

**IN FOCUS:**

## **The Quality of Reproductive Health Medicines Programme**

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*Key milestones and the road ahead  
for expanding access to affordable,  
quality-assured medicine and support*

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**August 2011 – March 2014**



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## Acknowledgements

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August 2014

**Reproductive rights...rest on the recognition of the basic right of all couples and individuals to decide freely and responsibly the number, spacing and timing of their children and to have the information and means to do so, and the right to attain the highest standard of sexual and reproductive health.<sup>1</sup>**

— International Conference on Population and Development, Cairo, 1994

Over the past several decades, the fundamental right to reproductive health has been recognized by world leaders as the key to healthy and productive families, communities and countries. An idea that would have raised eyebrows a generation ago has instead informed major global initiatives:

**Empowering women, girls, and families has far-reaching implications for health, poverty reduction and economic development.**

Access to safe, effective, and affordable reproductive health supplies, including contraceptives, has long been inadequate—and the need continues to grow. It is estimated that at least 222 million women in developing countries lack access to family planning methods. The impact of this gap on health and development is devastating: Unmet need for family planning accounts for an estimated 63 million unintended pregnancies in developing countries each year and an estimated 104,000 pregnancy-related deaths.<sup>2</sup> Furthermore, studies have shown that every \$1 invested in family planning yields a \$6 return.<sup>3</sup>

The Reproductive Health Supplies Coalition (RHSC) has worked to increase access to family planning products and other reproductive health supplies since 2007. The effort to place reproductive health at the top of the global agenda has gained momentum over the past several years, and the London Summit on Family Planning in July of 2012 was pivotal in this movement. At this forum, world leaders committed to extend family planning services to an additional 120 million women and girls in the world's poorest countries by 2020. The subsequent launch of Family Planning 2020 (FP2020) and the UN Commission on Life-Saving Commodities for Women's and Children's Health (UN Commission) has been critical for keeping this agenda on track and is focused in a number of key areas—from broad market-shaping interventions to targeted advocacy for policy and funding to ensure that specific medicines are more widely available in high-need regions.

While these efforts have been essential in bringing the issues of reproductive health to the forefront of mainstream policy planning and implementation, the focus of the global community to date has been primarily on expanding access to family planning, without specific attention to the *quality* of these products, methods, and services. Yet, without prioritizing quality, family planning leaders and policymakers are potentially undermining efforts to address the unmet need for reproductive health supplies. Ineffective—or worse, unsafe—reproductive health medicines are at best risky investments, and at worst, life-threatening.

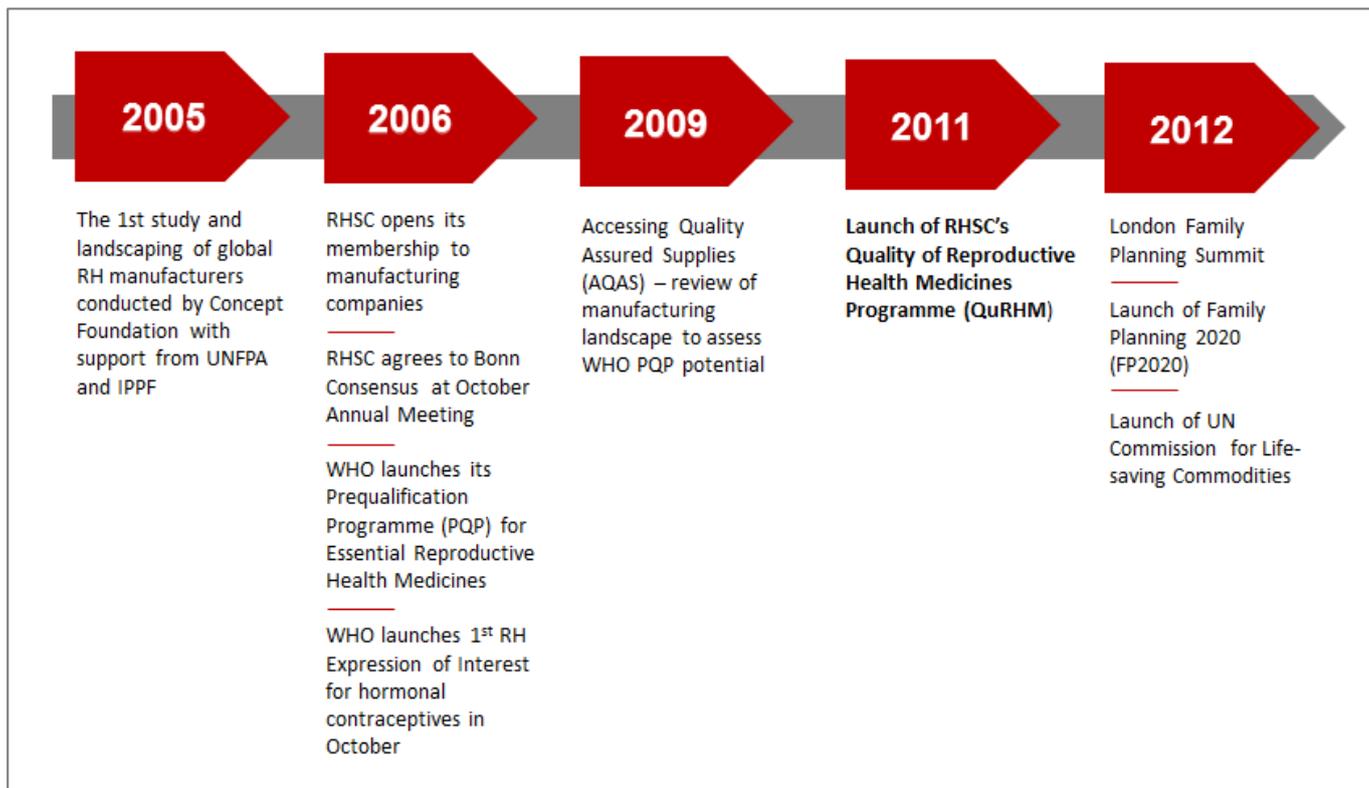
Fortunately, the movement to prioritize quality in reproductive health has benefited from global attention to the issue of access. The market has shifted in recent years, with the reproductive-age population in developing countries surging<sup>4</sup>, and donor-funded supplies manufactured primarily by multinational corporations giving way to more generic products. Yet, as demand grows and the pool of companies supplying products also expands, quality can no longer be considered a given.

