DRAFT GUIDANCE NOTE – version 2.0 - FOR TESTING AND FEEDBACK

TOPIC: SEMA Country Healthy Market Assessment

Context

Strengthening SRH product markets is the core of SEMA's mission. SEMA has developed a Healthy Markets Framework to help to understand and build consensus around market challenges. This will underpin design and discussion of solutions to the range of market problems, as well as allowing for the monitoring of progress of agreed interventions. The SEMA team developed the first version of this framework in 2022 leveraging lessons from the experiences of organizations such as GAVI, GFATM, USAID, Unitaid, Dalberg, and the Bill and Melinda Gates Foundation. The framework was consulted on with a wide range of partners, as well as being tested in three countries (Nigeria, Burkina Faso and Senegal). Lessons and feedback have been drawn from these experiences and this version represents a refined approach.

Introduction

SEMA is an organisation committed to advancing access to reproductive health services. Recognising the importance that access to safe, effective and affordable products that meet user needs plays within that objective, SEMA has a vision where healthy, equitable and resilient markets for sexual and reproductive health (SRH) products in low- and middle-income countries allow people, especially women and adolescent girls, to control their health and future. To promote that vision, SEMA's mission is to support country and global partners to design and drive coordinated data-based strategies that shape healthy, equitable, and resilient SRH markets capable of meeting communities' diverse needs.

As with markets for other global health technologies, persistent weaknesses in current SRH markets still prevent millions of people from being able to access comprehensive, quality, and affordable SRH products that fit their preferences. These weaknesses can lead to unaffordable prices, disruptions to supply, limitations in choice and availability, substandard quality and slow rollout of new products.
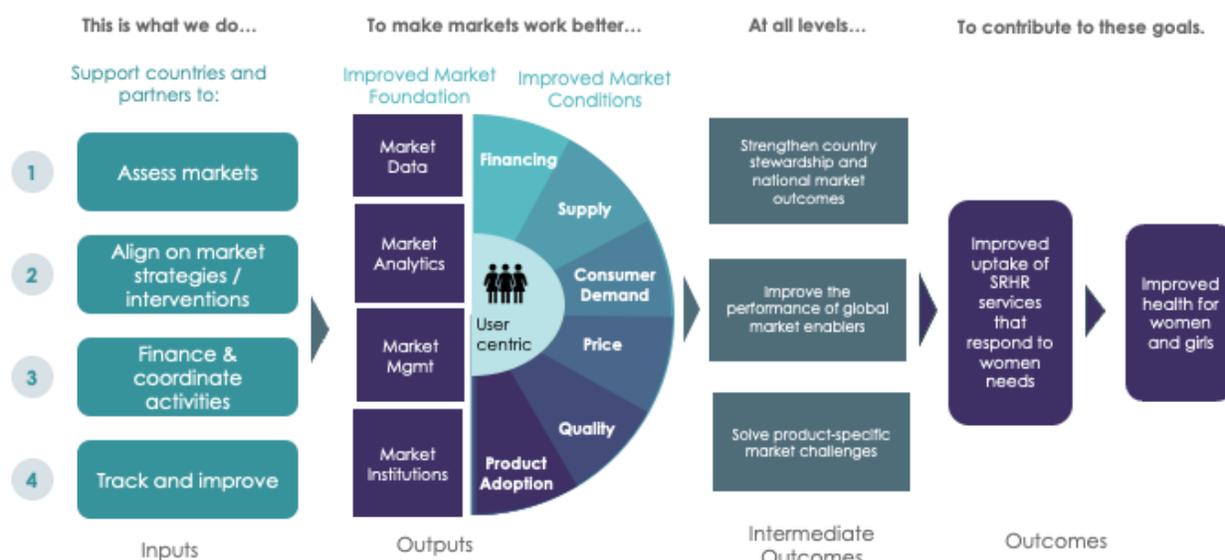
SEMA is bringing a four-stage market shaping cycle to addressing the challenge:

(i)   Assessing the market problem and diagnosing why there is a problem,

(ii)   Aligning on market strategies and interventions,

(iii)   Financing and coordinating activities with partners

(iv)   Tracking performance and improving delivery

Monitoring, adapting and ensuring continuous feedback loops between these three prongs is critical because markets are dynamic and can change, and it is essential to be ready to flex when the environment changes.

