

SEMA

REPRODUCTIVE HEALTH

**Medical Abortion (MA) Market Assessment
Summary**

Medical Abortion (MA) Product Background & Context

MA Combipack

- Recommended option for MA per WHO guidelines¹; co-packaged presentation of one 200 mg tablet of mifepristone & four 200 µg tablets of misoprostol (totaling 800 µg)
- 2 manufacturers that are WHO PQ/SRA approved and also serving LMICs (CR Zizhu, Sun Pharma)
- 2 additional manufacturers serve the LMIC market whose products are not currently WHO PQ'd or SRA approved but the manufacturers have indicated their intentions to pursue; several other manufacturers serve LMICs with products that are not WHO PQ'd / SRA approved, nor have they indicated an intention to pursue
- Currently the market in LMICs is dominated by the SMO sector; limited demand in the public sector, particularly in countries with more restrictive enabling environments, and currently there exists limited visibility into the true commercial sector

Misoprostol

- Recommended option for MA and Post Abortion Care (PAC) per WHO guidelines; includes four 200 µg tablets of misoprostol (totaling 800 µg)². Initially developed to treat peptic ulcers, but has since expanded to several additional uses in OB/GYN, including post-partum hemorrhage and medical abortion
- Generally considered a secondary alternative to MA combipack due to its slightly lower efficacy and higher incidence of side effects. However, misoprostol alone is still an important regimen as it is more affordable and relatively more available than products marketed and sold for abortion only, particularly in countries with more restrictive legal environments
- 8 WHO PQ/SRA-approved suppliers of misoprostol in LMICs (Acme, Apotex, Bial, Cipla, CR Zizhu, Line Pharma, Mylan and Pfizer).
- Estimating market size is challenging due to multiple indications

¹The WHO guideline recommends administration of the combination regimen of mifepristone and misoprostol for induced abortion; MA combipacks are the co-packaged presentation of the recommended regimen

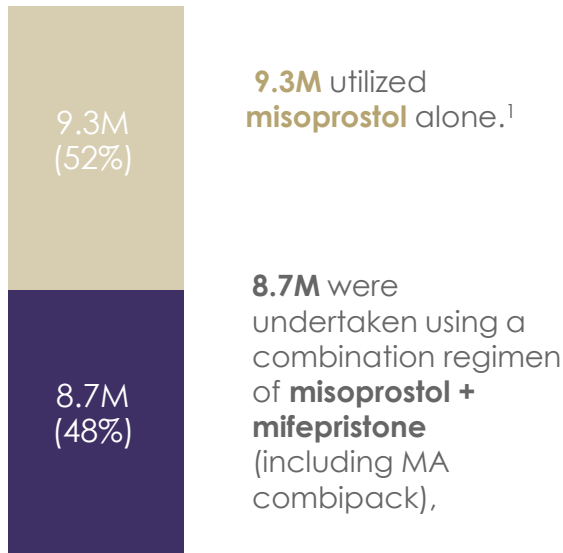
²The WHO guideline notes that repeated doses of misoprostol can be considered when needed to achieve success of the abortion process; it does not provide a maximum number of doses

Note: The letrozole + misoprostol combination regimen was introduced in the WHO's March 2022 Abortion Care Guidelines as a suggested regimen; however, only a high-level summary on the letrozole and misoprostol combination regimen was provided in the MA market assessment as this combination regimen is "suggested" and not "recommended" by the WHO given current level of evidence (See appendix for more information)

Overview of MA product availability & potential market

MA combipacks are considered the preferred regimen for medical abortion, but **misoprostol alone continues to be more widely available*** due to its multiple indications; therefore, increasing accessibility of medical abortion overall must necessarily include both products.

