

DRAFT GUIDANCE NOTE – version 2.0 - FOR TESTING AND FEEDBACK



TOPIC: SEMA Product Healthy Market Assessment

Context

Strengthening sexual and reproductive health (SRH) markets to meet communities' diverse needs is the core mission of SEMA, an organisation committed to advancing access to SRH products and related services. SEMA envisions a world where healthy, equitable and resilient markets for SRH products in low- and middle-income countries allow people, especially women and adolescent girls, to control their health and future. SEMA believes that by understanding and strengthening SRH markets, the ecosystem as a whole will function better and deliver expanded, and more country-led, resilient, equitable and sustainable access for those that need it.

To build a better understanding of national, product and global markets, SEMA has developed a Healthy Markets Framework (HMF). The HMF underpins assessment, design and discussion of solutions to a range of market problems and allows 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 a multiple stakeholders. The framework was consulted on with a wide range of partners, as well as being tested in three product categories (injectables, hormonal IUD and products for medical abortion). Lessons and feedback have been drawn from these experiences and this version represents a refined approach.

Introduction

SEMA is 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 recognises that market shaping initiatives over the past decade in global health generally, and reproductive health specifically, have delivered huge gains in terms of access and value for money. However, these initiatives have generally been designed and delivered by global actors in line with globally

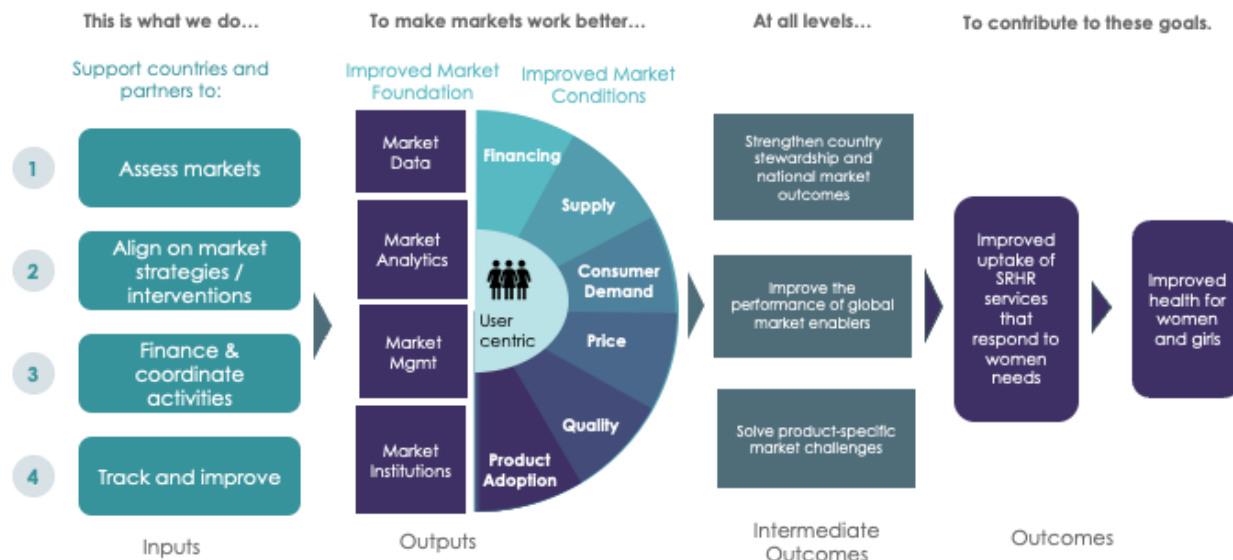
determined priorities. They have often been product-specific rather than holistic in nature and have been ad hoc and transaction cost intensive. They have also not empowered local actors to steward national markets. Over the next decade, as funding and procurement progressively transitions away from international donors, it is critical that the centre of gravity for market shaping efforts also shifts. SEMA's is supporting an approach to market shaping and access for SRH products that is founded on country leadership, priorities and capacity. This approach should also build a collaborative platform for all stakeholders to align on priority market problems, jointly problem-solve and coordinate resources more efficiently to overcome SRH market challenges.

SEMA brings 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

Effective deployment of these steps will strengthen market conditions which, in turn, will contribute to improved access and health outcomes as shown in the SEMA Theory of Change (TOC) in Figure 1 below. The column on the left summarizes these four key inputs. SEMA anticipates that these activities will generate the outputs in the middle column, which relate to improvements in market foundations and characteristics. The Theory assumes that success in these efforts will contribute to improved health outcomes, including increased effective uptake of health services and, over time, health impact.

