



SEMA
REPRODUCTIVE HEALTH

SEMA Injectables Market Assessment & Recommendations Summary

Ensuring sustained and strengthened
injectables access for women and girls

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	Executive Summary
6	Specific injectables in use
6	Current market state of injectables
8	Market assessment
11	Market opportunities and recommendations
12	Ensuring a bright future for injectables
14	Appendix
17	Acknowledgements

01

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.



02

Executive Summary:

Injectables, a popular family planning method

For the last 30 years, injectables have been a popular method for preventing pregnancy accounting for nearly one-fifth of the contraceptive market in LMICs.

There are a variety of injectable contraceptives available on the market, including “intramuscular” (IM) injections administered into the muscle, available at one, two or three month durations, and more recently a “subcutaneous” (SC) injection that is administered under the skin at three month durations.

At least one generic SC injectable is poised to enter the market in the next few years, presenting a significant opportunity to increase access. However, different financing, production, procurement, distribution and data collection challenges continue to undermine product availability.

This Healthy Markets Framework (HMF) Assessment highlights market opportunities for IM and SC injectables and makes several recommendations on how to sustain and expand access.

The three primary takeaways from the assessment are:

- 1. The lack of funding for procurement remains the main barrier to meeting global demand for injectables. This is also limiting demand across SRH products in general.**
- 2. IM injectables still dominate the injectables market. Shipments of SC injectables have been relatively modest over the last few years, with evidence of challenges to fulfill country orders. An increase is projected in the demand for SC injectables over time with secure, diversified supply, particularly if the price premium of SC versus that of IM injectables is reduced. The arrival of a generic SC injectable could make a significant difference when it comes to pricing, however uncertainties remain as to whether SC injectables will be able to fully realize their potential.**
- 3. Structural problems such as the lack of provider capacity and supportive policies to enable access are hindering the growth of the market for SC injectables and require special attention.**



03

Specific injectables in use

Product background

Depot medroxyprogesterone acetate (**DMPA**) is the dominant form of injectable birth control and is sometimes referred to by the brand name Depo-Provera even as generic versions have become increasingly common.

DMPA-IM

Intramuscular DMPA (DMPA-IM), is delivered through an injection traditionally given at a health facility by a doctor or nurse. Access to DMPA-IM has broadened in recent years as many countries have approved community-based distribution systems where trained community health workers can give the injections in homes or other non-clinical settings.

DMPA-SC

In 2014, subcutaneous DMPA (DMPA-SC), sometimes referred to by the brand name Sayana Press, was introduced to the market. DMPA-SC is delivered through a short, pre-filled syringe that can be easily self-administered by women and girls. It can also be delivered by a broad range of healthcare providers, including pharmacists and community health workers.

DMPA-SC when self-injected can provide more privacy and autonomy in women's and girls' reproductive choices. It also increases the options for local community access and reduces the burden of delivery through healthcare facilities. However, several countries have yet to approve policies allowing for self-injection or pharmacy delivery of this contraception method. The lack of such provisions limits the impact of this innovative method.

04

Current market state of injectables

Together, DMPA-IM and DMPA-SC products comprise nearly the whole of the injectable-contraceptives market in LMICs. These injectables account for more than 95% of total donor-procured distribution volume.¹ There is limited data on how much of the total market is represented by DMPA-IM and DMPA-SC, but it is clear that the two products are the predominant injectable products in the global market.

The use of injectables increased rapidly during the 1990s and early 2000s, emerging as the primary contraceptive choice in Sub-Saharan Africa. However, the rising popularity of contraceptive implants, which is a rod placed beneath the skin in the upper arms, has moderated this growth.²

The global contraceptives market continues to include a substantial proportion of injectables. Over the last five years, injectables shipped to LMICs for public sector delivery