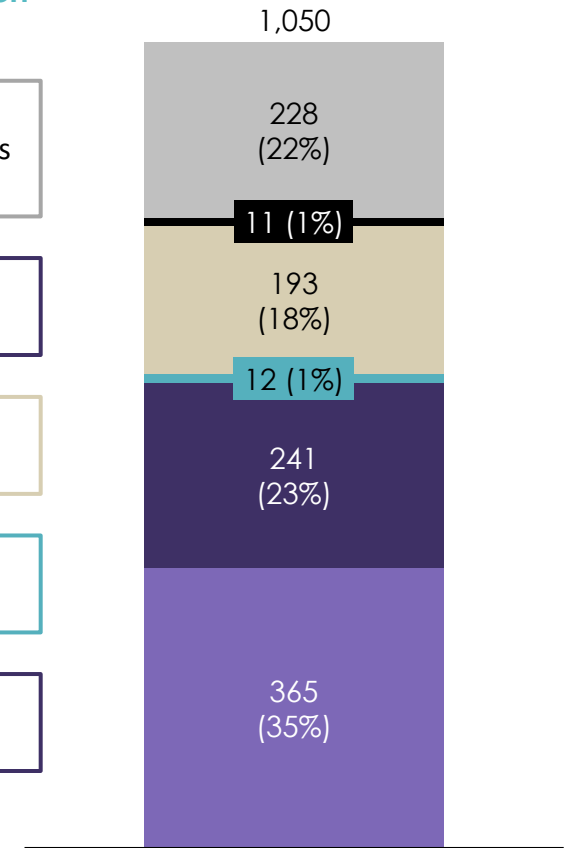
In 2019, there were **18.0M safe medical abortions in LMICs**



Number of safe abortions

In 2019, there were **1.1B WRA living in LMICs²**, out of which

- 228 (~22%) WRA** live in 32 LMICs where there is no access to any medical abortion commodities; these include LMICs across all legal contexts
- 11M (~1%) WRA** live in 2 LMICs where **only mifepristone** is available
- 193M (~18%) WRA** live in 18 LMICs where MA combipack and mifepristone is not available, but **misoprostol is**
- 12M (~1%) WRA** live in 2 LMICs where MA combipack is not available, but both **misoprostol and mifepristone are**
- 606M (~58%) WRA** live in 28 LMICs where **MA combipack is available**, including 365M WRA in India



WRA

Note: 1. LEAP Abortion & PAC Landscaping; includes some “less safe” abortions defined as not having sufficient counseling or assistance in self-managed abortions or using non-WHO PQ/ SRA-approved products and post abortion care, and post abortion care (PAC); 2 LMICs as categorized in 2022, WRA per most recent data in 2019; * “Availability” indicated in-country presence by medab.org, existing procurement volumes and/or supplier registration in country

MA market assessment¹ methodology



Desktop research building off **existing market assessments and available data sources**, including referencing SEMA's high-level market scan, past data collection efforts by the MA Combipack Market Shaping Group, and one-time market assessments sponsored by key partners



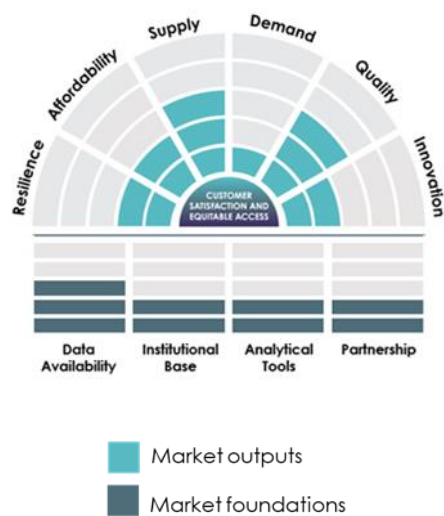
Participation in relevant **sessions at the International Conference on Family Planning** on abortion market shaping, research, and advocacy work done in LMICs or other relevant contexts



