

Experience from the Field



Supply-Side Insights from Bangladesh, Madagascar and Tanzania

Key learnings and recommendations for the integration of MMS into health programs of low- and middle-income countries

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Key messages

- This situation analysis offers a framework on the market, manufacturing and policy enablers and barriers for the local procurement and production of multiple micronutrient supplements (MMS) in three high-burden countries in South Asia and sub-Saharan Africa (Bangladesh, Madagascar and Tanzania), and includes learnings for other countries interested in introducing MMS into health programs.
- **Market assessment:** prenatal MMS is available in all three countries, but none of the products conform to the United Nations Multiple Micronutrient Preparation (UNIMMAP) formulation.
- **Market assessment:** Bangladesh has a vibrant pharmaceutical industry and also has the capacity to manufacture affordable and high-quality MMS locally. In Madagascar, domestic production capabilities are limited and MMS is currently imported. Hence, the most feasible way to ensure access to MMS in the near future is through government-or-donor-subsidized free distribution to all pregnant women. Tanzania is well placed to become a regional pharmaceutical manufacturing powerhouse.
- **Production assessment:** in all three countries, quality assurance and quality control mechanisms throughout the supply chain would need to be improved to ensure high-quality procurement and production of MMS.
- **Regulatory and policy assessment:** MMS is included in the essential medicines list (EML) in Madagascar, but not in Bangladesh and Tanzania. Including MMS on the EML would subject it to price controls, thus making it affordable for all.

Background

In the contribution entitled ‘The Introduction of Multiple Micronutrient Supplementation Requires a Comprehensive Systems Approach’ by Nita Dalmiya and Roland Kupka in this Special Report (pp. 42–45), UNICEF outlines a systems approach, one component of which is the market shaping of MMS for future country-level and regional scale-up. In partnership with UNICEF, *Sight and Life* conducted a situation analysis of the procurement and production of MMS in Bangladesh, Madagascar and Tanzania in October 2019 and April 2020. Because our study is still ongoing, the present article will only provide key findings of analyses conducted till now, while comprehensive reports are being prepared for individual countries. We applied the *Sight and Life* MMS Supply Analytical Framework (**Figure 1**) for this project.

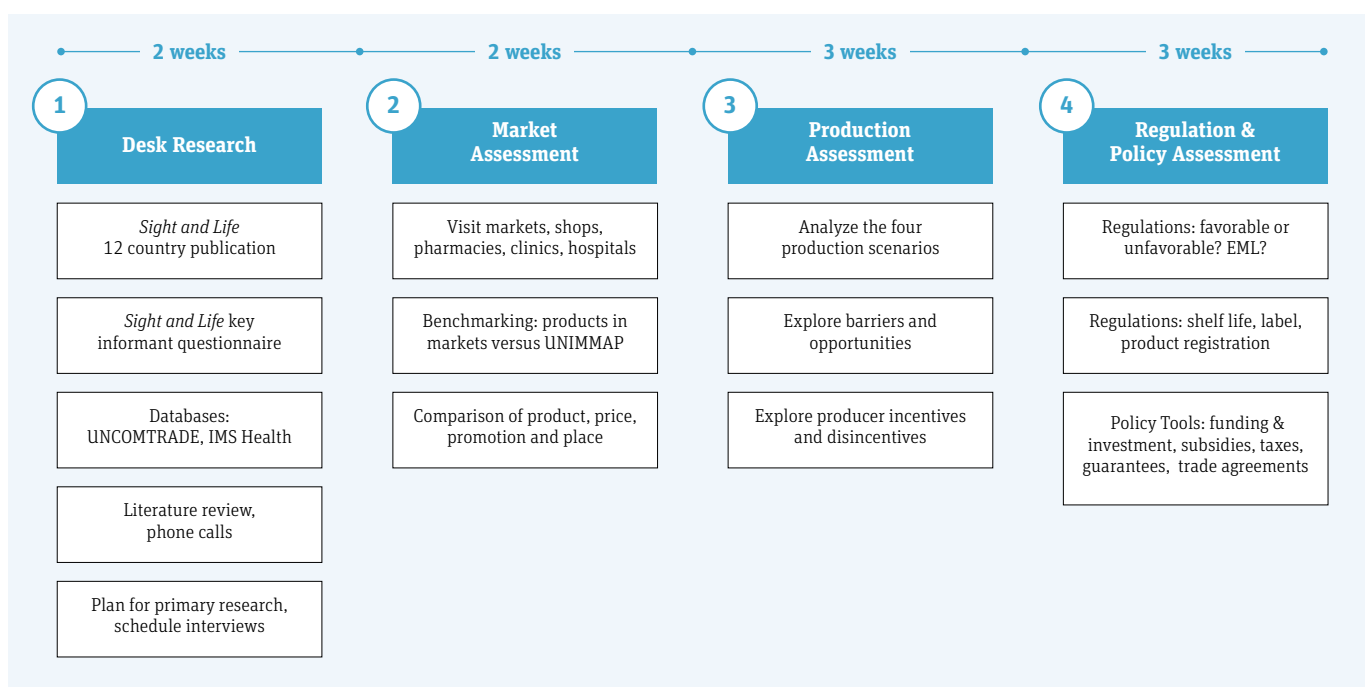
Notes:

1. Analysis is underway in Burkina Faso and will be shared in a subsequent publication
2. Described in ‘Procurement and Production of Multiple Micronutrient Supplements for Pregnant Women: A country assessment toolkit’ by Kalpana Beesabathuni and Kesso Gabrielle van Zutphen on pp. 90–101 of this Special Report

1. Market assessment

Bangladesh has a vibrant pharmaceutical industry and several brands of prenatal multiple micronutrients are available in the market. However, none of them match the UNIMMAP formulation. Most of the prenatal supplements contain a lower number or dosage of critical micronutrients. For example, selenium, which has been shown to have a positive impact on preterm birth, is missing or virtually absent in all of them.² However, a small handful of local manufacturers have already developed, or are currently developing, the UNIMMAP formulation.

In Madagascar, private pharmacies sell imported prenatal MMS products that can only be bought by affluent women, who constitute 16 percent³ of Madagascar’s total population. These imported MMS have a retail price ranging between US\$9.7 and US\$29.0 per package of 30 tablets. There is no free distribution

FIGURE 1: The SAL-MMS Supply Analytical Framework¹

of essential medicines in Madagascar despite it being one of the poorest countries in the world – 71 percent of the population lives below the international poverty line (existing on less than US\$1.90 per day).⁴ In the public distribution channel, there is only one supplement available. This supplement does not meet the nutritional requirements for pregnant women, as it lacks critical micronutrients such as iron, folic acid and selenium. Moreover, it is priced at US\$1.10 for a pack of 30 tablets and is thus not affordable for the poor.

In Tanzania, pharmacies import over 85 percent of the drugs and supplements. We found more than 10 brands of prenatal MMS in these pharmacies, but none of them conform to the UNIMMAP formulation and their price ranges between US\$7.0 and US\$10.0 per 30-count pack. These price points will be affordable to only the 10 percent of the pregnant women in Tanzania who belong to the ‘affluent’ consumer segment (i.e., with a household income in excess of US\$5.5 per day).

One supplement brand made by a local manufacturer, priced between US\$1.40 and US\$4.30 for a pack of 30 tablets, depending on the distribution channel, is more affordable than the imported products. This local brand is sold in both public and private pharmacies in Tanzania. In public facilities, the local brand is prescribed by practitioners. It is free for pregnant women who are anemic. However, it has fewer micronutrients than UNIMMAP and would need to be improved (see **Box 1**).

2. Production assessment

We found significant variability across the three countries for local and sustainable production of MMS, but quality assurance and quality control (QA and QC) remain a common bottleneck.