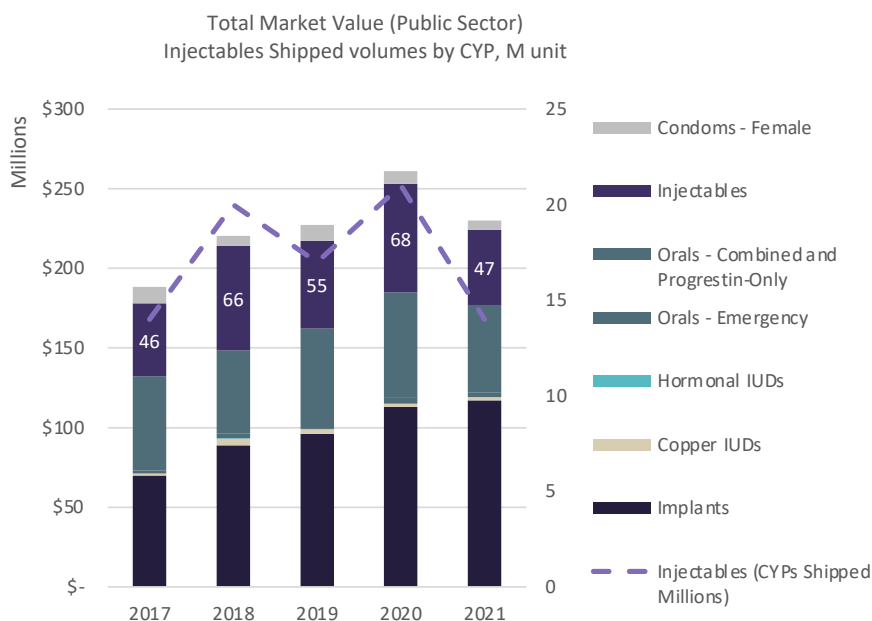
¹ UNFPA and USAID 2021 procured volume – Sources: UNFPA Contraceptives Spend 2021, UNFPA Contraceptive Price Indicator 2021, and 2021 USAID Overview of Contraceptive and Condom Shipments

² Haakenstad, A. et al. "Measuring contraceptive method mix, prevalence, and demand satisfied by age and marital status in 204 countries and territories, 1970-2019." *The Lancet*. July, 2022.

averaged 71 million units and \$56.4 million per year. As of 2021, injectables represented 18% of the total public sector contraceptive market in terms of aggregate value in these countries.³

The estimated total public sector market volume and value of injectables procured declined by 32% and 31% (respectively) from 2020 to 2021. This was partly due to pandemic-related supply and funding disruptions, but largely due to a change in market behavior in Bangladesh. Bangladesh bought an unusually large quantity of injectables in 2020 and far less in 2021, accounting for a full 40% of the worldwide market decline from one year to the next.⁴

Figure 1 - Injectables as a share of total public sector market value (2017-2021)^{5*}



* Excluding male condoms

DMPA pricing has been fairly stable over the last five years, possibly due to relatively static production, and it remains competitively priced, with an average cost per couple year of protection (cost/CYP) of USD \$3.09 in 2021 (assuming 4 units per year of protection and using UNFPA pricing, averaged across products). This is comparable to other popular family planning methods falling in the mid-range of pricing, USD \$2.24/CYP for 5-year implants and \$3.17/CYP for combined oral contraceptives⁶.

There are currently four DMPA-IM manufacturers prequalified by the World Health Organization (WHO). The small number of quality-assured manufacturers can be a risk since the vast majority of supply going to LMICs is obtained through donor-funded procurement and this is limited to manufacturers that have Stringent Regulatory Authority (SRA) approval and/or have been WHO-prequalified.

There are numerous manufacturers of DMPA-IM that have not been prequalified by WHO. These mainly cater to private-sector markets and countries with upper-middle-income status. Although information regarding the procurement, pricing and quality of products

³ Family Planning Market Report. Clinton Health Access Initiative and Reproductive Health Supplies Coalition. December 2022.

⁴ Family Planning Market Report. Clinton Health Access Initiative and Reproductive Health Supplies Coalition. December 2022.

⁵ Adapted from Family Planning Market Report. Clinton Health Access Initiative and Reproductive Health Supplies Coalition. December 2022. https://www.rhsupplies.org/uploads/tx_rhscpublications/Family-Planning-Market-Report.pdf

⁶ Family Planning Market Report. Clinton Health Access Initiative and Reproductive Health Supplies Coalition. December 2022.

from non-quality-assured manufacturers is limited, anecdotal evidence indicates that their prices can be up to 45% lower than those of pre-qualified products. In recent years, a small number of countries that traditionally relied primarily on donor-funded procurement have also engaged in direct procurement tenders with non-WHO prequalified manufacturers. As countries shift towards more self-financed procurement, the share of non-prequalified products in the market could increase over time.

