Quality of Reproductive Health Medicines Programme (QuRHM)

Update – RHSC Market Development Approaches Working Group

Lester Chinery, Director of Operations
New Delhi, India
7 October 2013
QuRHM definition

The Quality of Reproductive Health Medicines programme is an intervention designed to shape the future market-place for RH medicines.
Output summary

A programme funded through the RHSC by UK DFID and BMGF, to partner with the WHO prequalification programme.

Output 1 – Focus on manufacturers (Concept)

- Supporting WHO-PQ programme – to increase number of PQd products through providing technical assistance and guidance to generic manufacturing companies.

Output 2 – Focus on procurers (UNFPA)

- Harmonization of international QA approaches, definitions and policies, developing and launching an RH Expert Review Panel mechanism.

Output 3 - Focus on countries (Concept/UNFPA)

- Situational Analyses/Market Assessments (in four pilot countries)

Output 4 - Focus on RH stakeholders (Concept/RHSC)

- Raising awareness of the QuRHM programme and quality issues through advocacy and communication.

Oct 2013
Availability and access to QA generic medicines will:
1. Save money/increase volumes
2. Improve security of supply – more competition
3. Reduce risk

Common Definition QA

Improving RH commodity security in less developed countries

More – supplying QA products at affordable prices

Common Definition QA

Purchasing from QA generic manufacturers

Purchasing/requesting QA generic supplies

Supporting/promoting the quality agenda

QuRHM – theory of change

MANUFACTURERS

PROCURERS

COUNTRIES

INFLUENCERS

INTER-DEPENDANCY

Regulatory alignment

More – supplying QA products at affordable prices

Common Definition QA

Purchasing from QA generic manufacturers

Common Definition QA

Purchasing/requesting QA generic supplies

Supporting/promoting the quality agenda

QuRHM – theory of change

Steps to transition the RH medicines market

Oct 2013
Output 1 – Increased availability of affordable quality assured RH medicines

Focus on manufacturers – supporting WHO-PQ programme – to increase number of PQd products

- Provision of technical support and guidance to RH FPP and API manufacturers.
  1. To achieve WHO prequalified status
  2. To achieve “recommended for purchase” recommendation under the Expert Review Panel for RH mechanism (FPPs only)

- Programme targets – 20 FPPs and 11 API dossiers prequalified and/or accepted into PQP by May 2014
First study and landscaping of global RH manufacturers
44 companies in 15 countries
Less than 30% could meet international CGMP
Limited number of companies with potential to supply quality products to international marketplace

2005

RHSC opens its membership to manufacturing companies
RHSC agrees Bonn Consensus at Oct 06 Annual Meeting
WHO launches 1st RH EOI for hormonal contraceptives in Oct 06

2006

AQAS – review of manufacturing landscape - rescoping

2009

Launch of RHSC Quality RH Medicines programme (QuRHM)

2011

Launch of FP2020

London Family Planning Summit
Launch of UN Commission for life-saving commodities

2012

Oct 2013
Technical Support to Manufacturers

- TA available to any FPP/API manufacturer producing reproductive health medicines:
  - Capability to meet PQ requirements.
  - Willing to commit to achieving PQ and make necessary investments.
  - Emphasis on commitment to serving low and middle income markets at an affordable cost.

- >25 confidentiality/non-disclosure agreements in place between Concept and companies.

- TA currently being provided to 13 API and 20 FPP manufacturers in total.
Technical Support to Manufacturers

- October 12 – September 13:
  - 31 technical visits to FPP manufacturers across 13 individual companies covering 23 products.
  - 5 exploratory meeting with senior management of new prospects.
  - 17 technical visits to API manufacturers across 7 companies covering 10 APIs.
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Oct 2013
## API manufacturers x 13

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Oct 2013
## 8 Prequalified RH FPPs – August 2011