Figure 1: SEMA Theory of Change



The SEMA Healthy Markets Framework

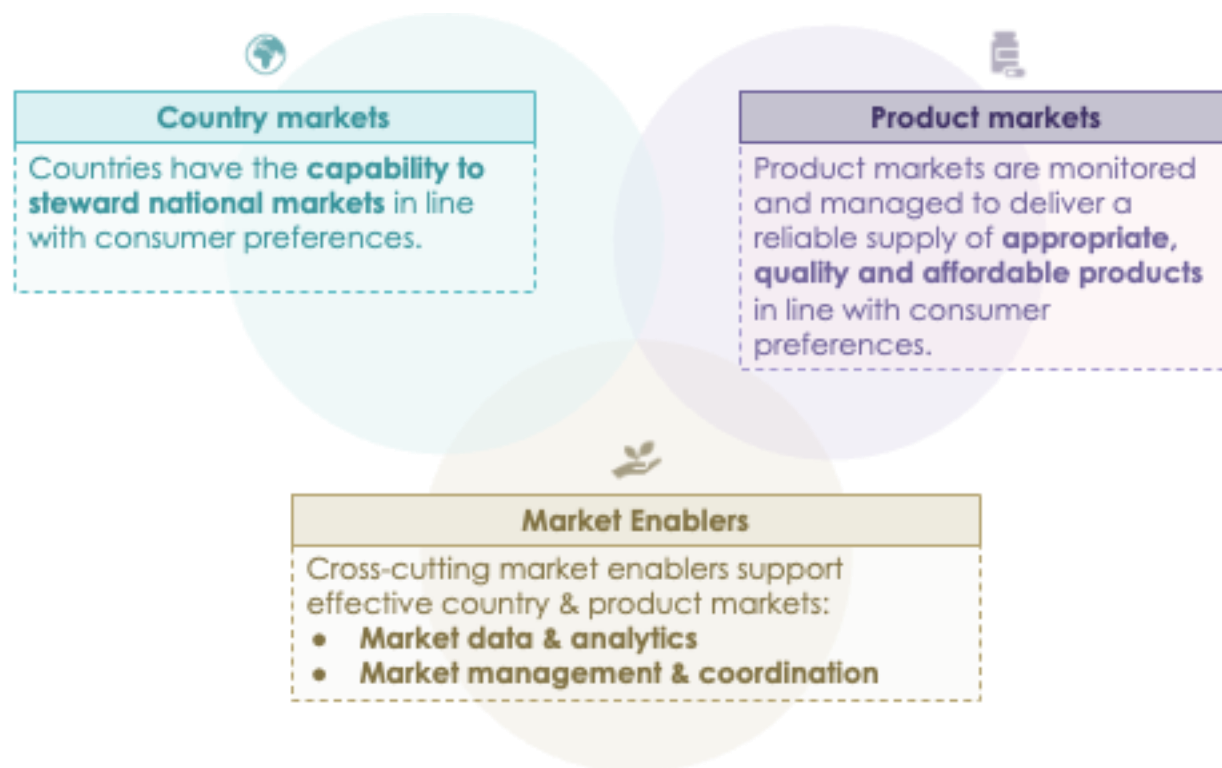
SEMA’s Healthy Markets Framework runs through SEMA’s operating model, providing a foundational source of information and understanding on market problems. In addition, success for the framework will also see it become a reference point for dialogue and consensus-building between partners (country governments, 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. **Market Enablers:** 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 does not provide the final word in market understanding but instead may 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 will be consistent in terms of market categories and dimensions. However, questions and indicators will 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.

