

# **Quality of Reproductive Health Medicines Programme (QuRHM)**

Update – RHSC Market Development  
Approaches Working Group

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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.

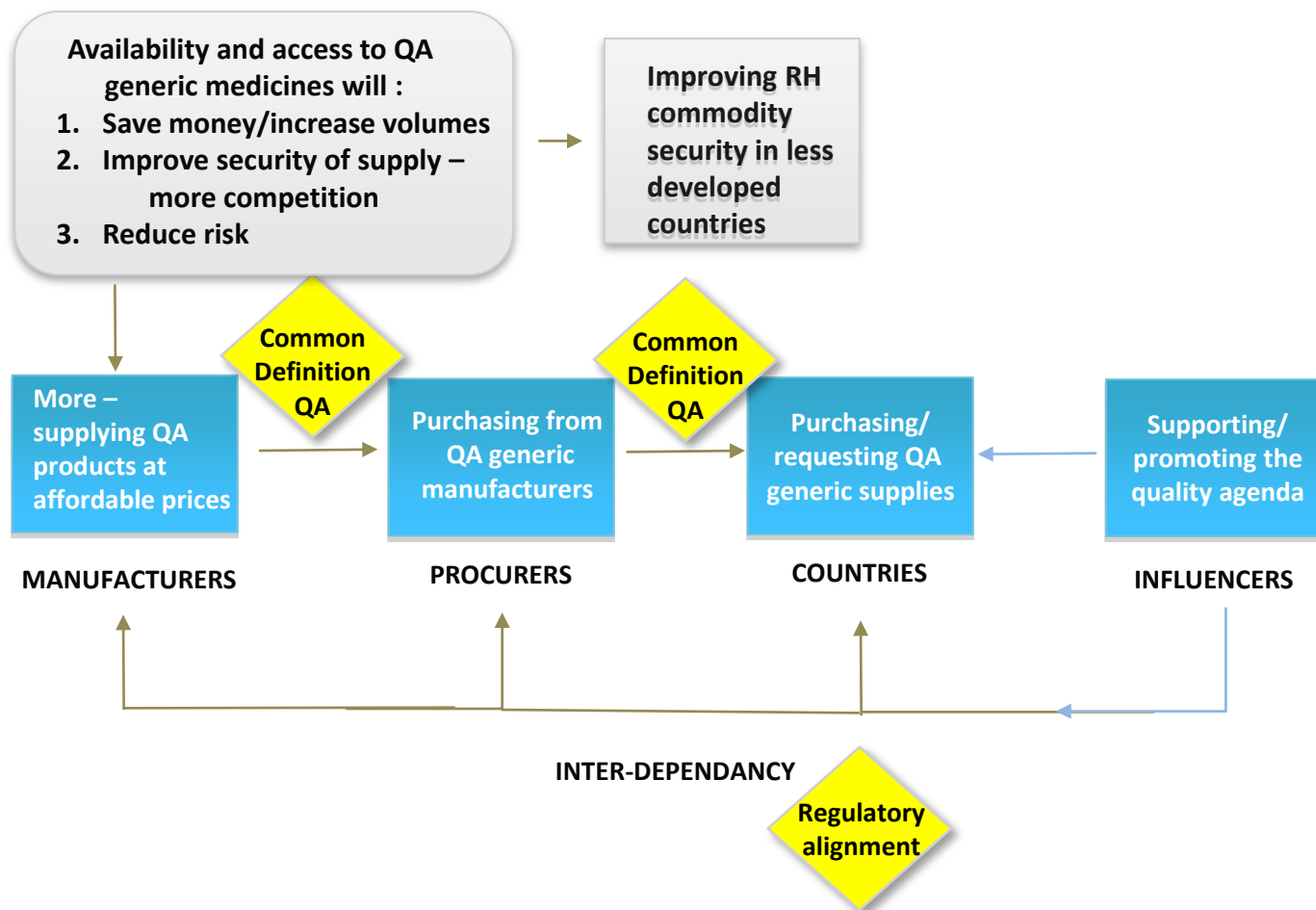
## **Output 3** - Focus on countries (Concept/UNFPA)

- 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.

