Creating an effective & sustainable ecosystem for reproductive health supplies by 2030

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<table>
<thead>
<tr>
<th>Acronym</th>
<th>Definition</th>
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<tbody>
<tr>
<td>API</td>
<td>Active pharmaceutical ingredient</td>
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<tr>
<td>BMGF</td>
<td>Bill and Melinda Gates Foundation</td>
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<td>CGA</td>
<td>Contraceptive Commodity Gap Analysis</td>
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<tr>
<td>CHAI</td>
<td>Clinton Health Access Initiative</td>
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<td>COG</td>
<td>Cost of goods</td>
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<td>CPR</td>
<td>Contraceptive prevalence rate</td>
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<td>CSP</td>
<td>Coordinated Supplies Planning</td>
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<tr>
<td>CSR</td>
<td>Corporate Social Responsibility</td>
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<td>EML</td>
<td>Essential Medicines List</td>
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<td>FP</td>
<td>Family Planning</td>
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<td>FP2020</td>
<td>Family Planning 2020</td>
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<td>GFF</td>
<td>Global Financing Facility</td>
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<tr>
<td>GHSC-PSM</td>
<td>Global Health Supply Chain Program – Procurement and Supply Management</td>
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<td>CIFF</td>
<td>Children’s Investment Fund Foundation</td>
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<td>General Membership Meeting RHSC</td>
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<tr>
<td>GNI</td>
<td>Gross National Income</td>
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<td>GFPVAN</td>
<td>Global Family Planning Visibility and Analytics Network</td>
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<td>IAP</td>
<td>Implant Access Program</td>
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<tr>
<td>ICPD</td>
<td>International Conference on Population and Development</td>
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<td>NGO</td>
<td>International Non-Government Organization</td>
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<td>IPPF</td>
<td>International Planned Parenthood Federation</td>
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<td>KEI</td>
<td>Key expert interview</td>
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<tr>
<td>LIC</td>
<td>Low-income country</td>
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<tr>
<td>L-MIC</td>
<td>Lower middle-income country</td>
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<td>MH</td>
<td>Maternal Health</td>
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<tr>
<td>MSI</td>
<td>Marie Stopes International</td>
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<tr>
<td>MVA</td>
<td>Manual Vacuum Aspiration</td>
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<tr>
<td>mCPR</td>
<td>Modern contraceptive prevalence rate</td>
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<tr>
<td>NGO</td>
<td>Non-government organization</td>
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<tr>
<td>NHIS</td>
<td>National Health Insurance system</td>
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<tr>
<td>NRA</td>
<td>National Regulatory Authority</td>
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<tr>
<td>OOP</td>
<td>Out of pocket</td>
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<td>PAC</td>
<td>Post abortion care</td>
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<td>PQ</td>
<td>WHO Prequalification</td>
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<td>PSI</td>
<td>Population Services International</td>
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<tr>
<td>R&amp;D</td>
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<td>Reproductive health</td>
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<td>Reproductive Health Supplies Coalition</td>
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<td>SDG</td>
<td>Sustainable Development Goals</td>
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<td>SA</td>
<td>South Asia</td>
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<tr>
<td>SEA</td>
<td>South East Asia</td>
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<tr>
<td>SMO</td>
<td>Social marketing organization</td>
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<tr>
<td>SRA</td>
<td>Stringent Regulatory Authority</td>
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<td>SRH</td>
<td>Sexual and reproductive health</td>
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<td>SRHR</td>
<td>Sexual and reproductive health and rights</td>
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<tr>
<td>SSA</td>
<td>Sub-Saharan Africa</td>
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<tr>
<td>TMA</td>
<td>Total market approaches</td>
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<tr>
<td>UHC</td>
<td>Universal health coverage</td>
</tr>
<tr>
<td>U-MIC</td>
<td>Upper-middle income</td>
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<tr>
<td>VFM</td>
<td>Value for money</td>
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<tr>
<td>WHO</td>
<td>World Health Organization</td>
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<tr>
<td>WRA</td>
<td>Women of reproductive age</td>
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<td>VAN</td>
<td>Visibility Analytics Network</td>
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To guarantee equitable access to family planning, maternal health, safe abortion and menstrual health services, the global reproductive health ecosystem must ensure that the supplies associated with those services reach women at prices they can afford; and cultivate the healthy markets needed to sustain product innovation and availability.
Summary of key issues and recommendations

In 2018, the Reproductive Health Supplies Coalition (RHSC) was tasked with identifying a collective vision of the reproductive health (RH) supplies ecosystem for the coming decade. In the first phase of that effort, a highly participative process was undertaken to analyze the RH supplies space from four distinct but interrelated perspectives: shape of the market, finance, procurement and supply chain. This report is the output of that process. It details key elements of the RH supplies ecosystem, summarizes the community’s vision for 2030, and sets forth a series of recommendations to support achievement of that vision. Key recommendations of the report are summarized below:

RECOMMENDATION 1

In the context of likely reductions in donor funding and more reliance on domestic government funding and out of pocket expenditure (OOP) by users, we need to broaden achievements in procurement, accessibility and efficiency across both public and private sectors to benefit all ecosystem participants. This means greater engagement with the private sector in all parts of the supplies ecosystem to:

+ Improve communications between sectors, ensure that participants appreciate others’ value propositions and sustainability criteria, and develop joint approaches to supplies planning such as technology introduction and market development.

+ Increase visibility and sharing of information, including among private sector actors, to improve the efficient flow of supplies through the ecosystem (for example, through development of Visibility and Analytics Networks at global and country levels, and promotion of their use by ecosystem participants).

+ Reduce obstacles to market participation (e.g. registration of products, legal restrictions on public sector procurement of medical abortion supplies) whilst maintaining quality; this includes streamlining systems to facilitate introduction of generic products and to safeguard quality in national and regional procurement.

+ “Do no harm” to private sector market development (for example, by maintaining healthy price competition and avoiding situations where manufacturers cannot compete with reduced prices of aggregate procurement programmes).

+ Broaden access to more efficient procurement by all actors, taking advantage of the opportunities offered by advances in technology (for example, through development of web-based market intelligence and eProcurement systems which are visible and open to all ecosystem actors).
RECOMMENDATION 2

Reduce the vulnerabilities that have resulted from small numbers of key suppliers and concentration of public sector procurement by:

+ Developing new technologies to provide more options for buyers and reduce reliance on single suppliers.

+ Designing and implementing market management strategies to assess global markets for deploying new products, including financing of market development, promotion to buyers, development of service provider skills, and consumer education.

RECOMMENDATION 3

Better understand, through research and other means, the factors that influence equitable access to RH supplies, to ensure scarce resources are directed to where they are most needed. In the context of current financing trends, we can expect growth in out of pocket (OOP) spending by consumers, but we have very little information on private sector markets. OOP will not be a problem everywhere as many consumers can afford to pay, but we need to identify the countries, and the population groups within countries, where support is needed to ensure equity of access.

RECOMMENDATION 4

To ensure equity in the decade ahead, promote inclusion of all types of RH supplies in Universal Health Coverage (UHC) schemes. UHC is key to increased equity for all. The supplies ecosystem has an important role in supporting advocacy with country governments to ensure the inclusion of RH supplies.

RECOMMENDATION 5

Help optimize the use of scarce financial resources in the public sector and leverage those which are available through:

+ Facilitating better alignment of donor finance, and inclusion of new donors in the ecosystem.

+ Supporting development of innovative financing arrangements.
CHAPTER 1
The reproductive health supplies ecosystem

The year 2020 marks the end of a decade that has witnessed some truly remarkable advances in widening access to a broad range of affordable, quality-assured contraceptive supplies. But it also marks the beginning of what promises to be some fundamental changes in the reproductive health (RH) landscape. Many of the donor-supported initiatives that have shaped today’s current supplies landscape, such as Family Planning 2020 (FP2020) and UNFPA Supplies, will likely undergo significant change. Others, like USAID’s Global Health Supply Chain Program – Procurement and Supply Management (GHSC-PSM) project, will be subject to rebidding. These large initiatives are important parts of a broader supplies ecosystem which includes a wide range of interacting participants including manufacturers, donors, international organizations, country governments, procurers, service providers in both the public and private sectors, and most importantly of all, the millions of women who use RH and family planning (FP) supplies.

Many within the donor community remain fully committed to financing RH supplies in the decade ahead. But how that commitment is operationalized will depend on a clearer understanding of what the next decade is likely to bring and where the community sees itself ten years hence. RH financing must respond to the realities of a new decade and a wider ecosystem of players. Most importantly, it must reflect a vision of the future in line with the values and priorities of the RH community as a whole, the development principles and targets of the Sustainable Development Goals (SDGs) and the International Conference on Population and Development Beyond 2014 (ICPD Beyond 2014), which aim to increase access to sexual and reproductive health (SRH) services and universal health coverage (UHC) by 2030. Within the SDG framework, the ecosystem focuses specifically on RH supplies as an essential element in service provision, aiming to strengthen and sustain availability of quality RH supplies.
Purpose of the supplies ecosystem work

The Reproductive Health Supplies Coalition (RHSC) has been asked to lead a community-wide process of visualizing an effective and sustainable ecosystem for RH supplies by 2030. This includes identification of emerging trends in the current landscape that promise to shape the environment in the next decade; an assessment of the relative effectiveness of efforts currently underway within the RH ecosystem to address current and future challenges, including the limitations of existing methods in addressing user needs; and a formulation of strategic directions for the supplies ecosystem, with special attention to the potential contribution of the donor community over the coming decade.

Method for the ecosystem analysis

This effort builds on the results of a consultation carried out in July 2018 which identified four conceptual themes of ecosystem development. The first is the “shape of the total market” for RH supplies; the second concerns financing – a cross-cutting theme for the whole ecosystem analysis; the third focuses on commodity procurement; and the fourth involves effective supply chains that provide end-to-end visibility from manufacturer to the last mile. Although there are other cross-cutting issues affecting all four themes, this has been a practical way of structuring the initial analysis of a complex system, with a view to developing an integrated vision of the ecosystem as a whole for 2030. Our analysis covers the principal supplies categories currently included in the ecosystem: FP, maternal health, safe abortion and menstrual health supplies.1

The ecosystem analysis has used the following inputs:

+ Quantitative work on current demand, supplies and finance, and identification of gaps for the different categories of supplies2;
+ Documentation on the context of the supplies ecosystem and current efforts under each of the four themes and supplies categories;
+ Interviews with 88 experts (donors, international organizations, manufacturers, technical specialists) to assess current work, and its strengths and weaknesses;3
+ Group discussions with expert constituents within each theme to validate key findings and identify critical issues and recommendations for future action;
+ Input and survey responses4 from participants at the RHSC General Membership Meeting (GMM) 2019.

Information was triangulated to identify consensus on advances and challenges, and where differences in opinion persist. Draft discussion papers covering the current landscape, critical issues and potential futures were prepared for expert meetings under each theme. Input from those discussions was used to develop the overall ecosystem vision and strategy recommendations for the next decade. Preliminary results were presented to a wider group of ecosystem partners at the RHSC GMM; feedback from that meeting has been incorporated in this final report.

Report structure

The report identifies and analyses critical issues in the current RH supplies landscape, and our collective vision of the principal areas of work for the coming decade. Although supplies are but a part of RH service provision and are embedded within overall RH policies and programmes (including investments in innovations and regulatory processes), the report maintains its focus on supplies. It aims to inform donor policy and to provide a framework for ecosystem participants to develop their own visoning for the coming decade. The report includes strategy recommendations based on collective thinking by the RH supplies community for priority areas of work but is not itself an action plan.

Chapters 2, 3, 4 and 5 of the report look at how we envisage the supply space during the coming decade. We identify current trends and critical issues in each of the four principal workstreams (shape of the market, finance, procurement and supply chain) for FP, maternal health, safe abortion and menstrual health supplies.

Chapter 6 proposes the 2030 vision for the supplies ecosystem based on analyses of trends in markets and client needs, and on inputs and discussions with partners from the supplies community. Chapter 7 presents strategy recommendations for the next decade.

Annex 1 includes those who participated in interviews and discussion groups, and Annex 2 summarises responses to the GMM participants’ survey.

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1 HIV/AIDS supplies have not been included as they are financed, procured and distributed through specific channels
2 Principal sources included the RHSC Commodity Gap Analysis 2018 (CGA), Track20, Clinton Health Access Initiative (CHAI) Family Planning Market Report 2017, Kaiser Family Foundation data, and various publications of the Guttmacher Institute (see list of references)
3 See Annex 1
4 A total of 91 conference participants responded to a short survey on the initial findings of the ecosystem analysis which were presented at the conference. A summary of responses is shown in Annex 2
CHAPTER 2
How do we envision the coming decade?

Access to affordable and quality-assured supplies is an essential part of RH service provision, and a basic right of all users.

Global partners in the RH supplies ecosystem have focused their work on the 135 countries in the lower- and middle-income groups and on supplies used to provide family planning and maternal health services, with the more recent addition of safe abortion and menstrual health supplies as priority areas. These priorities are expected to continue during the next decade.

This chapter analyses the demand and supply sides of the market, critical issues and the type of changes we may expect to see over the next decade for FP and other RH technologies and supplies. Chapters 3, 4 and 5 focus on the other 3 workstreams: finance, procurement and supply chain.

5 We use the term “supplies” to cover the whole range of contraceptive technologies, maternal health, safe abortion and menstrual health drugs and products included in the supplies ecosystem partners’ work.
2.1 GROWING DEMAND FOR FAMILY PLANNING AND REPRODUCTIVE HEALTH SUPPLIES

The overall market size for RH supplies and its growth depends on the number of potential users of RH services now and in the future, and their access to essential supplies. The number of potential users\(^6\) will change with demographic trends and shifts in the population age structure. Table 1 shows expected growth in the total number of women of reproductive age in different country income groups. Figure 1 shows that the proportion of men and women of reproductive age is expected to grow slightly (3%) in the low-income countries (LICs), but decline in all other income groups, with the largest decline (6%) in the upper middle-income countries (U-MICs).

