforts to ensure a stable and diverse supply of MH products are crucial to guaranteeing access to lifesaving drugs in SSA and, ultimately, to improving health outcomes in the region. Our study has shown that the availability and sourcing of essential medications in SSA currently has both strengths and vulnerabilities. While several countries have a diversified supply chain for products such as misoprostol and TXA, others depend heavily on sourcing from a narrow set of countries and manufacturers. On the one hand, oxytocin is predominantly sourced from India. On the other hand, magnesium sulfate is the most manufactured MH product in SSA. HSC remains a niche product, available in only a few countries; there is a recognized need for broader access to this critical medication. Additionally, the overreliance on importation of MH products and the absence of regional manufacturing capacity to meet regional demand underscore the importance of improving regional pharmaceutical capacity.

In conducting this study, we faced challenges in obtaining complete and detailed tender award information across all countries. These challenges included limited data availability and issues related to determining the size of the markets. As a result, we were not able to determine the existing supply gaps. Further efforts are needed to more precisely size the markets in SSA in the future.

This landscape assessment provides valuable insights into the current landscape of MH product manufacturing in SSA. Despite facing challenges related to importation, regulatory barriers, equipment limitations, and skilled labor shortages, manufacturers in the region are committed to increasing the production of these essential medicines. The outlook appears promising, with some manufacturers planning to expand production portfolios and address critical gaps in the supply chains for HSC, magnesium sulfate, oxytocin, and TXA. Collaboration between local governments, regional bodies, and international organizations is essential to overcome challenges and to foster a more robust MH product manufacturing industry. Strengthening the business and regulatory environment and improving access to regional and continental markets and corresponding market data will be crucial to ensuring the availability and affordability of these lifesaving MH products across the region.

The **Reproductive Health Supplies Coalition** is the world's largest network of reproductive health (RH) supplies organizations. Formed in 2004, we are a partnership of more than 500 public entities, private corporations, and NGOs working so that everyone in low- and middle-income countries (LMICs) can access and use affordable, high-quality RH supplies