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<tr>
<th>INN</th>
<th>Formulation and strength</th>
<th>Company</th>
<th>Manufacturing site</th>
<th>Date of PQ</th>
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<tbody>
<tr>
<td>Ethinylestradiol+ Levonorgestrel</td>
<td>Coated tablets 30µg+150µg</td>
<td>Bayer Schering Pharma AG</td>
<td>Weimar, Germany</td>
<td>26 May 09</td>
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<tr>
<td>Ethinylestradiol+ Desogestrel</td>
<td>Tablets 30µg+150µg</td>
<td>NV Organon</td>
<td>Oss, The Netherlands</td>
<td>29 Sep 10</td>
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<tr>
<td>Etonogestrel</td>
<td>Implant 68mg</td>
<td>NV Organon</td>
<td>Oss, The Netherlands</td>
<td>02 Jun 10</td>
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<tr>
<td>Levonorgestrel</td>
<td>Coated tablets 30µg</td>
<td>Bayer Schering Pharma AG</td>
<td>Weimar, Germany</td>
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<td>Levonorgestrel</td>
<td>Tablets 0.75mg</td>
<td>Gedeon Richter</td>
<td>Budapest, Hungary</td>
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<td>Levonorgestrel</td>
<td>Implants 2 rods x 75mg</td>
<td>Bayer Schering Pharma</td>
<td>Turku, Finland</td>
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<td>Lynestrenol</td>
<td>Tablets 500µg</td>
<td>NV Organon</td>
<td>Oss, The Netherlands</td>
<td>02 Jun 10</td>
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<td>Medroxyprogesterone acetate</td>
<td>Suspension for injection 150mg/ml</td>
<td>Pfizer</td>
<td>Puurs, Belgium</td>
<td>20 Aug 10</td>
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<tr>
<td>INN</td>
<td>Formulation and strength</td>
<td>Company</td>
<td>Manufacturing site</td>
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<tr>
<td>Desogestrel + Ethinylestradiol</td>
<td>Tablets 150µg + 30µg</td>
<td>Famy Care Ltd</td>
<td>Ahmedabad, Gujarat, India</td>
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<tr>
<td>Ethinylestradiol + Levonorgestrel</td>
<td>Tablets 30µg + 150µg</td>
<td>Famy Care Ltd</td>
<td>Valsad, Gujarat, India</td>
<td>29-Sep-2011</td>
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<td>Ethinylestradiol + Levonorgestrel</td>
<td>Tablets 30µg + 150µg</td>
<td>Cipla Ltd</td>
<td>Goa, India</td>
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<td>Ethinylestradiol + Levonorgestrel</td>
<td>Tablets 30µg + 150µg</td>
<td>Lupin Ltd</td>
<td>Pithampur, Madhya Pradesh, India</td>
<td>26-Aug-2013</td>
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<tr>
<td>Ethinylestradiol + Levonorgestrel</td>
<td>Tablets (91-day cycle pack) 30µg + 150µg</td>
<td>Lupin Ltd</td>
<td>Pithampur, Madhya Pradesh, India</td>
<td>26-Aug-2013</td>
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<td>Etonogestrel</td>
<td>Implant (X-ray detectable) 68mg</td>
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<td>Levonorgestrel</td>
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<td>Norethisterone</td>
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<td>Lupin Ltd</td>
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<td>Norethisterone enantate</td>
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<td>Bayer Schering Pharma AG</td>
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</table>
Output 1 - current status

**WORKING WITH MANUFACTURERS**

Increased availability of affordable quality assured RH medicines

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**PREQUALIFIED**
1. 6 generic COCs prequalified by WHO-PQP
2. 1 generic ECP prequalified
3. 2 RH APIs prequalified

**ACCEPTED**
1. 9 generic FPPs in PQ programme
2. 5 APIs in PQ programme

**ERP RECOMMENDED**
1. 15 generic FPPs recommended for purchase under ERPs 1 and 2

Draft Business Case completed

Oct 2013
THE BUSINESS CASE FOR QUALITY REPRODUCTIVE HEALTH MEDICINES

GEMS Caucus Meeting,
New Delhi, India
8 October 2013
Output 2 - current status

1. ERP/RH established and operational
   • 2 to date, 2 planned

2. UNFPA quality policy operational

3. USAID - PQ and ERP recognition

4. MSI - transition plan underway

5. IPPF revises quality policy

International procurers agree harmonized QA definitions, policies and practices

Oct 2013
Output 3 - current status

1. Situational analyses fieldwork completed
   - Data collected
   - Initial stakeholder engagement
   - Data analysis complete
   - Draft reports in process

2. Supporting government QA strategies in a key manufacturing country

3. Planning underway for follow-up key stakeholder meetings

Key stakeholders in 4 countries are planning/ implementing strategy for strengthening procurement criteria

Oct 2013
Country Studies
Key Outcomes and Findings

NEPAL
Objectives of the situational analysis

1. To determine the total Reproductive Health (RH) medicines market in Nepal and provide an analysis of the market by:
   - Total annual volumes and values by medicine type;
   - Total annual volumes by medicine type and segment;
   - Total volumes by medicine type of quality assured products;
   - Understand the characteristics of the public sector, social marketing and commercial/private segments of the RH medicines market.