These four steps can be seen as inputs in the SEMA Theory of Change set out below. Effective deployment of these steps will strengthen market conditions which, in turn, will contribute to improved access and health outcomes.

Figure 1: SEMA Theory of Change

The SEMA Healthy Markets Framework

SEMA's Healthy Markets Framework runs through SEMA's operating model, providing a foundational source of information and understanding on market problems. In addition, success for the framework will also see it become a reference point for dialogue and consensus-building between partners (country governments, advocates, implementers, investors, private partners, etc.) on market conditions and priorities for intervention. Further, the framework is providing for continuous monitoring of market conditions and health which will allow for the impact of interventions and progress against goals to be tracked.
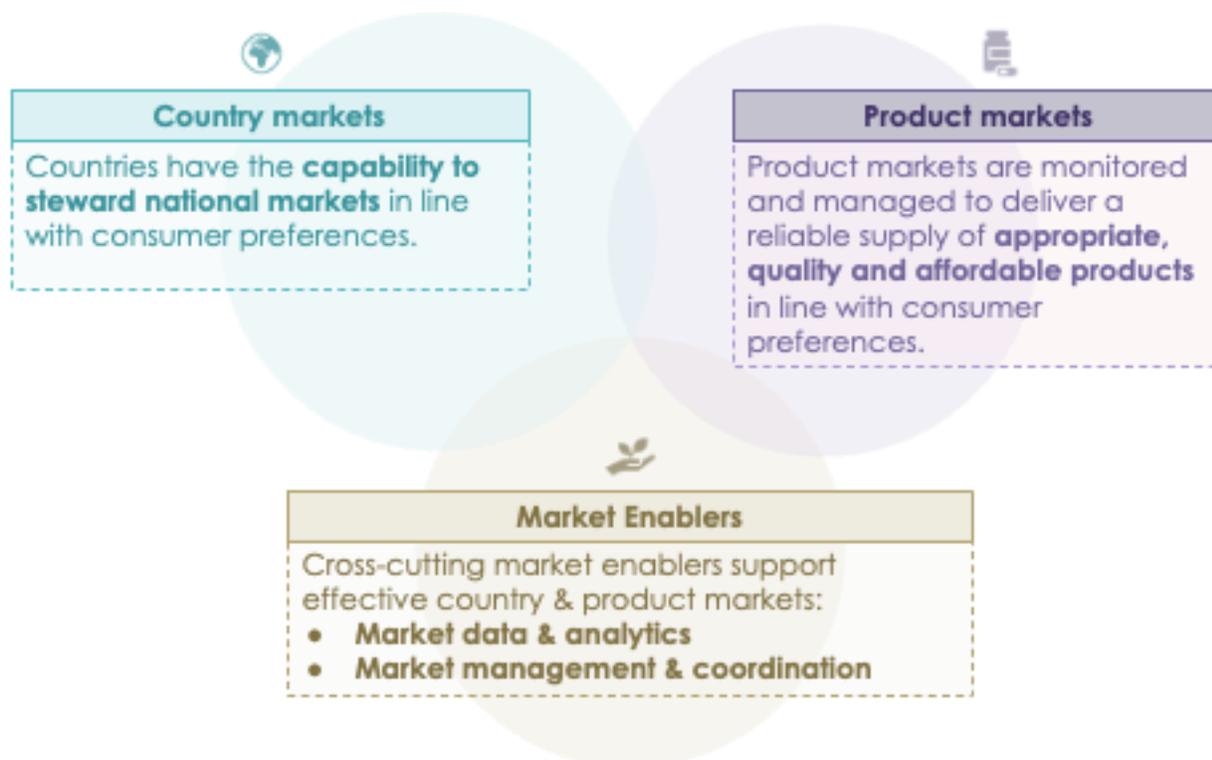
It is critical to establish the right units for effective market analysis. The Healthy Markets Framework considers markets at three inter-connected levels (illustrated in Figure 2). These are:

1. **Country:** The first level is **country-level** assessments, which consist of the interactions between buyers and sellers of products, both public and private, as well as the wider flow of products, within countries.