DMPA-SC has been introduced in more than 50 countries. Out of these, 30 countries have approved policies allowing for self-injection. Despite this, as of the end of 2022, only four low-income countries had access to self-injection at 75% or more of public facilities.⁸

Based on 2020 and 2021 procurement data from UNFPA, DMPA-SC represented on average 40% of total DMPA injectables procured by countries that bought both SC and IM products through UNFPA.⁹

The use of DMPA-SC varies across countries as survey data from early adopters of DMPA-SC shows. In Uganda, for example, 42% of injectables users surveyed in 2021 were using DMPA-SC, compared to 24% in Burkina Faso in 2022.¹⁰

The DMPA-SC Donor Consortium, formed in 2017, supports and coordinates donor and partner efforts related to DMPA-SC and self-injection availability. The consortium has supported ongoing monitoring of progress, issue resolution, and alignment of strategy and priorities across partners.

Perhaps the most significant limitation on DMPA-SC access is that there is currently only one supplier. This may change soon as a generic product is currently in development, and is expected to enter the market within three or four years.

05 Market assessment

SEMA utilizes the Healthy Markets Framework (HMF)¹⁰, an assessment tool, to understand potential market barriers, risks and opportunities. The HMF involves a collaborative approach that draws the perspectives and the insights of technical partners, practitioners, and policy experts. The HMF assessment also involves individuals from the countries where SEMA and global partners aim to enhance SRH product accessibility.

The HMF Assessment seeks to reflect all dimensions of market health, to clearly identify potential areas for action and investment by SEMA and other partners. The assessment helps to understand and ensure agreement on market challenges and supports discussion of potential solutions.

A robust SRH market is characterized by key elements such as a resilient supply-base that can effectively address consumer demand, even in the face of economic or logistical obstacles. Additionally, a healthy market requires strong financing mechanisms to meet consumer needs and a pricing system that maintains sustainable affordability in

⁷ Global DMPA-SC Self-Injection Status Report, Q3 2022, DMPA-SC Access Collaborative, CHAI, Jhpiego

⁸ UNFPA Contraceptives Spend Analysis 2021 www.unfpa.org/resources/contraceptives-spend-analysis-2021

⁹ PMA Data Lab Tool <https://datalab.pmadata.org/>, accessed March 6, 2023.

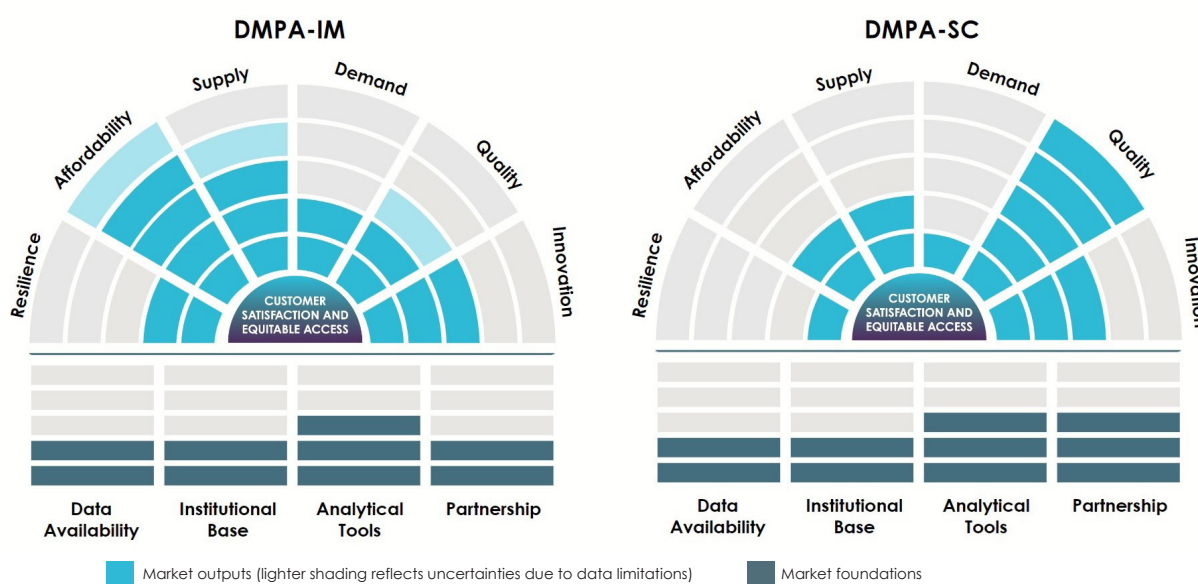
¹⁰ For detailed descriptions of the HMF and its intended use: SEMA Healthy Markets Framework Overview . This assessment was undertaken using SEMA's original HMF which has subsequently been updated to reflect the learnings from this and other assessments.

diverse markets. Other essential components include superior product quality, a thriving innovation pipeline, and well-established frameworks for regulation, procurement, and market-data gathering. Together, these factors contribute to the overall well-being of the product market in question.