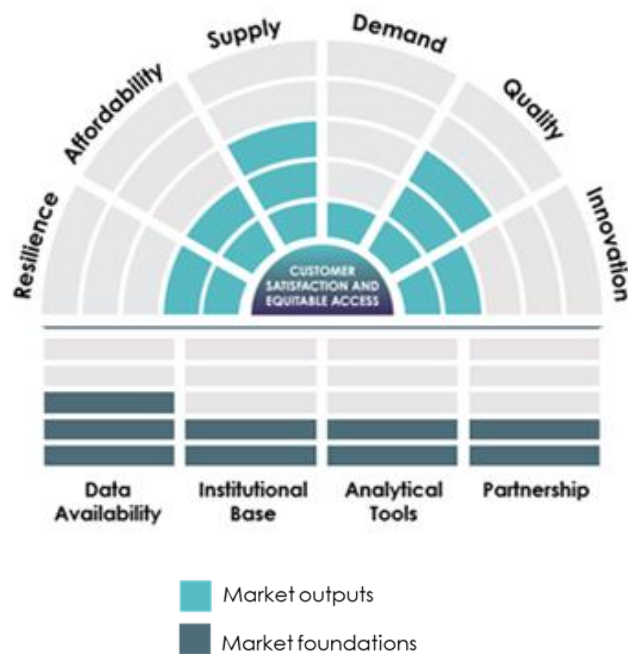
Robust 1:1 **stakeholder engagement with 42 key partners across 14 organizations**, identified via the MA Combipack Market Shaping Group (MSG), RHSC SAS working group, WHO key stakeholder conversations, and PUA group to solicit feedback and refine findings

MA Combipack: Market assessment summary (1/2)

HMF Domain	Score	Findings
Resilience	2	<ul style="list-style-type: none"> There are multiple WHO PQ/ SRA-approved manufacturers for the misoprostol API and the mifepristone API sourced by WHO PQ/ SRA-approved FPP MA combipack suppliers serving LMICs. Stigma and restrictive laws, policies, and guidelines have made it difficult to incorporate MA into national primary healthcare programs, limiting public sector funding for abortion-specific commodities like the MA combipack. Global funding picture is uncertain in the face of shifting donor priorities. This has impacted key partners' (e.g., SMOs, INGOs) ability to offer abortion services, including MA. Discussion on the next phase of investments is ongoing, as donors reevaluate strategic priorities and funding. Some ring-fenced funding exists at the global level to support public-sector introduction and scale-up programmatic and procurement activities related to MA combipack however, such funds have historically been largely underutilized.
Affordability	2	<ul style="list-style-type: none"> While progress has been made in recent years to reduce the price of WHO PQ/ SRA-approved MA combipack, relatively limited procurement volumes for these products contribute to challenges with consistently realizing affordable prices and achieving price parity with non-WHO PQ/ SRA-approved products. Two suppliers have indicated their intentions to move their non-WHO PQ/ SRA-approved products to WHO PQ/ SRA-approved status at an affordable price point; however, continued supplier engagement is vital to achieve supply security for affordable WHO PQ/ SRA-approved products, given evolving market dynamics. Some reports of price gouging in the commercial sector need to be better understood, particularly as a barrier to access.
Supply	3	<ul style="list-style-type: none"> There is currently sufficient WHO PQ/ SRA-approved Finished Pharmaceutical Product (FPP) supply to meet institutional demand (i.e., from SMOs, governments, and UNFPA); however, there is limited insight into non-WHO PQ/ SRA-approved supplier capacity and total demand. Stigma may prevent commercial sector distributors from stocking and providing MA combipacks.
Demand	1	<ul style="list-style-type: none"> User: ~8.7M medical abortions take place annually in LMICs using mifepristone + misoprostol; with notable volumes occurring in the SMO sector. Some reports of limited end user awareness of how to properly access / use MA combipack; abortion rights are also limited within the legal environment in some countries. There continues to be latent demand for MA contributing to the 7.8M abortions in LMICs that are considered "least safe". Country: Though historically public sector funding has been limited, there are positive indications of future procurement for MA combipack, including inclusion on EMLs, orders placed, and additions to tenders.
Quality	3	<ul style="list-style-type: none"> 2 WHO PQ/ SRA-approved products are currently available in LMICs with 2 additional suppliers indicating intentions to seek WHO PQ/SRA-approval for their MA combipack products in the future, as a result of the MA Combipack Market Shaping Group (MSG) efforts. WHO PQ/ SRA-approved products have been found to be significantly less likely to carry quality concerns vs. non-WHO PQ/ SRA-approved products. There is currently limited visibility into the quality of MA combipack products in the commercial sector, though some reports of counterfeit misoprostol and mifepristone have been recorded by partners.
Innovation	2	<ul style="list-style-type: none"> There are examples across countries of technology being leveraged to increase access to safe abortion (e.g., telemedicine, applications, hotlines) and to increase consumer and provider awareness of products and services.