Availability of supplies and access to them will depend on public sector finance, regulatory and procurement policies and practice, in-country commodity distribution, service provision in the public and private sectors, as well as users’ ability to pay for supplies in the private sector. Socio-cultural factors also affect access to SRH services for some user groups.\(^7\)

TABLE 1: PROJECTED GROWTH IN THE NUMBER OF WOMEN OF REPRODUCTIVE AGE (WRA) BY COUNTRY INCOME GROUP (MILLIONS)\(^8\)

<table>
<thead>
<tr>
<th>Income Group</th>
<th>2020</th>
<th>2025</th>
<th>2030</th>
</tr>
</thead>
<tbody>
<tr>
<td>LICs</td>
<td>191</td>
<td>222</td>
<td>254</td>
</tr>
<tr>
<td>L-MICs</td>
<td>795</td>
<td>844</td>
<td>887</td>
</tr>
<tr>
<td>U-MICs</td>
<td>308</td>
<td>312</td>
<td>314</td>
</tr>
</tbody>
</table>

Source: RHSC CGA 2019, based on UNDP WPP projections 2017\(^9\)

FIGURE 1: PROJECTED CHANGE IN THE DISTRIBUTION OF THE TOTAL POPULATION BY MAJOR AGE GROUPS

Source: Starrs et al (2018)\(^10\) (Data from UN Population Division, medium variant projections, 2017.31 Country classification by income is based on 2016 gross national income (GNI) per capita from the World Bank. Projections for 2030 assume income groupings will remain constant over time)

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6 Women in the reproductive age range with a manifest or latent need for RH supplies

7 For example, mores and taboos about adolescent Access to SRH, women’s ability to exercise their SRH rights, cultural attitudes to fertility, religious influences, community attitudes to SRHR etc.

8 These figures, and all other figures quoted from CGA, do not include China or Venezuela in the UMIC group

9 Reproductive Health Supplies Coalition. Global Contraceptive Commodity Gap Analysis 2019 (Forthcoming)

2.1.1 Increasing demand for family planning supplies in all country income groups

FP has direct benefits for users, and it has externalities for communities, for countries and at global level. As a “public good” which benefits users and the wider community, it attracts donor funds. It raises issues of women’s right to access as well as equity issues. But it is also a commercial good which must have a sustainable value proposition for manufacturers, distributors and service providers in the private sector.

Evidence suggests that the coming decade will see a substantial increase in the number of family planning users, which implies a corresponding increase in the volume of supplies required to satisfy that growth. Data from the RHSC Commodity Gap Analysis 2019 (CGA 2019) projects that there will be 487m family planning users across the 135 low- and middle-income countries by 2020, increasing to 531m in 2025 and 569m in 2030, an overall growth of 17% over the coming decade (2020 to 2030).

Behind this global increase is a host of variables exerting a powerful influence over the growth trajectory of FP in any single country or group of countries. These include variations in levels of demand, users’ access to FP information, approved methods and services; socio-economic variables such as education, household income and urban/rural split; past and present national FP policies; gross national income (GNI) which affects government allocation of resources to FP; and many others. Important differences show up when data is disaggregated to country level.

To develop a strategic overview we have followed the approach adopted by CGA2019, which divides our universe of 135 low- and middle-income countries into three groups defined by the World Bank on the basis of gross national income (GNI) per capita: low-income countries (LICs), lower-middle-income countries (L-MICs) and upper-middle-income countries (U-MICs). There are 34 LICs, 47 L-MICs, and 54 U-MICs. According to CGA 2019, 10% of current users of FP are located in the LICs, 65% in the L-MIC group, and 30% in the U-MIC group.

Among the 34 low-income countries, 85% are priority countries for FP support for at least one of the four principal donors (USAID, UNFPA, DFID, Gates Foundation). Nearly half of the 47 lower-middle-income countries are priority countries for one or more of these donors, but none of the 54 upper middle-income countries are donor priorities. Although the low-income countries account for just 10% current FP users, nearly 60% of donor funding for supplies is spent there. Most of the remaining donor funds (37%) are spent in the lower-middle-income group, with only four percent of donor funding going to upper-middle-income countries, mainly through NGOs.

In the family planning space, users access three categories of supplies: (1) supplies from public sector service providers (where public sector entities generally take on the cost of the procurement); (2) subsidized supplies accessed through private sector entities (such as NGOs or socially marketed products sold through pharmacies); (3) non-subsidized supplies at commercial prices through various private sector entities (pharmacies, clinics and other outlets in the for-profit private sector). According to CGA 2019, 57% of users in the 135 LMIC receive supplies from the public sector, five percent access supplies at subsidized prices in the private sector, and 37% pay full price out of pocket (OOP) for supplies from the private sector. The relative size of these groups differs widely by country and by country income. In the 34 LICs 70% of women use public sector services. In the 47 L-MICs this drops to 59%, and among the 54 U-MICs, use is evenly split between the public and the commercial private sectors. Spending, however, skews heavily towards the commercial private sector due to method mix and price structures (see below).

Future growth in FP use will depend on demographic trends, changing demand patterns, national FP policies, regulatory practices and resource allocation, and the ability of the public and private sectors to meet demand. These factors will lead to differential rates of increase in each country. Looking to the coming decade, if current trends continue, we expect the highest rate of growth of users to take place in the LICs (60% over the coming decade), and the largest growth in the absolute number of users to take place in the L-MICs (47.2m additional users).

11 “a consequence of an industrial or commercial activity which affects other parties without this being reflected in market prices, such as the pollination of surrounding crops by bees kept for honey.” In the case of FP, externalities may include lower demands on the health system for MCH and family planning services, individual freedom for men and women to enjoy a healthy sexuality, lower child-rearing costs for families, less demands on public infrastructure and services at community, national and global levels, etc

12 Groups based on country income are not ideal, as aggregate numbers are skewed by countries with large population numbers and/or FP policies focused on specific methods (eg India, Brazil), as discussed later in this report. For many programme development tasks, country specific information is needed. The country income groups are useful at strategic level as they enable identification of some trends and use of the CGA results.

13 However these countries do still receive some donations, eg some LAC UMIC receive earmarked RHSC funds

14 Donors or domestic governments

15 Donors or Governments also support the procurement of these supplies, allowing consumers to access them at a subsidized price
The supply implications of increased growth in the number of FP users will also depend on the array of methods available in any market and on the method mix clients choose. Currently, we see a large divide in the types of methods women receive from the public sector and the private sectors (Figure 2). CGA 2019 shows that long-acting and permanent methods dominate the public sector (67% of public sector users), while most private sector users (73%) choose short-term methods. Differences between method mix in the public and private sectors and the skew towards short-term methods in the private sector where users pay out of pocket (OOP) have equity implications, discussed later in this report.

2.1.2 Greater need for maternal health supplies

Demand for maternal health supplies is expected to grow steadily in response to demographic growth, a growing percentage of deliveries attended by qualified health workers, and greater use of lifesaving medicines by health workers attending home births. These factors are likely to outweigh the impact of declining fertility levels. Current data shows that the proportion of deliveries attended in health facilities varies widely amongst income groups in all developing regions, which affects equity in access to maternal health supplies (Figure 3).

To date, the global supplies community has focused predominantly on the three quality-assured lifesaving maternal health medicines (i.e., Oxytocin, Magnesium Sulfate and Misoprostol) identified by the World Health Organization (WHO), though there is growing consensus around the need to focus on a wider range of supplies.16 Data on overall demand for maternal health supplies is difficult to identify, as they are also used for other purposes. There were an estimated 127m deliveries in low- and middle-income countries during 2017, of which 72% were in health facilities and more likely to use lifesaving medicines.17 Market analyses by RHSC/Jhpiego in 201418 estimated ranges of overall cost of the three maternal health supplies at global level, and also for the three regions of Sub-Saharan Africa (SSA), South-East Asia (SEA) and South Asia (SA) which include most of the low- and middle-income countries. The figures suggest a current global market of between US$117m and US$262m, of which about half currently corresponds to the SSA, SEA and SA regions. The market analysis showed that if all women in the three regions were to have access to lifesaving supplies through increased facility-based births or better availability of supplies for home births, the cost of supplies in those regions could more than double (about 120%).

2.1.3 Increasing demand for safe abortion supplies in low- and middle-income countries

Safe abortion supplies covered by this report include the equipment required for manual vacuum aspiration (MVA) and the drugs required for medical abortion.

Globally there are an estimated 56 million abortions each year, of which 8 million are “least safe” and 17m involve “some risk”, using WHO definitions and estimates from the Guttmacher Institute (2018).19 Differences in abortion rates amongst countries are related to country income levels and the legality of abortion, with rates ranging from below 18 per 1,000 women aged 15-49 in Europe to around 50 per 1,000 in

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16 Tranexamic acid, anti-hypertensives, blood products, and possibly medicines for new-born 
18 Jhpiego/RHSC (2014, 2014a, 2014b) 
Safe abortion: Provided by healthcare workers and with a WHO-recommended method appropriate to the gestation. 
Less safe abortion: Use of an outdated method by a trained provider OR self-use of medical abortion drugs without adequate information or support from a trained person. 
Least safe abortion: Use of dangerous, invasive methods, such as ingestion of caustic substances, insertion of foreign bodies or use of traditional concoctions, by untrained persons.
FIGURE 3: PROPORTION OF WOMEN GIVING BIRTH IN A HEALTH FACILITY BY INCOME QUINTILE, 2017


FIGURE 4: TRENDS IN ABORTION RATES IN DEVELOPED AND DEVELOPING REGIONS NO. OF ABORTIONS PER 1,000 WOMEN AGED 15-44

Source: Singh et al (2018)
some South Asian and Sub-Saharan African countries. The Guttmacher Institute estimates that there are some 25m unsafe abortions per annum globally, and 97% of these are in the developing world. Country-level data shows that in countries where abortion is legal, women access supplies through both public sector and private sector services. Where it is not legal, women get their supplies through private sector clinics and commercial outlets. The Guttmacher report notes the gradual liberalisation of abortion laws, with 28 countries broadening conditions for legal abortion during the period 2000-2017.

Overall, abortion rates have been declining in developed regions, but have remained stable in the developing world (Figure 4).

Within these overall trends, there has been a major shift in the methods used for abortion during the last 15-20 years. Availability of medical abortion has radically changed the safe abortion landscape and has increased access for many women. Medical abortion is classified as “safe” if attended by a skilled health worker, and “less safe” if carried out by women on their own without medical supervision. Information on the overall market size for medical abortion is not available as many abortions are unreported, and misoprostol (one of the three drugs used for medical abortion, the others being mifepristone and methotrexate in combination with misoprostol) has many other indications. Misoprostol can be used alone and is the most frequent method due to its easy availability and low price but gives better results and less discomfort if used in combination with mifepristone. The drugs are also available in a combi-pack format, of which multiple brands exist. Marie Stopes International (MSI) and DKT estimate that there are about five million medical abortions annually.

Factors likely to increase future demand for medical abortion and MVA supplies are changes in the legality of the procedures, better information for potential users, availability of supplies in urban and rural areas, switching from other less safe abortion procedures, and increased use of MVA for post-abortion care in public sector health facilities. Switching to medical abortion has been a clear trend in some countries (Figure 5). Despite this trend, there is still growth in demand for MVA supplies as Ministries of Health increase use of MVA for post-abortion care (PAC), and practitioners switch from less safe methods.

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**FIGURE 5: GROWTH IN USE OF MEDICAL ABORTION VS OTHER TECHNIQUES ACROSS THREE COUNTRIES**

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% surgical*  % medical  % other

* surgical includes D&C and MVA

Source: Singh et al (2018)

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20 Singh, S. 2018 op cit. However it is important to note that abortion’s legal status does not always correlate to availability of services or supplies in public sector.
21 If abortion is not legal under any conditions (including PAC or risk to a woman’s life), the supplies are not legally available (for the purpose of abortion) in private sector clinics or outlets.
22 Misoprostol is not always easily available in rural areas or urban slums. Also, the misoprostol available in low- and middle-income countries is often substandard and/or counterfeit.
24 The Guttmacher study shows that in general rates are higher in countries where abortion is legal, however countries with the most restrictive abortion laws also have high rates of abortion. As abortion becomes more restricted more abortions become unsafe.
25 Singh op cit; KEI
26 KEI
2.1.4 Rapid growth expected in menstrual health supplies market

Menstrual health is a relatively new area of work for the global supplies community and its strategy is still under discussion.\(^27\) Market research shows the overall market for commercial products is large (US$24b in 2017) and expected to grow fast at 5.7% per annum in all regions, with the highest growth in the Asia-Pacific region and amongst low-income women. The products with the largest market share are sanitary napkins, with 45% of the commercial market.\(^28\) Although there are many locally made disposable and reusable menstrual health products and traditional methods of managing menstruation in low- and middle-income countries,\(^29\) the market is dominated by large commercial firms distributing through the commercial private sector. For small manufacturers producing compostable products with nationally-sourced materials, initial investment costs can be high.\(^30\) In addition, quality standards and regulatory processes are limited and incomplete, and there are safety concerns for products from small manufacturers.\(^31\)

Demand has risen in emerging economies as a result of manufacturers’ commercial marketing efforts and rising awareness of personal health, hygiene issues and informed choice for women motivated by NGOs and some governments. Demand growth will be affected by women’s ability to pay and may increase with rising income levels, but many low-income women cannot pay the cost of commercial supplies and last-mile distribution problems in rural areas also affect users’ access. In some countries governments have supported increased access through tax reductions, with mixed results.\(^32\) Some governments concerned about the risks of low-income girls missing school during their periods have started free distribution of products in schools and colleges.\(^33\) However, insofar as there is still no hard evidence identifying a direct causal relationship between absence from school and lack of menstrual health products, more research is needed to enable advocates to link access to menstrual health supplies to human rights and gender issues. The regulatory and quality assurance processes for menstrual health supplies are still being drawn up in most developing countries.