# QuRHM – theory of change





# **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

# RH manufacturer engagement

2005

## Event

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

2006

## Event

RHSC opens its membership to manufacturing companies

RHSC agrees Bonn Consensus at Oct 06 Annual Meeting

WHO launches 1<sup>st</sup> RH EOI for hormonal contraceptives in Oct 06

2009

## Event

AQAS – review of manufacturing landscape - rescoping

2011

## Event

**Launch of RHSC Quality RH Medicines programme (QuRHM)**

2012

## Event

London Family Planning Summit

Launch of FP2020

Launch of UN Commission for life-saving commodities

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.



# FPP manufacturers x 20

Company	COC LNG/EE	POP LNG	ECP LNG	DMPA	MPA/ EC	Miso	Mife	Oxytocin
1 India								
2 India								
3 Bangladesh								
4 Indonesia								
5 PR China								
6 India								
7 South Africa								
8 India								
9 India								
10 Slovakia								
11 Bangladesh								
12 Mexico								
13 Indonesia								
14 PR China								
15 Spain								
16 India								
17 India								
18 Indonesia								
19 Bangladesh								
20 India								

Oct 2013

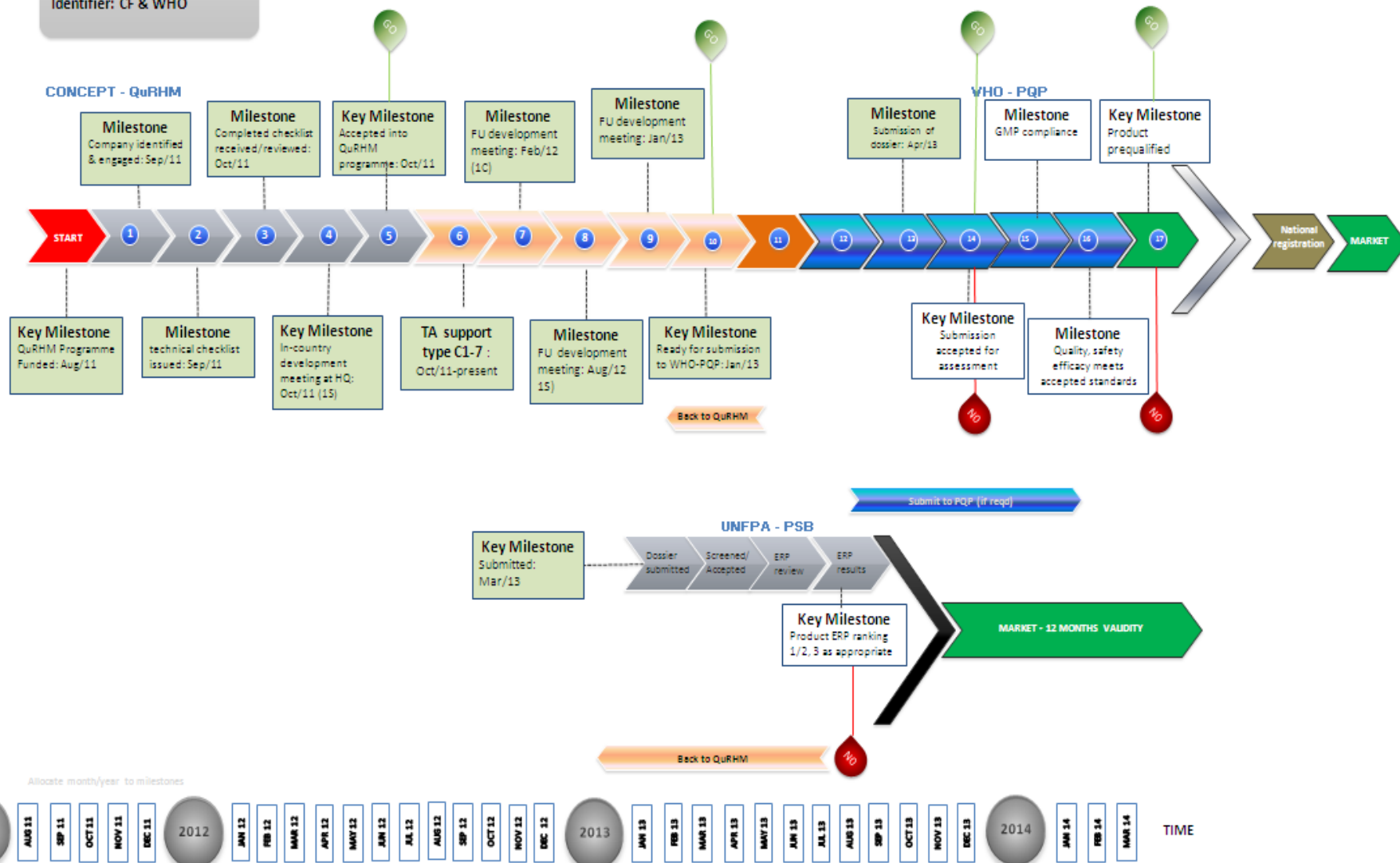
# API manufacturers x 13

Company	LNG	DES	EE	MPA	EC	MS	MF	OXY
1 RO China								
2 Latvia								
3 UK								
4 Mexico								
5 Mexico								
6 Italy								
7 Italy								
8 PR China								
9 India								
10 PR China								
11 PR China								
12 PR China								
13 RO Korea								

CRITICAL PATHWAY TO RH PRODUCT PREQUALIFICATION  
CONCEPT FOUNDATION AND WORLD HEALTH ORGANIZATION - QURHM AND PQP PROGRESS MONITORING

E.G. MED  
INTENSITY  
TA

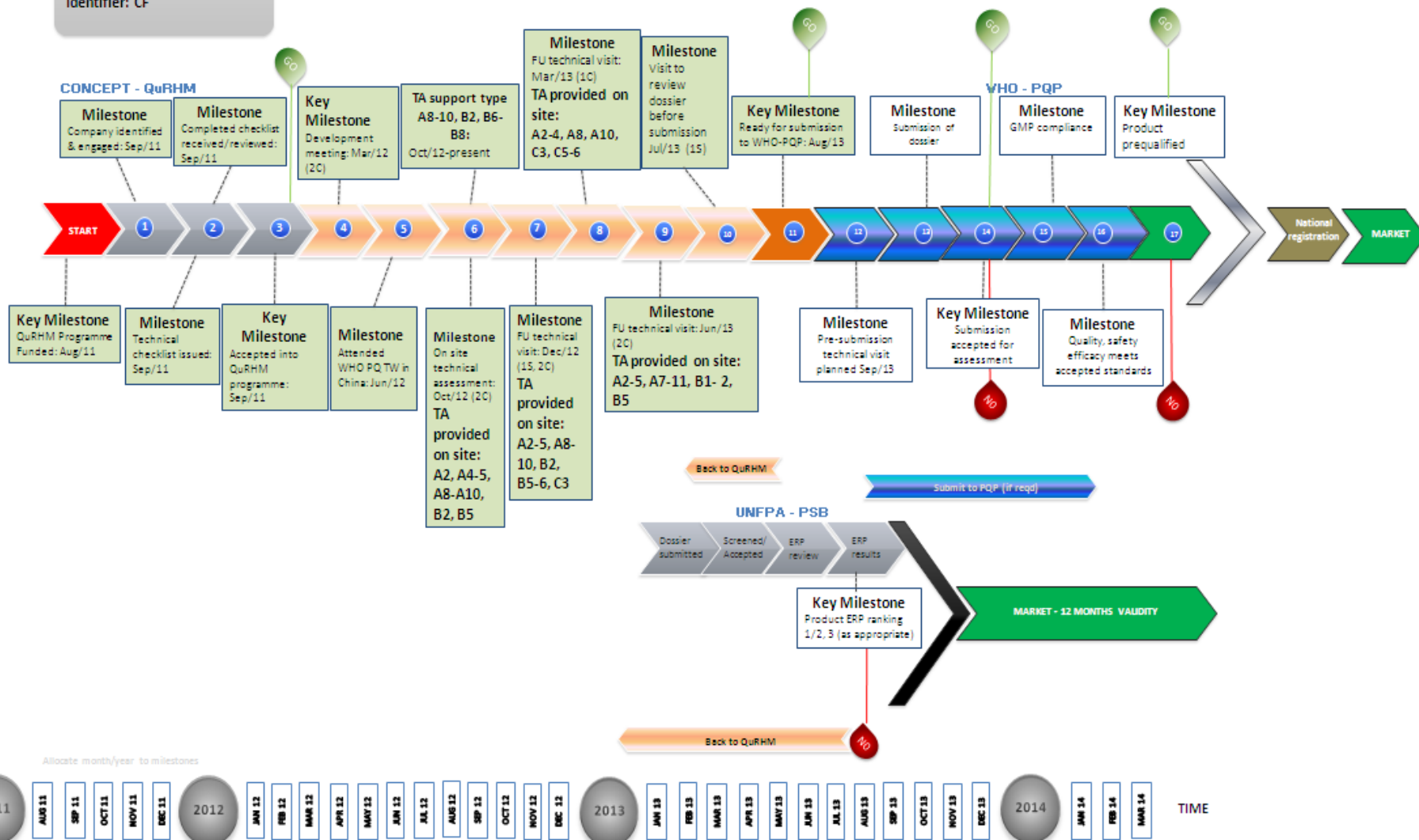
Company: XXXX  
Location: India  
Product Name: Misoprostol  
Composition: 200 µg  
Company Ref: XXXX  
Identifier: CF & WHO