The undeniable truth is that poor-quality products have grave health consequences—and delay sustained access and affordability. When manufacturers, policymakers, and procurers prioritize and invest in quality, they save time, money, and lives. In December 2013 in Sri Lanka, a young mother of one was issued the injectable contraceptive, DMPA, at a private clinic. She quickly went into anaphylactic shock to the contraceptive and died. The Cosmetic Devices and Drugs Regulatory Authority (CDDRA) acted to withhold the product upon investigation.<sup>5</sup> This was not a one off incident; in March 2012 the Sri Lankan Health Ministry temporarily banned DMPA due to the death of a woman following administration of the injectable contraceptive at a Health Center. It was later reported that the temporary ban had been lifted and the Health Ministry made arrangements to import DMPA solely

through the state procurement agency for distribution among government family planning clinics around the country.<sup>6</sup>

A quality agenda that strengthens all channels of the market, from production to consumption, relies on an internationally accepted set of quality criteria. Since its inception in 2001, the World Health Organization Prequalification of Medicines Programme (WHO-PQP) has become the preeminent indicator of quality for products sold in developing countries. Approval by a Stringent Regulatory Authority (SRA) and/or WHO prequalification is widely recognized as the most trusted mark of quality, and the global reproductive health community has coalesced around the WHO standards as a key factor in ensuring that women around the world receive the safe, effective, and affordable medicines they need.

**Timeline: Advancing the Quality of RH Medicines on the Global Agenda**



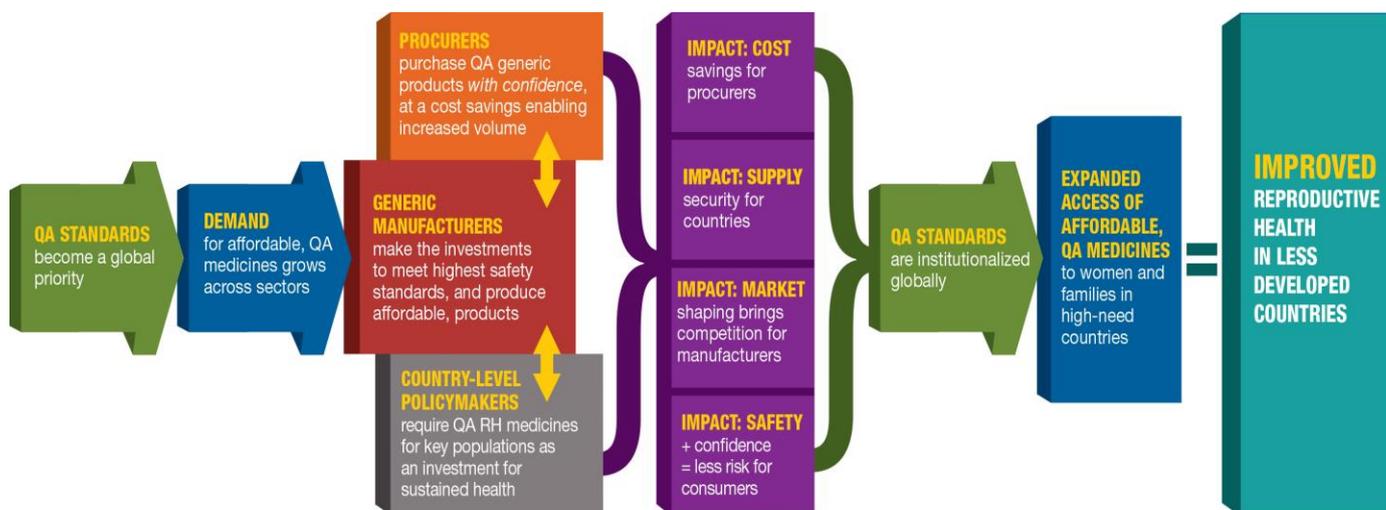
In response to the increasing concerns of international procurement agencies, the RHSC provided a small innovation grant to Concept Foundation to establish the quality landscape for generic reproductive health products. The results identified the need for significant technical support by many companies and a perceived lack of incentive to invest. The Quality of Reproductive Health Medicines (QuRHM) Programme was launched in August 2011 to stimulate the emergence of a vigorous market for quality-assured reproductive health medicines.<sup>7</sup> A project of the RHSC, funded by the UK Department for International Development (DFID) and managed by Concept Foundation in partnership with WHO and UNFPA, the QuRHM Programme was the first of its kind, uniting actors across levels of the reproductive health supply chain around the quality agenda. Building on existing efforts that were less formal and coordinated, the Programme's activities were organized into four outputs, each reaching a unique target audience, each reinforcing the others through a planned theory of change:

- Output 1:** Increased availability of affordable quality assured\* RH medicines for supply to less developed countries.
- Output 2:** Harmonized quality assurance definitions, policies and practises among major international procurement organizations.
- Output 3:** Commitment to strengthen national procurement criteria, based upon internationally accepted quality assurance definitions, developed by key stakeholders in four countries – Ethiopia, Kenya, Senegal and Nepal – working through RHSC members, WHO and UNFPA.

**Output 4:** Awareness of the QuRHM strategy and related quality issues raised among non-procuring donors and other RHSC members.

The QuRHM Programme was modeled on the past successes of the quality movement in other health areas, particularly those of the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund), which pioneered a quality strategy at the turn of the millennium and had a significant effect on the market of antiretroviral, anti-tuberculosis, and antimalarial medicines.<sup>8</sup> It was recognized from the outset that, in contrast to this market, the reproductive health medicines market is extremely fragmented, and the QuRHM Programme was designed to address its specific needs, fostering activity within the many communities that play a role in the development and delivery of reproductive health supplies and services—from the evaluation that certifies the integrity of a product and the sites where medicines are manufactured to policies and funding that determine when and how medicines reach consumers.

**Theory of Change: Investments in Quality Assurance (QA) & Collaboration across the RH Supply Chain Catalyze Sustained Development**



The theory of change outlined above results in more value for money spent in RH because procurers can leverage more volume for less cost when quality generic RH medicines are purchased. More volume of product will likely mean medicines are reaching more women and families. In fact, the QuRHM Programme projects a potential procurement savings of between US\$13.7 million and US\$32.4 million in 2016 alone.<sup>9</sup>

By working with manufacturers, donors, procurers, and governments to define, meet, and adhere to international quality standards, QuRHM has propelled the burgeoning quality agenda and helped ensure that, in the future, families will never have to choose between quality and access.