SEMA has developed a list of indicators for primary market dimensions, which guide a data-collection process in developing composite “scores” of 1-5 (with 1 being “unhealthy” and 5 being “very healthy”). The scores are used to populate a simple visual representation of overall market health.

The results are presented in the charts below:

A table presenting textual detail for these findings may be found in the appendix section.



The initial scope of this assessment included all injectable contraceptives, however, this was narrowed to focus on DMPA-IM and DMPA-SC, as they are predominant in the market.

The evaluation primarily targeted LMICs, while also considering the wider global market commonly catered to by manufacturers. It relied on publicly accessible data on injectables, as well as interviews conducted with donors, procurers, manufacturers, representatives from national governments, implementing partners, and other individuals actively involved in the global supply and distribution of injectable contraceptives.

It is worth noting that there are significant limitations regarding publicly available data, particularly concerning detailed information on market volumes categorized by product type (IM vs. SC), manufacturer, price, and location. Additionally, there is a noticeable absence of data regarding consumer preferences and demand, national-government procurement, and private-sector purchasing. Given these limitations, the assessment is focused on the public sector.

Overall, injectables are a trusted method in high demand but a lack of financing and other market barriers restrict access.

The assessment identified some significant areas of strength in the injectables sector. It found the market to be well-established with long-sustained consumer demand for DMPA-IM. It also found that injectables are relatively affordable compared to similar short-term contraceptives, and that the donor-funded part of the injectables market is able to procure quality-assured products.

However, there were also significant market weaknesses. The most critical of these are inadequate financing, and the fact that there are few suppliers of key manufacturing inputs, the latter of which compromises both product affordability and manufacturers' viability. Other weaknesses identified were a lack of sufficient high-quality market data and uncertainty with regard to future trends.

The evaluation also highlighted the **interconnectedness of IM and SC products when it comes to their demand, supply, and affordability**. To illustrate, a wide range of market stakeholders have reported anecdotal evidence suggesting that women, when provided with information and training about DMPA-SC, tend to show a preference for it over DMPA-IM. Should this prove accurate, it is expected that the demand for SC will gradually rise as the supply of SC becomes more secure, with the possibility of SC eventually replacing IM, particularly if SC pricing is similar to IM. Such a shift in preference towards SC and decreased demand for IM, could lead suppliers to stop producing IM, consequently weakening the resilience of the IM market. It is essential to closely monitor these trends to ensure a healthy and sustainable injectables market.

The three primary takeaways from the assessment are:

1. The lack of funding for procurement remains the main barrier to meeting global demand for injectables. This is also limiting demand across SRH products in general.
2. DMPA-IM is still predominant in the market. Shipments of DMPA-SC have been relatively modest over the last few years, with evidence of challenges to fulfill country orders. An increase is projected in the demand for DMPA-SC over time with secure, diversified supply, particularly if the price premium of DMPA-SC versus that of DMPA-IM is reduced. The arrival of a generic DMPA-SC could make a significant difference when it comes to pricing, however uncertainties remain as to whether DMPA-SC will be able to fully realize its potential.
3. Structural problems such as the lack of provider capacity and supportive policies to enable access are hindering the growth of the market for DMPA-SC and require special attention.



Market opportunities and recommendations

To address the market shortcomings identified in the assessment, the following recommendations are made. Some of these recommendations are specific to injectables, while others apply to the sexual and reproductive health sector as a whole.

Injectables

- **Evolve DMPA-SC partnership** in support of a long-term vision that enables routine product monitoring and investment decision-making to be driven by country market needs and to consider the broader injectables market, and eventually all SRH products.
- **Continue coordinated efforts to expand access to DMPA-SC**, aligned with broadened supply availability, including provider training and consumer awareness campaigns, and enhanced efforts to support and enable private sector delivery.
- Engage with **generic SC manufacturer to support launch plans**, including getting country regulatory approvals, and supporting countries to revise and implement national supply plans and facilitate coordination with local partners.
- Continue to **ensure growth and sustainability of DMPA-IM and DMPA-SC** by enabling appropriate supply diversification of quality-assured products, including key inputs.