CRITICAL PATHWAY TO RH PRODUCT PREQUALIFICATION  
CONCEPT FOUNDATION AND WORLD HEALTH ORGANIZATION - QURHM AND PQP PROGRESS MONITORING

E.G. HIGH  
INTENSITY  
TA

Company: XXXX  
Location: China  
Product Name: Misoprostol  
Composition: 200 µg  
Company Ref: XXXX  
Identifier: CF



# 8 Prequalified RH FPPs – August 2011

INN	Formulation and strength	Company	Manufacturing site	Date of PQ
Ethinylestradiol+ Levonorgestrel	Coated tablets 30µg+150µg	Bayer Schering Pharma AG	Weimar, Germany	26 May 09
Ethinylestradiol+ Desogestrel	Tablets 30µg+150µg	NV Organon	Oss, The Netherlands	29 Sep 10
Etonogestrel	Implant 68mg	NV Organon	Oss, The Netherlands	02 Jun 10
Levonorgestrel	Coated tablets 30µg	Bayer Schering Pharma AG	Weimar, Germany	26 May 09
Levonorgestrel	Tablets 0.75mg	Gedeon Richter	Budapest, Hungary	20 Aug 10
Levonorgestrel	Implants 2 rods x 75mg	Bayer Schering Pharma	Turku, Finland	23 Sep 09
Lynestrenol	Tablets 500µg	NV Organon	Oss, The Netherlands	02 Jun 10
Medroxyprogesterone acetate	Suspension for injection 150mg/ml	Pfizer	Puurs, Belgium	20 Aug 10

# 17 Prequalified RH FPPs – Sept 2013

INN	Formulation and strength	Company	Manufacturing site	Date of PQ
Desogestrel + Ethinylestradiol	Tablets 150µg + 30µg	Famy Care Ltd	Ahmedabad, Gujarat, India	14-Aug-2013
Ethinylestradiol + Levonorgestrel	Tablets 30µg + 150µg	Famy Care Ltd	Valsad, Gujarat, India	29-Sep-2011
Ethinylestradiol + Levonorgestrel	Tablets 30µg + 150µg	Cipla Ltd	Goa, India	22-Dec-2011
Ethinylestradiol + Levonorgestrel	Tablets 30µg + 150µg	Lupin Ltd	Pithampur, Madhya Pradesh, India	26-Aug-2013
Ethinylestradiol + Levonorgestrel	Tablets (91-day cycle pack) 30µg + 150µg	Lupin Ltd	Pithampur, Madhya Pradesh, India	26-Aug-2013
Etonogestrel	Implant (X-ray detectable) 68mg	NV Organon	Kloosterstraat, Oss, The Netherlands	23-May-2013
Levonorgestrel	Tablets 750µg	Famy Care Ltd	Ahmedabad, Gujarat, India	14-Jun-2013
Norethisterone	Tablets 350µg	Lupin Ltd	Pithampur, Madhya Pradesh, India	26-Aug-2013
Norethisterone enantate	Injection 200mg/ml	Bayer Schering Pharma AG	Berlin, Germany	05-Oct-2011