MA Combipack: Market assessment summary (2/2)

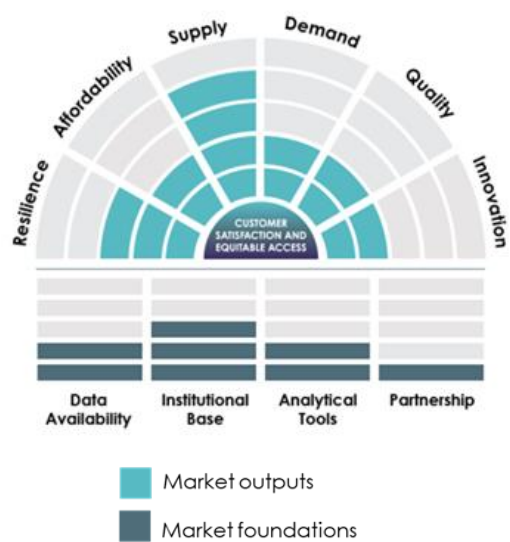


HMF Domain	Score (/5)	Findings
Data Availability	3	<ul style="list-style-type: none"> • Fairly robust data collection efforts by the MA Combipack MSG have produced high confidence volume estimates for UNFPA, SMO, and government procurement of WHO PQ/ SRA-approved products. • Limited visibility into the commercial sector, including non-WHO PQ/ SRA-approved volumes.
Institutional Base	2	<ul style="list-style-type: none"> • The MA combipack is a recommended option for MA according to the WHO and is considered a preferred, effective, safe option by many providers. • There is a relatively limited number of countries that have WHO PQ/ SRA-approved products registered, though that number has been increasing over the past few years. • Governments have historically been reluctant to procure MA combipack due to its unique indication for abortion; however, recent years have shown a shift towards higher degrees of support across LMIC public sectors.
Analytical Tools	2	<ul style="list-style-type: none"> • Existing work and analysis conducted for the MSG has focused on tracking progress against supply- and demand-side global outcomes (i.e., increased supply security for affordable, WHO PQ/SRA-approved MA combipacks in LMICs; increased proportion of procured MA combipacks that are WHO PQ/ SRA-approved products in LMICs); however, this work is limited to the public and social marketing sectors and is made available only to members of the MSG. • Currently no comprehensive market data collection or forecasting exercises exist which take into account all MA combipacks (i.e., WHO PQ/ SRA-approved and non-WHO PQ/SRA-approved) across all sectors (i.e., public, SMO, and pure commercial).
Partnership	2	<ul style="list-style-type: none"> • The last few years have seen notable progress on increasing availability of affordable, WHO PQ/ SRA-approved MA combipacks (e.g., via efforts by the MSG); however, progress is at risk due to limited procurement of WHO PQ/ SRA-approved products and available financing to scale-up and respond to demand for WHO PQ/ SRA-approved products. • Globally, several groups have prioritized increasing access to MA products, such as the RHSC Safe Abortion Supplies (SAS), WHO Prevention of Unsafe Abortion (PUA), and the MA Combipack Market Shaping Group (MSG), as well as other groups whose purviews touch on safe abortion, including PSI's Self-Care Trailblazers Group. Further, the WHO convened a series of consultations with key actors in 2022 to focus on increasing access to affordable, quality MA products and services. With the exception of the MSG, which has historically had a focused and funded MA combipack-related market-shaping scope, the focus of these groups and/or partnerships is broad, encompassing both the safe abortion or medical abortion markets overall and leveraging partners' existing funded work. • Some countries (e.g., DRC, Rwanda, Zambia) are supporting coordination efforts across public and private sectors (particularly via SMOs) as part of RH product introduction mechanisms to introduce and scale-up MA combipacks. • Despite several groups and partnerships at the global and country level, coordination and alignment on MA vision, goals and priorities between global partnerships and groups could be further enhanced to avoid fragmented efforts. Coordination could also be enhanced at the country level to support more strategic deployment of resources.