SRH/Family-Planning Cross-Product Considerations

- **Advocate for additional funding for SRH commodities.** Identify opportunities to support new or expanded financing mechanisms.
- **Enable routine market monitoring** across products and countries that reviews near-term, medium-term, and long-term demand forecasts; supplier capacity; pricing trends; quality and other factors.
- Enable routine systems for **collecting and disseminating data on user insights**, to inform routine supply planning and innovation priorities.



Ensuring a bright future for injectables

The future of the injectable contraceptives market will be influenced by several factors. One that is clear today is the introduction of a generic version of DMPA-SC, which is anticipated to have a notable effect on the injectables sector, creating an opportunity to strengthen the market specifically for DMPA-SC and restoring momentum to the overall injectables market. This will require further investments in expanding product access through provider training and raising consumer awareness.

Over time, demand for DMPA-SC is expected to rise, particularly with the more dependable supply multiple suppliers provide, and if pricing becomes more aligned with DMPA-IM. However, an increase in demand could exacerbate the current shortages of procurement funding that already present challenges to the SRH sector, especially if the price disparity is not eliminated.

This dynamic of shifting demand between DMPA-IM and DMPA-SC is one of several uncertainties around a number of injectable market variables, including pricing, supply, and self-injection policy, to name a few. Changes in one or more of these factors will impact demand in unpredictable ways, which in turn has the potential to impact the health and stability of the injectables market. To ensure a robust and sustainable market for injectables worldwide, it will therefore be necessary to monitor the market in increasingly comprehensive, ongoing and data-responsive ways – including across such variables as procurement, pricing and commodity financing.

SEMA is committed to the advancement of such oversight, including in such vital areas as the evolution of supplier markets and commodity financing.





Photo Credits: DMPA-SC unit. (Photo: PATH/Will Boase) [Click here](#)



Appendix

This market assessment is based on a scoring system from 1-5 for each dimension of the Healthy Market Framework. A perfectly performing market overall would score 5 on all dimensions. Scores are presented separately for IM and SC where relevant; combined scores indicate references to the overall injectables market.

Criteria	Score /5	Supporting information
Demand	IM: 2 SC: 1	<ul style="list-style-type: none"> • Demand assessment is focused primarily on the extent to which financing meets country demand. • Significant funding gap to fulfill country demand (\$92M in 2021 across FP commodities¹¹) and injectables make up a significant share of the overall commodity funding gap. Donor funding is not expected to increase. Projected increases in demand for injectables will need to be funded by other sources, or by shifts in the mix of methods that donors procure. • Historically strong consumer demand for IM. Injectables have become the predominant contraceptive method in sub-Saharan Africa, primarily through use of IM. • Anecdotal evidence from country representatives suggests that in some contexts consumer demand for SC is surpassing demand for IM when both products are made available. • Barriers to consumer access reported for SC /SI related to provider capacity, low demand generation efforts. • Barriers for private sector uptake: access to SC price of \$0.85, start-up costs, minimum orders, and marketing restrictions for SC.
Supply	IM: 3/4 * SC: 2	<ul style="list-style-type: none"> • PQ IM supply capacity is estimated to be sufficient to meet donor-financed demand, but tenuous given the low number of overall suppliers. Uncertainty about extent to which PQ-supply is sufficient to meet full country demand if additional financing is materialized. • Expanded IM generic PQ capacity planned in 2-3 years. Short-term capacity gaps are possible in the near term. • Unknown volume of IM supply provided by non-PQ suppliers. Additional supply capacity from non-PQ suppliers is available if country demand increases, though quality is uncertain. • Evidence of challenges to fulfill orders for DMPA-SC; generic manufacturer entry & capacity expansion anticipated in 3-4 years.

¹¹ RHSC Global FPVAN, "From Data Visibility to Action"