BOX 1: Market assessment: Key learnings and recommendations

The market assessment reveals a critical need for affordable MMS products that are UNIMMAP-compliant in low- and middle-income countries. Key considerations for facilitating this are noted below:

1. For countries like Bangladesh, which have multiple local brands of MMS in the market, there are several options to introduce MMS using local suppliers in programs. In Bangladesh, the options include two pharmaceutical companies that have both developed UNIMMAP-conformant products.
2. Despite varying levels of local brand availability in the three countries, the affordability of prenatal supplements is a key issue, especially for low-income women. Ensuring free access to MMS will be critical. Thereby, including UNIMMAP MMS in the EML will be an important price control lever. For example, in Bangladesh, once an item is on the EML, its price is monitored, fixed and cannot be exceeded even through commercial channels.
3. To increase product availability in an affordable manner, there is an opportunity for a cross-subsidy model in countries with low manufacturing capacity and rising disposable incomes, like Tanzania. In a cross-subsidy model, the same MMS would be available to

all pregnant women, with differential pricing based on income group or general ability to pay. An example of such a model can be found in Mexico: *Farmacias Similares*,⁵ a pharmaceutical chain serving the base of the pyramid in the country, provides unbranded but high-quality generic drugs and supplements that are up to 75 percent cheaper than branded drugs.

4. Meanwhile, for a country like Madagascar, which has no local manufacturing and chronic poverty, the most feasible way to ensure access to MMS in the short to medium term is through free distribution to all pregnant women, given that MMS is already on the EML of the country.

“Quality assurance and quality control (QA and QC) remain a common bottleneck”

Many Bangladeshi manufacturers have tableting, capsuling and blending capabilities and procure straight ingredients. Several facilities in the country have WHO Good Manufacturing Practices (GMP) certification and the capacity to meet all local demand and increase production if required. Some of them have US Food and Drug Administration approval. When demand surges, Bangladeshi manufacturers would have to import equipment in order to increase production capacity or build new facilities.

Local manufacturers expressed minimal challenges along the QA/QC value chain. However, in our interviews with international agencies that procure locally, and through our own experience in conducting independent lab tests, we found that some of these local products do not meet the label claims and GMP requirements. In Bangladesh, it is common for pharmaceutical companies to manufacture products for local markets under less stringent conditions than those used for products destined for export markets.

In Madagascar, there is no local MMS manufacturing capacity, and all drugs are imported. The government imposes a high import duty as well as value added tax (VAT) on raw materials for drugs. These together add up to 40 percent. Furthermore, social and physical infrastructure is underdeveloped and insufficient to support local production.

In Tanzania, one local manufacturer has the capacity to produce UNIMMAP-conformant MMS and can start manufacturing right away. The entire local pharmaceutical sector in the country would benefit if the government supports procurement from local manufacturers. There are 13 pharmaceutical companies in Tan-

zania and almost all of them cannot compete with the low-priced imported drugs. They are all producing below their capacity and would need an increase in minimum order volumes to stay competitive. It is possible for these local companies to receive more orders as they have access to the markets of the countries in the Southern African Development Community (SADC), which together have nearly 9 million pregnancies every year (see **Box 2**).⁶

BOX 2: Production assessment: Key learnings and recommendations

Through our interviews and analysis, we identified a number of key actions for countries looking to build local production capacity in the short, medium and long term.

For countries that have the capacity to begin local production in the short term (e.g., Bangladesh and Tanzania), the most important action to consider is:

Partnering with an international premix manufacturer to bring MMS to market in a cost-effective manner.

In our QA/QC analyses of local companies, common issues that emerged were achieving blending consistency and maintaining the stability of the vitamins. High-quality UNIMMAP premix is already being manufactured by leading companies. Partnering with one of these companies will allow local manufacturers to obtain the technical expertise and experience to address challenges in mixing the micro-nutrient ingredients before tableting.

For countries such as Madagascar that have the capacity to begin production in the medium to long term, the most important actions to consider are:

- Build **human resource capacity** to meet the lack of trained industrial pharmacists who can assist with the development of pharmaceutical products.
- **Upgrade** the physical infrastructure (electricity, roads, etc.) to enable last-mile access.
- **Create an enabling environment** (single-window clearance, elimination of kickbacks) for foreign investments and technology transfer, which will allow local producers to upgrade to state-of-the-art facilities.
- A single window clearance body will help **promote and sustain ever-increasing investment flows and will create a competitive investment environment** that promotes the business environment in the country.
- **Lower import duty and VAT on raw materials** for drugs and supplements so that local producers can be competitive with imported products.
- **Lower import duty and VAT on QA/QC equipment**, which is the prerequisite for high-quality production.