This paper was produced under QuRHM Output 4 to raise awareness of the Programme strategy and of related quality issues. It is based on a literature and landscape review; materials published at the start of the QuRHM Programme as well as under Outputs 1, 2, and 3, including founding and guiding documents, annual reviews, and country reports; findings from country-level workshops; and interviews with key stakeholders from around the world. It is intended to highlight, based on data and stakeholder feedback, the milestones achieved under QuRHM over the past two and a half years and the opportunities and challenges that lie ahead.

The work to advance the quality of affordable, quality assured RH products is far from complete. This paper captures a moment in time within the movement to improve reproductive health for women and families in less developed countries. The continued country-level work by UNFPA is critical in promoting global-level advocacy. In addition, Concept Foundation is continuing its work with manufacturers initiated under the QuRHM programme to ensure that generic reproductive health medicines continue to enter the prequalification pipeline and to ensure that there are sufficient products prequalified within each product category. The road ahead is promising if we remain focused and steadfast.

## ANALYSIS OF OUTPUTS 1-3

The QuRHM Programme brought together a constellation of actors, including manufacturers, procurers, and country leaders, to tackle the issue of quality in reproductive health medicines across the supply chain. Many stakeholders interviewed under Output 4 called the Programme “catalytic,” and it was widely agreed that the initiative was high risk with potentially high impact and that it made great progress in moving the quality agenda forward—though much ground remained to be covered, particularly at the country level (Output 3). The objectives and accomplishments of Outputs 1, 2, and 3, as well as the challenges, identified over the course of their execution, are outlined below.

### Output 1: Increased supply

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The availability of affordable, quality-assured medicines in developing countries depends on the willingness and capability of generic manufacturers to attain WHO prequalification of their products. Improving manufacturing standards and processes and preparing dossiers for submission to PQP is a complex and time-consuming process, and companies must weigh the benefits of expanding into new markets against a considerable investment of time, effort, and money, particularly high-need countries where margins are low and markets lack structure.

**In August of 2011, when the QuRHM Programme began, only eight reproductive health finished pharmaceutical products (FPPs) had been prequalified, all of which were innovator products produced by multinational brands. No active pharmaceutical ingredient (API) had yet been prequalified.** Barriers to entry into the market, long dominated by a small group of manufacturers, kept choices limited and prices high.<sup>10</sup> Chief among the concerns of generic manufacturers was the varied and fragmented nature of the market and existing buyer behavior which did not, in many cases, define specific requirements in terms of standards: With relatively secure supply channels already established, and purchasers not aligned on quality criteria, companies had little incentive to make the substantial investment of time and money required to pursue prequalification.

Before the QuRHM Programme, many generic manufacturers did not know how to navigate the PQ Programme and perceived that they had no incentive to invest the capital and time. The QuRHM Programme was able to increase the number of quality dossiers submitted to WHO, thereby facilitating a crucial step in global efforts to increase choice of quality products and competition for procurers in the market place.

Examples of collaborative efforts:

- Promoting the business case for PQ
- Joint workshops in key manufacturing countries
- Joint publications (e.g FAQs, Guidance on Bioequivalence Studies)

Under Output 1 of the QuRHM Programme, Concept Foundation raised awareness among manufacturers of the importance of quality, and presented companies with a “business case” for expanding into new markets, highlighting the large potential for growth. Later in this analysis is a summary of the challenges related to the guaranteed procurement of these products.

Concept Foundation also provided critical strategic counsel and technical assistance – through regular site visits, data and document review, regular teleconferences and communications – to manufacturers as they pursued prequalification. Support included counsel on:

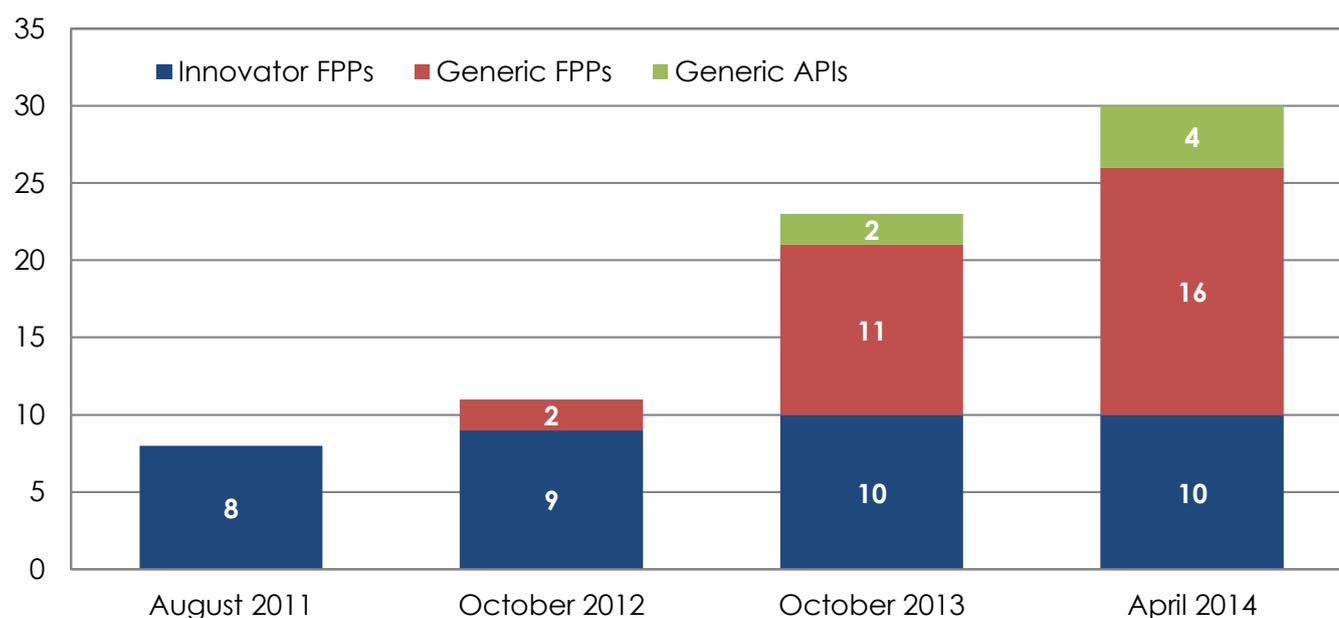
- **Good manufacturing process (GMP):** Technology transfer, HVAC systems, validation, quality risk management, good laboratory practice, site design, pharmaceutical engineering, site master file, advice on API, specifications, microbiology
- **Documentation:** Strategy for product dossier submission, defining specifications, APIMF revision, analytical method validation, stability study review, dossier preparation and review, clarification of WHO requirements, general training;
- **Bioequivalence:** Comparator sourcing, study design review, study protocol review, identification of clinical research organization (CRO), audit of CRO, review of study results and report;
- Other topics such as the business case for manufacturers and marketing.