\(^{27}\) RHSC has started work on the theme, hosting a webinar and including presentations from the maternal health working group in the 2019 General Membership Meeting

\(^{28}\) Credence Research 2016: Feminine Hygiene Products Market By Product Type (Sanitary Pads, Tampons, Menstrual Cups, Panty Liners & Shields, Disposable Razors & Blades, Others), By Distribution Channel (Supermarkets & Hypermarkets, Online Retailing, Department Stores, Pharmacy Stores, Others) - Growth, Share, Opportunities & Competitive Analysis, 2018 – 2026 : https://www.credenceresearch.com/report/feminine-hygiene-products-market


\(^{30}\) KEI

\(^{31}\) Lucy Wilson (2019). Addressing the gap: Integrating menstrual health into the broader SRHR discussion. Ppt presentation at the 2019 RHSC General Membership Meeting

\(^{32}\) Tax reduction is a blunt instrument which does not necessarily ensure that the people most in need benefit. In countries with value-added tax or the equivalent (eg India’s Goods and Services tax) careful design of the system is needed to ensure that reductions in tax to end-users are reflected in tax credits throughout the production and distribution chain

\(^{33}\) Regional governments in India have initiated a number of schemes, and efforts in the UK have been reported in The Guardian newspaper 13/3/2019: https://www.theguardian.com/society/2019/mar/13/government-hammond-to-provide-free-sanitary-products-in-secondary-schools
2.2 A CHANGING SUPPLY-SIDE LANDSCAPE FOR REPRODUCTIVE HEALTH SUPPLIES

2.2.1 Growing importance of the private sector, and a vulnerable supply-side market

Users access FP supplies via the public sector or through a diverse set of outlets we loosely call the private sector. The public sector consists of government-financed health facilities (hospitals, health centres, health posts). These may be managed and run by public sector employees or, as is frequently the case, services may be “outsourced” to staff of faith-based organizations and even non-governmental organizations. Likewise, the private sector comprises a range of outlets, including hospitals, clinics, pharmacies and shops. Within these outlets, a mix of different FP products and brands are provided, often at a range of price points. Products can be subsidized by donors, national governments or some combination of the two. While the tendency is to link the former with certain NGOs and social marketing organizations (SMO) and the latter with commercial for-profit operations, in real life the distinction is not so clear. Subsidized supplies are often accessed from ‘commercial’ type entities, and the same SMOs that distribute subsidized supplies may also have full-priced product lines that are not supported by donors. Unless specified otherwise, this analysis does not isolate NGOs and SMOs as a specific sector, but rather classifies that part of their work which channels non-subsidized products into private entities (clinics, pharmacies, sales kiosks, among others) as private sector.

Public sector health facilities receive FP supplies either through global procurement systems which provide WHO prequalified or Stringent Regulatory Authority (SRA)-approved products funded by donors, or through procurement by the countries themselves (which may or may not have WHO prequalification). The products are distributed through national supply chains. User charges depend on national policies. In many countries women using the public sector do not pay for FP supplies, but there may be other service-related charges.

Subsidized products within the private sector may also flow through national supply chains or may be procured and distributed directly by the NGOs and SMOs. These supplies are often free of charge to users in clinics, although they may have to pay service charges. Provision of subsidized supplies in the private sector is dominated by a few large international organizations (MSI, PSI, DKT, IPPF), as well as some large scale national SMOs who work primarily in LICs and L-MICs, with very few in U-MICs. Subsidized products within the private sector are present in only 49 of the 135 low- and middle-income countries, and nearly half of these fall within the LIC group.

Non-subsidized products rarely flow through government supply chains. They are usually supplied through commercial distributors and manufacturers’ agents. The commercial private sector is fragmented with no single representative and is rarely involved in national supplies planning or coordination initiatives. Prices to users of both subsidized and non-subsidized products are determined by the service providers. Likewise, the pipeline for regulatory approval of products at the country level is a challenge for both manufacturers and suppliers.

The relative sizes of these sectors was discussed in the previous section. In terms of the cost of supplies, non-subsidized products in the private sector account for 77% of global consumption costs, compared with 21% for public sector supplies and just 1% for products sold in the private sector at subsidized prices. This is largely due to the predominance of non-subsidized short-term methods in the private sector. Only one out of every five women uses contraceptive pills, but their cost is 69% of the overall total spending on supplies. Long-term methods which account for half of all users make up only nine percent of the total cost of supplies, partly because the actual cost of supplies is relatively small, but also because in any cohort of long-acting and permanent method (LAPM) users, only a small proportion obtained their method that year. Most are protected by a method received in past years. Short-term methods dominate the cost in all income groups, with the highest proportion of costs on short-term methods in U-MICs (95%), and 83% in L-MICs and 84% in the LICs.

In terms of costs by sector, CGA 2019 shows clients purchasing supplies from private sector entities make up the largest share of total costs in the U-MICs (90%) and L-MICs (62%). Within the LICs, private sector costs represent 30% of the total, due to the much larger roles of the public sector and subsidized products within the private sector.

34 These organizations also contribute to public sector provision, and in some countries, operate commercial programmes as well.
35 These figures show estimated consumption costs in 2018, based on CGA2019 analysis.
The upstream FP supplies market has specific characteristics which affect its capacity to meet and adapt to changes in demand. The global market has a small number of research and development (R&D) manufacturers, many of whose contraceptive products are WHO prequalified or SRA-approved, along with a larger number of generic manufacturers, only some of which have WHO pre-qualified contraceptives. There are two major buyers in the public sector – USAID and UNFPA – who between them procure 97% of donor-funded supplies. The limited number of prequalified products and major buyers makes the public sector market a challenge for new products, and vulnerable to disruptions in supply, as discussed in detail below.

With a few notable exceptions, the range of FP options has seen limited innovation in recent years. Most innovation has been the work of R&D companies or NGOs supported by donors or other actors in the international supplies community. Both groups have also played an active role in creating demand for their new products. By and large, however, given subsidies and price pressures, the profit margins on FP technologies in emerging economies are relatively low, which reduces the incentive for innovation. Many manufacturers see the potential for cost recovery as laying largely in the developed economies where commodity prices are higher.

### 2.2.2 Quality concerns in maternal health supplies

Most users in low- and middle-income countries access maternal health services and supplies through the public sector where supplies are generally free. Rising numbers of deliveries attended by qualified health workers will increase use of maternal health supplies, but availability of recommended drugs is still a problem for those who deliver at home without a skilled attendant.

Supplies of the three lifesaving products which have been the focus of work to date (oxytocin, misoprostol and magnesium sulfate) are normally available in the public sector. There are also many suppliers of these products, including R&D and generic manufacturers. The drugs are typically inexpensive and so therefore price is not a major barrier to access; but supply problems can occur if public sector funding is inadequate to ensure timely procurement or if weak supply chains hinder the flow of supplies to the last mile.

There seems to be a general consensus across the maternal health community that the principal supply-side problems relate to the quality of manufactured products, and the deterioration of products in the supply chain (oxytocin must be kept refrigerated, and misoprostol is unstable in humid conditions). As these products offer low profit margins under the best of circumstances, manufacturers may not be prepared to invest in the initial and ongoing costs of completing WHO prequalification procedures or multiple in-country registrations. Poor or even uncertain quality means the drugs could have less potency, and therefore be over-prescribed by doctors for preventive and curative services. (See more discussion of these points in sections 2.3 and 2.4)

### 2.2.3 Supply-side obstacles for safe abortion products

The supply of medical abortion services is affected by legal obstacles, stigma, and the unwillingness of service providers to offer medical abortions, which provide them with less income than either dilation and curettage (D&C) or even MVA. Supply is also affected by women's lack of information on medical abortion methods and where to access them.

In countries where abortion is legal and provided by the public sector, users can access medical abortion supplies through government health facilities. It is hard to estimate the proportion of products supplied through the public sector as misoprostol in produced in a variety of dosages and has many other indications. MSI and PSI estimate that 1/16 of the total misoprostol consumed in the public sector is used for medical abortion.

Users also access medical abortion supplies through a range of SMOs which dispense products in their own clinics or through social franchises and pharmacies. In countries where medical abortion is not legal, many

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36 CHAI 2017 FP Market report, p11 Exhibit 9, and CHAI 2018 FP Market report. Total figures of USAID and UNFPA-procured FP methods are the same for both 2016 and 2017 (US$133m) although the actual numbers for each entity fluctuate due to timing of donor disbursements.

37 The FP landscape for R&D incentives in FP parallels that of R&D for vaccines. Pharmaceutical companies are not financially motivated to carry out expensive R&D for low-income markets due to the difficulties in recouping high investment costs. See Wilson, P. (2010). Giving developing countries the best shot: An overview of vaccine access and R&D. Oxfam/MSF.

38 See Guttmacher (2013) Adding It Up methodology tables (Table 26) for number of women in LMIC accessing ANC and delivery services in health facilities.


women purchase misoprostol directly from pharmacies and carry out the procedure themselves without medical supervision. There is still stigma attached to abortion and although pharmacies may be prepared to carry the products, they often don’t promote them or train pharmacists to provide guidance for users. The only information for users is in the package inserts, which often cover all uses of misoprostol and make it difficult to identify correct usage for medical abortion. Also, many products bought by women in pharmacies are not quality-assured. Access to supplies through pharmacies is better in countries where abortion is legal, in higher country income groups and in urban areas. The cost of supplies is not high but price to users may be inflated at the pharmacy level, creating more difficulties for low income women.

Although there are many suppliers of misoprostol, there are very few WHO prequalified suppliers of the active pharmaceutical ingredient (API) of mifepristone, thereby creating potential vulnerability in supply. Combi-packs which include both misoprostol and mifepristone are now available. The IPPF Medical Abortion Commodities Database lists 12 combi-pack brands manufactured by 4 manufacturers, of which only one is SRA-approved. Combi-packs are not available everywhere due to registration problems for mifepristone, which is only used for abortion, and due to additional difficulties in registering products that contain more than one API. Many women therefore use misoprostol alone, which is less effective but more freely available.

While misoprostol is being sold commercially with and without the involvement of SMOs, distribution of combi-packs is largely done through partnerships between commercial distributors and SMOs.

Supplies for MVA for post-abortion care (PAC) are accessed primarily through the public sector. For safe abortion, access may be through the public sector if abortion is legal, or through private clinics or through a range of other providers. The principal supplier of MVA supplies is DKT which markets the IPAS product, the only one on the market which has The Food and Drug Administration (FDA) approval for re-use, making it highly competitive with competing products. These MVA supplies are procured by governments, UNFPA, commercial procurers and NGOs (MSI, PSI, DKT, IPPF), with an estimated 70% in the private sector and 30% in the public sector – mostly through government tenders.

2.2.4 Menstrual health supply-side dominated by large commercial manufacturers

Most women who use commercial menstrual health products access them through commercial establishments, with some limited supply by SMOs. Main distribution channels are supermarkets and convenience stores, with smaller volumes channelled through pharmacies. There is a range of products available including sanitary pads and napkins, tampons, panty-liners and menstrual cups.

The global commercial market is dominated by large transnational manufacturers. There are also many national and regional manufacturers, as well as small enterprises which produce at community-level. Registration may be required in some countries where quality standards exist, but in general quality control of local manufacturers is weak. There is innovation in all sectors of the market, with local producers looking for alternative and disposable materials, and large producers looking for new products to expand their markets.

Equity concerns in the supply of menstrual health products include lack of availability in remote areas and cost barriers for low income women and adolescents. Women who cannot afford to buy products make their own, using a range of materials and methods which may be unsafe or unreliable.
2.3 CRITICAL DEMAND AND SUPPLY SIDE ISSUES

Demand is rising for RH supplies and expected to continue rising. Some of this growth will be in demand for public sector services, but there will also be growth in demand in the private sector. The rate of growth in demand for FP will be highest in the poorest countries that today have low contraceptive prevalence rates (CPR). These countries are currently the destination of most donor support for contraceptive procurement — and will likely remain so over the coming decade. The greatest absolute increase in users will take place amongst the L-MICs where the population is much larger. There are equity concerns and obstacles to access including regulatory barriers to new products, as well as price and availability barriers for users who seek supplies in the commercial private sector.

Current public sector procurement platforms and mechanisms introduce vulnerability into the marketplace, especially in FP where there are a few large manufacturers of WHO prequalified or SRA-approved products and a few large buyers, and in medical abortion where there are very few quality-approved suppliers of API for mifepristone. Obstacles undermining a healthy marketplace for FP include low profit margins, competition from subsidized products, complex and time-consuming registration processes, little innovation in product lines, perceived consumer preferences for non-generic options, and inadequate insight into market demand. Obstacles to the development of a healthy market for medical abortion supplies also include legal restrictions on abortion.

Specific market issues in each category of RH supplies are:

**FAMILY PLANNING**

- Demand is rising, with the biggest expected percentage rise in number of users in LICs, and the biggest rise in actual numbers in L-MICs.
- The public sector dominates the supply landscape for LICs, with a larger role for the private sector in the L-MIC and U-MIC groups.
- There are potential problems related to both equity and choice in the shift from public to private sector provision. Women may not be able to afford their contraception, and their choice of method may be limited due to the preponderance of short-term methods in the private sector.
- The donor market for procurement is limited to a few suppliers and a few large buyers, making the supply side of the market vulnerable to disruption. This vulnerability is mitigated in part by innovations in product introduction and new financing arrangements, and is also affected by price or volume guarantees.

**MATERNAL HEALTH**

- Demand for maternal health supplies is rising due to growing numbers of women delivering in health facilities or with skilled assistance at home. The biggest relative increase is expected in LICs, with greatest absolute growth in numbers in L-MICs. Most of the demand for maternal health supplies is met by the public sector and this is likely to continue in the coming decade.
- The greatest supply-related concerns among maternal health specialists are product quality and risks of deterioration due to incorrect handling in the supply chain.
SAFE ABORTION

+ There is rising demand for medical abortion supplies as women switch from other methods. Demand for MVA supplies is also growing as a result of switching from less safe methods, and for use in PAC.

+ Where abortion is legal, medical abortion supplies are often provided by the public sector, but many users still access misoprostol through the commercial private sector (pharmacies). In such instances, the provision of information on dosage and use can vary from good to non-existent. Supply is impeded by the lack of registration of mifepristone and combi-packs, and providers’ unwillingness to supply products and services, regardless of legal status.

+ Although the manufacturing cost of misoprostol is low, the retail price to consumers may vary widely depending on the point of sale/distribution.

+ The sustained supply of quality abortion products is threatened by WHO prequalification of only one API for mifepristone. There may also be vulnerability for supply of MVA equipment where one quality-approved product dominates the market.

MENSTRUAL HEALTH

+ Demand for menstrual health products is rising and expected to grow in future.

+ Practically all supply is through the commercial private sector and paid by users OOP, with cost barriers for low income women; there may also be weaknesses in the supply chain and in distribution to the last-mile.

+ The absence of universally accepted standards for the manufacture of menstrual health products undermines prospects for local production as well as importation of new products.