3. Regulation and policy assessment

Across all three countries, greater regulatory and policy coherence could improve the affordability of MMS. Of the three countries, Bangladesh has the most effective regulatory environment for local companies to produce MMS affordably. The Drug Administration has set a price ceiling on finished supplements, a low import duty of 5 percent on the straight ingredients and a prohibitively high import duty on finished supplements from foreign companies. In Madagascar, the regulatory environment is also supportive, in that imported drugs are exempt from import duty and VAT. This facilitates the easy and relatively quick importation of MMS for pilots and programs. In Tanzania, the regulatory environment for local companies to produce MMS and other pharmaceutical products at affordable prices needs strengthening. Local manufacturers would need a tax subsidy, especially a reduction of VAT on raw materials, to lower the price of the product to the consumer. Various government ministries would need to work together to create an enabling environment for local pharmaceutical manufacturing.

Currently, UNIMMAP MMS is on the EML in one of the three countries (Madagascar). MMS is registered as a drug, which makes it easier to integrate the supply of MMS into the health system. MMS is not as yet part of the EML in Bangladesh and Tanzania, although with the establishment of Technical Advisory Groups for MMS in both these countries, these bodies may be in a position to advocate its inclusion.

However, the lack of QA/QC processes makes **high-quality procurement difficult**. Each batch of MMS would need to be sent out of the country for lab analysis, which is expensive and is not feasible for local manufacturers. Strong monitoring and enforcement by regulatory authorities is recommended to ensure adequate storage and warehousing conditions and to check the label claims of imported products (see **Box 3**).

BOX 3: Regulation and policy assessment: Key learnings and recommendations

Key recommendations for an enabling regulation and policy environment for a country that is interested in establishing high-quality local production of MMS:

- Develop a revenue structure that minimizes VAT and import duty on raw materials for drugs, including on packaging material.
- Consider imposing import duty on finished drugs and supplements and an import ban for any product that is adequately manufactured by local companies, to ensure local industry stays competitive.
- Harmonize QA/QC processes, standards and compliance across all the products being manufactured locally.

Key recommendations to strengthen the enabling environment for a country that is procuring MMS from abroad:

- Exempt import duty and VAT on finished drugs and supplements such as MMS.
- Establish a strong QA/QC protocol for the batch testing of imported products, along with strong enforcement of storage and warehousing conditions and checking the label claims of imported products.

It is important to note that, in both the local production and overseas procurement scenarios, including MMS in the EML will be a critical factor in enabling integration into maternal nutrition programs. For further details, please see ‘The Case for Reintroducing Multiple Micronutrient Supplements in South Africa’s Essential Medicines List: Creating an enabling environment for nutrition-specific interventions in antenatal care’ by Madhavika Bajoria, Kalpana Beesabathuni and Klaus Kraemer on pp. 61–67 of this Special Report.

“Including MMS in the EML will be a critical factor in enabling integration into maternal nutrition programs”

Conclusion

This situation analysis has described the key elements of the market, manufacturing and policies that are likely to influence the local procurement and production of MMS in three high-burden countries, and offers generalized lessons for other countries interested in introducing MMS into their health programs. We found significant variability across the three countries in terms of local and sustainable procurement and production of MMS. Adequate WHO-GMP-certified manufacturing capacity exists in Bangladesh, along with many local brands. Madagascar is not in a favorable position to produce locally. Meanwhile, in Tanzania, political will, access to SADC markets and technology transfer could be leveraged to support affordable local production of MMS. None of the three countries surveyed had products as per the UNIMMAP formulation, either through private retail or public distribution channels.

In all three countries, greater policy coherence could improve affordability through one or more competitive and sustainable price ceilings, import subsidies, commercial tax exemptions and company tax subsidies. A guiding dossier could help build capacity for QA and QC throughout the supply chain, which is a

prerequisite for ensuring high-quality procurement and production of MMS.

In conclusion, a potential scale-up of MMS will need to be viewed holistically, taking into account manufacturing, policy and human capacity/skill factors, as these will together influence the implementation, sustainability and affordability of MMS in the three countries discussed here and beyond.

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