Outcome Report of Roundtable on RH Commodity Supply Among Developing Countries

Peter E Hall
Consultant, PPD
PPD declarations on reproductive health commodities

International Forum on Population and Development, Wuhan, China. 7-9 September 2004 - Yangtze Declaration
“Commit ourselves to use best practices and share resources including reproductive health commodities, among developing countries for effective reproductive health policies, programmes and services aimed at improving the quality of life of women, men and children.”

Partners Annual Board Meeting 2003, Jakarta, Indonesia, 15-17 October 2003 - Jakarta Declaration
“We pledge commitment to work on the Kochi Agenda for Action by: Establishing mechanisms for sharing affordable commodities through South-South networks; ……”

Partners for Population and Development

International Workshop for Senior Officials on Capacity Building in Programme Management in Population and Development

Beijing 7-12 November 2006
Call on governments and international donors, as a matter of urgency, to secure firm political commitment for ensuring the availability and accessibility of affordable and quality reproductive health commodities, especially for the poor, the disadvantaged and underserved groups

Encourage the use of quality generic drugs, to help address the commodity supply and security needs of lower and middle income countries, provided that the active pharmaceutical ingredients (APIs) and production facilities conform to internationally accepted Good Manufacturing Practices; that data are available to comply with regulatory requirements; and their cost remains significantly lower than other branded products.
Urge South-South collaboration to maximize economic advantages, while ensuring that Government tenders include quality criteria. In this context, we urge the rapid development of prequalification criteria and their implementation for reproductive health commodities and particularly hormonal contraceptives.

Encourage South-South collaboration in the transfer of manufacturing technology of appropriate reproductive health commodities, particularly to Africa.
Millennium Development Goals

A new target was recently adopted by the United Nations General Assembly, “to achieve universal access to reproductive health by 2015”, under Millennium Development Goal 5, to reduce by three quarters the maternal mortality ratio.

While the new target ensures the centrality of universal access to reproductive health in improving maternal and infant health and poverty reduction in the MDGs, it will require adequate funding and access to products for reproductive health not only of assured quality but at the lowest possible price.
Roundtable on RH Commodity Supply Among Developing Countries

Developing Countries: RH Commodity Needs and Indigenous Suppliers’ Practice. Quality Control of RH Commodities. Transparency of RH Commodity Supply Chain.
Opening Session - Dr Zhao Baige

• Huge demand for RH commodity supply and service in countries of the South.
• Challenges to countries of the South in RH commodity supply and service.
• China’s practice and commitment.

Pressing demand has generated appropriate technologies BUT “all countries should further enhance their management standards and enable their commodities to comply with international quality standards so as to promote internationalization of RH commodity supply”. Made commitment that China will provide training and contraceptives to developing countries in next five years.
Where are we?
Experiences from China, India, Indonesia and South Africa from both programmes and manufacturers.
There are manufacturers ready to meet needs BUT procurement and service delivery agencies are facing severe financial difficulties and have urgent need of access to low cost products of assured quality, as well as supportive mechanisms, such as greater use of the commercial sector to allow resources to be focused on poorer users.
What are countries looking for?

There are a number of manufacturers of contraceptive and other RH health products in PPD member states.

Governments and international donors are looking for sustainable supplies of products of assured quality at the lowest possible cost to meet the goal of achieving supply security for reproductive health commodities.

Can these manufacturers meet the identified need?
Questions by the RHSC on the manufacture of generic hormonal contraceptives

• Can generic pharmaceutical manufacturers in lower and middle income countries make quality products available to donor agencies, governments, social marketing organizations at a more affordable price, while meeting the requirements of stringent regulatory agencies?

• Can any of these companies participate in the development of a total market approach which provides a “second tier” of products in the private sector that are affordable to some of those who are currently using free or subsidized public or social marketing sector products, and allow those programmes to focus on poorer users?
Generic hormonal contraceptives

Study 1. “Qualitative study”
• 41 Companies were visited in 13 lower and middle income countries: Brazil, Chile, PR China, Costa Rica, India, Indonesia, Mexico, Oman, South Africa, (Taiwan), Thailand, Uruguay and Viet Nam.

Study 2. “Quantitative study”
• Assessment of the manufacturing competence of 14 companies in Brazil, Chile, China, Colombia, India, Oman, Pakistan, South Africa and Thailand.
Findings

- Although all 44 factories visited comply with national GMP, it is probable that less than 30% would meet cGMP requirements of WHO, PIC/S or any stringent regulatory authority.
- A further 20% could comply with some investment and improvements in quality management and practice.
- The other 50% of the facilities visited are manufacturing products under conditions that give cause for concern.
Findings

• There is enormous production overcapacity, particularly in China and Thailand, and to some extent in India, where companies produce their annual quota of oral or injectable contraceptives in a single period of 4-8 weeks in a year. This is not only uneconomic but raises major quality issues, particularly in the revalidation (or lack of revalidation) of production and environmental procedures, as well as worker training.
Findings

• Few companies (<25%) have the capability of developing registration dossiers required for the export of products to countries with strict regulatory requirements.

