

Report on

Roundtable on Generic RH Commodity Supply among Developing Countries

Jointly Organized by:
Partners in Population and Development (PPD)
and
National Population and Family Planning Commission (NPFPC)
Government of the People's Republic of China

Venue:
Beijing Friendship Hotel, Beijing, China

Date:
07 November 2006

Introduction

Partners in Population and Development (PPD) and National Population and Family Planning Commission (NPFPC) of China jointly organized a Roundtable on Reproductive Health Commodity Supply among Developing Countries on 7th November 2006 at the Beijing Friendship Hotel in Beijing, China. The roundtable brought together generic reproductive health commodity manufacturers from China, India, Indonesia, South-Africa, Thailand in addition to prominent experts in the field from around the world. The objective of the Roundtable was:

- exchanging information about research and development of RH commodities in various countries,
- analyzing problems in RH commodity supply and security and thereby promoting South-South cooperation in this particular field.

The Roundtable was sponsored by PPD, NPFPC and Ministry of Commerce of the People's Republic of China, and UNFPA.

The Roundtable was officially opened by H.E. Dr. Zhao Baige, Vice Minister of NPFPC. Mr. Sangeet Harry Jooseery, Executive Director of PPD also addressed participants at the opening ceremony of the Roundtable.

The following made presentations at the Roundtable:

- Dr. Jotham Musinguzi, Treasurer, PPD Board and Director of Population Secretariat, Uganda
- Mr. Jianhua Cai, President, China Training Center of Reproductive Health and Family Care (CTC)
- Dr. Siswanto A. Wilopo, Deputy for FP and RH of BKKBN, Indonesia
- Mr. Peter Hall, PPD Consultant
- Mr. Humberto Zardo, Pharmaceutical Operations Improvement, Irvine, California, USA
- Mr. David Smith, Chief, Procurement Services Section, UNFPA, New York
- Mr. Lester Chinery, Managing Director, ICON/IPPF
- Mr. John-Heyns Ferreira, Director Fresenius Kabi, South Africa
- Mr. Ashutosh Jyotiprasad Taparia, Executive Director, Famy Care, India
- Ms. Ida Rahmi Kurniasih, PT.KIMIA FARMA (PERSERO), TBK
- Mr. Tongli Yao, Vice President and General Manager, Beijing Tiantan Biological Products Co., Ltd.
- Mr. Xiaojun Mu, Vice President, Peking University Pharmaceuticals
- Mr. Zhijun Lu, General Manager, Guangzhou Regenex
- Mr. Phillip ZP Cui, Vice President, Shanghai Fosun Pharmaceutical (Group) Co., Ltd.
- Ms. Hua Chen, Deputy General Manager, Beijing Zizlu Pharmaceutical Co., Ltd.
- Mr. Jinglun Wang, General Manager, Shenyang Liren Medical & Tchnological Co., Ltd.
- Mr. Zhenxiu Wang, Marketing Director, Qingdao Double Butterfly Group Co., Ltd.

The Roundtable was divided into the following three substantive sessions:

- Developing Countries: RH Commodity Needs and Indigenous Suppliers' Practice
- Quality Control of RH Commodities
- Transparency of RH Commodity Supply Chain

OPENING SESSION

H.E. Dr. Zhao Baige, Vice Minister of National Population and Family Planning Commission of China

In his opening speech H.E. Dr. Zhao Baige, Vice Minister of National Population and Family Planning Commission of China appreciated the presence of representatives from UNFPA, IPPF and experts and scholars from Egypt, Uganda, Indonesia, Bangladesh, Zimbabwe and Morocco, and entrepreneurs engaged in manufacturing of RH commodities in India, Indonesia, South Africa, Thailand and China. She said that such participation fully reflects the new partnership among governments, NGOs and businesses community and proves huge demand for RH commodity supply and service in countries of the South and the expectations from the Roundtable are to further improve the supply and service of RH commodities in countries of the South. She observed that the present world witnesses a growing awareness that success in family planning and promotion of RH commodity supply and service are intimately related to the realization of the MDGs, but we have a long way to go and severe challenges to face for realization of the goals, which are:

1. Low expenditure on RH commodities
2. Low total contraception prevalence rate worldwide
3. Pressing demand for RH commodities on the African continent

Along with such a pressing demand for RH commodities in developing countries, a large group of appropriate technologies have taken shape internationally with support from UNFPA, WHO and IPPF. Countries including China, India and Indonesia have built up fairly strong productivity and market capacity. 90.2% of the couples of reproductive age in China have access to FP/RH services. It is now necessary to identify the mechanism on how to provide such services and commodities to more extensive groups, how to acquire information about demands for RH services in different localities, and how to upgrade supply capacity in the developing countries.

