

SEMA Hormonal IUD Market Assessment & Recommendations Summary

Expanding access to Hormonal Intrauterine Device in
support of sexual and reproductive health and rights
(SRHR)

JULY 2023

Increasing equitable access to sexual and reproductive health (SRH) products is critical to saving lives, promoting gender equality, and advancing communities

About SEMA

Global efforts in the last decade have enabled 60 million additional women and girls to access SRH products. However, these efforts still fall short at meeting consumer needs, particularly the needs of communities in LMICs.

To address the challenges, a multi-stakeholder Steering Committee undertook a consultative process from 2020 to 2021. The committee engaged with over 100 stakeholders globally to envision how to support healthier, more equitable, and more resilient markets for sexual and reproductive health. The group consisted of country leaders, public and private implementers, civil society members, donors, and market representatives who came together to create Shaping Equitable Market Access for Reproductive Health, or SEMA Reproductive Health.

SEMA was announced in July 2021, during the Generation Equality Forum in France, and is currently being incubated within Amref Health Africa. The initiative received support from country governments in Burkina Faso, Nigeria, and Uganda, as well as strategic partnerships from the United States Agency for International Development (USAID), the Foreign, Commonwealth and Development Office of the United Kingdom (FCDO), the United Nations Population Fund (UNFPA), and the Reproductive Health Supplies Coalition (RHSC). Additionally, the Children's Investment Fund Foundation (CIFF), Gates Foundation and the French Ministry for Europe and Foreign Affairs (MEAE) provided initial funding for SEMA.

SEMA currently acts as a collaborative platform and financing vehicle that works with partners across the entire ecosystem of sexual and reproductive health. The initiative aims to better coordinate donor investments, leverage existing expertise, build additional capacity, and optimize limited resources to support healthier markets. By fostering collaboration and coordination, SEMA seeks to optimize resources and achieve greater impact in pursuit of our shared goals.

TABLE OF CONTENTS

4	Introduction
5	Background
6	SEMA Healthy Markets Framework Assessment
9	Market opportunities and recommendations
9	Next Steps

Introduction

Access to sexual and reproductive health (SRH) services and products can transform the lives of women and girls. Access is currently undermined by a range of factors, including restrictive policies, weak health systems, misinformation, poor counseling and social stigma. In addition to these barriers, inadequate product availability and choice is also a critical and growing constraint to faster progress in many countries.

Shaping Equitable Market Access for Reproductive Health (SEMA) was established to transform markets for SRH products. SEMA envisions a world where SRH markets in low- and middle-income countries (LMICs) are healthy, equitable and resilient. In the envisioned world, all people, especially women and adolescent girls, can access the reproductive health products they need.

SEMA has partnered with country and global SRH stakeholders to identify the market challenges that are hindering access to SRH products and to develop interventions to address those challenges. Through this work, SEMA aims to catalyze action to transform private and public markets to better meet SRH needs.



Product attributes

The Hormonal Intrauterine Device (hormonal IUD) is a highly effective, long-acting reversible contraceptive (LARC) method that also provides important non-contraceptive health benefits. These benefits include the treatment of heavy menstrual bleeding and potential reduction in iron-deficiency anemia. The product delivers a localized release of hormone, and results in relatively low overall levels of hormone in the blood system compared with other hormonal methods. The side effects can therefore be less pronounced than those of other hormonal contraceptives. The hormonal IUD can be used immediately postpartum and post-abortion.¹ The product can also reduce menstrual cramping and offer a rapid return to fertility after removal.

Despite notable hormonal IUD uptake in high-income markets, access has historically been limited in LMICs. However, in recent years the SRH community has implemented several hormonal IUD pilot projects in sub-Saharan Africa (SSA). These have demonstrated high continuation rates (81-95% at 12 months) and high satisfaction (80-98% of users report being satisfied or very satisfied).² Further, users across several studies reported they would have chosen a short-acting method or no method at all if the hormonal IUD was not an option. These findings suggest that women do not see the hormonal IUD as interchangeable with other LARCs, and therefore that the method may fill an important gap in the market.