Criteria	Score /5	Supporting information
Affordability	IM: 4/5* SC: 2	<ul style="list-style-type: none"> • Uncertainty on suggested score for IM reflects the lack of pricing data for non-PQ IM products as well as uncertainty regarding manufacturer attractiveness. • Stakeholder interviews indicate that due to affordability concerns, maintaining the current price of DMPA-SC is a critical factor to sustaining and increasing demand for DMPA-SC. The price of SC relative to IM will have a significant impact on the demand for both products. • There are varying perspectives on potential for longer-term pricing of SC relative to IM. Higher prices for SC may be necessary to support manufacturer sustainability. Sustainable price of SC is highly dependent on the price of Uniject. • Average price of IM has had little variation over time, despite new market entrants, suggesting a price anchoring effect. Price estimates for non-PQ IM vary. Some reports indicate general price parity between PQ and non-PQ products; others suggest substantial pricing differences, with non-PQ prices up to 45% lower than those for PQ goods. • Potential manufacturer exit/discontinuation, suggest challenges on manufacturer attractiveness for IM, though some generic suppliers indicate a strong commitment to the market. Single source suppliers of important inputs – such as pre-qualified active pharmaceutical ingredients (API) or the Uniject device for SC products – creates difficulties in negotiating prices for key cost drivers.
Resilience	IM: 2 SC: 1	<ul style="list-style-type: none"> • Reliance on a few pre-qualified (PQ) manufacturers of IM poses a resilience risk, particularly with uncertainties around future commitments from major manufacturers. • DMPA-SC market reliance on a single manufacturer is a high risk, but generic products are anticipated (3-4 years). • Single-source API supplier to all three generic IM manufacturers is an additional resilience risk for the market. Same supplier will also provide API to the new generic SC product. • Reliance on sole supplier for the Uniject injection device is another vulnerability for DMPA-SC. • Financing concentrated with a few donors poses ongoing resilience risks on both supply and demand.
Quality	IM: 2/3* SC: 5	<ul style="list-style-type: none"> • PQ-products have reliable quality assurance (QA) and quality control (QC) processes in place. • Quality of non-PQ products may be an issue, though other mechanisms exist to support quality beyond PQ/SRA approval. • Potential for quality issues to become more relevant if procurement shifts to increased direct country procurement. • Uncertainty reflects lack of visibility on market share of non-PQ products and QA/QC requirements for MOH procurement.

Criteria	Score /5	Supporting information
Innovation	Combined: 3	<ul style="list-style-type: none"> • Most relevant products in the pipeline include: New generic SC, 6-month injectables (Levonorgestrel), 4-month interval approval for current SC, and new or improved delivery devices for self-injection. • Evidence that products in development are aligned with consumer preferences for longer-acting injectables and support other considerations including reduced cost per couple-year of protection (CYP). • Lack of systematic process to identify and evaluate consumer needs to inform innovation priorities.
Data Availability	Combined: 2	<ul style="list-style-type: none"> • Market data are available to key stakeholders through existing structure, but limited data are available to the general public. • Limited data on consumer demand and preferences. There is not a systematic process to aggregate, synthesize, and disseminate findings from research studies. • Procurement and planning processes are not linked to consumer or product-usage data.
Institutional Base	Combined: 2	<ul style="list-style-type: none"> • There are significant policy barriers related to service delivery, particularly for DMPA-SC availability in private sector channels and self-injection. • There are also barriers that affect all SRH commodities, such as supply chain challenges at different levels, including procurement & planning capabilities (cross products).
Analytical Tools	Combined: 3	<ul style="list-style-type: none"> • Forecasting tools and coordination mechanisms have improved, but data limitations remain, as described above. • There is near-term monitoring of supply risks relative to demand, but no routine monitoring of medium-term or longer-term trends. Various stakeholders have access to pieces of this data, resulting in a fragmented view of the market.
Partnership	IM: 2 SC: 3	<ul style="list-style-type: none"> • Current coordination mechanisms support aggregated demand forecasting and supply coordination for DMPA-IM and DMPA-SC along with a broad view across SRH products. • Dedicated partnership to support DMPA-SC coordination may need to evolve to better support and enable continued scale-up moving forward.

* Reflects uncertainty or limited data available to inform the assessment scoring.



Acknowledgements

The injectables market assessment was led by Global Impact Advisors and relied on contributions from members of a consultative group who supported the assessment process in addition to other key stakeholder interviews.

Core team contributors include:

- **Dr. Kayode Afolabi**, Independent, Nigeria
- **Chris Cavendish**, MSI
- **Lester Chinery**, Concept Foundation
- **Caitlin Corneliess**, PATH, Access Collaborative
- **Sylvia Lin**, Bill & Melinda Gates Foundation
- **Judith Mboya**, CIFF
- **Cristina Palau**, UNFPA
- **Gita Ramamurti**, CHAI
- **Mindy Scibilia**, CHAI
- **Roxy Tola**, MSI
- **John Vivalo**, USAID
- **Julia White**, RHSC
- **Prashant Yadav**, Center for Global Development



Millions worldwide
lack access to
the reproductive
healthcare
they need.

**SEMA is working to
change that.**