She said that at the moment, there are mainly three problems existing in the supply chain of RH commodities, i.e., (1) commodity quality and price; (2) supply channel and capacity; (3) information exchange. All these problems are closely related to capacity building.

She announced that China will undertake substantive measures including provision of training, capacity building and donation of contraceptives to the developing countries in the next 5 years. She hoped that through our concerted effort, we will push forward the attainment of the global goal of achieving universal access to RH services, promote the realization of the MDGs and thereby make our due contribution to the development of all mankind.

Mr. Sangeet Harry Jooseery, Executive Director, Partners in Population and Development (PPD)

At the very outset of his speech, Mr. Harry Jooseery thanked H.E. Dr. Zhao Baige, National Population and Family Planning Commission (NPFPC) of China and Ministry of Commerce of the Government of the People's Republic China for all the support and assistance provided to PPD in the organization of this Roundtable. He then welcomed the delegates from China, India,

Indonesia, South Africa and Thailand and thanked them for their keen interest in Reproductive Health Commodity Security.

He said that this workshop is a follow-up of a study that PPD conducted on the capability of manufacturers of generic hormonal contraceptives in lower and middle income countries and also the mapping up exercise conducted by UNFPA in 18 countries on the issue. PPD organized a successful workshop in Agra, India in 2005 on "*The Role of Generic Drug Products in Meeting Reproductive Health Commodity Needs in Lower and Middle Income Countries*" at which important issues aiming at promoting generic drugs were discussed. Today we have a group of manufacturers together with specialists in the field of Reproductive Health Commodity Supply and Security to share updated information and development on Reproductive Health Commodity and also to provide a platform for all stakeholders to discuss the challenges and the way forward. One of the key areas of intervention for PPD in the coming years is Reproductive Health Commodity Supply. Developing countries have the highest level of fertility rate, maternal, infant and adult morbidity rates. The challenge forward is to promote Reproductive Health and Rights as a key route to all these poverty related problems. None of the MDGs can be achieved without addressing Reproductive Health issues. A recent study undertaken by UNFPA/WHO/UNICEF shows the correlation between contraceptive prevalence, maternal mortality, abortion rate and infant mortality. For every 1 million shortfall in contraceptive supply assistance, there are:

- 360,000 unwanted pregnancies
- 150,000 induced abortions
- 800 maternal deaths
- 11,000 infant deaths
- 14,000 deaths of children under the age of 5 years.

In countries with high contraceptive prevalence rate and high unmet need, some may believe local manufacturing of contraceptives to be a possible solution. However, a number of factors need to be considered before embarking on local manufacturing namely, technical capacity, regulatory standards and systems, distributional and marketing conditions.

It is important that an integrated approach be adopted to address the issue of Reproductive Health Commodity Security. It is unfortunate that many governments still look at the Reproductive Health Commodity Security from the supply perspective. Availability, accessibility and affordability encompass issues of supply management, quality of care, demand creation and national environment. The complexity of Reproductive Health Commodity Security also resides in understanding the specific socio-cultural environment and customizing supply to the market segments. Effective contraceptive security depends on the ability to forecast, finance, obtain, deliver sufficient supply and choice of high quality contraceptives to every person that need them.

The reproductive-age couples in developing countries are growing at a rapid pace which is expected to increase by 23% between 2000 and 2015 and thus the demand for contraceptives supplies have been exceedingly increasing. Ensuring access to our people to the high cost patented contraceptive commodities manufactured by the multinational companies in the west is becoming difficult over time. Generic hormonal contraceptives manufactured by your companies can play a significant role to ensure contraceptive supply security in developing countries.

However, we need to make sure that the production facilities conforms to international standards, access to high quality Active Pharmaceutical Ingredients (API) are ensured and capacity to develop full registration dossier for the products and Site Master File (SMF) for the manufacturing sites strengthened among the pharmaceutical companies in developing countries. While many of the developing countries' manufacturing sites and their products are of adequately high standard to undergo WHO prequalification process and registration in the country of importation, some of them might still require improvement to attain that standard.