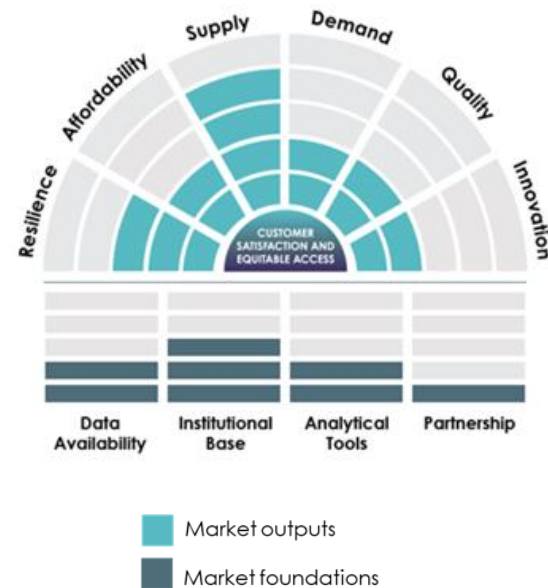
Note: 1. "QA" or "quality assured" is defined in this assessment as WHO prequalified or SRA approved, though institutions' individual definitions may vary

Misoprostol: Market assessment summary (1/2)

HMF Domain	Score	Findings
Resilience	2	<ul style="list-style-type: none"> • There are multiple WHO PQ/SRA-approved misoprostol API manufacturers (e.g., Piramal, Everlight), with indications that Piramal has the largest market share. Looking forward, regular engagement with Piramal and the other WHO PQ/SRA-approved manufacturers of misoprostol API will be important to monitor any key supply-side developments and mitigate any potential risks to supply security. • Misoprostol is included in country EMLs and is procured by governments, UNFPA, NGOs, SMOs, often under its maternal health indications (e.g., PPH) instead of explicitly for MA.
Affordability	2	<ul style="list-style-type: none"> • Misoprostol is generally more affordable than the MA combipack and is often covered by health insurance within maternal health. • Non-WHO PQ/ SRA-approved products continue to be available at a lower price than WHO PQ/ SRA-approved options. • There is variation in price across geographical regions, including some stakeholder reports of excessive markups, especially in the commercial sector. Further, providers and prescribers across public and commercial sectors may levy informal surcharges.
Supply	3	<ul style="list-style-type: none"> • Misoprostol is available in more LMICs and UMICs than other medical abortion commodities due to its multiple indications. • There are 8 WHO PQ/ SRA-approved suppliers of misoprostol available in LMICs: Acme, Apotex, Bial, Cipla, CR Zizhu, Line Pharma, Mylan and Pfizer.
Demand	1	<ul style="list-style-type: none"> • In low-income countries the relatively inexpensive misoprostol only regimen was used in 87% of all medical abortion and post abortion care services, compared to 46% and 65% in lower middle and upper middle-income countries, respectively. • Misoprostol alone was used in 9.3M medical abortions in LMICs in 2019 (and as a part of the combination regimen mifepristone and misoprostol for an additional 8.7M abortions). • There is a disconnect between policies/laws and knowledge of healthcare workers and end-users; the end-user might not be provided with the appropriate counselling and guidance on misoprostol use (within legal parameters), which may limit use, or result in side-effects, which may increase reliance on health-based facilities despite successful completion of self-managed abortion. • Stakeholders expressed challenges with accurately quantifying misoprostol demand due to its various indications, particularly for MA, where misoprostol is often used as a secondary line of treatment (e.g., when the MA combipack is not available, and for later term abortion following MA combipack usage to complete evacuation of the uterus). • There is limited visibility into commercial sector procurement.
Quality	3	<ul style="list-style-type: none"> • Some stakeholders perceive the shelf-life of miso to be short. Prior studies showed degradation over time due to moisture; all WHO PQ/ SRA-approved suppliers have therefore upgraded to using double aluminum blister packs, but some concerns remain. • WHO PQ/ SRA-approved misoprostol is available in 37 of the 44 LMICs where misoprostol is available, representing 266M WRA with access to WHO PQ/ SRA-approved misoprostol. • Further, some countries are not actively monitoring the quality of misoprostol over time, which is particularly concerning in markets with a proliferation of supply, as in the commercial sector. • Due to the multiple indications, instructions in packaging inserts may not give appropriate guidance on use for medical abortion or storage, which has implications on the quality of and access to information to execute safe abortions.
Innovation	2	<ul style="list-style-type: none"> • As with MA combipack, there are examples across countries of technology being leveraged to increase access to safe abortion and to increase both end user and provider awareness of products and services available within the legal framework. • In March 2023, WHO PQ approved Bial's Misofar vaginal tablets which have a 36-month shelf-life; this is an improvement compared to the 18-24 months shelf-life of other misoprostol product in the market.



