

GENERIC  
MANUFACTURERS  
*for* REPRODUCTIVE  
HEALTH

Uniting generic manufacturers.  
Improving lives.

**Plenary Session:**  
*Partners in Expanding  
Access to Quality Assured,  
Affordable Products*

RHSC Annual Meeting  
*11 October 2013*

# Current GEMS members

- **China Resources Zizhu Pharmaceutical Co., Ltd.**
- **Cipla Limited**
- **Famy Care, Ltd.**
- **HELM AG**
- **Naari AG**
- **PT. Tunggal Idaman Abdi**
- **Shanghai Dahua Pharmaceuticals Co., Ltd.**

# About the GEMS

An alliance of seven generic reproductive health pharmaceutical companies located throughout Asia, Africa and Europe

- Distribute products in more than 50 countries, spanning 6 continents
- Have the capacity to reach *millions more women* in high-need countries
- RHSC caucus
- Membership is *expected* to grow

# The Story of the GEMS

- **GEMS were formed around a group of key generic manufacturers asked to participate in the London Family Planning Summit in 2012**
- **Recognizing the value in working together and improving visibility and raising the image of the sector**
- **Group recognized the opportunities to do more through working together more formally**
- **Formal grouping established in Bangkok February 2013, based upon an agreed Terms of Reference outlining the basic functions of the group**
- **Functioning as a Caucus of the RHSC from mid 2013**

# About the GEMS

Members produce the quality, affordable products women need

- Full range of essential hormonal contraceptives and most of the key maternal health medicines
- Committed to providing reliable information to women and their families

# GEMS Commitment

Members currently or will meet the highest benchmark of quality assurance for their products

- At least one female contraceptive or reproductive health medicine pharmaceutical product that is listed on the World Health Organization (WHO) List of Essential Medicines
- Listed under an Expression of Interest issued by the WHO Prequalification of Medicines Programme

# Meet Our Members

# What Unites Us

## *Sweetie Jimmy, Cipla Limited*

- Meet PT Tunggal
- Why Cipla joined GEMS



# Our Shared Commitments

- Like all RHSC members, GEMS share a fundamental belief: Access to essential medicines is a human right
- Our alliance is positioned to maintain a secure supply of affordable, quality-assured RH products and medicines that women need *and deserve*
- We are committed to collaborating with partners in every sector to make our work more effective and efficient

# PT Tunggul (Indonesia)

- **Founded in 1970; 500+ employees**
- **State-of-the-art manufacturing facilities with 2 operating lines of hormone and non-hormone products**
- **Until 2005, pioneer of Depo Provera manufacturing in Indonesia under licence of UpJohn / Pharmacia / Pfizer company when they ceased marketing activities of the product locally**
- **Produce one-month and three-month injectable contraceptives, oral contraceptive and emergency contraceptive pill**
- **Reach women in 21 countries, including Uganda, Senegal, Rwanda, Madagascar, Burundi, Malawi, Ethiopia, Kenya and the Congo**
- **End of 2013, annual production capacity will double: 50M vials/year**

# PT Tunggal (Indonesia)



- **Midwives deliver high-quality injectable contraceptives and reliable, life-saving information to women**
  - >230 representatives countrywide to work directly with 38,000+ midwives across Indonesia's hundreds of islands

# Cipla (India)

- **Founded in 1935 by Dr. K.A.Hamied with the promise, “Never again will India be starved of essential drugs.”**
- **Manufacture 2000+ products in 65 therapeutic areas**
  - **Introduced HIV “triple cocktail therapy” at less than a ‘Dollar a Day’ in 2001**
  - **First Indian pharmaceutical company to be prequalified by WHO in 2001**
- **Operate 34 state-of-the-art manufacturing sites with approval from major regulatory authorities, including USFDA, WHO, MHRA, TGA, MCC**
- **Serve women and communities in 170+ countries**

# Cipla (India)

- **Produce a few select essential Reproductive Health, wish to expand the portfolio**
  - **Levonorgestrel /Ethinyl Estradiol, 150mcg/30mcg tablets (WHO qualified)**
  - **Misoprostol 200mcg tablets (ERP approved)**
  - **Emergency Contraceptive (ERP approved)**
- **Support women gaining the power to express and defend their right to control their lives by providing access to the right RH medicines**
- **Working with partners including UNFPA, PSI, VSI, and MSI to supply quality medicines to women in high-need regions**