+ Opportunities exist to ensure more affordable menstrual health supplies by engaging major international manufacturers, exploring options for expanded corporate social responsibility (CSR), and by maximizing opportunities for coordinated procurement.
CHAPTER 3
Changing trends in reproductive health supplies financing

3.1 PAST TRENDS AND THE CURRENT LANDSCAPE

The overall annual cost of FP and maternal newborn health services (including care related to unintended pregnancies) in all developing regions is estimated by the Guttmacher Institute at US$32bn, of which 20% is for FP and 80% for maternal and newborn health.55 Guttmacher figures do not disaggregate the supplies from total RH service provision costs. But separate analyses conducted by partners in the RH community do shed some light on the cost of supplies by therapeutic area. Estimates by the RHSC, for example, show a current annual spend of US$3.3bn for FP supplies in the 135 low and middle income countries.56 The 2014 RHSC/Jhpiego landscape analysis for maternal health supplies estimated an annual combined cost of between US$47 and US$131m for the three lifesaving maternal health products in Sub-Saharan Africa, South Asia and Southeast Asia.57 The Clinton Health Access Initiative (CHAI) is currently carrying out a market scoping study of medical abortion supplies, but the results are not yet available. Rough estimates suggest that the cost of medical abortion supplies may be comparable to that of the three lifesaving maternal health supplies58, while the cost of the global market for menstrual health supplies is estimated at over US$24bn.59 These estimates suggest that the market value of menstrual health products is at an order of magnitude60 greater than FP, which in turn is one to two orders of magnitude greater than maternal health and medical abortion supplies.

56 RHSC 2019 CGA
58 55% of all abortions classified as “safe”. If all of these are carried out through medical abortion, 80% using misoprostol alone and 20% using combipacks, we could estimate around US$50m total supplies cos (cost to users). The order of magnitude would not change significantly substituting a certain % of MVA supplies for medical abortion supplies (author’s back-of-the envelope estimates).
59 Credence Research op cit
60 Around ten times greater
3.1.1 Financing for family planning supplies

FP supplies are financed by donors, domestic governments, and OOP by individual users purchasing supplies from private sector entities. Public sector financing (donors and domestic governments) is motivated partly by the externalities of FP (its use by individuals also benefits the collective), as well as equity considerations regarding the right of all women and men to access a range of FP methods.

The following diagram (Figure 6) offers a simple illustration of how different funding sources flow into the procurement of FP supplies. Most of the stock procured through government and donor funds ends up being used within the public sector. But in some countries a portion of that finds its way into the private sector, either through direct allocations to NGOs and SMOs, or simply by means of theft or diversion. The former is sold to users, typically at subsidized prices; the latter may simply be sold at full commercial prices. The balance of supplies is procured by commercial operators but ultimately paid for OOP by users. The cost to consumers of these supplies is usually well above the price paid by governments or donors.

Data from CGA 2019 show that overall $3.33 billion is currently spent on supplies in the 135 low- and middle-income countries. Donors fund 5% of spending on FP supplies, domestic governments fund 14%, and the remaining 81% is paid for OOP in the private sector. Proportions vary in the different country income groups, with a far higher donor presence in the LICs. Domestic government spending is highest in the L-MICs, and OOP is by far the dominant element in the U-MICs (Figure 7).

Both within and across country-income groups there is great variability in FP supplies spending. Country spending depends on national policies, fiscal allocations and the participation by subsidized private sector organizations as well as donor contributions. For family planning supplies, OOP spending in the private sector...
sector is highest among U-MICs, but this aggregate figure is largely due to data from large countries like Brazil which have led to a limited public sector role in provision of contraception. This pattern may not necessarily be indicative of global trends as income rises.

The variability in these spending patterns within GNI groupings underlines the importance of monitoring the impact of country policy decisions on FP supplies financing. Analysis by the Global Burden of Disease Health Financing Collaborator Network shows that as countries grow economically they spend more per capita on health; and as countries’ tax systems mature and fiscal space grows, the financing mix transitions towards a declining share of donor and OOP finance and a higher percentage of domestic government finance. These trends are expected to continue over the next 30 years. Although current information does not show this pattern for FP, in the medium to long term it would be reasonable to expect that it will, particularly if FP is included in universal health coverage, as discussed later.

**Donors**

Donor funding for FP covers the cost of not only supplies, but also demand creation, service delivery and supply chain strengthening. USAID has long been the largest overall FP donor, providing 70% of all FP funding during the 10-year period 2004-2014. Other large donors include the UK’s Department for International Development (DFID) and the Bill & Melinda Gates Foundation (BMGF) (10% and 8% respectively in the same period), with a group of European donor countries covering 7%. The bulk of European donor funding goes to UNFPA and UNFPA Supplies. UNFPA is not itself a donor but channels donor funds from UK, the Netherlands and other European donor countries to priority countries.

Many donors fund FP supplies within the envelope of their overall RH/FP programme support. Supplies account for roughly 30% of the total spending. USAID is the largest funder of FP supplies, contributing 47% of the total in the period 2011-2015. In 2016 and 2017, the total amounts spent on supplies both by USAID and by UNFPA procurement using donor funding was around US$133m. UNFPA also offers Third Party procurement (TTP) for national governments and other not-for-profit entities.

By and large, donors have concentrated their FP supplies spending in the LICs and L-MICs where needs are greatest (59% of donor funding for supplies goes to LICs, 37% to L-MICs and only 4% to U-MICs). Each donor has its own specific criteria for deciding which countries to support, but highest priority has been given to the 69 FP2020 countries, the 46 UNFPA Supplies priority countries and the 24 USAID priority countries. There is considerable overlap amongst the three groups, but donors have largely committed to supporting them until countries can take greater responsibility for financing supplies themselves from domestic sources, either through tax revenues or fully commercial procurement.

By and large the commercial private sector has not been a direct beneficiary of donor support, although the private sector does benefit from demand creation efforts, market information, and service provider training that donor support makes possible.

**Domestic government funding**

Figures from CGA 2019 show that domestic government funding for supplies currently accounts for 14% of the total in the 135 low and middle income countries. The proportion is 17% in LICs which are still largely dependent on donors for supplies. In L-MICs the government contribution is higher at 29% and drops again to 8% in the U-MICs. While these aggregate figures disguise important differences amongst countries and each GNI grouping, they are important indicators of the current state of play and potential future developments.

FP supplies funded by domestic governments are channelled through public sector service providers or through private sector entities which make the supplies available at subsidized prices. Domestic funding can play an important equity role by ensuring supplies reach those most in need, including the lowest income groups and rural populations who cannot access alternative services or cannot afford the prices in the private sector. In some countries domestic government financing also allows private sector entities to offer price subsidies and to support national health insurance schemes providing care for under-served groups.

Domestic government funding for FP supplies is part of the national health budgets, which are themselves financed by a mix of tax income, grants and

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65 RHSC (2019) CGA 2018
concessionary loans (for example World Bank loans disbursed through the Global Financing Facility or GFF). Contraceptive Security Indicators for USAID-supported countries indicate that governments are spending around $55m of loans or basket funding (pooled funding arrangements involving multiple donors and/or multiple sectors) on supplies, but the total figure is likely to be higher, as data are not available for many countries.

Insofar as FP supplies represent more of a material input than a driver of development leading to national self-sufficiency, donors have long been trying to move out of supplies financing and encourage countries to finance more themselves. As government spending on health correlates with rising national income, it is reasonable to expect that as national income increases, governments will take on a larger share of the cost of FP supplies and services, but for many low income countries, donor support will remain critical.

Important initiatives to encourage greater domestic government spending on FP supplies include FP2020, UNFPA Supplies, USAID transition programmes, and the GFF. FP2020 has been successful in increasing national commitments to domestic resource mobilization, with 40 of the 69 priority countries currently committed to an FP budget. However there are important caveats to such commitments: existence of an FP budget line, while important, does not per se guarantee that the money will be allocated or spent in priority areas such as RH, and there is no guarantee that it will be spent on supplies. UNFPA Supplies aims to reduce its contribution progressively, identifying stages in the development of FP programmes where governments have the capacity to take over part of the supplies costs. USAID transition programmes also aim to increase domestic government contributions over a period of time. The GFF includes FP supplies in its overall support packages and encourages governments to spend grant and loan funds on supplies. Unfortunately, the relative success of such efforts to date is unclear insofar as the GFF does not collect disaggregated data on supplies expenditures, or even on family planning as distinct from the broader category of reproductive health.

**Out of pocket (OOP) spending**

OOP spending in the private sector amounts to a high 81% of total spending on FP supplies in the 135 low- and middle-income countries (CGA 2019). It is significant in all country groups, ranging from 34% of all spending on FP supplies in LICs, to 65% in L-MICs to 92% in U-MICs. Almost all OOP (98%) is spent on non-subsidized commercial products within the private sector, with only 2% used for subsidized products. There is more OOP spending on short-term methods, which are more readily available in the private sector than long-acting methods and tend to be costlier on an annual basis. Further, long-acting methods are not necessarily available from many private entities such as pharmacies.

Retail prices for supplies in the commercial private sector vary widely by country. They are also often several times more expensive to consumers than the same products in the public sector. But it is important to note that private providers and pharmacists do not have easy access to comparative price information or sufficiently high volumes to negotiate better procurement prices. Some initiatives such as Doctorstore in India (a Pregna initiative supported by the RHSC Innovation Fund, and now supported by DKT Healthcare India) have developed online platforms to bypass middleman, thereby reducing prices to providers and ultimately to end users.

Retail pricing in the private sector still constitutes a grey area for the supplies community. Pharmacies and private clinics set their own prices in line with local market conditions. The only reliable private sector price information comes through retail audits, which are expensive and often have limited coverage.

Information on those who pay OOP is also incomplete. SMO surveys show that socially marketed products are used by all income quintiles. And certainly, where public sector services are unavailable, paying out of pocket may be the only option available, regardless of how “affordable” any individual product happens to be. But the prevailing method mix of the private sector also has equity implications for those paying OOP.

67 But see previous discussion in section 3.1 of this report
69 All data from the RHSC CGA 2018
70 http://www.doctorstore.in/
71 KEI
72 Information used in CGA includes data purchased from IQVIA; data from retail audits conducted by FP Watch, Track20, SHOPS Plus Private Sector Assessments, and survey data from DHS and PMA2020 on prices paid by women using private sector sources.
73 KEI
Long-acting reversible contraceptives and permanent methods (LARC and LAPM) have a lower annual cost than short-term methods but are typically less available in the private sector. But even when they are available, their high upfront cost may often place them out of reach of low-income women. Of course these potential obstacles are not necessarily applicable to all who pay OOP. Many people who use the private sector can afford to pay. To ensure funding is focused where it is most needed, we need better information on who is paying OOP; together with better analyses of their ability to pay, especially in LICs.

### 3.1.2 Maternal health

Research suggests that maternal health supplies are predominantly financed either OOP or by domestic governments. Nevertheless, up to 10% to 20% of the total cost of maternal health supplies is covered by donor funding and procured by multilateral agencies including UNFPA. GFF loan and grant funds are allocated to maternal health but as in the case of FP supplies, it is hard to track how much of this is spent on supplies. Maternal health supplies are normally free to users in the public sector although some do pay OOP, officially or unofficially.

As most spending on maternal health supplies occurs in the public sector or through service fees to consumers, the principal challenges associated with financing are the adequacy of domestic resource allocations and actual spending levels, which may lag behind budgeted figures. The prices of maternal health supplies—particularly in the case of the three lifesaving products—are highly variable, from pennies in the case of magnesium sulfate, to more expensive oxytocin. However, there is no evidence within the RH community that price as such has been a major barrier to procurement by countries. Domestic procurement is price-sensitive, which can raise concerns over quality assurance if countries seek the cheapest products. Problems of insufficient financial allocations and quality are especially acute in countries where procurement is decentralized, and specific provinces set their own priorities and purchase locally.

### 3.1.3 Safe abortion

Information on the overall market size and cost of medical abortion is not available, although a market scoping exercise is currently being carried out by CHAI.

Most medical abortion is financed OOP by users who buy supplies in pharmacies. The cost of misoprostol is low and although prices may be inflated at the point of sale, research suggests that many women are prepared to pay. The cost of mifepristone and combi-packs is higher and may represent a barrier to access for some low-income women and girls. But medical abortion is not used on a regular basis, and most specialists in this field agree that the price of supplies is not considered to be the major issue although there are still equity concerns in access for the very poorest. Where abortion is legal, supplies are often financed by country governments and services are typically available in the public sector. Donor finance has been used to support awareness creation and market development for medical abortion products. MVA supplies are financed by the public sector for post-abortion care and for safe abortion, and by private sector service providers who pass the cost on to users in their service fees.

### 3.1.4 Menstrual health

Commercial menstrual health products are paid OOP by users with limited, if any, direct donor interventions. Domestic government contributions have been mobilized through the elimination of sales and other taxes in some countries (e.g. Kenya, Canada, UK, India, Colombia, Australia), and recently the Scottish government became the first in the world to provide free menstrual health products in schools and colleges. Users who cannot afford commercial prices use their own (often unregulated and/or unsafe) methods and materials, leading to health and equity concerns.
3.2 FINANCING CHANGES IN THE DECADE AHEAD

3.2.1 Family planning

Anticipated declines in donor funding for FP supplies

To date, USAID has been by far the largest funder of family planning supplies, followed by DFID and BMGF. Despite recent changes in US administration policy, US funding for FP as a whole has remained fairly stable, although there is annual volatility in figures due to the timing of disbursements. Based on feedback from across the donor community, however, expectations are that donor financing for FP is not likely to rise to any significant degree and may very well fall. Funding for FP supplies may be even more vulnerable as donors shift their priorities from material support to more development financing aimed at weaning countries away from reliance on donor funding.

Donors will likely remain the principal source of commodity financing in the LICs (49% of total supplies spending in those countries, according to CGA 2019). And given their smaller economies, lower budget allocations to health, and typically nascent private sectors, these countries are likely to remain donor-dependent in the foreseeable future. Donors expect L-MICs and U-MICs to take on greater responsibility for financing FP supplies in the future. Both UNFPA Supplies and USAID have developed transition processes which aim to help countries take on supplies financing gradually, staging withdrawal of donor funding.

Innovations designed to stretch donor dollars for supplies and increase domestic contributions have been developed by the global supplies community in partnership with donors. Aggregation of global demand, volume guarantees and coordination of procurement through the RHSC’s Coordinated Supply Planning Group (CSP) have been used to increase value for money and to smooth and coordinate the flow of supplies (see more discussion in chapters 4 and 5 on procurement and supply chain). These initiatives are expected to be ongoing, either in their current form or subsumed within new initiatives such as the Global FP VAN, and there may be opportunities to expand them.

Key future role for domestic government financing

Domestic resource mobilization has been a priority within the supplies community for a long time. Domestic government health spending usually increases as country income rises, more effective tax collection and the development of formal budgetary and financial monitoring processes allows for a larger fiscal space.

