

GENERIC
MANUFACTURERS
for REPRODUCTIVE
HEALTH

Uniting generic manufacturers.
Improving lives.

Background on issues generics face around prequalification

20 June 2017

Overview of current procurement practices

Not seeing the expected return on quality investments.
Procurement practices are at two extremes:

- Requirements restrictive to only innovators - international
- Happy to procure from generics, but primarily based on price, i.e. less or limited focus on quality assurance - countries

No visibility in terms of volume forecasting or product investment allocations.

Medicines procurement example

- Hormonal contraceptive public sector procurement and supply for LMICs remains reliant on two major agencies UNFPA and USAID.
- In 2015, more than 99% value of hormonal products supplied were sourced from three innovator companies.
- Statistics consistent with previous years.

UNFPA TOP 50 VENDORS 2015	US\$	%
1. BAYER PHARMA AG Germany	44'213'181	45
2. PFIZER OVERSEAS LLC (EXPORT DIVISION) USA	26'484'692	27
3. MSD BV Netherlands	25'983'673	27
TOTAL VALUE	96'681'546	99
TOTAL HORMONAL CONTRACEPTIVE SPEND	97'366'428	
28. Famycare Ltd India	1'300'945	1

Source: UNFPA Procurement Statistics 2015

Medicines procurement example

- By contrast, many LMIC markets have sizeable volumes of non quality assured products (by standard international definition).
- Purchased directly by Governments and still in some instances supplied through international tenders and SM operations.

E.G.

Injectables39,989,621 (61 programs)

The Maternal Health Challenge

- Unlike FP methods, limited numbers of key maternal health medicines are managed through international supply chain mechanisms, with the majority provided direct to country through multiple mechanisms.

What the GEMs have to offer

Caucus launch in 2013: group of manufacturers committed to providing more women with affordable, safe and effective contraceptives and essential RH medicines.

- 26 generic FPPs (14 from GEMs members) and 8 APIs (4 from GEMs members) WHO prequalified or SRA approved
- 2 FPPs on ERP list (out of 6 generics in list)
- Other products under review for WHO prequalification

Over 60 LMICs covered, including priority FP2020 countries.

What the GEMs have to offer

Since 2013:

- 5'679'901 maternal health medicines shipped to LMICs
- 594'054'024 contraceptives shipped to LMICs
 - 105'122'327 injectables
 - 1'046'780 implants
 - 453'355'637 combined oral contraceptives and progestin-only pills
 - 27'268'868 emergency contraceptives
 - 7'260'412 IUDs

Bridging the gap between QA generic manufacturers and procurers

Goals:

- Continuing to meet and maintain quality standards
- Matching demand with supply
- Accessing markets; ensuring sustainability of supply