Misoprostol: Market assessment summary (2/2)



HMF Domain	Score (/5)	Findings
Data Availability	2	<ul style="list-style-type: none"> The size of the misoprostol market for medical abortion is unknown, as misoprostol has multiple uses beyond medical abortion (including PPH management, post abortion care, gastric ulcers); however, given stigma surrounding medical abortion, keeping information aggregated could provide certain advantages for accessibility (e.g., in countries with more restrictive policies, acknowledging the portion of misoprostol used for medical abortion could reduce the overall quantity of misoprostol procured) in the short-term. In the long-term, the lack of data on misoprostol for MA perpetuates the stigma because there is limited discourse and visibility into consumption (e.g., some providers report medical abortion as post abortion care because they are afraid of backlash). However, several countries have identified understanding misoprostol's usage as a key priority and conduct forecasts and quantification for misoprostol primarily for non-MA indications and post abortion care. Countries (e.g., Liberia) have started conducting a forecast for MA regimens, including misoprostol. Insight into uptake of non-WHO PQ/ SRA-approved products in both the public and commercial sectors is a challenge, as many LMICs have porous borders and nascent regulatory systems.
Institutional Base	3	<ul style="list-style-type: none"> Misoprostol alone is a recommended regimen for MA, per WHO guidelines though is considered a secondary alternative to the MA combipack due to its slightly lower efficacy and higher incidence of side effects. Misoprostol has several indications beyond medical abortion, which makes it widely registered and available in LMICs and therefore an important alternative where MA combipack or the combination regimen of mifepristone and misoprostol is not available. A total of 37 countries have also included the misoprostol only regimen in national guidelines for induced abortions. Overall, misoprostol is available in over 89 countries (17 LICs, 28 LMICs).
Analytical Tools	2	<ul style="list-style-type: none"> There is limited forecasting and quantification into the market for misoprostol as used for medical abortion specifically; further, it is unclear if key stakeholders would be interested in pursuing this kind of quantification, since identifying the portion of misoprostol used for medical abortion could potentially lead to lower volumes of misoprostol being procured in countries where its presence is most valuable (i.e., those countries with most restrictive abortion policies that already limit access to other abortion options). Many countries conduct quantification for misoprostol overall. Some countries (e.g. Liberia, Uganda) have specifically begun quantifying misoprostol underneath consumption of MA commodities.
Partnership	1	<ul style="list-style-type: none"> Some members of the MSG have expressed interest in supporting interventions targeting misoprostol (e.g., due to practical concerns about access to MA combipacks in countries with more restrictive regulatory environments); however, the MSG's scope was determined based on an assessment of market barriers for MA products which revealed priority concerns around MA Combipack at the global level, and as a result, the MSG's market shaping efforts have not focused on misoprostol. As described in the MA Combipack section, several global groups prioritize access to MA products including misoprostol. Please see above for further details.

Key market shortcomings identified from the MA market assessment (1/2)

PRIORITY SHORTCOMINGS

Restrictive laws, policies, and funding environments limit procurement of and access to MA

Despite some advocacy efforts, **legal and policy environments remain largely restrictive in countries**, and donor funding restrictions (e.g., USG) contribute to limited procurement of MA commodities (including leveraging available ring-fenced funding)

Stigma impacts end user awareness and uptake as well as MA product availability

Stigma can prevent key actors (e.g., regulators, policymakers, donors, procurers, distributors, service providers) from **making commodities and services available** and **prevent end users** from **accessing services** easily, and **understanding MA options available**