# Output 1 - current status

## WORKING WITH MANUFACTURERS

Increased  
availability of  
affordable  
quality assured  
RH medicines

- 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**

# THE BUSINESS CASE FOR QUALITY REPRODUCTIVE HEALTH MEDICINES

GEMS Caucus Meeting,  
New Delhi, India  
8 October 2013



# Output 2 - current status

## WORKING WITH PROCURERS

International  
procurers agree  
harmonized QA  
definitions,  
policies and  
practices

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

# Output 3 - current status

## WORKING WITH COUNTRIES

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

Oct 2013

### 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

# 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:

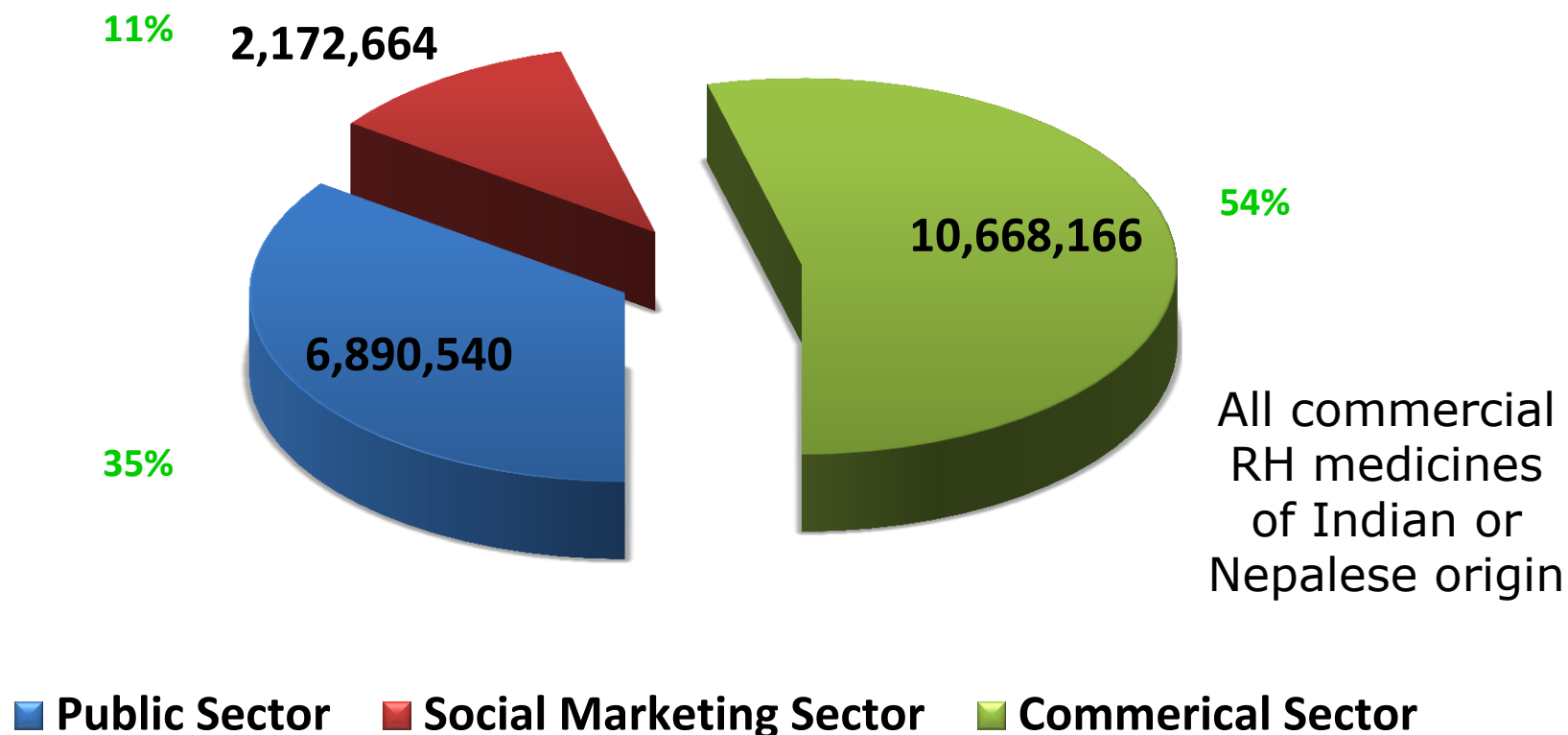
- Limited information about the QA processes adopted for procurement in the public sector at the regional and district level
- Variation of unit prices - lack of transparency in how unit prices are established;
- On the stock-out/stock piling issue of RH medicines: need for a formal coordination mechanism 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