2. **Product:** Product markets are made up of the interactions between buyers and sellers of individual **products/product categories** across multiple countries**.**

3. **Global Ecosystem:** In order for country markets and product markets to work effectively, well-functioning support is also needed at the global level. This includes global funding and procurement mechanisms, but also critical globally-coordinated enablers, such as quality assurance, market information or market shaping.

If markets and functions at all three overlapping levels are healthy, then the overall ecosystem will also be healthy. This will be reflected in improvement in high-level indicators that track access, equity and sustainability.

Figure 2: A healthy ecosystem depends on transformation of the inter-connected market levels

The Healthy Markets Framework delivers a simple approach for ongoing monitoring and understanding of the health of markets at all three levels. The framework is not providing the final word in market understanding but instead is poised to trigger additional technical deep-dives to better understand identified priorities. Healthy Market Assessments are guided by a structured set of questions and indicators. They are undertaken in a participatory manner and serve as a platform for dialogue on priorities for action and investment. Assessment updates will be undertaken on a regular basis, with results reported on dashboards, to allow for progress to be monitored. The structure of assessments at

the three levels are consistent in terms of market categories and dimensions. However, questions and indicators differ at the three levels to reflect the different characteristics of healthy markets at national, product and global level.

Like other assessment frameworks, the SEMA approach captures familiar market performance concepts such as price, supply and quality. However, the SEMA framework introduces some less commonly-seen ideas:
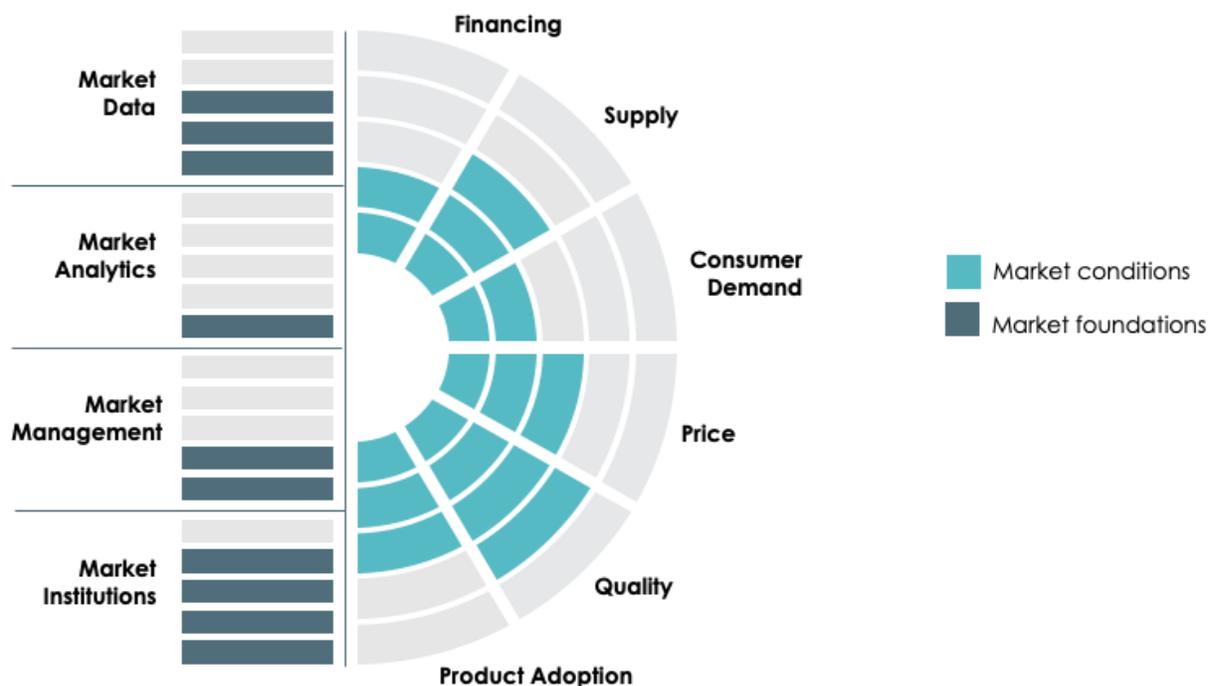
- Recognizing that SEMA's fundamental measure of whether a market is performing well is the extent to which it is meeting the needs of consumers equitably, consumer perspectives and needs are integrated into to almost every dimension of the assessment framework

- The framework includes a component to assess the underpinnings required for market shaping and market management to function effectively (e.g., how feasible it is for the market players to understand the problem, design solutions, and coordinate implementing interventions or whether the supportive policies and institutions are in place for markets to function effectively) – what we call "market foundations." It is in this space that SEMA's comparative advantage in programmatic intervention lies.