Lack of data and corresponding limited understanding of demand

Relatively **limited visibility into commercial sector volumes** (including mark-ups) as well as into **end user and provider behaviors** impacts **the ability of stakeholders to design informed market shaping strategies**

POTENTIAL FOCUS AREAS

- **Administer funding mechanism to support advocacy for less restrictive policies**
- **Administer funding mechanism to support opportunities to work within the legal framework** (e.g., leverage partner models to increase end user literacy on legal framework, rights, access, improve trainings of health care workers, SBC interventions)
- **Support country gov'ts via TA to coordinate introduction and scale-up of quality CAC services** (including procurement of WHO PQ/ SRA-approved MA products)
- **In-depth end user and provider research** at the country level
- **Complement existing data collection efforts** with commercial sector volume tracking across products, including MA

Key market shortcomings identified from the MA market assessment (2/2)

PRIORITY SHORTCOMINGS

Limited coordination

Coordination and alignment on MA vision, goals and priorities between **global partnerships and groups** could be further enhanced to avoid fragmented efforts. Coordination could also be enhanced at the country level to support more strategic deployment of resources.

Limited supply and procurement of affordable WHO PQ/ SRA-approved product

- While significant **progress has been made** against a MA Combipack market shaping strategy developed by the MA Combipack Market Shaping Group (MSG) to **increase the availability of WHO PQ/ SRA-approved MA combipack products**, WHO PQ/ SRA-approved **procurement volumes remain relatively low** making it challenging to consistently realize affordable pricing.
- **Continued work is required** to ensure **multiple affordable WHO PQ/ SRA-approved products** will be available in the market over time.

POTENTIAL FOCUS AREAS

- Align the **global community including donors** to a common problem and set of priorities that are both specific and actionable
- Facilitate a more coordinated approach across sectors **in country where relevant** to ensure synergistic coordination of relevant actors (e.g., establish referral networks b/w commercial, SMO, public sector)

- Continue MA Combipack Market Shaping Group **work with non-WHO PQ/ SRA-approved suppliers to achieve WHO PQ/ SRA-approved status to ensure supply security over time** and continue efforts to **increase procurement of WHO PQ/ WHO PQ/ SRA-approved products to foster increased affordability**
- **Strengthen national regulatory systems, monitoring, and feedback**
- **Proactive engagement with mifepristone and misoprostol finished product and API suppliers** and procurers to understand supply risks, cost drivers, and potential interventions if required

While all identified market shortcomings will be important to address over time, in the **near term**, the market assessment highlighted **limited WHO PQ/ SRA-approved MA combipack procurement volumes** as a key barrier to achieving a healthy MA market; SEMA is currently prioritizing key supply- and demand-side interventions to address this critical market barrier

