Quality Workstream - Update
Concept Foundation

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6 October 2015
Recap of progress so far

2005
The 1st study and landscaping of global RH manufacturers conducted by Concept Foundation with support from UNFPA and IPPF

2006
RHSC opens its membership to manufacturing companies
RHSC agrees to Bonn Consensus at October Annual Meeting

2009
Accessing Quality Assured Supplies (AQAS) - review of manufacturing landscape to assess WHO PQP potential

2011
Launch of RHSC’s Quality of Reproductive Health Medicines Programme (QuRHM)

2012
London Family Planning Summit
Launch of Family Planning 2020 (FP2020)
Launch of UN Commission for Life-saving Commodities
Recap of progress so far

QA STANDARDS become a global priority

DEMAND for affordable, QA medicines grows across sectors

GENERIC MANUFACTURERS make the investments to meet highest safety standards, and produce affordable, products

COUNTRY-LEVEL POLICYMAKERS require QA RH medicines for key populations as an investment for sustained health

PROCURERS purchase QA generic products with confidence, at a cost savings enabling increased volume

IMPACT: COST savings for procurers

IMPACT: SUPPLY security for countries

IMPACT: MARKET shaping brings competition for manufacturers

IMPACT: SAFETY + confidence = less risk for consumers

QA STANDARDS are institutionalized globally

EXPANDED ACCESS OF AFFORDABLE, QA MEDICINES to women and families in high-need countries

IMPROVED REPRODUCTIVE HEALTH IN LESS DEVELOPED COUNTRIES
Recap of progress so far

- August 2011: Innovator FPPs: 8
- October 2012: Innovator FPPs: 9
- October 2013: Innovator FPPs: 10
- April 2014: Innovator FPPs: 10
  - Generic FPPs: 2
  - Generic APIs: 4
  - Total: 16
Where are we now?

• Significant progress has been made in the last half decade;
  • Continuing to work towards increasing the availability of quality assured RH products → misoprostol, oxytocin, magnesium sulphate, DMPA

• Forecasting → injectable contraception; validating the market need

• Procurement at the country level for MH products → Uganda meeting (UNCO/GRAMPS)
Where are we now?

• PQ as the starting point → significant issues remain around access to markets

• Focus on country registration of RH products → mapping the regulatory pathway for key RH products in target markets; working with manufacturers and country regulators/WHO Collaborative Registration

• Conduct of country level research to better understand the stakeholder perceptions of quality assured generic RH products and their availability
## Visibility of QA generics at the country level - outline of methodology

<table>
<thead>
<tr>
<th>Phase 1 Interviews</th>
<th>Phase 2 Interviews</th>
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<tbody>
<tr>
<td><strong>Preliminary Research</strong>&lt;br&gt;(March 10 – April 13, 2015)</td>
<td><strong>Expanded Country-Based Interviews</strong>&lt;br&gt;(June 8 – August 17, 2015)</td>
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<tr>
<td>Research conducted in 10 markets – Burkina Faso, Ghana, Kenya, Malawi, Nepal, Nigeria, Senegal, Tanzania, Uganda and Zambia</td>
<td>20 additional interviews in each of the 9 African markets</td>
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<td>5 interviews were completed face-to-face in each market</td>
<td>Research in Nepal was suspended after the April 2015 earthquake</td>
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<td></td>
<td>A total of 228 interviews completed in the 9 African markets (across phases 1 &amp; 2)</td>
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</table>
Visibility of QA generics at the country level - outline of methodology

Stakeholder Groups

Key decision-makers and stakeholders in:

- government,
- manufacturing and the private sector, and
- NGOs, CSOs, media, academia, and think tanks

All have subject-matter expertise in the reproductive health space and reproductive health medicines and decision-making authority within their organizations

Note: throughout the report, these individuals are often referred to as “key stakeholders”
Support for Increasing the Availability of Quality-Assured, Generic Reproductive Health Medicines

Key finding:
Overwhelming support for expanding availability of QAGRHMs

Support for Increasing Availability of Quality-Assured, Generic RHMs

- Government: 90% support (73% strongly)
- Private sector: 94% support (63% strongly)
- Influencers (NGOs, CSOs, academia, media): 92% support (66% strongly)
Key finding:
Impressions of actors/concepts/products

Favorability
(Showing Very Favorable, Very/Somewhat Favorable)

- Generic medicines: 83% Very Favorable, 36% Favorable
- Contraception: 91% Very Favorable, 62% Favorable
- Maternal health medicines used in child delivery: 83% Very Favorable, 54% Favorable
- Quality-assured, generic contraception: 84% Very Favorable, 50% Favorable
- Injectable contraception: 77% Very Favorable, 49% Favorable
- Contraceptive implants: 81% Very Favorable, 48% Favorable
- Quality-assured, generic reproductive health medicines: 81% Very Favorable, 45% Favorable
- Generic reproductive health medicines: 79% Very Favorable, 33% Favorable
- Locally-manufactured, generic reproductive health medicines: 45% Very Favorable, 18% Favorable