Nevertheless, increases in overall health spending are not necessarily reflected in greater spending on FP supplies. Success at motivating domestic government funding for FP supplies has been uneven, despite the international community’s efforts and the support of national advocacy groups. FP2020 has refocused attention specifically on supplies by encouraging country commitments to financing.

Difficulties in mobilization of domestic government funding for FP supplies include lack of fiscal space, other competing government priorities, cash flow and working capital problems for purchase of FP supplies, lack of ammunition for effective FP advocacy, and poor accountability and tracking of domestic contributions. Long-term recipients of donor support have often come to rely in the first instance on donors, rather than increasing their own contributions, especially in the event of structural changes in financial administration. For example, when Kenya decentralized, decisions on domestic funding for FP supplies were also decentralized and as a result the domestic contribution dropped drastically. Donors stepped in to fill the gap.

A key driver of domestic government resource mobilization for FP seems to be popular demand as perceived by key decision makers. This can come from a relatively high mCPR which convinces governments that strong demand for FP is there. But it can also come from increased commitment to social and policy issues such as universal health coverage (UHC), which includes FP.

At present national health insurance schemes (NHIS) finance only a small percentage of FP supplies. Such contributions are often considered a first step towards
UHC, insofar as they pool risk and require similar design and administrative systems. However, NHIS are usually restricted to specific population groups (e.g. employed workers and their families) and specific service providers. Key questions for donors and the RH supplies community in the transition from NHIS to UHC are which RH services will be covered, who will provide them, and how will supplies procurement be included in the UHC system design. For example, private sector service providers who do their own procurement may be included in the schemes and reimbursed for services, or they may receive supplies in kind from centralized government procurement systems; or governments may focus on UHC by the public sector itself, with health facilities supplied through national procurement and supply chains.

Inclusion of FP in UHC strategies holds out the promise of ensuring more equitable access to FP supplies. It also offers the potential to stimulate private sector markets if service provider participation and reimbursement systems are well designed. At the end of the day, UHC may very well be the primary catalyst required to get countries to fill the growing gap likely to result from declining donor support. But UHC needs political commitment, resources, national capacity for stewardship and quality control, and time to implement. Furthermore, effective advocacy will be essential to ensure that FP is included in UHC schemes right from the start.

**More OOP for FP in the short and medium term**

Reductions in donor financing, slow mobilization of domestic government funding, and broader economic growth suggest that individuals’ OOP spending on FP supplies will likely rise in the coming decade. If current trends continue, most OOP spending will be on short-term methods in the private sector. This presents equity problems on a number of fronts. On the one hand, those in the poorer wealth quintiles may simply find themselves unable to pay unless there are reasonable public sector alternatives or FP supplies are available at subsidized prices. And with the private sector having only a limited footprint in the LARCs market, the cost burden on the poor could be exacerbated as they find themselves having little alternative but to choose the most-costly options (resupply methods are the most expensive in annual cost terms).

### 3.2.2 Maternal health supplies primarily financed by domestic governments

Some degree of funding for maternal health supplies may continue within the envelope of donor funding for maternal health programmes, but most of the finance in the coming decade is expected to come from country governments and OOP, with some private sector contributions resulting from the growth of health insurance schemes. The biggest challenge will be to ensure adequate allocations of supplies at central and decentralized levels, and that budgets are actually spent on procurement of quality products. Maternal health is already a high priority in GFF grant and loan funding and this is likely to continue. Maternal health is not a controversial area of SRHR, and therefore likely to be included from the start in development of countries’ UHC schemes. However, evaluation of GFF investments will be required to confirm this.

### 3.2.3 Government and out of pocket spending for safe abortion

Most donors currently engaged in the safe abortion space have focused their efforts on advocacy and occasionally on product market development, rather than the procurement and delivery of safe abortion supplies and/or devices such as MVA. Current funders include Denmark, EU, UK, Netherlands, Norway, Sweden and CIFF, among others. Current perceptions across the development community are that donor funding for medical abortion may decrease in the future, particularly with the chilling effect of the extended Mexico City policy and growing risk of pro-natalist policies in some countries. The SheDecides movement was established to counteract the negative impact of the policy, and donors have pledged support for its aims, but the movement itself focuses on advocacy for change rather than programme funding. Safe abortion has not been included explicitly as a priority in donor support to Reproductive Maternal Newborn, Child and Adolescent Health (RMNCAH).

Domestic government financing for medical abortion and MVA supplies is likely to continue where abortion and PAC are legal and offered in public sector health facilities. Domestic funding will become a larger element in the overall mix if more countries legalize abortion and include medical abortion in public sector
services. However, it is difficult to track spending on safe abortion supplies, either by domestic governments or by donors.\textsuperscript{88}

Donors have funded SMOs for market development, information and user awareness-raising, but they have not explicitly funded supplies on any significant scale and this is unlikely to change. SMOs look to sell MVA and medical abortion supplies at breakeven prices.\textsuperscript{89} OOP payments by users at retail outlets are likely to continue to cover a large percentage of the overall costs, but as supplies are not expensive or used on a routine basis, they are not expected to cause major equity problems unless retail prices are inflated by middlemen, pharmacies or service providers.\textsuperscript{90}

\subsection{Out of pocket spending on menstrual health supplies}

By and large, commercial menstrual health products are paid OOP by users and this is likely to continue well into the future. While interest in menstrual health has grown dramatically in recent years—to the point it has even become the subject of an Academy Award film—it is unlikely to attract donor funding for any but pilot schemes to test its importance for specific SRHR, health and educational outcomes.

Taxation reduction is a form of domestic government contribution which, if carefully designed, could be rolled out and assume a larger role. But current research has also found that even after import and other taxes are removed, savings are not necessarily passed along to consumers. There may also be possibilities of funding from manufacturers, either as part of their corporate responsibility initiatives, or through volume pricing agreements.

\begin{flushleft}
\textsuperscript{88} idem
\textsuperscript{89} KEI. The large SMOs may cross-subsidise between products and between regions.
\textsuperscript{90} There are of course many factors other than price which affect equity in access to safe medical abortion supplies through pharmacies including stigma, women’s lack of information, product quality, unwillingness of pharmacies to stock and sell the products, etc
\end{flushleft}
### 3.3 CRITICAL ISSUES IN FINANCING OF REPRODUCTIVE HEALTH SUPPLIES

Family planning and maternal health supplies will likely see reduced donor funding over the coming decade. Meanwhile, mobilization of domestic resources, while promising in the lower- and middle-income countries, is unlikely to be sufficient to fully compensate for the reductions in donor support. The growing gap will have to be covered by OOP payments in the private sector or through blended insurance schemes. For other RH supplies (safe abortion and menstrual health) OOP spending in the private sector is also likely to grow.

UHC is a potential driver of domestic resource mobilization that could help compensate for anticipated declines in donor funding. It is, however, a long-term goal for many countries and unlikely to be achieved on a significant scale during the coming decade. In the absence of UHC, current financial trends of increased OOP spending and reduced public sector funding will disadvantage low income groups. Ensuring a more equitable price-availability combination for users will be a key challenge for the supplies community during the next decade. Even in the lowest income countries where the public sector is the largest FP provider, there will be a growing role for the private sector to develop the foundations for a healthy private market as national income rises and counteract the risks of relying solely on the public sector.

#### Critical issues in financing for different categories of RH supplies:

**FAMILY PLANNING**

- If current trends in donor finance, domestic resource mobilization and OOP continue, the public sector will not cover needs and OOP expenditures will make up an increasingly larger share of funding for FP supplies. Although some users access subsidized products within the private sector, most OOP spending will be for supplies at full commercial prices.
- Many LICs that today remain heavily dependent on public sector provision of FP supplies are likely to remain so in the coming decade. It is critical therefore that the international donor community continue to support supply-related investments in those countries.
- Even in the lowest income countries where public sector provision of FP prevails, there will be a growing role for the private sector to counteract the risks of relying solely on donor or government funding, and to develop the foundations for a healthy private market as national income rises.

**OTHER RH SUPPLIES**

- The funding mix for maternal health supplies is not expected to change. Furthermore, members within the maternal health community do not see major equity issues with OOP spending as few users pay OOP directly. There is a need for effective mobilization of domestic government funding (overall budget allocations and their use), especially in decentralized countries, to ensure that quality supplies are available for all users. This may entail monitoring of GFF spending, and advocacy for inclusion in UHC.
- As countries legalize abortion and provide services in the public sector, governments are likely to increase spending to meet the demand for services, both for MVA and medical abortion supplies. However, OOP spending is likely to remain high. Most in the safe abortion community do not see this as an equity problem, as product costs are typically low and incurred only occasionally.
- Menstrual health is likely to continue to be financed OOP by users. Efforts are underway to overcome financial barriers to access though reductions in sales tax and to secure more affordable product options though either volume guarantees or subsidized pricing as part of corporate social responsibility.
CHAPTER 4

Procurement

4.1 OVERVIEW OF THE PROCUREMENT MARKET

The global market for FP supplies is worth $3.3bn and of that total, approximately 19% ($624M) is procured for the public sector. Donors contribute about a quarter of spending for the public sector ($159 million) divided fairly evenly between the two main procurers, USAID and UNFPA.

The balance of spending—nearly three-quarters ($465 million)—is procured by country governments, either directly or through third party procurement such as UNFPA Procurement (formerly AccessRH) (Figure 8). So, while the focus of procurement efforts within the development community has traditionally been on donor expenditures, these contributions pale in comparison to what country governments are spending and they are truly dwarfed by the total value of OOP expenditures.

Other RH supplies

The overall market for the three lifesaving maternal health drugs in the three regions of SSA, SEA and SA is estimated at between US$47m and US$131m.91 Most of these drugs are procured by domestic governments for public sector use, but some are procured through local distributors and suppliers, particularly in countries where procurement is decentralized and provincial health authorities are responsible for purchase.

An estimated 10%-20% of procurement is still done by UNFPA and UNICEF for governments. As well as products from R&D manufacturers, there are many generic suppliers, not all of which are WHO prequalified.

The overall market size for medical abortion supplies is estimated to be comparable to that of the maternal health supplies market, with the caveats noted in Chapter 2.2.1 of this report. There are many suppliers of both mifepristone and misoprostol, but only a few (three each) that are WHO prequalified; and there is only one WHO prequalified supplier of the API for mifepristone.92 There are several manufacturers of combi-packs, but the rules for WHO prequalification are more complex for multi-drug packs and so far only two have stringent regulatory

91 Jhpiego (2014) op cit
92 IPPF Medical abortion commodities database at https://www.medab.org/
authority (SRA) approval. SMOs are marketing and, in some cases, developing their own combi-pack brands using misoprostol and mifepristone supplies already in the market. Depending on the legal status of abortion at country level, procurement is carried out by domestic governments, SMOs and the commercial private sector. Thus far, the donor community has not used its own resources to procure medical abortion supplies.

MVA supplies are procured by governments for safe abortion services and for PAC, by UNFPA, NGOs and commercial procurers. Figures on overall market size are not available, but the IPAS supplies distributed by DKT are the only ones approved by FDA as re-usable. Concerns have been raised that as governments begin to procure with their own resources, they may be less focused on product quality and may choose cheaper alternative products.

The global market for menstrual health products is estimated at US$24 billion, with no direct finance from donors or domestic governments, although sales tax exemptions can be considered a domestic government contribution. There is a large number of suppliers and procurement is done through commercial channels.

Neither the maternal health, medical abortion or menstrual health markets is as concentrated as the FP market in terms of procurers or manufacturers/suppliers. Experts in these areas therefore feel the market is less vulnerable to disruption as a result of withdrawal or delays by manufacturers or procurers. With only one FDA approved supplier, the MVA market may be more vulnerable.

Source: CGA2019

93 Others have WHO prequalified or SRA misoprostol – see medab database
94 KEI
95 KEI. This also applies to other RH supplies.
**4.2 FAMILY PLANNING – HIGH PROFILE GLOBAL PROCURERS AND VULNERABLE SUPPLY MARKET**

FP supplies in the public sector are procured primarily by country governments and international donors. These donors include UNFPA, which procures WHO prequalified FP supplies for its own programmes and third parties (often country governments), and USAID which procures through a contracted organization and delivers supplies in-kind directly to recipient countries. Country governments may procure through UNFPA or through local or regional suppliers (including generics manufacturers). Large NGOs such as PSI, DKT, MSI, IPPF procure through UNFPA, but also receive donated supplies in-country through national supply chains. Procurement for the commercial private sector, which accounts for over 80% of the total market value of FP supplies, is carried out through commercial procurement agencies or directly by manufacturers’ in-country agents and distributors.

Donors and most of the large NGOs only buy SRA or WHO prequalified products to ensure quality. Country governments may stipulate WHO prequalification themselves, but many remain highly price-sensitive and often procure from other suppliers at lower prices, though subject to specific country regulations over quality control. Country governments may also favour local manufacturers over international companies.

The FP supplies market for the public sector is dominated by a few suppliers and a few large buyers making it highly vulnerable to interruptions in production or procurement (see Chapter 2.2 of this report). There are also growing concerns over limited innovator investment in the global market in the long-term, another factor which will lead to greater concentration of the market on a small number of existing products with few alternatives.

With so few suppliers to meet the multiple requirements demanded by international procurers, the market has little flexibility to respond to changes in demand, as manufacturers have significant lead-times and need some guarantee of continuing orders before increasing production levels for each product. The two major buyers, USAID and UNFPA, together purchase the bulk of all short-term methods and implants for the public sector, so any interruption of their purchasing also has repercussions for manufacturers.

Previously, reference was made to efforts by the donor community to overcome procurement vulnerabilities by seeking out generic alternatives to R&D or “innovator” brands. And it is important to point out that these efforts have met with increasing success. But there have also been challenges: the generics’ reluctance to invest in securing SRA or WHO prequalification; uncertainty that certification of quality assurance will generate the sales required to justify the cost; and the costs of seeking product registration at country level, to name but a few. But there is another challenge—and that has been the reluctance by many countries to procure generics, particularly when branded alternatives are also available. Given the recent withdrawal of innovator brands discussed above, much of this reluctance may soon become a moot point. But the need to generate credibility for generic products is an issue that cannot be left to the generic manufacturers alone. Unlike their innovator counterparts, generics do not typically have the commercial infrastructure required to build brand loyalty at country level. Community support and funding will be required if we expect to achieve outreach, effective branding, and market placement of generics.