## FPPs and APIs Included in the 5<sup>th</sup> WHO Invitation for Manufacturers of RH Products to Submit an Expression of Interest to the WHO PQ Programme

Submitting a dossier is a complex and time-consuming process, and stakeholders reported that the assistance provided to manufacturers under Output 1 gave them the confidence and guidance necessary to successfully engage with and complete the WHO prequalification process.

FPPs	APIs
<u>Oral hormonal contraceptives</u> <ul style="list-style-type: none"> <li>- ethinylestradiol + Desogestrel, 30µg + 150µg</li> <li>- ethinylestradiol + levonorgestrel, 30µg + 150µg</li> <li>- levonorgestrel, 30µg</li> <li>- levonorgestrel, 750µg (2 pack); 1.5mg (1 pack)</li> <li>- norethisterone, tablet 350 micrograms</li> <li>- norgestrel, tablet 75 µg</li> </ul>	Desogestrel estradiol cypionate estradiol valerate ethinylestradiol etonogestrel levonorgestrel medroxyprogesterone acetate mifepristone misoprostol
<u>Injectable hormonal contraceptives</u> <ul style="list-style-type: none"> <li>- medroxyprogesterone acetate, depot injection 150mg/ml, in 1-ml vial</li> <li>- medroxyprogesterone acetate + estradiol cypionate, injection 25mg + 5mg</li> <li>- norethisterone enanthate, injection 200mg</li> <li>- norethisterone enanthate + estradiol valerate, injection 50mg + 5mg</li> </ul>	
<u>Implantable contraceptives</u> <ul style="list-style-type: none"> <li>- two-rod levonorgestrel-releasing implant, each rod containing 75mg of levonorgestrel (150mg total)</li> <li>- etonogestrel, implant, 68mg of etonogestrel</li> </ul>	
<u>Oxytocics</u> <ul style="list-style-type: none"> <li>- oxytocin, injection 10 IU, 1-ml</li> <li>- mifepristone 200 mg tablet (only to be used in combination with misoprostol)</li> <li>- misoprostol 200 microgram tablet</li> </ul>	
<u>Prevention and treatment of eclampsia</u> <ul style="list-style-type: none"> <li>- magnesium sulphate, injection 500 mg/ml, in 2-ml and 10 ml ampoule</li> </ul>	

## QuRHM Results: WHO Prequalified Products, August 2011-April 2014



Before QuRHM, there were no more than two prequalified RH products in any category (hormonal contraceptive method or key maternal health drug) and no prequalified generic products at all. By introducing competition in the form of new, quality-assured, generic products, and clearing the way

for a pipeline of medicines (six formally under assessment<sup>11</sup>) across all target product categories, the QuRHM Programme has shifted the dynamics of the reproductive health medicines market and generated a downward pressure on prices that will be amplified as this momentum continues in years to come.

## Output 2: Quality focused procurement

As manufacturers begin to produce a more robust supply of quality-assured products, it is essential that major international procurement organizations, and the donors which fund them, are simultaneously making strides to strengthen and align their quality assurance policies and practices. Part of the incentive for investment on the part of the generic industry is an expectation of a level playing field of opportunity, something which a harmonized approach to quality purchasing can help to achieve (e.g. as the market for sub-PQ standard products is reduced by adherence to higher quality standards).

Under Output 2 of the QuRHM Programme, most major procurers have incorporated new criteria into their quality assurance policies and began to formalize and implement these policies. At the same time, an interim mechanism was established to broaden the pool of available products while manufacturers pursued prequalification, giving procurers more choice in a supply-constrained environment.

**The Expert Review Panel (ERP) for reproductive health medicines was established under Output 2 as an interim risk assessment mechanism to fuel the pipeline of quality-assured products for procurement.** The ERP facilitates temporary procurement of certain recommended products while manufacturers work towards achieving WHO prequalification or a Stringent Regulatory Authority (SRA) approval. The secretariat for the ERP for RH medicines is managed by UNFPA.

The first step of the ERP procedure is for a procurement agency to release an expression of interest inviting manufacturers to submit a product dossier for ERP assessment. The dossier must include: product information (including API), formulation and dosage; pharmacopoeial standards and evidence; data to support identified shelf life and storage stability of products; product safety and efficacy; and GMP status of the manufacturing site.<sup>12</sup>

Product dossiers are evaluated by a panel of at least three experts, convened by WHO, with experience in the assessment and regulation of pharmaceuticals. The experts, using a set of unified, transparent criteria, give each product a risk assessment categorization of 1/2 (lower risk), 3 or 4 (higher risk). Products receiving categorizations of 1/2 are deemed eligible for procurement for the 18-month period following ERP review, during which time they are expected to be under consideration by PQP or an SRA. Products receiving a categorization of 3 are only recommended if the risk of not procuring them overrides the risk of procuring them. Products receiving a categorization of 4 are not to be procured.

The ERP mechanism, designed to provide flexibility and choice in response to the challenges faced by the procurement community, was enormously successful. For products recommended by the ERP and later prequalified by WHO, the average transition time, between submission to the RH ERP and prequalification, was 17.2 months.<sup>13</sup> By providing an interim quality assurance step for manufacturers and procurers, the ERP accelerated the prequalification process while temporarily widening the pool of low-risk products for immediate distribution to women in need.

### The global market for contraceptives

\$14.3B in 2012  
\$20.1B by 2018

Opportunities are growing primarily in Asia-Pacific, Latin America, and ROW (Africa and Middle East) countries.

### History of ERP

The first ERP was coordinated by WHO in 2009 for the Global Fund to help provide procurement agencies with a mechanism to help assess risk level and provide information on urgently needed products that are not yet PQP or SRA approved. Since then, the ERP procedure is used by UNFPA, UNITAID and others.

Though DFID funding for the QuRHM Programme has ended, the ERP has been extended until the end of 2014, with the possibility of a further extension thereafter.