- Darker colors used to indicate intensity.
Key Finding:
Idea of Quality-Assured Generic RH Medicines more favorable than brand names

<table>
<thead>
<tr>
<th>Category</th>
<th>Favorable</th>
<th>Unfavorable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contraception</td>
<td>62%</td>
<td>7%</td>
</tr>
<tr>
<td>Quality-assured, generic RH</td>
<td>45%</td>
<td>2%</td>
</tr>
<tr>
<td>&quot;Brand-name&quot; RH medicines</td>
<td>34%</td>
<td>4%</td>
</tr>
<tr>
<td>Natural family planning</td>
<td>33%</td>
<td>11%</td>
</tr>
</tbody>
</table>

Favorability:
- Contraception: 91%
- Quality-assured, generic RH medicines: 81%
- "Brand-name" reproductive health medicines: 66%
- Natural family planning: 66%
Empowering women/families to choose family size and space births save lives is a powerful narrative.

<table>
<thead>
<tr>
<th>Associations with Quality-Assured, Generic RHMs</th>
<th>Very Well</th>
<th>Total Well</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provides women with more options and choices</td>
<td>61%</td>
<td>92%</td>
</tr>
<tr>
<td>Empowers women and families to better choose their family's size and the spacing of pregnancies</td>
<td>61%</td>
<td>90%</td>
</tr>
<tr>
<td>Helps the country achieve its goals in terms of family planning</td>
<td>51%</td>
<td>89%</td>
</tr>
<tr>
<td>Reduces maternal and newborn deaths</td>
<td>51%</td>
<td>84%</td>
</tr>
<tr>
<td>Helps citizens lead healthier lives</td>
<td>47%</td>
<td>83%</td>
</tr>
<tr>
<td>Affordable</td>
<td>40%</td>
<td>76%</td>
</tr>
<tr>
<td>Meets the highest safety standards</td>
<td>40%</td>
<td>73%</td>
</tr>
<tr>
<td>Passed country's quality-assurance tests and are subject to strict country-level regulation</td>
<td>38%</td>
<td>74%</td>
</tr>
<tr>
<td>A good long-term investment for the country</td>
<td>37%</td>
<td>75%</td>
</tr>
<tr>
<td>Passed international, rigorous quality-assurance tests</td>
<td>37%</td>
<td>71%</td>
</tr>
<tr>
<td>Readily available</td>
<td>37%</td>
<td>68%</td>
</tr>
<tr>
<td>Reduces stress on the services the country provides by promoting family planning</td>
<td>31%</td>
<td>68%</td>
</tr>
<tr>
<td>Promotes a productive workforce</td>
<td>29%</td>
<td>73%</td>
</tr>
<tr>
<td>Supports gender equality</td>
<td>26%</td>
<td>56%</td>
</tr>
<tr>
<td>Trustworthy and reliable</td>
<td>25%</td>
<td>74%</td>
</tr>
<tr>
<td>Creates greater competition in the marketplace</td>
<td>21%</td>
<td>50%</td>
</tr>
</tbody>
</table>

**Important For Quality-Assured, Generic RHMs To Do**

- Empower women and families to better choose their family's size and the spacing of pregnancies (36%)
- Provide women with more options and choices (26%)
- Reduce maternal and newborn deaths (26%)
- Help citizens lead healthier lives (19%)
- Help country achieve its goals in terms of family planning (17%)
- Meet the highest safety standards (14%)
- Pass international, rigorous quality-assurance tests (10%)
- Be affordable (8%)
- Be a good long-term investment (6%)
- Promote a productive workforce (6%)
- Be trustworthy and reliable (6%)
- Support gender equality (5%)
- Reduce stress on the services the country provides by promoting family planning (5%)
- Be readily available (5%)
- Create greater competition in the marketplace (1%)
- Other (specify) (2%)
Key finding:
WHO and medical professionals are most trusted validators

Top-Tier Trustworthy Sources
(Showing A Lot, A Lot/Somewhat)

- WHO: 97%
- OB-GYNs: 96%
- Doctors: 97%
- UNFPA: 93%
- USAID: 92%
- Nurses: 94%

- WHO: 72%
- OB-GYNs: 68%
- Doctors: 67%
- UNFPA: 61%
- USAID: 59%
- Nurses: 58%
Forward challenges

• Supplier base remains an issue
• Uptake by procurers at the national/international level
• National registrations; barriers to market
• Raising awareness of QA generic RH medicines at national level
• As new technologies come on stream →
  • Ensuring access by women in LMICs
  • Supply security
  • Competition
  • Price