Current state of the market

There are currently two internationally quality-assured³ hormonal IUD products available in LMIC markets. One is made by Bayer (Mirena®) and one by Medicines360 (Avibela®). Mirena® has been approved by the United States Food and Drug Administration (US FDA) for up to eight years of pregnancy prevention. The Medicines360 product (under the brand name Liletta®) is also approved by the US FDA for up to eight years of pregnancy prevention. In addition, Pregna, Meril, Apcor, and HLL Lifecare also manufacture hormonal IUD products.

In 2019, members of the SRH community created a Hormonal IUD Access Group. The aim of the Access Group was to design and implement a comprehensive market-shaping strategy to increase access to the hormonal IUD in LMICs. This access strategy rests on three pillars:

1. Introduction in countries ready and interested in adopting the hormonal IUD with support for critical demand-side activities
2. Improved affordability of existing quality-assured hormonal IUD products
3. Long-term market health and supply security, achieved by ensuring the right number of quality-assured suppliers are active – at appropriate scale – in LMIC markets over time

¹ Note: The World Health Organization's Medical Eligibility Criteria for Contraceptive Use categorizes immediate postpartum insertion [<48 hours] of the h-IUD as a category 1 [no restrictions] in non-breastfeeding women, and as a category 2 [benefits outweigh the risks] in breast-feeding women.

² Rademacher KH, Sripipatana T, Danna K, et al. What have we learned? Implementation of a shared learning agenda and access strategy for the hormonal intrauterine device. *Glob Health Sci Pract.* 2022;10(5):e2100789. <https://doi.org/10.9745/GHSP-D-21-00789>

³ Approved by a stringent regulatory authority, or WHO prequalified

Since it was launched, significant progress has been made in implementing the access strategy. In 2021, the Bayer and Medicines360 products were included for the first time in the UNFPA and USAID procurement catalogues, making the hormonal IUD available to the public sectors in LMICs at an affordable price. Madagascar, Nigeria, Rwanda and Zambia started hormonal IUD rollout in 2021, with more than 100,000 units procured for distribution. Governments and partners are now planning to introduce the product in other countries, such as the Democratic Republic of Congo (DRC), Kenya, Malawi, and Uganda.

03

SEMA Healthy Markets Framework Assessment

About SEMA's Healthy Markets Framework

SEMA strengthens SRH country and product markets to improve SRH outcomes. To support this goal, SEMA developed a Healthy Markets Framework (HMF)⁴ for assessing the health of national and product markets, as well as cross-cutting market enablers. SEMA's assessments are intended to serve as a platform for building consensus on key market challenges, as well as opportunities for action and investment by SEMA and other partners. SEMA recommends that assessments be routinely updated to monitor results and track progress towards healthier market conditions.

The HMF seeks to reflect all major dimensions of market health. SEMA defines these dimensions as:

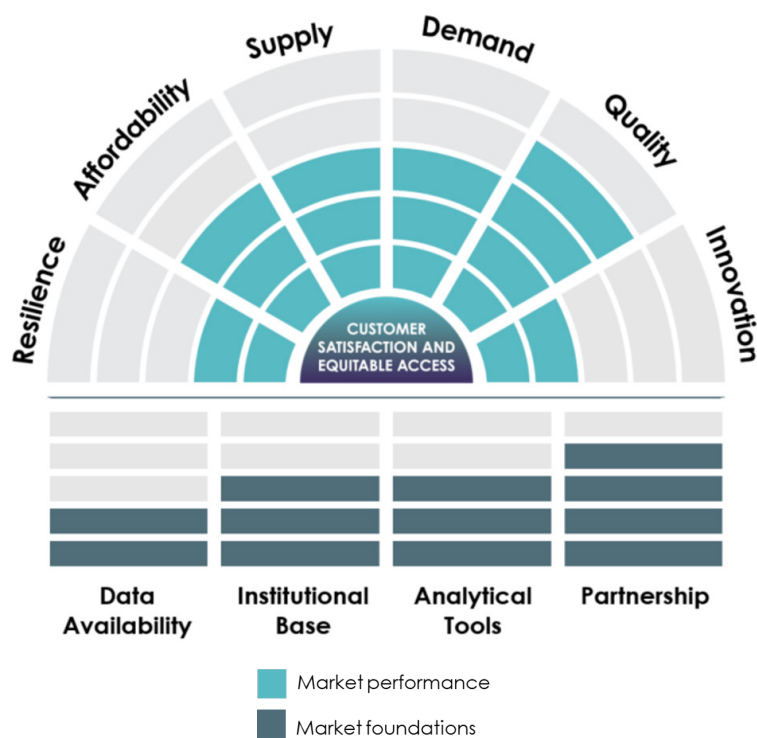
- Resilient supply capable of meeting consumer demand, even amid economic or logistical challenges;
- Resilient financing to meet consumer demand;
- Pricing structures that ensure a sustainable level of affordability across varied markets;
- High product quality;
- A robust innovation pipeline; and
- Adequate structures for regulation, procurement, and market data collection.

The HMF includes a list of indicators to support the assessment of these primary market dimensions. The indicators guide a data collection process for developing composite scores of 1-5 (with 1 being 'unhealthy' and 5 being 'very healthy'). These are then used to populate a simple visual representation of overall market health.

Assessment scores

This section summarizes hormonal IUD market health against each of the HMF components. It is important to recognize that the hormonal IUD has only been introduced in a limited number of LMICs, and that a phased rollout approach is being used to scale up the product. The following assessment ratings therefore reflect this very specific context.

⁴ For detailed descriptions of the HMF and its intended use, see [SEMA Healthy Markets Framework Overview](#). This assessment was undertaken using SEMA's original HMF, which has subsequently been updated to reflect the learnings from this and other assessments.



Market foundations	
Data Availability (2/5)	Data is only available for the small number of countries that are actively introducing the hormonal IUD and/or have supply plans in place. Timely provision of data to inform supply production decisions is also a challenge. Additionally, quality information on consumer insights is still limited, as most consumer data collected so far has been single point-in-time information.
Institutional Base (3/5)	A supportive national and global institutional environment is emerging. The hormonal IUD has been added to institutional buyer catalogues, and LMIC country registrations are increasing. Countries are beginning to add the product to public sector supply chains, and supportive WHO guidelines and statements are now in place. However, only a small number of countries are actually introducing the product.
Analytical Tools (3/5)	The Hormonal IUD Access Group issues a public sector procurement forecast that is shared with key partners. However, the forecast is only updated annually, and is currently focussed on the public sector only.
Partnership (4/5)	Governments, donors, procurers, implementing partners, and suppliers have agreed a phased, focused market strategy. Global and country-level efforts are currently coordinated via the Hormonal IUD Access Group, however these activities will be at risk if funding for the Access Group is not sustained.
Market performance	
Resilience (2/5)	Geographic diversity of hormonal IUD manufacturing is expected to increase in the coming years as both manufacturers plan to develop new production facilities. Product financing is currently adequate but donor dependent.
Affordability (3/5)	Recent efforts have resulted in affordable pricing for hormonal IUD public sector procurement in LMICs. Ongoing collaboration across key stakeholders will be required to facilitate continued affordability over time, and for channels beyond the public sector.
Supply (3/5)	At present, two suppliers offer an affordable, internationally quality-assured hormonal IUD product (currently focused on public sector supply). Additional suppliers manufacture non-quality assured products. The current supply capacity is sufficient to meet initial demand, but continued collaboration is required to ensure future supply security.