**With systems in place to ensure the entry of more quality-assured products into the market, UNFPA established a landmark new procurement policy based on international standards.** As the lead UN agency for procurement of RH products and medicines, UNFPA's policy – published and disseminated in 2011 – served as a model for other policies referenced later).

UNFPA's Quality Assurance Policy Quality Criteria

Pharmaceuticals under WHO PQP with:

- Prequalification by WHO
- Approval by an SRA
- Recommendation by WHO ERP

**UNFPA classification of RH medicines**

Medicines under WHO PQP:

- oral hormonal contraceptives
- injectable hormonal contraceptives
- implantable contraceptives
- uterotonics
- magnesium sulphate

**Major international procurers convened three high-level procurement workshops to develop a path forward on the issue of quality.**

At these annual meetings, procurers shared insights and experiences and discussed the challenges of quality procurement. Some of these challenges included a limited supplier base, country registration processes, and user acceptability.<sup>14</sup> In addition to driving progress under Output 2, these meetings provided a forum for communication and collaboration among stakeholders, and contributed to a more holistic understanding of the global reproductive health medicines landscape.

**As a result of these events, several other international procurers established procurement policies based on internationally accepted quality assurance criteria.**

Procurer	New quality-assurance policies
USAID	SRA, PQ and ERP quality policy
International Planned Parenthood Federation (IPPF)	SRA, PQ and ERP quality policy
Marie Stopes International (MSI)	SRA, PQ and ERP quality policy for products purchased with DFID funds
Crown Agents	SRA, PQ and ERP quality policy for products purchased with DFID funds
Population Services International (PSI)	Ongoing discussions about transition planning

While Output 2 focused primarily on procurers, its success was crucial in strengthening the business case for manufacturers by encouraging procurers to commit to purchasing only quality-assured products. As the momentum builds and more procurers strengthen and align their quality standards, generic manufacturers will find better opportunities in the quality market and face a greater pressure to achieve prequalification.

## Output 3: Country engagement

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Time and again, history and experience has shown that to realize sustained progress on health, economic and development reforms at a country level, national and local leaders must drive and own the adoption and implementation of these efforts. With unique cultures, traditions, and outlooks – as well as distinct governing systems, policies and economies – each country begins the reform process with its own set of opportunities and challenges to assess and address. To better understand these nuances and develop an appropriate action plan, the RH community, as well as the broader global health community, is consistently looking for opportunities to build country-level capacity to collect the data and other evidence demonstrating the need for and impact of interventions.

Though limited in project scope, Output 3 of the QuRHM Programme focused on working with key stakeholders and decision makers in four focus countries – Ethiopia, Kenya, Nepal and Senegal – to raise awareness of quality and catalyze the work needed to advance the long-term goal of strengthening their national procurement criteria based on internationally accepted quality standards. This initial three-year period has proven to be pivotal for laying the groundwork for sustained reform in these countries.

National policymakers, advocates, and key stakeholders played a vital role in a thorough country assessment to understand the structures, policies, opportunities, and challenges for RH reform. While this in-depth analysis is invaluable for donors, procurers, manufacturers and social marketers currently working or seeking to work within the four pilot countries, the landscaping model used during the Programme will be a critical resource for additional countries seeking to pursue similar reform efforts in the future.

Below is a summary of the country-level activities of Output 3, which was designed as a two-phase approach, with leadership and coordination by UNFPA and the Concept Foundation.

- Phase 1: situational study and analysis in each of the four countries
- Phase 2: country workshops with key stakeholders

### Phase 1: Situational Analysis

To understand each country's RH medicines market as well as the broader regulatory and policy environment, UNFPA and the Concept Foundation worked with the Royal Tropical Institute, Netherlands (KIT) to conduct a thorough situational analysis in each of the four countries. Along with providing a clear set of actionable data and an assessment of the distinct challenges and opportunities within each country, this process provided an opening to engage key stakeholders as study participants and leaders in this phase.

The analyses consisted of stakeholder mapping, desk review, key informant interviews and literature review. The study objectives were:

1. To research, establish and document the total RH medicines market in each of the four countries, providing an analysis of the market and by set categories
2. To research, establish and document the range of RH medicines registered/authorized in each country (cross-referenced with products identified under objective 1).
3. To research, establish and document the policy environment for RH medicines with specific emphasis on purchasing policies and procedures and quality assurance

More information about these studies, their methodology and their country-specific results and analyses can be found at [www.conceptfoundation.org](http://www.conceptfoundation.org).

### **Selection criteria for QuRHM's four focus countries**

*Ethiopia, Kenya, Nepal and Senegal*

- Procurer activity
- Supply of contraceptive type
- Donor focus
- NGO activity
- Political environment
- Regulatory environment

## Phase 2: Country Workshops

In 2014, UNFPA and Concept Foundation facilitated workshops in Ethiopia, Nepal and Senegal on the status of RH medicines and the landscape and environment for improved policies and programs in country. In the workshop, the high-level stakeholders identified concrete recommendations to inform country action plans that can help guide the future work – see page 13 for a summary of key recommendation from the workshops held in Senegal, Nepal and Ethiopia. Though the recommendations for each of the action plans are specific to each country, taking into account barriers and opportunities, three thematic areas emerged and repeatedly identified in the workshops as requiring immediate attention at the country level:

- **Coordination.** Country stakeholders frequently cited interdepartmental coordination as a problem in each of the countries. Departments involved in procurement of products identified that they could improve communication and collaboration with departments involved in registration, as the two processes are integrally related. Moreover, ministries of health can strengthen alignment with ministries of finance in order to seek to secure sufficient budgetary support.
- **Capacity.** Country leaders noted that building capacity must be a top priority. Due to budget constraints, procurement and regulatory processes in pilot countries were underfunded and lacked the human capacity, both in volume and in expertise, required for smooth implementation of quality assurance policies. Streamlining and coordinating processes to adhere to international standards will help country decision-makers take advantage of shared information and resources while they build capacity internally.
- **Implementation.** Country stakeholders acknowledged that quality assurance policies are essential but expressed concern about the challenge of implementation. For procurement policies to be effective, top decision-makers in each country—including ministers of finance—must understand the benefits of investing in quality and must ensure that any quality infrastructure receives adequate operational support. This will require awareness-building, training and the sharing of resources.