# Nepal RH Medicines Market by Segment Volume: 2011-2012

Total Market Volume by Sector





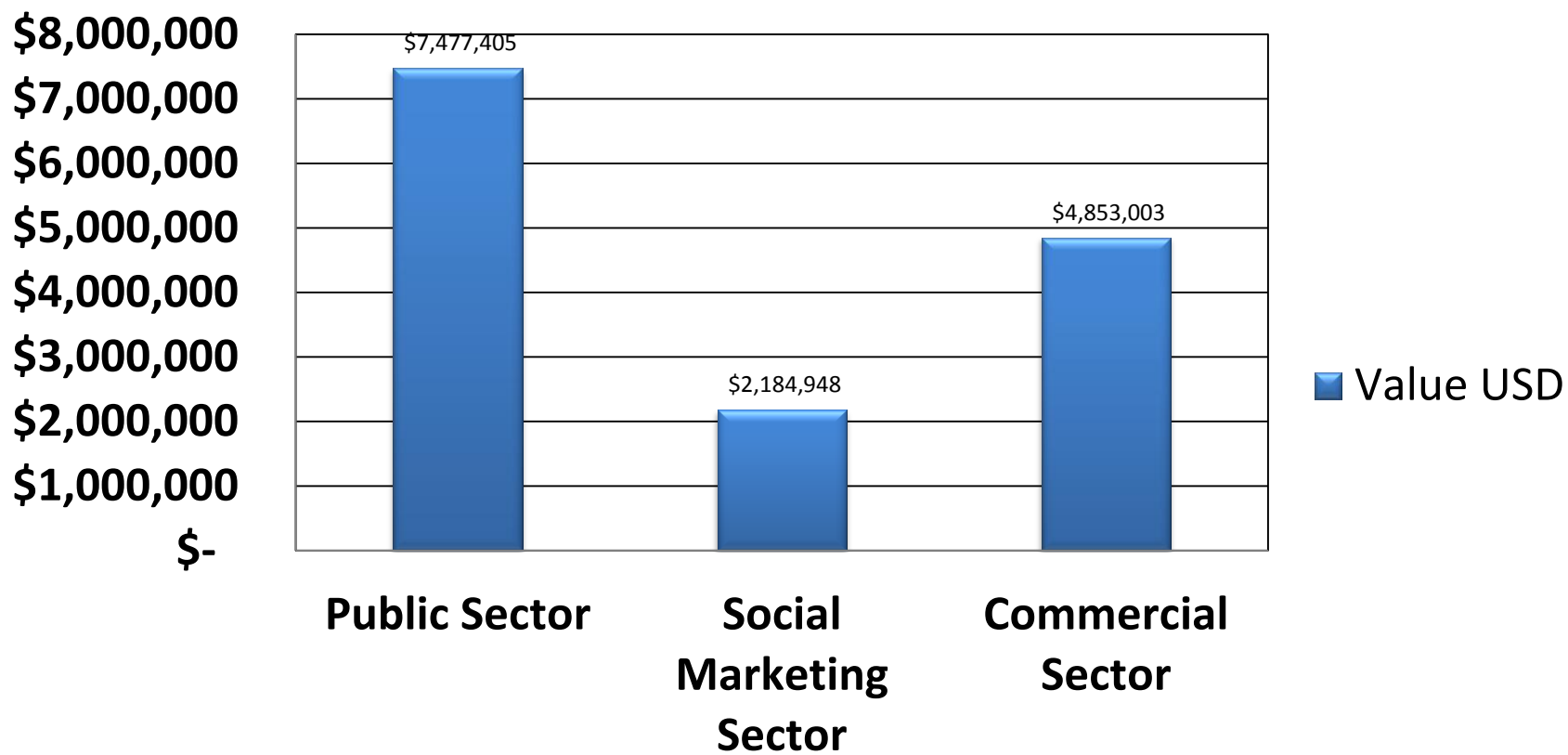
# Kenya RH Medicines Market by Volume: 2011-2012