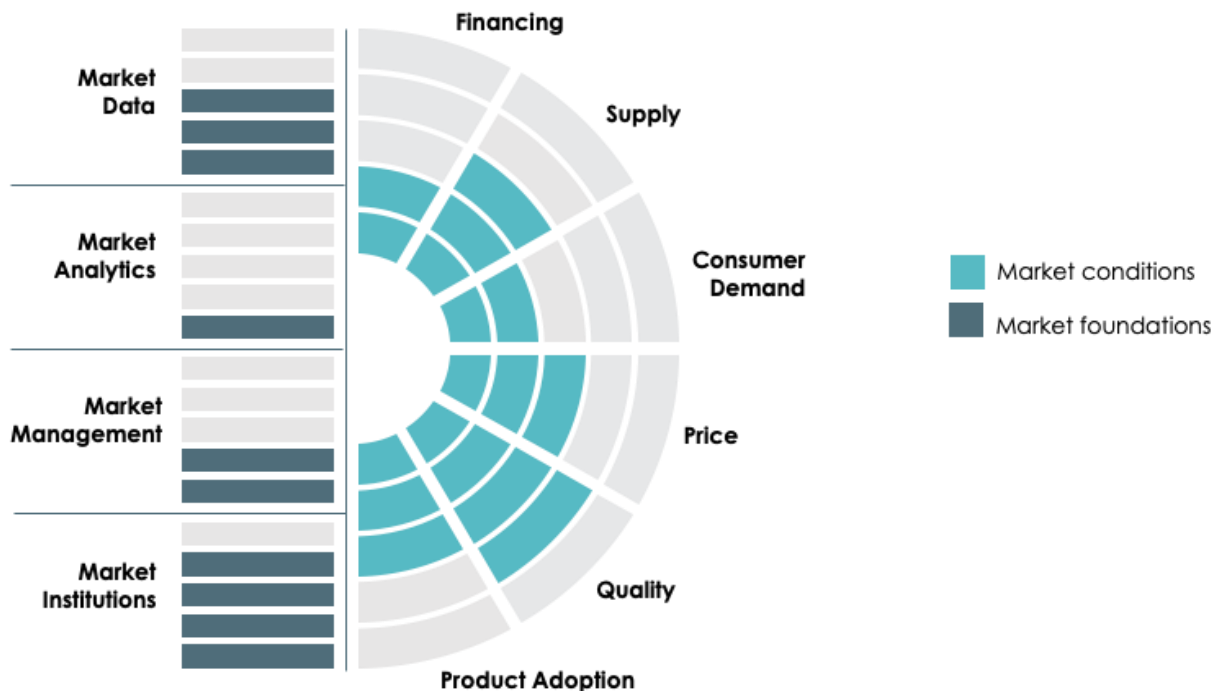
The Product Healthy Markets Framework

The figure below sets out the basic elements of SEMA’s product market 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 product healthy market assessment results

Template to complete this to be provided by SEMA.



The elements of the Product 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. 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 recognizes 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). It is important to consider such institutional inefficiencies in the overall context of market shortcomings and potential solutions. Further, even where key market shortcomings are traditional market failures, it is important to have the foundational institutional capability (such as market 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 product 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 product markets and understand consumer access and need? Is data available to key market participants, such as manufacturers? What is the availability of private sector data? Are consumer insights researched and available?

Relevant data:

- Quality and availability of data required to assess market health against this framework (including disaggregation by public and private sector)
- Availability of data to consumers/users on e.g. price, availability, quality
- Information transparency to manufacturers to incentivize/plan (forecasting, financing outlook)

- ii. **MARKET ANALYTICS:** Is there capacity and funding to produce market shaping and consumer insight studies, tools and reports? 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:

- Global demand forecasts available and providing visibility into current and future demand (public and private)
- Funding for analytical tools, such as market diagnostics, COGs analysis, etc...

- iii. **MARKET MANAGEMENT:** Is there a functioning forum for supporting agreed objectives, setting market strategy, taking action and monitoring progress? Are partners making available the funding (either on a cross-cutting basis or product-specific basis) required for the market analytics and interventions needed to deliver access objectives?

Relevant data:

- Level of organization of key players (funders, procurers, countries, providers) in support of access objectives
- Level of funding and availability of functions and tools needed for market interventions in support of access objectives
- Degree of consensus around access goals

- 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:

- Global-level evidence-base and policy environment supportive (e.g. WHO guidelines)
- Policy environment at national level supportive (as measured by number of countries introducing/sustaining)
- Capability of procurement platforms to employ strategic approaches and different purchasing methods
- Identification of any relevant supply chain, service delivery or regulatory issues

B. Market Performance Outputs

- 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 procure product demand generated by the system (both public and private channels)? Are adequate financing mechanisms and policy frameworks 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
- Supportive policies for access – e.g. financing frameworks (insurance, subsidies)
- Current budget gaps for product procurement
- Annual funding and procurement volumes, including historical trends and forecasts (disaggregated by source/channel)

- Share of volumes procured through different types of buyers
 - Funding share of largest 3 funders
 - Future financing forecasts (for all categories) including shift to more 'sustainable' sources
- ii. **SUPPLY:** A fundamental measure of whether markets are functioning well is that supply and demand are meeting, intermediated by available prices, to create market equilibrium or balance. This dimension therefore pairs closely with the 'financing' dimension above. This element assesses whether total global product supply is sufficient, and sufficiently resilient, to meet funded demand from country systems over time.
- o **Key overall question:** Is there sufficient global supply capacity and availability to meet current and future financial demand? Is the product supply-base sufficiently broad, robust, responsive and geographically diverse to maintain global supply in the face of shocks? Are there significant risks of supply disruption due to manufacturer dependence or geographical location? Has supply been historically reliable? Are there symptoms of supply stress such as long lead times? Are there mitigation measures that could help cope with supply shocks?