These themes are consistent with the challenges that emerged in the situation analyses. However, it was not until the 2014 workshops that these cross-country threads became tangible and actionable. In Senegal and Nepal, task forces have been identified to continue the discussions and the development of the country action plans. The workshops are an important first step in improving coordination, capacity and implementation challenges in each country.

On the next page is a list of sample recommendations identified in the workshops.

The full country workshop reports can be found at [www.unfpa.org](http://www.unfpa.org).

## Country Workshop Outcomes: Sample Key Recommendations for Action

Country	Sample key recommendations
Ethiopia	<p><b>Establish a permanent multisectoral consultative forum, for stakeholders to discuss and implement action points and develop a full implementation plan</b></p> <ul style="list-style-type: none"> <li>• Revise <b>regulation of importation</b> of donated medicines</li> <li>• Establish transportation and storage <b>guidelines for supply chain and rational drug use</b></li> <li>• Develop a system for <b>integration of medicines approved by SRAs</b> into the Ethiopian market place</li> <li>• <b>Expand post-marketing surveillance and pharmacovigilance</b></li> <li>• Increase ISO accreditation of the National Quality Control Laboratory, also increase funding and technical support</li> <li>• Implement the national regulatory authority, FMHACA, representation at WHO PQ GMP inspections on a regular basis</li> <li>• <b>Promote the use of generic products</b>, strengthen feedback mechanisms</li> <li>• Improve ongoing <b>professional training of healthcare professionals</b></li> <li>• Strengthen the <b>involvement of cultural and religious leaders</b></li> <li>• Address the current and ongoing issue of the language barrier in remote areas</li> </ul>
Nepal	<p><b>Establish a task team of key national stakeholders to coordinate and further the quality agenda in Nepal, to be supported by UNFPA CO and WHO CO</b></p> <ul style="list-style-type: none"> <li>• Consider <b>procurement through relevant UN agencies</b></li> <li>• Advocate for a <b>draft policy on medical devices</b> and equipment to be approved and implemented</li> <li>• Use <b>quality assurance of HIV/AIDS</b> as an <b>example for improving quality assurance</b> of RH medicines</li> <li>• Strengthen the regulatory framework via the department of drug administration (DDA)</li> <li>• Increase the <b>capacity of the National Medicines Laboratory</b>, inspect and assess private quality control laboratories</li> <li>• Train up <b>personnel in procurement and supply chain management</b></li> <li>• Review management of phasing out of products and introducing new products</li> <li>• <b>Scale up post-marketing surveillance</b></li> <li>• Improve collaboration between the logistics management division (LMD) and DDA</li> <li>• Review and <b>scale up the exemption from registration</b> policy and processes</li> </ul>
Senegal	<p><b>Establish a task force comprising key national stakeholders to lead in following up on the key recommendations from all stakeholders involved in quality assurance of RH medicines</b></p> <ul style="list-style-type: none"> <li>• Advocacy for increasing the capacity and financial resources of the department of pharmaceuticals and medicines (DPM) to lead the quality of RH medicines agenda</li> <li>• <b>Train up pharmacists on quality assurance</b>, supply chain/procurement logistics in the national supply pharmacy (PNA)</li> <li>• Explore use of public-private partnerships to <b>improve distribution</b> to remote areas</li> <li>• Advocate for establishment of <b>an autonomous NMRA</b></li> <li>• Increase <b>support to registration expert committees</b> to improve functionality</li> <li>• Strengthen coordination of <b>Pharmacovigilance</b> at the DPM level , advocate for pharmacovigilance at all levels of government</li> <li>• <b>Increase capacity</b> in terms of legal mandate, and human and financial resources of the <b>National Control Laboratory for Medicines (LNCM)</b></li> <li>• Formalise, streamline and <b>improve communication and coordination</b> between the PNA and DPM for <b>quality control</b></li> <li>• Improve and increase the <b>local manufacture of medicines</b> to reduce dependency on external resources</li> <li>• Improve synergies between the public sector, social marketing sector and private sector; explore ways to reduce the gaps existing in the market place</li> <li>• Increase the <b>range of RH products in the market place</b> via public-private partnerships and social marketing</li> </ul>

## GAME CHANGING ACHIEVEMENTS

When asked about the QuRHM Programme's greatest achievement, five answers were repeated time and time again by stakeholders. The QuRHM Programme:

**Elevated the quality agenda.** Stakeholders widely agreed that one of the most significant achievements of the QuRHM Programme was to raise global awareness of the quality agenda across every sector. Stakeholders from around the world have committed to and invested in the quality movement, with each sector's participation reinforcing the others.

**Catalyzed critical market-shaping interventions.** The QuRHM Programme caused a shift in market dynamics, and the processes strengthened and streamlined over the course of the Programme will continue long after it ends. The market is fuller and more open, and women are closer than ever to getting the quality medicines they need.

**Created greater competition for generic QA products.** Before the QuRHM Programme there were no quality assured generic RH products. Today, because of the work of the QuRHM Programme, there are 16 generic RH products prequalified by WHO. Greater competition of product creates a rich pipeline for safe and affordable products for women and families.

**Provided the forum and tools for future country-level work.** The QuRHM Programme engaged country-level stakeholders in assessing the country landscape, including opportunities to advance the quality agenda and the barriers to doing so, as well as to chart the path forward. With the focus on country ownership and sustainability, several efforts have developed that support the forward movement of QuRHM Programme's work.

- UNFPA has created a new quality task team to help expand access to global resources and assistance at the country level.
- RHSC named quality to be one of four strategic pillars in framing its work over the next 10 years.<sup>15</sup>
- Family Planning 2020 has incorporated quality language into its [principles platform](#), in a public recognition of the importance of quality to the goal of expanding access to life-saving contraceptives to 120 million additional women by 2020.
- The UN Commission on Life-saving Commodities made quality a priority in its [recommendations for 2015](#), specifically addressing the issues of increasing the field of manufacturers and strengthening and standardizing country registration and assessment.<sup>16</sup>
- The World Bank is introducing new guidelines emphasizing "value for money" over cost. The Bank's decision to define new policies around "value for money" comes at a critical time for the reproductive health community, and is partly a result of the business community—contractors and vendors who submit proposals to the Bank—coming together to ensure that quality is a factor in procurement funding decisions.<sup>17</sup>

**Fueled the movement.** Stakeholders agreed that QuRHM helped bring attention, clarity and inspiration to a part of the RH movement that was overseen by many (as referenced in the Introduction). Bringing together partners across sectors and levels, has created the depth and wide support that all impactful movements require. It is a movement that permeates throughout the community. As intended under **Output 4**, the community will build upon these significant achievements through continued activities and dissemination, and continue to fuel the movement.

