Expanding Access to Quality Assured Maternal Health Medicines

Concept Foundation
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Quality agenda - progress to date

**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
Approach MH medicines and contraceptives

QA STANDARDS
become a global priority

DEMAND
for affordable, QA medicines grows
across sectors

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

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

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
WHO Prequalification

- August 2011: 8 Innovator FPPs
- October 2012: 9 Innovator FPPs, 2 Generic FPPs
- October 2013: 10 Innovator FPPs, 11 Generic FPPs, 2 Generic APIs
- April 2014: 10 Innovator FPPs, 16 Generic FPPs

September 2015 - 28 FPPs (18 generics), 5 APIs

- 2 MH medicines
  - 1 misoprostol
  - 1 oxytocin
Existing challenges?

• Expanding number of quality assured MH medicines available for purchase.
  • Business Case for manufacturers - visibility of market fundamentals -
    • Size/scope,
    • Distribution channels
    • Customer profile
    • Pricing
Existing challenges?

• Raising awareness of the specific quality issues and their impact.
  • Publishing and disseminating existing evidence of quality status - misoprostol and oxytocin
  • Increasing visibility at international level
PQ as the starting point

• PQ as the starting point → significant issues remain around access to markets for MH medicines.
  • Focus on country registration → mapping the regulatory pathway for key products; working with manufacturers and country regulators/WHO Collaborative Registration to facilitate early registration
  • Country level research to understand attitudes and perceptions towards quality
  • Communicate with national stakeholders to raise awareness of quality issues
  • Market mapping to establish and address purchasing and distribution modalities
Optimal procurement of affordable and quality assured life-saving commodities for maternal health - 8-10 September 2015

- Workshop conducted in Kampala under auspices of UNCO, in collaboration with WHO
- Six countries - Tanzania, Uganda, Kenya, Zimbabwe, Zambia and Malawi
- Regulators, procurers, supply chain professionals
  - Collaboration and information sharing between countries
  - Inform on quality issues
  - Discussing purchasing approaches - new and modified technologies