Over the last decade, donors and international organizations have intervened in the market on multiple occasions to aggregate and smooth demand. A variety of interventions under the rubric of “market shaping” has encouraged innovation and new technologies through public-private partnerships in product introduction, and through demand creation by the public and subsidized private sectors.

One apparent trend that is giving rise to concern, however, is the growing reluctance by donors to support the introduction of innovations that promise greater efficacy, longer continuation, responsiveness to client needs, cost savings and/or efficiency. This stands in sharp contrast to the 1990s, for example, when introductory trials of products such as Norplant received considerable donor support. Given the tight profit margins facing manufacturers—far tighter than prevailed two decades ago—some cost sharing arrangements may be required to facilitate greater innovation in the marketplace.

One recent example is the Population Council’s one-year vaginal ring Annovera®. Although current production costs prevent it from becoming a viable option in most developing markets, the Council’s interest in pursuing cost efficiencies in manufacturing and procurement hinges on some assurance that the product will be accepted in critical developing markets. Donor support for acceptability and introductory
trials could play an important role in encouraging new product innovation. This is also true for new products which are biosimilar to successfully marketed products such as Mirena produced by Bayer (branded LNG-IUS), which has been approved in developed country markets for over twenty years. For example, Medicines360 is working with service delivery NGOs to get its FDA approved LNG-iUS registered and marketed in sub-Saharan Africa at a lower market price to stimulate demand and fill a market gap. Other products are in the pipeline for approval by stringent regulatory authorities but may need support for product prequalification and introduction.

Key issues in FP procurement

REDUCED PRICES THROUGH AGGREGATION AND ALIGNMENT OF PURCHASES HAS BENEFITTED PUBLIC SECTOR PROCUREMENT

In the public sector, strategies for aggregating demand have dominated the procurement conversation for decades. Donors have aligned their procurement and coordinated timing, enabling manufacturers to optimise their production. Greater manufacturing efficiencies have been passed on to the procurers through reduced prices, providing increasing value for money (VFM) for donors and country governments in eligible countries (the 69 FP2020 countries). Examples are the Implant Access Program (IAP) and the Sayana Press Initiative.

The principal participants in this space have been the donors and the R&D manufacturers. While reduced procurement prices are widely seen to have increased product affordability, many manufacturers, both generic and innovator, believe that they have affected price competition in the rest of the market. The market for many products has become more dependent on donor-financed buyers and innovator manufacturers, which makes it more vulnerable to contraction in the event of cutbacks in donor funding, withdrawal by the innovator companies, or higher product prices when donor-funded programmes end.

PRIVATE SECTOR HAS REMAINED MARGINALIZED FROM EFFORTS TO MAXIMIZE ECONOMIES OF SCALE OR TO LEVERAGE THE PURCHASING POWER OF OOP EXPENDITURES.

Except in countries where the pharmaceutical sector is organized into large national franchises – such as in Latin America – by and large, the commercial private sector has not benefited from harmonized or aggregated procurement. And even where franchises do exist, the potential purchasing power never exceeds national procurement volumes, which may not be large enough to stimulate price negotiations. Global procurement mechanisms of the type used by UNFPA Supplies or USAID do not exist outside the donor-funded public sector and neither the private sector nor its clients have benefitted from them.

96 Clinton Health Access Initiative (2015) Case Study: Expanding global access to contraceptive implants. Available at: <https://clintonhealthaccess.org/content/uploads/2015/08/Case-Study_LARC.pdf>
THERE ARE STILL ISSUES TO ADDRESS IN THE PUBLIC SECTOR SPACE

A risky procurement market

The public sector procurement market is dominated by a few large institutional buyers, a few large suppliers, a host of regulations that govern entry of new players, and pricing structures that often result in low profit margins. We have already discussed a number of disincentives facing generics as they decide whether to enter the global market. But there is also growing doubt over the long-term commitment of R&D developers to the donor/procurement market – particularly in light of recent negotiated price reductions. The driving force of any commercial business is financial interest. But when that is undermined, continued engagement is threatened – and the public sector procurement market suffers.

Concerns over declining profit margins transcend the generic/R&D manufacturer divide. They are a recurrent theme among all manufacturers within the RHSC, exacerbated by what is also perceived as increasing and often unreasonable procurement demands on the part of the donor community: demands for information; for new coding; for manufacturing certification; for country registration, among others. In the words of the manufacturers, FP supplies do not generate a large profit margin, new entrants find it hard to compete on price, and both international and country regulatory requirements are an additional obstacle. 98

Quality when quality costs more

Manufacturers often bear the burden of getting and maintaining WHO prequalification or SRA approval, which is required by international procurers, donors, and some countries. 99 Manufacturers also face difficulties and delays in complying with country regulations. There are concerns about product quality if non-WHO prequalified products are procured by countries for use in the public sector, or if quality-assured products available in the private sector benefit from public sector subsidies, which affects other manufacturers’ ability to compete. There is on-going debate over the potential for alternatives to WHO prequalification that can assure quality but does not place an undue burden on manufacturers. A step in this direction are the protocols and methods for quality control of non-WHO prequalified products developed by international NGOs (e.g. the MSI QARMA matrix).

Opportunities for more price reductions and other innovations

Minimum volume guarantees have proven to be an effective mechanism for achieving price reductions in specific products. But they have, in effect, turned the R&D manufacturers into commodity providers. Their success has depended to a large degree on the ability of development partners, including donors, to assume the costs of training, transport, and other services – costs that were once included within the original price. Many low and middle-income countries have called for more flexible pricing arrangements – arrangements that might involve slightly higher prices, but that include the broader service package for which many of the R&D manufacturers are known.

Much of the work by donors to improve procurement terms (pricing, lead time, etc.), has been done through the aggregation of purchases. UNFPA Procurement, for example, evolved out of AccessRH, which was itself the operationalization of the Volume Guarantee initiative, designed by the RHSC’s Systems Strengthening Working Group in 2012. But its relative effectiveness, and that of other similar mechanisms, is limited to the purchasing power of the procurer around which they are structured – basically USAID and UNFPA. Except in the case of certain volume guarantees, procurers are unable to leverage any more than their own purchasing power. There is much untapped potential out there.

98 KEI
99 Concept Foundation provides technical support for manufacturers in WHO pre-qualification, but no win a fee-paying basis. See: https://www.conceptfoundation.org/about-concept-foundation/what-we-do/access-to-family-planning/
Information and transparency

Global procurers have access to market information through existing mechanisms such as the RHInterchange and the Global Family Planning Visibility and Analytics Network (GFPVAN) currently in its early stages, but more complete and accurate information is needed by in-country procurers, together with improvements in the transparency of procurement processes.

NEED FOR WIDER PARTICIPATION IN THE ADVANCES ACHIEVED BY DONOR-FUNDED PROCUREMENT

By and large, the development community has focused its supply strengthening efforts on countries where that support stands to make the greatest difference: amongst the low-income countries and, within them, the public sector. This concentrated effort makes sense, and as was noted earlier in the report, should remain a priority for the development community.

But there is a growing concern that as countries graduate, they not only cease to receive direct development assistance, but also become marginalized from many of the global strategies, innovations and approaches that could continue to have a lasting impact on commodity security. As countries begin procuring on their own, for example, many no longer qualify for the reduced prices associated with volume guarantees unless such access is explicitly not precluded. Countries may continue to procure through UNFPA with the concurrent quality guarantees, but there may be a shift towards cheaper products by price-sensitive country procurers, raising quality issues. Nor have the advances in procurement benefitted the private sector, which is the area where most growth can be expected in the next decade—particularly amongst the countries entering the lower and upper middle-income groups. Private sector users are still paying commercial retail prices OOP, although they include some of the people who can least afford them.

Identifying ways to extend the benefits achieved in public sector procurement to a wider range of countries and to the private sector is a priority for the supplies ecosystem. Innovative approaches such as e-commerce offer new opportunities to manage procurement more efficiently and to do so in line with all players’ interests — manufacturers, procurers, and private sector actors. There are already a number of experiences in eProcurement which provide learning experiences and may have potential for wider application — for example the Global Fund’s Wambo platform at international level, and the Doctorstore platform in India. eProcurement is potentially an inclusive innovation which can be available to a wide range of users, providing access for all to favourable prices which can be passed on to users. There is also ongoing work in the development of ideas for market intelligence platforms (e.g. by the Centre for Global Development), which can also be inclusive and available to partners from all sectors. And finally, work is currently underway in Kenya to help private pharmacists source medical supplies more affordably and efficiency directly from national wholesalers. If successful, the pilot initiative, called MedSource, could be applied to other countries or groups of countries.

LIMITED PROCUREMENT CAPACITY AT COUNTRY LEVEL

Transition countries which have relied on donor-funded procurement through UNFPA or USAID may lack in-country procurement skills. As a result, they may not obtain the best procurement terms for supplies. There may also be issues of transparency and stewardship of procurement; legal barriers to procurement of specific products in some countries; and country conditions which may favour certain suppliers at the expense of quality.
4.3 GREATER ROLE FOR NATIONAL GOVERNMENTS AND PRIVATE SECTOR IN PROCUREMENT OF OTHER REPRODUCTIVE HEALTH SUPPLIES

Markets for most RH supplies other than FP are characterized by a large number of suppliers (R&D and generic) and large numbers of buyers in both the public and commercial private sectors, resulting in a less vulnerable market space. These products are, by and large, low cost and so pooled procurement would likely have only a limited benefit in reducing prices.

Most procurement for maternal health supplies is carried out by country governments at central or decentralized levels, with only a small percentage of the total being procured by the international organizations and very little going through the commercial private sector.¹⁰⁴

There are many R&D and generic suppliers for the three principal lifesaving maternal health products—misoprostol, magnesium sulfate and oxytocin—which have been the focus of work within the RH supplies ecosystem – at least since the establishment of the UN Commission on Lifesaving Commodities. Not all these products are WHO prequalified or SRA approved.¹⁰⁵ There is some quality control in countries with centralized procurement, but country procurers are often price-sensitive and may, to obtain the lowest price point, buy lower quality products from lower cost suppliers. In many countries national regulatory authorities (NRA) need strengthening and work is needed to develop more national procurement capacity and quality assurance processes, especially in countries where procurement has been decentralized.

Misoprostol is used for medical abortion and other maternal health indications. It is on the WHO Essential Medicines List (EML) and is procured through both public sector and commercial private sector channels. As it is an inexpensive drug with multiple suppliers, there are fewer concerns about the price-sensitivity of national procurers. Mifepristone is on the WHO EML as a complementary rather than a core product. And as it is only used for medical abortion there are legal barriers to country registration, meaning supplies can be limited in some countries. There are also very few WHO prequalified (PQ) suppliers of the mifepristone API which may affect supply. Combi-packs include both misoprostol and mifepristone and are designed specifically for medical abortion. Registration procedures are also more complex as these packs contain more than one drug.

In the area of menstrual health, sanitary pads and other comparable supplies are procured and distributed through commercial channels to shops, pharmacies and other retail outlets. There are some local products and innovations in use of materials, usually limited to local procurement within a country.

Quality standards for menstrual health products exist but are not used consistently at global or national levels. This has led to some concern about the safety of products and possible impacts on users’ health.

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¹⁰⁴ Bahl, K. et al (2016), op cit; KEI RHSC Maternal Health Supplies Caucus
¹⁰⁵ WHO prequalified RH products op cit
4.4 SUMMARY OF CRITICAL ISSUES IN PROCUREMENT OF ALL REPRODUCTIVE HEALTH SUPPLIES

- The global community’s procurement efforts have to date been concentrated in the public sector where important price reductions have been achieved, particularly for certain FP supplies. According to participants across the RH community, these reductions, while clearly increasing user access, have also had an impact on the market, with price competition becoming an obstacle to entry by other manufacturers and affecting profit margins and value propositions.

- Procurement of other RH supplies has received somewhat less attention from the global supplies community. Country governments are responsible for most maternal health procurement, and commercial private sector systems are primarily used for medical abortion and menstrual health supplies.

- Weaknesses in the existing procurement systems are:
  - Limited purchasing power using public sector financing.
  - Limited incentives for manufacturers. Long-term pricing arrangements undermine manufacturers’ ability to compete with one another, and limit incentives to engage in the marketplace.
  - Advances in public sector procurement have not benefitted the private sector procurement.
  - Limited public sector procurement capacity at country level

- E-commerce offers new opportunities to manage procurement more efficiently by capitalizing on all players’ interests – manufacturers, procurers, and both public and private sector actors. It has potential to provide favourable pricing to all, which can be passed on to users.

- Quality is very important, but the gold standard quality requirements of WHO prequalification and SRA are complex and expensive. As a result, many manufacturers whose financial goals can be met by targeting domestic and/or regional markets do not seek prequalification although their products may reach the quality standards. Some countries may require WHO prequalification for their own tenders, but many are more sensitive to price. As more procurement is carried out directly by countries the challenge for the RH supplies community is finding a quality control framework which does not become an obstacle to manufacturers.
5.1 THE CURRENT SUPPLY CHAIN DIALOGUE

The RH supply chain links actors at both global and country levels, from international manufacturers to users. Products move from manufacturers to central warehouses at country level. National supply chains take the products as far as service providers. There are often multiple in-country chains for the public and private sectors. The final link is from service providers to users (the “last mile”, also known as the “first mile”). This is a grey area—particularly in the private sector—with incomplete information on quantities or prices of either subsidized or commercially-priced products.106

The current dialogue on public sector supply chains has focused on three broad sets of issues:

- Overall end-to-end visibility to ensure effective monitoring and coordination of supply flows. Data quality and transparency are essential for good decision-making at all stages along the supply chain. At the global level, the RHSC’s Coordinated Supply Planning (CSP) group plays a key role in coordinating donor procurement of FP supplies for the public sector, fostering dialogue and mutual trust between supply chain participants and facilitating adjustments to prevent stock-outs and/or over-supply. This work will be enhanced by the GFPVAN which is currently being scaled-up with a view towards linking-up with VANs at country level. Standardization of product descriptions is also underway in order to ensure inter-operability of systems at global and country levels.107

Supply chain management and operations at country level. Several diagnostic tools have been developed to identify supply chain strengths and weaknesses, and to support strengthening of infrastructure and technical capacity for stewardship, management and implementation at country level. Competition amongst the developers of these different models is in some cases overwhelming countries (see below).

Potential for integration of FP supply chain with other RH and health supplies to enhance efficiency of infrastructure and systems.