The National Healthy Markets Framework

The figure below sets out the basic elements of SEMA's country-level framework. The left-hand column of the framework is made up of the Market Foundations elements. Alongside that, the market is unpacked into six key dimensions of performance. The questions and characteristics apply across the whole market, encompassing both public and private sectors.

Since the aim of the framework is to create a platform for greater common understanding of market challenges and support ongoing high-quality discussion on priorities, it is important to have an accessible approach to presentation of assessment results. The graphic approach in Figure 3 offers a potential structure. The chart is based on scoring each dimension of the framework from 1 to 5. A score of 1 represents poorly-performing and 5 would be highly-performing. A perfectly-performing market overall would score 5 on all dimensions and the solid blocks would be completely filled. We will develop a list of key indicators for each market characteristic and set of supply and demand questions.

Figure 4: Illustrative presentation of national healthy market assessment results

Elements of the National Healthy Markets Framework

The following section provides additional rationale and explanatory text for the different elements in the framework. It is intended to help teams that are undertaking an assessment and accompanies the materials set out in the results template and rating scale guidance. It is important to recognize that data availability is variable across countries and assessments will therefore need to be undertaken flexibly and pragmatically. Assessment teams should seek to gather both quantitative and qualitative data and exercise judgement in applying the framework. Narrative considerations on market performance under each dimension should be included to provide a rationale for assessment and to set out relevant data issues. The overall approach should be considered as draft. Feedback and ideas on how to strengthen and clarify the quality and practicality of the assessment are highly welcome.

A. **Market Foundations:** The framework recognises that many market shortcomings stem from institutional inefficiencies (such as limited procurement capacity or inefficient regulation) rather than more traditional market failures (such as high barriers to entry, limited competition or imperfect information). Further, even where key market shortcomings are traditional market failures, it is important to have the foundational institutional capability (such as data availability and market management capability) required to address them. SEMA's framework therefore starts with an assessment of the institutional underpinnings required for markets, and market shaping, to function effectively.

- **Key overall question:** Does the market have the institutional underpinnings required to function well, to be well understood and shaped?

- **Key sub-questions and data:**
  i. **MARKET DATA:** Is there availability of the quality data required to monitor, analyse and shape national markets and understand consumer access and need? What is the availability of private sector data? Are consumer insights researched and available?

     Relevant data:
     - Quality and availability of data about product/service availability, consumption, quality and pricing, by product
     - Availability of data to conduct forecasts, create budgets, and support planning
     - Overall transparency of market data, including private sector
     - Availability of consumer insights for different population segments

  ii. **MARKET ANALYTICS:** Is there capacity and funding to deploy market management and consumer insight tools? Are the processes in place for routine tools such as demand planning? Can technical and analytical work needed to understand specific market barriers be undertaken?

     Relevant data:
     - Capacity, processes, and data for routine demand planning (both public and private sector)
     - Alignment of supply planning processes with funding cycles
     - Annual budgeting and financing processes informed by SRH forecasts and priorities

  iii. **MARKET MANAGEMENT:** Is there a forum for setting market strategy, taking action and monitoring progress on the existing product portfolio, new introduction opportunities and consumer needs? Does government have the capacity to lead and manage market health, including product introduction and desired balance of access across sectors and channels to ensure a resilient market?

     Relevant data:
     - Working Group or forum to discuss market problems, prioritize issues, take action, and monitor progress
     - Capacity and data to set market strategy and objectives by product category
     - Forum or group to evaluate product portfolio and new product opportunities
     - Strategy and/or targets defining desired balance of access across channels and sectors

iv. **MARKET INSTITUTIONS:** Are the supportive policies and institutions necessary for national markets to function well and deliver for consumers in place? Does the effectiveness of key supportive market functions such as financing, procurement, supply chain, regulation, product selection, etc… create market barriers?