# Our Commitment to Quality

## *Arun Joshi, Naari AG*

- Meet China Resources Zizhu Pharmaceutical Co., Ltd.
- Why Naari AG joined GEMS

# Our Commitment to Quality

- **GEMS members are committed to participating in WHO Prequalification of Medicines Programme**
  - Encourage harmonization of regulatory and ideally purchasing procedures
- **Achieving this benchmark quality standard bolsters the reputation of all GEMS members *and* instills confidence in consumers at every level**
  - From global procurers ... to women and families

# China Resources Zizhu Pharmaceutical Co., Ltd.

- Largest supplier of oral contraceptive to Chinese government
- Manufacture emergency contraceptives, combined oral contraceptives, misoprostol and a range of Active Pharmaceutical Ingredients (APIs)
- First RH manufacturer to receive WHO prequalification for the active ingredients in the most commonly-used combined oral contraceptives: *levonorgestrel* and *ethinylestradiol*
- Products reach communities in 21+ countries



# China Resources Zizhu Pharmaceutical Co., Ltd.

*“China must get products prequalified by WHO’s Prequalification Programme... since this company is the furthest forward... it could be a model for other companies to achieve the same level and apply for WHO prequalification.”*

*-Mme Cui Li, Vice-Minister, former National Population and Family Planning Commission (NPFPC)*

# Naari AG (Switzerland)

- **Founded in 2008 as an integrated female health company**
- **Produce APIs, and niche generic, diagnostic, and innovation products**
- **Reaching communities in 23 countries**
- **Driven by our brand mission: Empowering women**
- **Core principles: Quality and innovation**

# Naari AG

*“Quality Assurance must be the backbone of the pharmaceutical industry – both to maintain the trust of our customers and to ensure that women can make choices about their health with confidence.”*

*-- Dr. Manfred A. May, chairman, Naari AG*



# Our Commitment to Affordability and Choice

## *Ed Oosterman, HELM AG*

- Meet Famy Care, Ltd.
- Meet Shanghai Dahua Pharmaceuticals Co., Ltd.
- Why HELM joined GEMS

# Our Commitment to Affordability and Choice

- GEMS demonstrate that we can offer affordable RH products and medicines *without* compromising quality
- By manufacturing a range of ingredients and products – from daily to long-acting methods – we help women make the choice that's right for them.

# FamyCare

- **Founded in 1991 as India's first dedicated contraceptive manufacturer**
- **Products, including COC and IUD, reach communities in 70+ countries**
- **Recognize and overcoming the challenges to becoming a quality-assured manufacturer**
- **First generic company to have its COCs (Zinnia-Levo based and Daisy- Deso based) and EC (Revoke) prequalified under WHO Prequalification program**
- **Two production facilities have successfully passed WHO Geneva GMP Audit**

# FamyCare

*“Our desire to work in tandem with UNFPA and other partners in reproductive health community to expand access to quality contraceptives for millions of women in developing world motivates us each day.”*

*-- Mr. JP Taparia, chairman, Famy Care Ltd.*

# Shanghai Dahua Pharmaceuticals Co., Ltd.

- **Established in 1991**
- **Produces Sino-implant (II), a 2-rod contraceptive implant, that is available for approximately \$8 per unit**



# Shanghai Dahua Pharmaceuticals Co., Ltd.



# Helm AG (Germany)

- **Developing and marketing pharmaceutical products for 40+ years**
- **1500+ employees working in more than 30 countries**
- **Product line spans a range of therapeutic areas**
- **In women's health, collaborate with Fresenius Kabi (FK) to market Petogen**
  - 3-month injectable DMPA
  - Registered in 40+ countries; 250M vials sold to date
  - First LTA with UNFPA signed in 2006

# Helm AG (Germany)

*“We joined GEMS because we share a mutual goal with fellow members – and a vision for what women’s health and strong communities can look like globally. Helm is committed to doing what we can individually and with our partners to help meet the FP2020 goal, and expand access to critical reproductive health supplies.”*

*- Joerg Handke, executive director for Pharmaceuticals, Helm AG*

# Looking Ahead

- **Communicate to external audiences the importance of generic manufacturers in delivering quality products to the women who need them most**
- **Develop a common vision and shared materials to be used in external communications**
- **Pool resources to find solutions to common challenges**
- **Leverage public forums and platforms to bring visibility to the shared value and unique purpose of GEMS**
- **Identify opportunities for contributing to community goals**
- **Facilitate discussion and engagement with external audiences around generic industry perspectives and ideas**

# Questions & Answers