2. To identify the range of RH medicines registered/authorized in Nepal.

3. To establish the policy environment for RH medicines with specific emphasis on purchasing policies, procedures and quality assurance.
Nepal- Policy and Regulatory Environment

- Policy environment for RH medicines governed by the general provisions in the Health Policy, Drug Policy and the Drug Act and various related spin-off supplements;
- Overcrowded policy environment;
- Efforts to revise the Drug Policy and develop an operational plan by the Department of Drug Administration (DDA) are yet to be concluded;
- The National Medicines Laboratory is not collaborating with the WHO Prequalification programme, targeted toward supporting the regulatory environment in Nepal;
- The Drug Registration Rules requires registration of the product in Nepal prior to import;
- The Drug Act, it’s Regulations and the Schedules need to be reviewed in the context of increased domestic manufacturing of drugs and current best practice in quality assurance mechanisms.
Nepal - Stakeholder environment and engagement

- Key stakeholder workshop held in March 2013, participants included:
  - The Logistics Management Division (LMD) - MoHP
  - The DFID/NHSSP, USAID/DELIVER and GIZ/HSSP projects, and a public private partnership with FPAN and MSI/SPN
  - Players in SMO sector - CRS Company, MSI/SPN and PSI

Key discussion items:
- Limited information about the QA processes adopted for procurement in the public sector at the regional and district level
- Variation of unit prices - lack of transparency in how unit prices are established;
- On the stock-out/stock piling issue of RH medicines: need for a formal coordination mechanism for interagency sharing of RH Medicines information;
- Concerns on variations in unit prices at retailer outlets between rural and urban areas
- Discussions around risk management of importation of drugs and the need to establish efficient system for quality risk management
Nepal RH Medicines Market Overview

• Between 2011-2012, 20m units of RH Medicines were procured in Nepal
  1. 47% - Oral hormonal Contraceptives
  2. 34% - Injectable hormonal contraceptives

• Total value of all RH Medicines in Nepal during 2011 was US$14.5m
  – 42% - Oral hormonal contraceptives
  – 30% and 18% for injectables and implants

Total Market Volume by Sector

- Public Sector: 6,890,540 (35%)
- Social Marketing Sector: 2,172,664 (11%)
- Commercial Sector: 10,668,166 (54%)

All commercial RH medicines of Indian or Nepalese origin

Total Market Volume by Sector

- Public Sector: 162,400,863 (95%)
- Social Marketing Sector: 3,546,066 (2%)
- Commercial Sector: 5,807,632 (3%)

Graph showing the market volume distribution by sector.
Nepal RH Medicines Market by Value: 2011-2012

Total Market Value by Sector

- **Public Sector**: $7,477,405
- **Social Marketing Sector**: $2,184,948
- **Commercial Sector**: $4,853,003

Value USD
Quality Assured Products Overview

• QA product volumes are 2.9% of the overall market in Nepal
  – QA Products – 566,540 units
  – Non-QA – 19,164,830 units

• QA product values are 19.1% of the total market
  – QA Products - $2,697,560
  – Non-QA products - $11,817,796
  – Implantable hormonal contraceptives are 72% of the total value of all QA products
QA RH Medicines Market Volume by Type

Quality Assured RH medicines by Type

- Injectable Hormonal: 237,600
- Oral Hormonal: 142,800
- Implantable Hormonal: 89,200
- Prostaglandins and Oxytocics: 96,940
Output 4 - current status

1. New quality policy launched by DFID
2. New KFW quality policy guidelines developed
3. Other non direct procuring donor briefed
4. Advocating for QA generics within FP2020 and UNCLSC
5. Providing progress reports through RHSC membership

Awareness of the QuRHM strategy and related quality issues raised among donors and other RHSC members

Oct 2013
BUSINESS CASE
Influencers – in the purchasing of RH medicines

The RHSC is revising its strategic plan based upon 4 pillars:
• QUALITY
• EQUITY
• CHOICE
• AVAILABILITY

CHOICE “Women and men should have supplies they know are both safe and effective. Good reproductive health depends on ensuring the quality of the RH supplies we buy and distribute – and equally important instilling a sense of public and individual confidence in their quality”

The quality message is now embedding itself within influential key stakeholder groupings.
Looking ahead

The QuRHM Technical Advisory Committee (TAC) is revising its Terms of Reference.

- The positioning of QuRHM/quality within the RHSC.

- To envisage and map the strategic direction and possible next steps, post March 2014.

- Assess progress to date and identify remaining challenges within the current programme.
Thank - you