Relevant data:
- Policy environment at national-level supportive of accessibility and choice, including financing policies and frameworks
- Procurement and contracting regulations sufficiently flexible to reduce manuf/supplier dependency
- Transparent, timely and accessible regulatory processes
- Supply chain systems that support continuous flow of products and data

B. MARKET CONDITIONS

i. **FINANCING:** In a healthy market, supply meets demand. In a standard market analysis, financing can be thought of as equivalent to demand. However, in markets for global health products, particularly SRHR, the very significant role of donor funding means that financing needs to be considered separately from health system demand for products. Further, SEMA, like other SRHR partners, is concerned with access (i.e. the scale of markets and the extent to which consumer needs are being reached rather than simply whether markets are functioning efficiently). For these reasons, SEMA HMF considers 'financing' and 'consumer demand' as separate dimensions. This dimension is concerned with the adequacy, and resilience, of financing to secure the supply needed to meet demand from country systems.

Key questions: Is financing adequate to pay for products supplied and to fund demand generated by the service delivery system (both public and private channels)? Are adequate financing mechanisms in place? Is financing predictable and sustainable? How volatile are different sources of financing, including donor, government, private sector and out of pocket? Are there significant risks of financing shocks? Are there mitigation measures or plans that can help cope with such shocks?

Relevant data:

- Historical levels and sources of financing for procurement (pledged and disbursed) disaggregated by source (e.g. donor, government, private, out of pocket)
- Number of financial sources
- Alignment of forecasts and budgeting cycles, decision-making
- Supportive policies for access – e.g. financing frameworks (insurance, subsidies)

- Current procurement budget gaps for product procurement

ii. **SUPPLY:** A fundamental measure of whether markets are functioning well is that supply and demand are meeting, intermediated by financing and available prices, to create market equilibrium or balance. This dimension therefore pairs closely with the 'financing' dimension above. This element assesses whether products coming into national supply chains are sufficient, and sufficiently resilient, to meet funded demand through the system over time and to ensure adequate product availability and mix at point of service.

Key questions: Is there adequate supply of products entering national supply chains to meet funded system demand and ensure adequate availability at point of service? What are overall product volumes supplied to the market, through both public and private channels? Is there sufficient availability through the supply chain to meet system demand? Is there adequate product availability and mix at point of service? Is national supply sufficiently broad, robust, responsive and geographically diverse to maintain supply in the face of shocks? Are there significant risks of supply disruption for specific product categories due to manufacturer dependence or geographical location? Has supply been historically reliable? Are there symptoms of supply stress such as long lead times and stock-outs? Are there mitigation measures that could help cope with supply shocks?

Relevant data:

- Overall product volumes supplied through all channels, public and private
- Product availability by type of outlet/provider, geography
- Number and location of manufacturers by product category
- Number of products per product category with regulatory approval
- Sustainable market opportunities for private sector, including depth and maturity of the sector
- Annual supply volumes vs annual procurement needs by product (last 2-3 years)
- Average national (or point of import/receipt) procurement lead times (including historical trends)
- Historical periods of national (point of import) shortages or stock-outs and root causes

iii. **CONSUMER DEMAND:** As set out above, SEMA, like other global health partnerships, is concerned not only with narrow definitions of market efficiency but also with access and health outcomes. That means that its assessment of market health needs to capture wider concepts of demand, such as consumer need and preferences. The extent to which the market is delivering at a scale sufficient to meet these wider definitions of demand will determine whether desired access and health outcomes are being achieved.

Key questions: Is the overall system meeting wider consumer demand and preferences across the product mix or is there significant unmet need? If so, what are the market barriers that contribute to preventing that wider demand being met?

