

**Statement of**  
**Mr. Sangeet Harry Jooseery, Executive Director**  
**Partners in Population and Development (PPD) at the**  
**Roundtable on Generic RH Commodity Supply among Developing**  
**Countries**

I am pleased to welcome you to this Roundtable on Reproductive Health Commodity Supply. In the first instance, I would like to thank Dr. Zhao Baige, Vice Minister of the National Population and Family Planning Commission of the Government of the People's Republic of China for all the support and assistance provided to PPD in the organization of this Roundtable. I welcome particularly the delegates from China, India, Indonesia, South Africa and Thailand and thank them for their keen interest in Reproductive Health Commodity Security.

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.

As you are aware, 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. I am happy to inform you that 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 I invite you all to take advantage of this.

I wish before ending to thank all the facilitators for this workshop namely Messrs Siswanto Wilopo, Xijun Yan, Jyoti Singh, Peter Hall, Humberto Zardo, Prof. Yifei Wang, David Smith, Lester Chinery for having kindly accepted to share with us their vast knowledge and experiences. Thanks to the co-sponsors and organizers namely, the National Population and Family Planning Commission of China, the China Contraceptive Supply and Development Centre and the China Center for Reproductive Health and Family Care. I wish you fruitful deliberations.

Thank you for your attention.