The prevailing international system demands exchange of all pharmaceutical products to undergo a number of very stringent national and international regulatory processes. Although most of the companies in the developing countries are producing these products following the Good Manufacturing Practices (GNP) of the National Drug Regulatory Authorities (DRA) and World Health Organization (WHO) in strictly hygienically maintained manufacturing sites, both the products and the manufacturing sites have to undergo prequalification procedures by WHO as a precondition for procurement by the international donors and UN agencies for public sector in developing countries. WHO will conduct shortly its prequalification exercise for Reproductive Health Commodities and that specific products like OC, DP and emergency contraception are on their priority list. WHO will also conduct capacity building workshops on Reproductive Health Commodity Security and all concerned could take advantage of this opportunity.

Substantive Sessions: Presentation and Discussion

After the Opening Session, Country Reports of China, South Africa, India, Indonesia was presented, which was followed by substantive sessions as mentioned below:

- Session I: Developing Countries: RH Commodity Needs and Indigenous Suppliers' Practice
- Session II: Quality Control of RH Commodities
- Session III: Transparency of Reproductive Health Commodity Supply chain

Copies of the Country Reports and presentations are attached with this report for information.

The discussion of the Roundtable centred on different aspects of manufacturing, quality control, storage, marketing, distribution and the role of generic drugs towards ensuring commodity security as economic, safe and effective substitute of patented and costlier contraceptive commodities.

It was observed that there are huge demands for RH commodity and service in developing countries and this has generated the development of appropriate technologies for the manufacturing of generic drugs. But countries need to further enhance their management standards and enable their commodities to comply with international quality standards. On the other hand, procurement and service delivery agencies, faced with severe financial difficulties, desire to access 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.

Participants of the Roundtable recommended the development of a Handbook to provide all relevant information on the prequalification procedures for generic drugs and also that an inventory of generic drug manufacturers be compiled.

Manufactures

The discussant observed that the manufacturers of the developing countries should maintain high standard and quality of their products to be able to compete in the international market. In order to gain access to the markets in the developing countries the products should be cost effective. But manufacturers should bear in mind that under no circumstance the quality of the products could be compromised to maintain price of the products lower. Manufacturers should brand their products and conducts advocacy to promote the brands. Advocacy tools on product quality information could be developed and made them available in the internet through the company websites. There are questions and concerns about safety of developing country products which is a great challenge for developing country manufacturers. High standard of manufacturing conditions and quality of products will ensure safety of the products and address the concerns. Manufacturers should also have their products undergone WHO prequalification process and WHO safety and quality standard should be followed before going into massive production. Training support is needed for the manufacturers to be able to fulfill the requirements of the WHO prequalification.

Since international procurement system is complicated and strong competition exist in the market the manufacturers need to develop long-term strategy taking prevailing international marketing and procurement strategy into consideration to be able to compete with their stronger rivals from developed countries.

Countries

In order to reduce dependence on the international donor assistance developing countries should allocate resources in the national budget for procurement of RH commodities. Countries should also seek foreign assistance to develop and set up systems and infrastructure for procurement, storage and distribution of RH commodities. Support of local government national and international NGO's and experiences of experts in the related field could be obtained. The regulatory authorities in the Countries are advised to define and set up standards for measuring quality to ensure safety in the country level. WHO could conduct advocacy with govt. and regulatory bodies. Despite all these efforts Quality of products are affected during procurements, storage and distribution in the market. Necessary remedial measures should also be in place to ensure safety and maintain the standard during these processes.

Role of PPD

There was a general consensus that PPD should take lead in the reproduction supply and security issues while China stands ready to assist PPD in its endeavor. PPD can facilitate effective partnership between Private and public sectors as a catalyst in achieving this objective. PPD can work with the developing countries to attach high priority on family planning. PPD can play important role in building capacity in the country level. The Governments and manufacturers should move forward under PPD's leadership. PPD can assist member countries to obtain prequalification for generic drug manufactured in the developing countries. PPD can involve the manufacturers in reproductive health commodity security issues. Using the PPD's platform

manufacturers can reach out their products to the international market as long as they maintain high quality of their products. Developing country manufacturers should remain abreast of consistently evolving quality of products internationally in order to maintain highest standard of their products. Continuous monitoring and assessment of market demands and matching supply will ensure sustained presence in the market.

PPD can facilitate exchange of information among the countries. As the preliminary step, PPD will produce Hand Book for Manufacturers with all information. PPD can also assist countries in acquitting necessary logistics and mechanism for procurement, storage and distribution of RH commodities. Building partnership among Government, NGOs, business sectors, civil society is positive step forward towards achieving comprehensive RH commodity manufacturing, supply and security in which PPD can play a catalytic role.

The closing session was again addressed by H.E. Dr. Zhao Baige, Vice Minister of NPFPC and Mr. Harry Sangeet Jooseery, Executive Director of PPD.