Relevant data:

- Unmet need
- Method mix by sector, geography, and wealth quintile
- Discontinuation and switch rates by method/product
- Availability of demand forecasts by channel; forecast accuracy measures
- Supportive policies for access – e.g. CBD, OTC status,
- Effective provider counselling and product knowledge

iv. **PRICE:** As with other metrics in the framework, the access-oriented view of healthy markets used by SEMA and other global health players, means that price needs to be considered more widely than in the traditional economic framework, which principally sees price as the mechanism which adjusts to bring supply and demand into line with each other. Lower prices will drive greater access. However, affordability needs to be assessed in a more sophisticated manner. For example, the sustainability of markets needs to be considered and this metric also needs to capture whether pricing is allowing for key participants through the supply chain, in both public and private sectors, to function effectively and sustainably. This metric should also consider questions of interaction between public and private sectors, for example whether pricing in the public sector or subsidised parts of the non-state sector is undermining the health of other parts of the national market.

Key overall question: Does pricing support consumer need and access, as well as market sustainability? Are products available at the national level to both public and private channels at competitive and affordable prices? Do margins through the distribution chain affect affordability? Do pricing policies in parts of the system affect sustainability and access in other channels? Is pricing at point of service equitable across methods, geographical regions, income groups and service channels to meet the needs of all consumers?

Relevant data:

- Prices paid at national level by government and private procurers
- Pricing mark-ups through the system (procurement, wholesalers, distributors, point-of-sale/dispensing)
- Public sector pricing policies
- Average end user price by channel
- Pricing variations by geography or channel
- Ability of people of different wealth quintiles or geographic areas to access a rationally diverse set of methods/options

v. QUALITY: While consumers in rich, strictly regulated countries can generally rely on the efficiency and safety of the health products available to them, a large majority of people in resource-limited countries are at risk of receiving poor quality products. The quality assurance policies and frameworks applied to SRH product markets are highly variable by country, delivery channel and product category. As are result, a wide variation in product quality is observed in markets, raising significant risks for consumers. This metric assesses the quality of products in the market and the extent to which market structures are supportive or not of better quality.

Key overall question: Does the market adequately support the product quality that is critical for consumer wellbeing and health? Do products supplied to the market meet appropriate quality standards? What are the quality assurance standards applied to different supply channels, both public and private? Do the structure of particular product markets at national-level affect quality outcomes? Are false or counterfeit products prevalent? Do financing, buying practices and consumer behaviour drive better quality? Are consumers able to distinguish quality products from non-quality products?

Relevant data:
- Analysis of quality assurance standards met by manufacturers in the market (disaggregated by channel, including historical trends)
- Products in market (registered) meeting international QA standards
- Evaluation of quality supply vs demand
- Levels of substandard/counterfeit products on market
- Variation of quality across different product categories
- QA requirements for procurement by channel
- Consumer awareness and discrimination of quality issues
- Provider awareness and discrimination of quality issues
- Price differential for QA product vs non

vi. PRODUCT ADOPTION: Over the last several decades, the speed with which SRH products and technologies widely available in higher-income countries have been introduced into more resource-scarce settings has been very slow. Further, the level of investment in SRH technologies directly oriented towards the needs of consumers in resource-scarce settings has also been very limited. The importance of a market being able to support continuous innovation and product introduction is particularly important for products or sectors where new technologies are emerging, or where they are available but underused. But continuous innovation is an important feature even for mature markets for established products in order

to ensure that consumer needs are being understood and met and to understand the landscape of emerging technologies.

Key overall question: Are market actors meeting consumer needs through product innovation and introduction? Do existing products include latest available technologies? Do they align with consumer preferences and needs? Is there policy commitment to strengthen this alignment? Are there any additional barriers to new product introduction, such as policy or regulatory factors? Are new product priorities reflecting consumer needs systematically identified, evaluated and introduced? Do budget allocations respond to, and support, product introduction priorities and plans? Are consumer insights on products systematically gathered to inform product introduction priorities?

Relevant data

- Alignment of existing products with consumer preferences/needs
- Commitment to evidence-based policy to respond to user needs
- Inclusion of products in market on WHO Essential Medicines List and national EML
- Regulatory processes to register new products
- Ability to assess user needs, evaluate product portfolio and value proposition of new products
- Length of the cycle of product introduction and rollout
- Ability to budget and coordinate product introduction efforts (especially across sectors)
- Time to adaptation and provider awareness (public and private)