SMOs have access to public sector supply chains for FP supplies in some but not all countries. The commercial private sector supply chains are normally independent and have not been included in the development dialogue to date, although they play an important role in distributing some family planning and maternal health supplies in decentralized health systems, and menstrual health and medical abortion products in all countries.

The final link is from service providers to users (the “last mile”). This is a grey area—particularly in the private sector—with incomplete information on quantities or prices of either subsidized or commercially-priced products.
5.2 CRITICAL SUPPLY CHAIN ISSUES

Efficiency and effectiveness

There is broad-based consensus within the RH community that ensuring supply chain efficiency is critical, if only to ensure that all the gains achieved through more efficient FP procurement are not lost once the product arrives in country.109 There are, however, different opinions about how to enhance efficiency. Whilst integration of FP with other products does hold out the potential for maximizing use of infrastructure and resources, and for strengthening country ownership, many within the RH community recognize that dedicated supply chains have contributed to the success of FP programmes in reaching the last mile—in much the same way that dedicated supply chains have contributed to the success of initiatives in HIV/AIDS and vaccines.110

Supply chain efficiency is important for maternal health supplies, as oxytocin requires cold storage and misoprostol is sensitive to humidity. While innovations with heat stable products are under development, existing supplies will likely dominate markets for the foreseeable future. Improvements to supply chain integration may need major investments in infrastructure as well as improved supply chain management procedures.111

There is also ongoing debate over arguments to adopt more of a hard-nosed business approach in ensuring efficient supply chains.112 Perhaps the most recent manifestation of this debate has surrounded efforts to shift responsibility for supply chain management away from the public sector towards the private sector, where effectiveness and efficiency have long been the norm.113 While instances of such outsourcing (e.g. Senegal’s Informed Push Model114) have indeed demonstrated significant benefits, sceptics have argued that past investments in supply chain strengthening could be lost by looking for solutions outside the public sector. They also point to the frequent lack of trust between governments reluctant to give up control, and private sector agents who may not see the government as an attractive client or a reliable payer.

National capacity for direct operation and management of the supply chain, or for stewardship

Country capacity for supply chain management is affected by the state of infrastructure, information systems, and availability of human resources including management skills, all of which vary widely amongst countries. Capacity strengthening is needed in management and use of information for decision-making, especially in countries which opt to implement and manage the supply chain themselves. If outsourcing to the private sector is the preferred alternative, capacity building in forecasting, contract supervision and stewardship will be essential.115

Covering supply chain costs

Despite the massive investment to date in supply chain strengthening, many regional and even local authorities have not undertaken systematic analyses to calculate the cost of delivering products to the last mile. These costs are typically not included in donor allocations for RH supplies. Some countries monetize a percentage of the donated products to cover supply chain costs. Some donors do add a certain percentage to donations to cover supply chain costs, but the incentives for recipient governments must be carefully designed to avoid procurement inefficiencies.

Using a tool developed by John Snow, Inc, the RHSC is currently working with rural health authorities in Peru, Bolivia, Guatemala and El Salvador to estimate supply chain costs. It is also currently funding the William Davidson Institute to develop a new costing tool that uses proxy data to fill information gaps when necessary.

Over the past decade, many countries have moved to decentralize procurement of FP supplies. But results have been mixed. While originally intended to encourage greater local autonomy and ownership, the results have all too often yielded higher prices, erratic supplies, and increased corruption, leading

110 A study in LAC showed that health workers were using 50-60% of their time on supply chain functions (Nora Quesada op cit).
112 KEI; The RHSC SSWG has developed a paper on the advantages of pursuing more efficient approaches to SCM in the future. It makes a strong case for outsourcing in general. See: https://www.rhsupplies.org/uploads/tx_rhscpublications/A_Business_Approach_to_Transforming_Public_Health_Supply_Systems.pdf
114 This was later passed on to the MoH, and is no longer functioning
115 KEI
116 Quesda, N. Op cit
to bribery, theft and counterfeit products on the market. Local authorities rarely require the product volumes necessary to secure better prices and there is often high dependence on the private sector when supply shortfalls occur. Countries such as Mexico have re-centralized procurement which they view as having contributed to improvements in contraceptive prevalence.

**Aligning country and global interests**

Although donors have invested in national supply chain development, at the end of the day, supply chains are country-owned and managed, and respond to specific country characteristics and conditions. National capacity for management and stewardship of these diverse supply chains will become more important as donor investment declines.

Also of critical importance is the need to ensure greater alignment between global and country systems, both to maintain efficiency gains, and ensure a smooth flow of supplies to the last mile. Specific areas where alignment and communication are needed include planning and forecasting, information systems and visibility networks.

**Lack of coherence in either supply chain management or approaches to address supply chain weaknesses.**

Support to enhance supply chain management has been provided by a range of donor agencies, both for FP and RH more broadly. These include the Gates Foundation’s Supply Chain Maturity Model, USAID’s National Supply Chain Assessment Tool, John Snow, Inc’s Supply Chain Compass, the Empower School of Health’s PSM Competency Assessment Tool, the GHSC-TA’s Opportunities Framework, and PtD’s Human Resource Capacity Development in Public Health Supply Chain Management. These and the many other tools developed to identify and address supply chain weaknesses are not aligned or integrated by development partners at country level. There is also lack of consistency in the criteria for assessing supply chain success, some donors focusing on stock-outs, others on the range of products available, others on the supply chain’s ability to cover the last mile, others on efficiency and supply chain costs. As a result, partners have contrasting views of the issues and opportunities present in a given supply chain. Programmes are designed, implemented, and funded in silos which are based on these contrasting views, resulting in duplication of effort, unnecessary competition, and in the worst cases, interference with one another. Because of this, advancement of supply chain maturity is often hindered due to the existence of multiple maturity assessment tools.

The community needs to determine how to come together to systematize an approach to understanding what countries need in terms of supply chain interventions. The relevance of each assessment is a function of country context. For this reason, it is unrealistic to assume that one assessment should be considered the gold standard. Given that donors have different ways of defining supply chain maturity, greater coherence in vision and messaging in this space would benefit the community. Having a unified map to highlight where gaps exist would decrease confusion within countries and ensure that partners allocate their resources most effectively.

**Potential for inclusion of the private sector users in national FP supply chains**

With growing OOP expenditures in an expanding private sector, equitable access to supplies will hinge on their availability and affordability. Mark-ups along commercial supply chains result in higher prices. The integration of both subsidized and donated FP products in national supply chains has helped ensure affordable pricing. Integration of the commercial private sector into public sector supply chains also offers potential for reduced prices to a wider group of end users.

**Inclusion of private sector in supply chains for other RH supplies**

Commercial supply chains are already used for the distribution of medical abortion supplies to pharmacies and private sector clinics, and for the distribution of menstrual health products to commercial outlets and to pharmacies. In countries with decentralized procurement, private sector supply chains are also often used to distribute maternal health supplies from central to regional levels. Projections suggest growth in all these areas in the next decade, with the concurrent need for development of public sector capacities for stewardship.

5.3 SUMMARY

The tension between efficiency and effectiveness in the supply chain has led to the development of different supply chain models for FP and other RH supplies. Logically, integration of multiple products into a single system holds out the promise of greater efficiency; but experience has shown that the most effective delivery of single product categories (such as FP) has often been through vertical systems. The distinct attributes of supply chain functionality do not align themselves neatly along therapeutic lines. The fact that certain maternal health supplies require a cold chain suggests a more natural affinity with vaccines; whereas supplies for medical abortion and menstrual health have benefitted from private sector supply chains.

All the different models stand to benefit from good information systems and data visibility. They also depend on the ability of supply chain managers to use information for better decision-making. FP supplies need visibility at the global level due to the participation of donors and multi-lateral procurement agencies. The RHSC’s GFPVAN is an important step in this direction and potential for linking it with country VANs is currently being explored.

Private sector supply chains may be easy or more efficient for some individual providers or networks of providers but can lead to higher user prices due to multiple mark-ups along the chain.

There has been little integration of the public and private sectors in RH supply chains, but much can be gained where both sectors participate as supply chain operators and/or users. Better integration and participation require strong country capacity for supply chain stewardship.
The critical issues identified in the previous pages are all, to some degree, interrelated and overlapping. Both the commonalities and the differences have shaped our vision for exploring how we can address the challenges we expect to occur the next decade.

The big questions to be answered are: Where do we want to be? What products will be available in markets? Which clients are served well and which clients are underserved, due to lack of access or unaffordable prices? What innovations will be supported? Where can we make a difference and where do we have capacity to do so? Does our current toolkit, which has been honed over years of work in the public sector, contain tools that offer value to the private sector, whose participation is vitally needed? And how can we learn from the diversity of the current ecosystem, and build on experience to advance our future goals?

The vision laid out in the following section is based on inputs from a wide range of supplies ecosystem partners and other experts who have participated in discussions and provided feedback on preliminary analyses and conclusions. The ecosystem itself is an assemblage of individuals, groups and organizations working in the supplies field. With partners working in different markets and with many different areas of expertise and points of view, we cannot expect full consensus on how to move forward. But we hope that a shared vision for the next decade will provide the basis for working together to achieve our overall goals and help direct resources and efforts to the most essential tasks.

This section presents the vision, and the following section outlines strategic recommendations on how to work towards achieving it.
6.1 ECOSYSTEM AIMS FOR 2030

Our aim during the next decade is to develop a sustainable, inclusive and equitable RH supplies ecosystem which contributes to achievement of the Sustainable Development Goals (SDG) in low- and middle-income countries.

The relevant SDGs are Goal 3 (Ensure healthy lives and promote well-being for all at all ages), Goal 5 (Achieve gender equality and empower all women and girls), and Goal 17 (Revitalize the global partnership for sustainable development). Targets and their indicators for Goal 3 refer specifically to access to SRH services and FP (target 3.7), access to UHC (target 3.8) and access to affordable essential medicines (targets 3.8 and 3b); targets 5.6 and 5.6.1 focus explicitly on universal access to SRHR. In terms of targets for partnerships, we highlight coordination among existing mechanisms for cooperation on and access to science, technology, and innovation and enhanced knowledge sharing (target 17.6).

The supplies ecosystem is a means to an end. Its role is to ensure that RH supplies are available to enable the global community to meet its development goals; that there is broad choice, systems for quality-assurance and equitable access to supplies by all income groups whether that be through the public or private sectors.

Our vision aims to see partners working together to meet the supply needs of people in low- and middle-income countries, balancing the interests and value propositions of all ecosystem participants.

Where do we want to be? What products will be available in markets? Which clients are served well and which clients are underserved, due to lack of access or unaffordable prices? What innovations will be supported? Where can we make a difference and where do we have the capacity to do so?
6.2 STRATEGIC FOCUSES FOR WORK IN THE NEXT DECADE

Over the coming decade, the ecosystem for RH supplies will necessarily work within the framework of the SDGs, building on existing work and experience, and developing innovative approaches with a wide range of partners. The principal focuses of work will include the following:

**Seeking inclusiveness in the supplies space**

The supplies ecosystem includes a wide range of participants: product developers, manufacturers, donors, international organizations, think tanks, country governments, procurers, service providers in the public sector and private sectors, advocacy organizations, and most importantly of all, the millions of women who use RH supplies.

To date the global supplies community has focused largely on the public sector. There are, however, important changes in market dynamics on both the demand and supply sides, with growth in the demand for all categories of RH supplies and changes in the supplier landscape. These trends point to the need for wide participation in the ecosystem and a growing role for non-public sector partners to ensure both innovation and stability during the next decade.

In FP, declining donor support will lead to greater OOP expenditures and a growing role for the private sector in the development and supply of products to users. In procurement, the public sector is likely to maintain a dominant role in the area of maternal health and may take on a larger role in safe abortion supplies, which are currently procured mainly through the SMOs and the commercial sectors. Menstrual health supplies are likely to remain the prerogative of the commercial private sector. The private sector already manages the supply chain for many products, and also participates in some aspects of national supply chains.

There is currently a host of obstacles to greater private sector participation in the supplies ecosystem. For both R&D and generic manufacturers, there are low profit margins on RH supplies in emerging economies, uncompetitive commodity markets, and obstacles to the entry of new and underutilized technologies, such as cumbersome registration procedures and fees. For service providers, obstacles include low margins on FP services due to competition from free or subsidized supplies and, of course, the stigma associated with provision of medical abortion. And for potential private sector participants in national procurement and supply chains, there is a lack of trust between the public sector and private sectors.

These factors point to the need for greater inclusiveness throughout the supplies ecosystem to ensure wide participation and cooperation among the public, private non-for-profit, and commercial private sectors. Existing and new systems for development, registration, introduction, procurement, information, market intelligence and quality assurance need to be flexible and appropriate for all partners.

**Supporting a healthy market**

The supplies community has been witness to important developments and advances in the public sector. There is an acute need to continue to strengthen and sustain public sector provision of RH supplies, especially in the LICs which will largely remain donor-dependent for FP supplies during much of the coming decade. Priority areas for public sector support include:

+ A pipeline of technologies to address the limitations and costs of products currently in markets
+ Information and visibility globally through the GFPVAN, and potentially at country levels through country VANs for FP and other RH supplies
+ Capacity building in procurement and supply chain stewardship and management
+ Quality assurance of all RH supplies – how to ensure quality when countries procure for themselves and the private sector uses its own procurement channels
+ Promotion and advocacy with donors and country governments to ensure that public sector funding for supplies benefits the poorest countries, and the poorest individuals in all LIC, L-MIC and U-MIC

Many within the RH community have argued that volume guarantees, price subsidies and other market shaping efforts have created barriers to market entry and affected competition, prejudicing the interests of private sector participants.

To ensure equitable access to a full range of new and existing technologies, the supplies ecosystem will have an important role in supporting development of a healthy total market that includes the public and private sectors, in all its manifestations. The private sector already plays a dominant role in the provision of
menstrual health and safe abortion supplies, and is a key player in the maternal health and FP spaces. There are important opportunities to share experiences in these different commodity markets to move forward.

The supplies ecosystem, therefore, must have a dual role: sustaining and broadening advances in the public sector without impacting negatively the private sector; but also encouraging wider participation by the private sector, both as a service provider and source of lessons learned. There are opportunities for mutual learning and experience-sharing which can help us better reach all commodity markets and country groups. Even in the LICs which are likely to remain donor-dependent over the next decade, a nascent but healthy private sector can reduce the risks associated with changes in government policy, instability and natural disasters which can change country resource allocation priorities.

To meet the needs of diverse user groups, the RH supplies ecosystem will need to ensure awareness and harmonize all partners’ differing interests and value propositions.