Appendix

Medical Abortion (MA) Product Background & Context

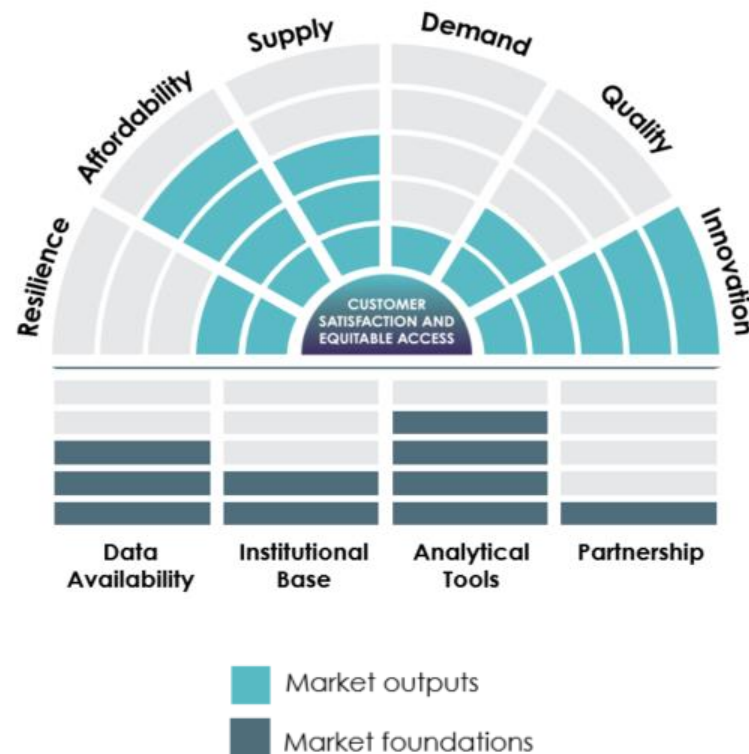
Letrozole + Misoprostol Regimen

- Combination of letrozole and misoprostol introduced as a “suggested” regimen in the March 2022 WHO Safe Abortion Guidelines; not yet “recommended” due to the current level of evidence
 - From a clinical perspective, the letrozole regimen could be a promising option to induce medical abortion, but more clinical evidence is required to understand the most suitable regimen (i.e., dosing and timing) and its efficacy in comparison to existing treatment (e.g., clinical studies have not yet compared the letrozole & misoprostol combination regimen to the mifepristone & misoprostol “gold standard” regimen)
 - From a market perspective, the letrozole combination currently offers little upside in terms of affordability or accessibility when compared to the other more widely available and affordable option of misoprostol alone
 - However, in countries where mifepristone is not widely available (e.g., more legally restrictive environments), the addition of letrozole could be considered advantageous in terms of increasing potential for successful termination of pregnancy without increasing side effects

Overall, more research is needed to better understand the potential clinical and market benefits that the letrozole combination may offer when compared with the existing recommended options of MA combipack and misoprostol alone

How does SEMA assess the health of a market?

To assess the health of a market, SEMA has developed a tool – the Healthy Market Framework- which assesses markets (national, product, global) against the criteria described above using different qualitative and quantitative indicators .



- SEMA has developed a list of key indicators for each market dimension and set of supply and demand questions
- These indicators will guide a data collection process to use the frameworks and develop composite “scores” for each which would help us populate a simple visual output to understand the strengths and weakness
- Regularly, SEMA will commission partners to conduct assessments in countries, with products, and of the global ecosystem to assess the current state of the markets
- This framework will be updated on a regular basis to allow high-level monitoring of these markets across time, to help evaluate market interventions, and to identify areas of need that may develop in the future
- SEMA will also assess the utility and availability of indicators to streamline and improve data needs

UNDERSTAND - PRODUCT MARKET – Assessment Dimensions

A healthy, equitable, sustainable SRH market exists when products are available and accessible to meet the diverse needs of consumers.

RESILIENCE

The product supply-base is sufficiently broad, robust, responsive and geographically diverse to maintain supply in the face of shocks. Product financing is predictable, sustainable, and responsive to changes in consumer demand.

AFFORDABILITY

Products are available to both public and private channels at competitive, affordable and cost-effective prices. Pricing allows for manufacturer sustainability. All purchasers can equitably access prices offered by manufacturers.

SUPPLY

There is sufficient supply capacity to meet current and future financed demand.

DEMAND

Financing is adequate and organized to purchase supply and meet consumer demand.

QUALITY

Products supplied to the market meet appropriate quality standards and there is a robust framework for quality assurance. Financing, buying practices and consumer behavior drive better quality globally.

INNOVATION

Products in the market align with consumer needs. There is an active pipeline of consumer-driven innovation. Product development and innovation priorities reflecting consumer needs are systematically identified, evaluated, budgeted for and introduced.

MARKET FOUNDATIONS

Product markets have the foundational functions needed to be healthy, well-understood and shaped effectively.

- i. **DATA AVAILABILITY:** Quality data are available, for both public and private sector, for all relevant market players to monitor, analyse and shape product markets and understand consumer insights and need.
- ii. **INSTITUTIONAL BASE:** The policies and institutions necessary for product markets to function well and deliver for consumers are in place. Key market functions such as procurement, supply chain, regulation and product selection are supportive of access.
- iii. **ANALYTICAL TOOLS:** There is capacity and funding to support routine tools such as demand forecasting as well as tailored technical analysis needed to understand specific market barriers.
- iv. **GLOBAL PARTNERSHIP & ORGANIZATION:** Key players are organised to agree market strategy, fund analysis and interventions, and deliver action.