• Many companies would like to access technical assistance to:
  - meet cGMP requirements; and
  - develop registration dossiers that meet stringent regulatory requirements
cGMP and issues that influence the quality of a product

1. Starting materials (APIs, excipients, primary container)
2. Premises (WHO TRS 908, annex 4, 12.24)
3. HVAC (WHO TRS 902, 908, and 937 ISO 14644)
4. Water for pharmaceutical use (WHO TRS 929, annex 3 and 937)
5. Equipment
6. Methods, Specifications & Sampling (WHO TRS 929)
7. Qualification / Validation (WHO TRS 937)
8. Training
Can we access high quality products?

Yes, if the active pharmaceutical ingredients (APIs) and production facilities conform to internationally accepted GMP standards; and data are available to comply with regulatory requirements. From the two studies reported, up to ten companies could comply in 2007 with minimal additional technical or procedural inputs and a further three to four could potentially do so in 2007 with investment and technical assistance.
http://mednet3.who.int/prequal/
Essential RH medicines for prequalification

Essential medicines for RH agreed by an InterAgency Working Group and the RHSC for eventual inclusion in the prequalification programme.

An Expression of Interest now on WHO’s website [http://mednet3.who.int/prequal/](http://mednet3.who.int/prequal/) for these contraceptives:

- levonorgestrel, 150µg + ethinylestradiol, 30µg, tablet
- levonorgestrel, tablet, 30µg, 750µg (pack of two), 1.5mg (pack of one)
- medroxyprogesterone acetate (DMPA), depot injection, 150mg/ml
What are the consequences?

Donor and procurement agencies wishing to access generic pharmaceutical products will only purchase products that have been prequalified by WHO (including condoms and IUDs prequalified by UNFPA) and adopt a procurement policy based on that used by the GFATM.

It is critical that several of the companies visited in the assessment visits apply now for prequalification. Once several companies have prequalified, others will want/need to improve the quality of their products. This will have an impact not only on international supplies but on the overall quality of products in producing countries.
What needs to be done?

• Develop an advocacy strategy and informational materials for governments, national NGOs, international partners and other stakeholders, including healthcare providers and consumers on:
  - the WHO prequalification programme;
  - the need to use only suppliers prequalified by WHO for the procurement of injectable and oral contraceptives and eventually other RH commodities.
  - the broader issues around generic products.
Obstacles in Supply of China’s Essential Medicines to Developing Countries for Reproductive Health

- Lack of know-how on local demands, laws & regulations
- Limited understanding on standards & protocols of international procurement
- Little information on priorities & demands from developing countries
- Unfamiliar with laws & regulations in target countries
- Lack of knowledge on international rules and regulations in pharmaceuticals, as well as marketing capacity internationally
- Poor and unsophisticated communication with international procurement organizations & distributors in target country
What do we expect from the generic manufacturers?

Donors and procurement agencies are looking for sustainable supply of the highest quality products at the lowest possible cost to meet the goal of achieving contraceptive supply security. This is what we are expecting manufacturers of generic contraceptives to deliver.
Total market segmentation

1\textsuperscript{st} Tier

High-price commercial sector products

Affordable commercial products created through the PPP

Donor subsidized branded products – Social Marketing

Government/donor products, supplied free of charge or at minimum cost recovery

2\textsuperscript{nd} Tier

Free/subsidized distribution Tier

Partners for Population and Development

International Workshop for Senior Officials on Capacity Building in Programme Management in Population and Development

Beijing

7-12 November 2006
Other key points

• Monitoring demand and supply being managed better BUT dependent on guaranteed funding. Must continue to underpin support by governments and donors.

• Logistic and information systems still need operational support and training.

• Partnerships are key. Partnerships are required between governments, the private sector, NGOs, civil society and the media.
Other key points

Databases can provide essential information.

China Training Centre has developed a database of China’s Essential Medicines for Reproductive Health

www.metabase.com

PPD encouraged to assist with development of, and provide linkages to, other databases.
What is the role of Partners for Population and Development?

Partners has discussed RH commodities for some years but in the past year has taken action, it has conducted both studies and organized workshops on RH Commodity Security.

This will become a key area of intervention for Partners over coming years.

(Harry Jooseery, ED, PPD)
Partners for Population and Development

Major action areas:
• Stimulate dialogue and exchange of information
• Transfer of knowledge and technology through training and the provision of technical assistance through South-South modalities.
• Advocacy and resource mobilization
• Research on commodity security in member states, eg, partnering with ICON/IPPF on total market assessments.
Partners for Population and Development

• Stimulate dialogue and exchange of information
  - Forum for manufacturers
  - Production of handbook on generic manufacture of medicines for RH
  - Organization of national or regional workshops

Must develop a feasible and functional workplan.