**Ensuring equity**

User trends suggest an increased role for the private sector, particularly the commercial private sector, in the next decade. In the long-term, UHC should help address many of the barriers that impede access to services and supplies; but in an environment of resource constraints and limited capacity for stewardship, it is unreasonable to expect major advances towards UHC in the next decade, especially in the group of 35 countries classified as “low income”.

Potential growth in the role of OOP expenditures for FP poses a risk to equitable access to supplies and services for low-income groups. The supplies ecosystem will need to promote and support development of an equitable availability-price combination for private sector users, ensuring that those least able to pay are not prejudiced. Better cooperation and joint programming could help ensure that advances in planning, market information and procurement are available to all sectors, including full access to new technologies and innovations with significant health benefits.

**Improving efficiency**

More efficient use of scarce resources will contribute to the ecosystem aims. Today’s ecosystem partners have the skills and experience necessary to enhance the efficiency of resource mobilization, procurement, supply chain operations, and market intelligence, and they are expanding their expertise through greater use of digital systems. There is enormous scope for more work by the ecosystem in these areas, sharing experiences and “wins” with all partners to ensure there are all-round efficiency gains.

**Attention to quality of supplies**

In today’s RH ecosystem, responsibility for safeguarding the quality of supplies has largely fallen to bilateral and multilateral partners, and this will likely remain the case in the coming decade. During the next decade, however, efforts will be required to ensure that the search for quality assurance does not become a major barrier, either to new products or new manufacturers, be they R&D or generic manufacturers. The ecosystem can contribute its expertise to identify needs for innovative products, bottlenecks, supply vulnerability and barriers to entry. Strategies for reducing these problems and supporting innovation will contribute to the development of healthy and sustainable markets.
CHAPTER 7
Recommended strategies for the next decade

RECOMMENDATION 1

Reawaken awareness of the benefits/value proposition that can only come from leveraging the strength and purchasing power of the global RH community.

Such power can be leveraged to set standards for international procurement, and to ensure supply chain visibility from manufacturers to the last mile. This will be particularly important with the increased focus on the private sector, the advent of more country-based strategies for national and regional procurement and the inclusion of private sector in procurement planning.

RECOMMENDATION 2

Forge new partnerships, including with the private sector, at all points and links in the ecosystem.

Identify specific areas for cooperation which could include joint work with other procurement systems (GAVI, GF-Wambo), new public-private information links, development of eProcurement platforms available to public and private sectors, joint strategy planning and programme implementation, and attention to the interfaces between global and country activities (e.g. GFPVAN/country VANs).
RECOMMENDATION 3

Ensure that the notion of a healthy total market stands to benefit the public sector, but without undermining the private sector.

Use the ecosystem’s leverage and access to a wide range of participants to ensure that efforts undertaken with a view to increasing access to RH supplies, “do no harm” to the private sector. For example, donors could require that interventions for the public sector carry out an appraisal of their likely impact on the private sector prior to funding – as they do now with technical, financial and environmental impact appraisals. If there are negative impacts (e.g. on market competitiveness, creating barriers to entry, among others), remedial strategies can be developed.

RECOMMENDATION 4

Leverage donor funding to promote equity, be it through schemes to mobilize domestic resources for RH, or through efforts to raise private sector capital such as development impact bonds.

By sharing information and experience in different country groups, the ecosystem can promote schemes requiring comparatively low actual expenditure of donor funds (e.g. volume guarantees, bridging finance); and/or allocations that benefit the poor through public sector funding, total market approaches and cross-sector strategic planning.

RECOMMENDATION 5

Reduce the vulnerabilities of a public sector supplies market through more effective market management.

The supplies ecosystem should use its access to decision-makers to play a proactive role in facilitating market entry for new technologies and for generics. Such efforts could identify potential danger points in the RH supplies markets, maintain information bases of alternative products and their availability, advocate for lowering of barriers to entry, and in case of market failure, coordinate remedial action.

RECOMMENDATION 6

Ensure RH supplies are included from the start in discussions on UHC design.

Leveraging the appeal of maternal health services within UHC could open the door to inclusion of other RH supplies such as FP and safe abortion and serve to promote reimbursement schemes which foster full participation by the private sector. The supplies ecosystem has an important role in monitoring country plans for UHC, and in supporting national advocacy for RH in UHC. Quality data is required to demonstrate the potential cost-benefit of RH services and private sector participation.
**RECOMMENDATION 7**

Support development of quality assurance mechanisms which protect consumers but do not constitute an insuperable barrier to market entry.

The ecosystem has a role to support streamlining, flexibility and cost reductions in WHO PQ/SRA, and strengthening and rationalisation of NRA procedures.

**RECOMMENDATION 8**

Identify and address procurement and supply chain weaknesses which affect product quality.

Although some issues, such as provision of better cold chains, require major in-country investments, there are other areas such as capacity building which are appropriate for external funding.

**RECOMMENDATION 9**

Address the whole ecosystem rather than the value proposition of each participant within it. Meeting the challenges of the next decade will depend on the ecosystem’s ability to support existing and new participants and strengthen the links amongst them.

The ecosystem has an important role to play in promoting a collective understanding of different value propositions, making clear the sustainability requirements of different participants, developing methodologies to ensure all parties’ interests are considered in programme design and planning, fostering mutual awareness and promoting joint design and implementation of initiatives.

**RECOMMENDATION 10**

Better understand OOP expenditures and the role of the private sector to ensure that: 1) public sector funding is directed to those most in need, and 2) private sector resources are allocated where they offer the greatest promise in reducing inequities.

In some countries, rising OOP expenditures may not be a concern, if those who are paying can afford it. But if the cost burden is falling on the very poor, support may be needed to improve equity. In all countries, use of the private sector and OOP expenditures is correlated with a skew towards short-term methods, and policy adjustments or incentives may be needed to encourage wider availability of long-term methods as well as new products in the private sector.
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Annex 1: Participants in interviews and discussion groups

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<td>Nicolette Hutter</td>
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<td>Ian Mountford</td>
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<td>Nancy Muller</td>
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<td>Mindy Scibilia</td>
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<td>Frank Van de Looij</td>
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<td>Alfons van Woerkom</td>
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<td>Monique Vledder</td>
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<td>Michelle Weinberger</td>
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<td>Lucy Wilson</td>
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<td>Chris Wright</td>
<td>GAVI, The Vaccine Alliance</td>
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<td>Beth Yeager</td>
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Annex 2: General Membership Meeting Feedback Survey

Kathmandu March 2019

Summary of responses (91 respondents)

1. Please identify which type of organization you are from:
   + Country government 2%
   + Donor 6%
   + Foundation 2%
   + Multi-lateral organization 9%
   + NGO 52%
   + Manufacturer 9%
   + Research organization 3%
   + Other 17%

2. The proposed dual role for the supplies ecosystem, working with both public sector and private sector, has focused on FP supplies. Do you think the proposal is valid for other areas of RH supplies (maternal health, menstrual hygiene, medical abortion, others)? (Yes/No)
   + 94% - yes

Can you explain why you answered this way? (open-ended)

Responses relevant to the question itself:
+ The focus on the dual role isn’t so much a proposal as a recognition of the reality as RH goods and services are delivered by both sectors. We know that women also source their maternal health, menstrual hygiene and medical abortion services/products in the private sector as well as the public sector. The approach should be holistic and ensure that all points of view are considered
+ Although many supplies are accessed in the private sector, the public sector has an important stewardship and oversight role to ensure quality, affordability and accessibility
+ Focus on the private sector is an important aspect of sustainability as donor finance will be lower in future

Note: Not all the responses correspond directly to the question of the dual role of the supplies community in public and private sectors. There were also answers focused on whether we should integrate FP and RH supplies systems in general:
+ Integration FP/RH is necessary, supplies for the different areas often use the same channels. There is no inherent reason to separate the different types of supplies, given the overlap and synergy between them. The supplies community should take an integrated approach and address the whole package of RH supplies
Medical abortion should be integrated with FP; MH and menstrual hygiene are less pharma-specific and have many channels to address needs.

3. Is there a role for the global supplies community to support private sector participation in FP/RH supplies provision in-country? (yes/no)

96% - yes

Yes, but the global community needs to gain a much deeper understanding of the private sector and then identify what role might make the most sense.

How? (open ended):

- Global supplies community can help build trust through advocacy with public sector on the importance of the private sector role, facilitating communications, sharing information and experiences where collaboration has worked, acting as a knowledge broker, and fostering alignment of objectives.
- Facilitate inclusion of and engagement with the private sector in global and in country discussions; e.g. via supply coordination groups and partnerships in-country, experience-sharing, linking private sector into on-going national projects.
- Inclusion of private sector in volume guarantees and in benefitting from reduced procurement prices; help private sector source FP supplies locally or regionally.
- Promote debate and awareness of the impact of reduced prices of public sector procurement on the private sector market – e.g. effects on price competition and value propositions for RH supplies in the private sector.
- Assist the private sector with information on market opportunities, data-sharing, dissemination of best practices.
- Assist with registration processes and reducing barriers to market entry, whilst promoting global standards for quality and affordability in private sector and accountability for quality in private sector.
- Encourage health financing systems which foster private sector engagement (e.g. UHC including private sector service providers).
- Support for out-sourcing public sector supply chain tasks to private sector.

4. We have identified obstacles to private sector participation in different spaces in the FP supplies ecosystem. These include low margins on FP, uncompetitive commodity markets, barriers to market entry for R&D and generic manufacturers, lack of mutual trust between public sector and private sector.

Do you agree that these are obstacles? (yes/no)

93% - yes

Do you have any comments on these points? Are there other important obstacles to private sector participation? (open-ended)

- The supplies community should facilitate communications, so the public sector has better information and a more holistic understanding of the market, its dynamics, the impact of aggregation and reduced procurement prices on the private sector, and private sector decision-making criteria. There is downward pressure on prices and lack of competitiveness due to influx of donor-supported products, which means the private sector is squeezed too much and profit margins are too low. The private sector has no voice or influence on policy.
- Obstacles vary from country to country but there is always underlying mistrust and tension between public sector and private sector. There is resistance of MoH to inviting the private sector to the table. Multi-laterals, NGOs and government staff don’t have the time (or remit) to reach out to private sector.
+ Other obstacles are corruption, bureaucracy, inefficiency, government inability to pre-pay, PQ/SRA, public procurement legislation
+ Existing quality “gold standards” represent an obstacle for the private sector due to the cost and time investments in getting and maintaining PQ or SRA approval. There is room for development of acceptable but less demanding standards which still safeguard consumers but facilitate market entry by new manufacturers
+ It is difficult for the public sector to develop good stewardship over the private sector due to lack of information and need for development of stewardship skills

Do other areas of RH supplies have similar obstacles? (yes/no)

93% - yes
+ There are less obstacles for maternal health supplies than for medical abortion supplies

5. Do you think the obstacles identified in question 4 apply in many places, or are they specific to some countries?

84% - apply in many places
16% - apply in specific countries

Do you know any countries where such obstacles exist? (open-ended)

+ Most LIC, most countries where donors intervene, most countries in SSA

Some specific countries mentioned too
+ Problems of corruption, rigid and inappropriate quality controls, lack of understanding of private sector by public sector officials and policy-makers

6. How can the global supplies community help reduce obstacles to private sector participation? (open-ended)

+ Promote dialogue between government and private sector (mentioned many times in different forms); foster understanding of the market and help create political will to design market strategies which include private sector; advocacy with governments on importance of private sector participation, disseminating positive experiences; inclusion of private sector in coordination mechanisms; foster mentors and champions of private sector participation. Act as a bridge, broker and neutral safe space for all participants
+ Help reduce barriers to entry through better and clearer information on registration requirements and demand; support development of a database with information for product registration. Provide subsidies to ease market entry
+ Develop market intelligence platforms to enable sourcing for certified products, with information on availability, costs, economies of scale, stock levels, manufacturers and vendors. Online platforms functioning as supplier, virtual warehouse and distribution system
+ Encourage government to out-source supply chain functions

7. We have identified that data visibility is important at global level for planning, coordination of procurement, optimizing production for manufacturers, and efficient supply chain operations.
Are some or all of these factors also important at country level? (Yes/no)

Yes - 100%

Is there a need for country VANs? (yes/no)

Yes - 94%

How could the global community help to develop them? (open-ended)

+ VANs are seen as a public sector rather than a private sector initiative and respond to public sector needs. They are very important to improve coordination in humanitarian settings where lots of agencies are involved
+ Other proposals for global supplies community support:
  + Demonstrate how global and country VANs can work together, e.g. through a pilot country VAN
  + Share information on VANs to increase understanding at country level; forums for experience sharing
  + Get government buy-in
  + Share lessons learnt and tools
  + Develop standard web-based solution
  + Training and capacity building in VANs and in use of information for decision-making
  + Provide funding and IT support

8. Global procurers have safeguarded quality through WHO pre-qualification of FP products. This has limited the number of products procured with donor funds and affects price competition. If more procurement is done by countries and private sector procurers in the future, what can the global community do to promote quality safeguards? (open-ended)

Standards:

WHO PQ is the gold standard but is too costly for small manufacturers and needs large volume to justify it; seek methods to streamline it or provide alternative QC processes for countries which procure non-WHO pre-qualified products. WHO plus country requirements are overkill and makes the process very expensive; align country and WHO quality standards, provide support for manufacturers with PQ processes, and review potential for regional quality certifications

Capacity building on quality in-country:

Capacity building and better training for national procurement functionaries so they have better understanding of meaning of quality, standards and approvals; develop quality guidelines, norms and standards for use in-country; identify labs for quality assurance testing for non-PQ products

Setting priorities for QA:

Identify local suppliers in key countries for key bottleneck items and support them with certification processes and costs. Generic manufacturers from low income countries should be prioritized and the cost of registration waived. PQ should look at manufacturers’ products delivered to both the international and domestic markets to ensure quality in both, as often there are two production lines

Consumer awareness and participation:

Promote and provide a platform for consumer feedback; advocate for consumers to have a voice in quality control; disseminate information on products which fail QC
THE REPRODUCTIVE HEALTH SUPPLIES COALITION

The Reproductive Health Supplies Coalition is the world’s largest network of reproductive health (RH) supplies organizations. Formed in 2004, we are a partnership of nearly 500 public entities, private corporations, and NGOs working so that everyone in low- and middle-income countries (LMICs) can access and use affordable, high-quality RH supplies. In 2018, we made huge strides in increasing contraceptive access to the women and girls who need it most.

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