## Total Market Volume by Sector



# Nepal RH Medicines Market by Value: 2011-2012

**Total Market Value by Sector**

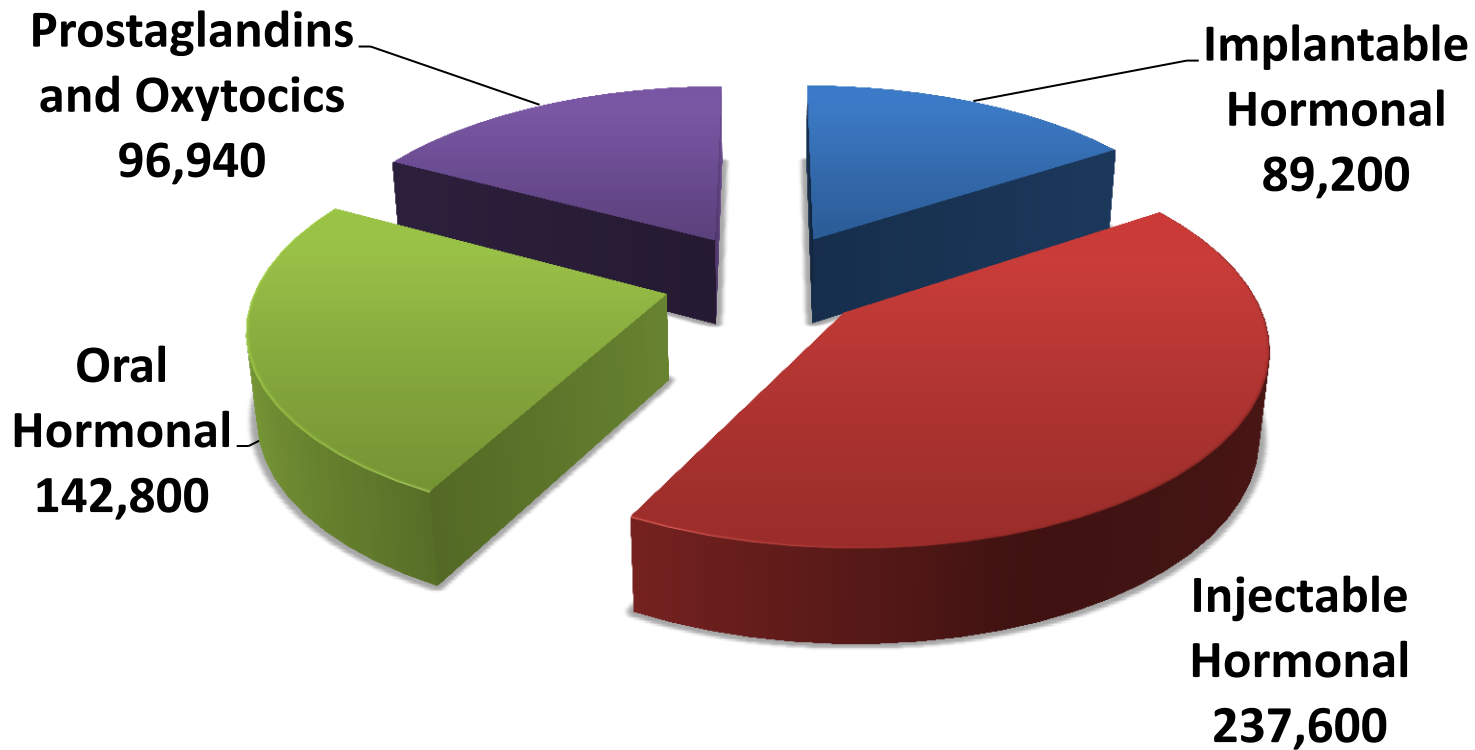


# Quality Assured Products Overview

- 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



# Output 4 - current status

## WORKING WITH RH INFLUENCERS

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

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

## 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**