Relevant data:

- Product volumes supplied (historical trends and future forecasts)
 - Annual supply volumes vs annual procurement needs (last 3 years) disaggregated by market segment (e.g. public, private sector)
 - Average procurement lead times (including historical trends)
 - Number and geographical location of manufacturers (of finished product as well as API where appropriate)
 - Market share of largest manufacturer
 - Number of products with regulatory approval (finished product and API where appropriate)
 - Market attractiveness for new or existing manufacturers (e.g. disincentives due to free/subsidized products)
 - Annual supply volumes vs annual procurement needs (last 3 years)
 - Historical periods of shortage and root causes
 - Risk assessment of supply disruption (e.g. due to export bans, capacity diversion to other products or to high-income markets, manufacturer exit, etc..)
 - Assessment of manufacturer ability to respond quickly to demand spikes
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- and disbursed) disaggregated by source (e.g. donor, government, private, out of pocket)
 - Number and structure of funders

- Funding share of largest 3 funders
- Future financing forecasts (for all categories) including shift to more 'sustainable' sources
- Donor planning and budgeting cycle that can foresee and respond to changes in consumer demand
- Evidence of shifts in financing patterns to support evolving consumer demand (e.g. in terms of new methods)

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 overall question:** Is the overall product market meeting wider consumer demand and preferences is there significant unmet need? If so, what are the market barriers that contribute to preventing that wider demand being met?

Relevant data:

- Use and consumption volumes by channel (historical trends and forecasts) compared to estimated potential consumer use
- Unmet need
- Discontinuation and switch rates
- Availability of demand forecasts by channel
- 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 it is 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 and balanced 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 product market.

WORK IN PROGRESS – UNDER REVIEW

- **Key overall question:** Does pricing support consumer need and access, as well as market sustainability globally?
- **Key sub-questions and relevant data:**
 - Are supplier prices a barrier to access? Is pricing at a cost-effective level? Does pricing allow for manufacturer financial sustainability? Are competitive pressures affecting prices? What are the key underlying production cost issues?
 - Is pricing equitably available to all those who purchase from suppliers (including governments, different service channels, institutional buyers)?

Relevant data:

- Product prices offered by manufacturers to purchasers, disaggregated by market category as appropriate (e.g. by institutional procurers, private sector, country income level)
 - \$/Couple Year of Protection (CYP)
 - Number of manufacturers in the market
 - Risk of manufacturer exit
 - Cost of Goods Sold (COGS) analysis (to the extent available) and potential for COGs reductions at increased scale of production
 - Manufacturer margins
 - Prices paid by procurers and importers, including variability within country categories and types of procurer
 - Ability and willingness of different procurers to pay prices offered
- 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 can be highly variable by procurer, country, delivery channel and product category. As a 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?
 - **Key sub-questions and relevant data:**

WORK IN PROGRESS – UNDER REVIEW

- Do products supplied to the market meet appropriate quality standards? Does the structure of the market affect quality outcomes? Is quality an issue for the inputs into finished products? Are false or counterfeit products prevalent?
- Do financing, buying practices and consumer behaviour drive better quality? What are the quality assurance standards applied by different procurers, both public and private?

Relevant data:

- Number of manufacturers meeting internationally-recognized quality assurance standards
- Shares of market volumes (disaggregated by channel, including historical trends) that meet international QA standards
- Analysis of share of Active Pharmaceutical Ingredients (API) and other inputs that meet international quality assurance standards
- Volumes of substandard/counterfeit products on market
- Volumes of products procured of different QA standards disaggregated by procurer
- Number of procurers (e.g. Social Marketing Organisations, donors, governments, private providers) who require internationally-recognized QA products
- QA standards of key procurers

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?
- **Key sub-questions and relevant data:**
 - Do existing products meet consumer needs? Is there an active pipeline of consumer-driven innovation? Are there any additional barriers to new product introduction, such as policy or regulatory factors?

WORK IN PROGRESS – UNDER REVIEW

- Are product introduction priorities reflecting consumer needs systematically identified, evaluated and delivered? Are key actors (e.g. countries, manufacturers) actively introducing new technologies? Does funding respond to, and support, product introduction priorities and plans? Are consumer insights on products systematically gathered to inform product introduction priorities?

Relevant data:

- Evidence of consumer insights, user preferences, product acceptability, etc... from target markets
- Number of products in development pipeline, and stage of development
- Funding (if available) for product development, clinical trials and registration (disaggregated by private and public sector)
- Evidence of additional potential barriers to new product development (e.g. IP)
- Number of plans (by manufacturers or providers) for product rollout into new countries and markets
- Donor funding for product introduction
- Number of countries adopting and rolling out products in this category over last 3 years
- Number of countries with plans to adopt and roll out products in this category over next 3 years