Demand (3/5)	Adequate financing is currently in place for public sector procurement to meet initial demand. Additional longer-term financing will be necessary as country and consumer demand increases. Further research is required to understand demand for this product. For example, it is important to know which users are seeking the hormonal IUD, and how the product addresses the needs of new users, as well as users of other family planning products.
Quality (4/5)	Two suppliers produce hormonal IUD products that meet international quality standards at affordable prices for public sector LMIC procurement. As procurement through government and non-state channels increases, retaining international quality standards will be crucial.
Innovation (2/5)	A growing number of countries are ready to introduce the product into their public sector. But funding for critical demand-side introduction efforts is constrained. On the product development side, work is underway on the use of different hormones and shapes.

Assessment findings

This assessment has generated key insights, while also revealing shortcomings and risks – all of which can serve to identify priorities for the next stage of hormonal IUD market shaping. The main findings are as follows:

1. Market foundations are now solid. A well-functioning global partnership is driving strategy, coordination, forecasting, analysis, and delivery. The product has been added to supply chains and procurement catalogues, while policy frameworks have been developed. Market data, though relatively limited, is also strengthening as a growing number of countries introduce and begin to scale up the hormonal IUD.
2.
 - a. To support ongoing market development towards sustainability and equitable access, it is critical that the **global partnership remains adequately resourced**.
 - b. **Enhancing data visibility** will also be essential, moving forward.
3. There is currently an adequate supply of affordable and quality-assured product. However, if the market is to grow in line with desired country strategies, additional effort, coordination and **investment will be required to ensure that supply remains diversified, available and affordable**. In order to introduce and scale-up the hormonal without fear of supply disruption, governments need assurance that there will continue to be an appropriate number of reliable, quality-assured suppliers offering the hormonal IUD at an affordable price.
4. On the demand-side, **additional research is needed to understand the profile of users**, including whether they are new family planning users and/or users shifting from other methods.
5. If the goals of the Access Group strategy are to be achieved, then **additional resources will also be required to support demand-side country introduction efforts**. These resources include training, supportive supervision, and end-user education/awareness.

Current efforts are primarily focused on the public sector and on donor-financed products. Over time, more attention should be given to exploring the integration of these products, along with other under-utilized interventions, into private and commercial channels. Additionally, resilience and overall market performance will be strengthened by expanding financing beyond global procurers to governments and other buyers.

04

Market opportunities and recommendations

Priorities for market development

To address market shortcomings and continue the process of market development, SEMA has identified three priority solutions:

- 1. Supply:** Support Access Group efforts to ensure timely availability of diversified hormonal IUD supply is maintained over time, at adequate levels of scale and affordability.
- 2. Demand:** a) Conduct further research to guide market strategy and understand the demographics and preferences of users selecting the hormonal IUD. As part of this, assess how the product meets the needs of new contraceptive users and those shifting from other modern methods. b) Secure near-term, targeted, catalytic funding for early country-led introduction activities. This support should be delivered in a way that aligns with and builds country-led, cross-product introduction capacity.
- 3. Global coordination and partnership:** Ensure support is in place to continue developing market foundations and coordination to promote and improve market health. Specifically, in order to achieve supply security, affordability and widespread access, the following actions are required: monitoring supply and demand; supporting country and partner coordination; and tracking the ongoing execution of the market-shaping strategy.

05

Next Steps

Establishing cross-cutting mechanisms and functions

As the Hormonal IUD Access Group implements its strategic approach, SEMA recommends that the SRH community work on establishing cross-product mechanisms and functions that can better support the agreed access goals. These mechanisms and functions include comprehensive data and analytics, as well as financing support for in-country product introduction and other market priorities. SEMA also recommends strengthened coordination and alignment among the global SRH community around market interventions and actions.



Millions worldwide
lack access to
the reproductive
healthcare
they need.

**SEMA is working to
change that.**

This assessment of the **Hormonal Intrauterine Device market** is based on previous analysis and inputs provided by the **Hormonal IUD Access Group** and developed in partnership with the **SEMA team**.