## LESSONS LEARNED

Stakeholders and other organizations involved in the QuRHM Programme identified several learned lessons that helped to shape the strategic imperatives outlined in the next section, because with each challenge comes opportunity to create change.

**Lesson 1: While the reproductive health supply chain is comprised of a number of interdependent elements, activities remain fragmented—and left unchecked, this practice threatens to undermine progress made toward achieving the longer term goals of the quality agenda.** Any intervention aimed at wholesale health systems reform requires optimal coordination and collaboration. No single donor, procurement agency or other key stakeholder dominates the reproductive health market, and each actor in the supply chain, from production to delivery, makes decisions that both influence and depend on the decisions of other actors. Manufacturers will only continue to invest in raising standards if they can be sure that as a result their products will be purchased; national and international procurers will only require prequalification if there are enough prequalified products from which to choose. Sharing information and streamlining processes are therefore especially important—and especially difficult. Manufacturers, procurers, and countries would benefit from continued technical assistance, shared resources, and guidance from the global community.

**Lesson 2: The “business case” for quality is an essential component for moving the quality agenda forward.** By working with all stakeholders simultaneously, the QuRHM Programme set out a pathway towards the availability of more quality products, working to change the behavior of manufacturers and procurers, while building awareness and support among key stakeholders and finally focusing on national stakeholders. In the early stages of the Programme, however, both manufacturers and procurers felt that they were, in the words of one stakeholder, “acting on faith,” and that they could not trust others to come to the table quickly enough. Some of the generic manufacturers who have achieved prequalification and have registrations in countries remain concerned about the speed and level of uptake on the part of international procurement agencies. The business case remains an issue for manufacturers and an essential component of future stakeholder messaging, and it must take account of incremental changes in the market as they occur—so all stakeholders feel confident that they can move forward without jeopardizing a system that has worked well for them for many years.

**Lesson 3: Communication, transparency, and flexibility are critical for a project of this size and scope to succeed.** Some stakeholders warned of the pitfalls of an “all-or-nothing” approach, because operational realities rarely keep pace with policy change. They emphasized the need for global leaders to adapt to changing conditions and unforeseen events, while continuing to share information that will help stakeholders make decisions and minimize waste in a fragmented market.

**Lesson 4: Country stakeholders are hesitant to integrate international standards into procurement policies and practices because they fear a loss of country independence.** The global health community has advocated for country independence in all areas—including sustainable, non-donor-dependent funding for essential supplies and services—as countries strengthen their health systems and infrastructure. A set of international quality criteria presents an alternative, and seemingly somewhat contradictory, point of view. Stakeholders explained that countries might also lose revenue, in the short term, by relinquishing control of dossier reviews and site inspections and by purchasing prequalified products manufactured in other countries rather than boosting production at home.

**Lesson 5: Implementation in-country is one the most significant challenges facing the quality agenda.** Stakeholders agreed that the QuRHM Programme made progress on broadening the pool of generic manufacturers producing affordable, quality-assured products and making the case for quality to international and national procurers who otherwise might have been reluctant to commit. Though the groundwork has been laid, implementation of improved quality-assurance policies at the country level will pose significant challenges. Implementation is a complex undertaking, and does not necessarily follow policy changes and action plans. Countries must improve interdepartmental coordination and build capacity before implementation can begin in earnest. Registration, in particular, remains a complicated and time-consuming process that varies by country and is often hampered by insufficient infrastructure and human resources. Manufacturers hesitate to invest time and money in

prequalification when they see national registration as yet another large barrier they must overcome before realizing sales.

**Lesson 6: Decision-making and sustained progress is often challenged by religious and cultural beliefs or simply a lack of reproductive, maternal, newborn and child health information.** Some stakeholders noted that the movement has seen setbacks because reproductive health supplies have not traditionally been considered medicines since they do not treat diseases. Moreover, women are unaware of the availability and cost benefits of quality-assured generics, given the market dominance of innovator products—and are hesitant to switch to unfamiliar products to which they're unaccustomed. In many developing countries, introducing family planning as an imperative is difficult due to barriers of culture, literacy and general lack of awareness. The more everyone, from policymaker to patient, recognizes the importance of reproductive health products to the physical and financial well-being of countries, the faster the progress of the quality of reproductive health medicines movement – and the sooner the improvements in health outcomes can be realized.

## THE PATH FORWARD: STRATEGIC IMPERATIVES

There has been enormous progress on the issue of quality in the past decade, and the QuRHM Programme has been instrumental in paving the way forward. But there is more work to do.

Stakeholders emphasized that many individuals and organizations are relying on the continuation and expansion of activities that QuRHM has put in motion. Commitments and investments made in the past two and a half years will pay dividends in the years to come, and the global community must ensure that they were not made in vain.

There was wide agreement that the approach moving forward should be multifaceted; different entities are equipped to take ownership of different aspects of the quality agenda. Donors, in particular, have the wherewithal to take a leading role by integrating quality criteria into their funding mechanisms as DFID has done during the Programme.

Stakeholders identified several strategic imperatives that will help move the quality agenda forward in the coming months and years. These are highlighted below.

**Build on the QuRHM Programme's progress in shaping the RH medicines market.** The challenge, post-QuRHM, will be ongoing implementation and monitoring of policies and practices achieved, and building on the advancements made, under the Programme. With a fragmented market, and many different entities relying on each other, the initial years of market-shaping are the most difficult. But the QuRHM Programme has built towards a "tipping point," where all levels of the supply chain are reinforcing each other in a positive feedback loop. Stakeholders agreed that the next five years will be critical in the effort to preserve the momentum. Though the Programme made great progress with oral and emergency hormonal contraceptives and misoprostol, there is still a limited supplier base for injectable contraceptives. There is only one PQP product in this category, owing to limited experience in the manufacturing sector and incentives from donors or procurers as well as the length of time required to meet WHO requirements. The focus going forward must be on injectable contraceptives, where only two innovator FPPs have been prequalified by WHO.

**Strengthen health systems.** As WHO has emphasized in the past, the goals of the global health community will not be achieved without investing in health systems. No matter how powerful the interventions, health outcomes will continue to suffer if there is not an adequate system for delivering these interventions to people in need. Country procurement and regulation must be improved as quality-assured products become more widely available at a price ministries of health can afford. Stakeholders agreed that a continuation of country-level engagement to strengthen national procurement criteria, as stated in Output 3, should be the primary focus of the quality agenda going forward. Supply security remains a problem, and national and international procurers must be able to deliver affordable, quality-assured products to consumers, regardless of budget cycles, changes in donor support, and other uncontrollable circumstances. Strengthening health systems is the only way to ensure this happens.

**Develop strategic messaging to help move the agenda forward.** Many stakeholders noted that global messages and talking points would provide a useful framework for discussion and advocacy in the future. Many also suggested that countries that are already making investments in systems reform would benefit from these messages, tailored to key regional and national audiences. This requires an organized strategic communications effort, and it should take into account input from *all* stakeholders. Respondents universally agreed that messages related to the quality agenda cannot be determined by a select few. Messages must also be broader than prequalification and regulation: They must build trust and confidence, help consumers understand they will not have to worry, and also educate consumers about the long-term cost savings of quality-assured generic medicines. While these messages will emerge from a global framework, they must be tailored to the needs of each country, and crafted with insights from situation analyses and from leaders who understand the landscape.

**Improve and expand the business case.** To date, the case for investing in quality has been made primarily to manufacturers and individuals involved in procurement who have a background in health. Though messages have been effective, they must evolve as the quality landscape changes and be tailored to reach a wider group of stakeholders who play a role in the policy and funding that affect family planning. Ministers of finance must understand the benefits—specifically, the financial return—of investments in quality. It is not enough to make the case for quality to those responsible for product procurement and regulation. The case must be made to those responsible for financing these activities, and it must be tailored for this purpose. Finance ministers must understand the real, quantifiable results of investing in quality. At the same time, the community must do more to support generic manufacturers who invest in quality. Manufacturers who have devoted large amounts of resources have been met with appreciation but few material benefits. In fact, coming out of the London Summit on Family Planning in 2012, the Generic Manufacturers Caucus for Reproductive Health (GEMS) formed to demonstrate its commitment toward supporting the FP2020 community and achieving the highest quality standards as determined by the WHO Prequalification Programme. If the community fails to recognize generic manufacturers for their investments and look for opportunities to introduce these lower cost quality assured products into their markets, we risk losing the participation of a vital piece of the supply chain.

**Define a vision for harmonization of procurement and registration that takes account of on-the-ground realities.** This vision should include short-, medium-, and long-term priorities. Stakeholders had differing opinions of the likelihood or even desirability of true harmonization, but they agreed that any progress at the global and country levels would require continued education, advocacy, and capacity building. Country work is critical because “stringent quality assurance cannot and should not remain limited to donor-funded medicines.”<sup>18</sup> But country work is difficult, so activities must be broken out by priority, and the global community must define short-, medium-, and long-term objectives.

- **Short-term objectives** should include building capacity of procurement and regulatory mechanisms while taking advantage of global resources, like WHO prequalification, that will help fast-track the delivery of essential products. Countries should prioritize quality control, including pharmacovigilance, to ensure that products already circulating the market are of an assured quality.
- **Medium-term objectives** should include improving procurement and regulatory processes by coordinating and streamlining operations and raising regulatory standards.
- **Long-term objectives** should include building local industry and strengthening health systems with the ultimate goal of becoming independent of donor support.

**Expand efforts to include other products, countries, and strategic approaches.** The QuRHM Programme focused on the *quality assurance of hormonal reproductive health supplies in four pilot countries*. Stakeholders saw four specific opportunities to scale up quality activities, now that the stage has been set.

- **Regulate the quality of condoms and other methods.** As one stakeholder put it “Just because they’re not medicines doesn’t mean they’re not dangerous.”
- **Invest in quality control.** In addition to monitoring ongoing progress in countries, provide support to ensure the reporting of adverse effects and other pharmacovigilance activities.
- **Consider packaging that provides a visual indication of quality assurance in low-literacy communities.** For instance, the popular “blue lady” branding on public sector contraceptives became a trusted icon for safety and reliability among women in low-literacy communities.
- **Engage stakeholders in other countries.** Expand research to countries outside the four pilot countries, and replicate discussions with country-level stakeholders about policy change and implementation. To this end, UNFPA is developing a model for country-level workshops, based on those convened under the QuRHM Programme, to be used in other countries.

Efforts are continuing with donor support to improve the quality of more products, as well as ensuring that RH medicines are available at country-level in terms of remaining procurement barriers and national registration. There is also broad consensus that more needs to be done to improve knowledge and awareness of quality generics in countries.

As noted previously, stakeholders agreed that the next five years, despite the transition of the QuRHM Programme, represent a crucial opportunity for the quality agenda. In recognition of the need for ongoing support and the work that remains to be done, a streamlined version of the QuRHM Programme's Technical Advisory Committee (TAC), consisting of the Concept Foundation, UNFPA, USAID, FHI 360, and WHO, is being established to address issues of coordination and procurement. It will continue to meet and provide updates to partners on progress.

Moving forward, the progress and learnings of the QuRHM Programme are serving as foundational building blocks for efforts working to carry the quality and market-shaping agendas forward. The quality of RH medicines is a core component in the strategies of Family Planning 2020, the Commission on Lifesaving Commodities and the RHSC. Stakeholders at all levels are engaged and share the vision that first created QuRHM – a system in which women and families can fully trust that the RH medicines they need are safe, reliable and affordable. While there is a long road ahead to realize this vision, the momentum is gaining force each day and success is on the horizon.

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**APPENDIX 1: Output 4 Stakeholder Interviews – Conducted February-March 2014**

<b>ORGANIZATION</b>
<b>Donors</b>
Bill & Melinda Gates Foundation
DFID
USAID
MinBuza
<b>Country-level Decision Makers</b>
<b>Senegal</b>
PNA
Bayer HealthCare
DPM
Reproductive Health Supplies Coalition
<b>Nepal</b>
Logistics Management Division
Crown Agents
<b>Other</b>
<b>NGOs</b>
UNFPA
Marie Stopes International
PATH
<b>Manufacturers</b>
HELM AG
China Resources Zizhu Pharmaceutical Co. Ltd.
PT. Tunggal Idaman Abdi
<b>Global</b>
World Health Organization

Additional stakeholder input was provided by the QuRHM Programme's Technical Advisory Committee (TAC) at the February 2014 meeting in New York City.

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