

Generic Manufacturers for Reproductive Health: Expanding Access to High-Quality Family Planning Supplies

Introduction

More than 200 million women and girls in developing countries who want to delay or avoid becoming pregnant do not have access to modern methods of contraception, resulting in an estimated 75 million unintended or mistimed pregnancies each year. This puts the lives of women and newborns at risk and undermines the safety and security of families, communities and entire nations. In contrast, when women and families have access to family planning resources, including access to safe, affordable contraceptives, their lives and communities are transformed.

The Generic Manufacturers for Reproductive Health (GEMS) Caucus has been formed under the auspices of the Reproductive Health Supplies Coalition (the Coalition) to help meet the needs of women and families who want to take control of their own reproductive health. GEMS is a select group of manufacturers committed to providing more women with affordable, safe and effective hormonal contraceptives and essential reproductive health medicines, enabling them to make their own family planning decisions with confidence. These companies offer a diverse portfolio of affordable and demonstrably quality-assured generic hormonal contraceptives for women and families. GEMS and the Coalition have joined forces on a focused initiative in a few high-need countries to provide more choices and ensure a consistent supply.

About Generic Manufacturers for Reproductive Health (GEMS)

- **GEMS is an alliance of seven generic reproductive health pharmaceutical companies located throughout Asia, Africa and Europe.** Members distribute products in more than 50 countries, spanning all seven continents, and have the capacity to reach millions more women in high-need countries with reproductive health products. Membership is anticipated to grow.
- **GEMS members produce the low-cost products women want.** GEMS members produce the full range of essential hormonal contraceptives and most of the key maternal health medicines, and are committed to providing reliable information to women and their families to ensure they are confident using their products.
- **GEMS members are committed to producing quality-assured products.** All member companies of GEMS manufacture at least one female contraceptive or reproductive health medicine pharmaceutical product that is listed on the World Health Organization (WHO) List of Essential Medicines and/or has been listed under an Expression of Interest issued by the WHO Prequalification of Medicines Programme.
- **GEMS members serve communities.** GEMS focuses on expanding access in low-resource nations and are committed to serving these regions long term. Collectively, through shared resources, networks and research, members will reach the women in the world's poorest communities who need these products most.

Advancing Family Planning 2020

The Family Planning 2020 (FP2020) initiative has set a goal of providing reproductive health supplies, information and services to an additional 120 million women by 2020. This goal cannot be reached without collaborating with generic manufacturers to distribute cost-effective and high-quality generic reproductive health medicines. GEMS members work to advance the efforts of FP2020, the Reproductive Health Supplies Coalition (RHSC) and the UN Commission on Life-Saving Commodities.

Prequalified Products

As of August 2013, three members of GEMS have met the World Health Organization (WHO) Prequalification of Medicines Programme standards – the most vigorous standards of product guidelines – for at least one of their products.

Company	Product and Background Information
China Resources Zizhu Pharmaceutical Co. Ltd. (China)	<p>Ethinylestradiol: Active pharmaceutical ingredient (June 2013)</p> <p>Levonorgestrel: Active pharmaceutical ingredient (August 2013) <i>Zizhu is the first reproductive health manufacturer to receive WHO prequalification for levonorgestrel and ethinylestradiol – the active ingredients in the most commonly used combined oral contraceptives. Levonorgestrel is also used in the manufacture of emergency contraceptives, implants and other oral pill types.</i></p>
Cipla Limited (India)	<p>Ethinylestradiol/Levonorgestrel tablets: combined oral contraceptive (December 2011)</p>
Famy Care, Ltd. (India)	<p>Ethinylestradiol/Levonorgestrel tablets: combined oral contraceptive (September 2011)</p> <p>Levonorgestrel tablets: emergency contraceptive pill (June 2013) <i>This is the first generic emergency contraceptive to receive WHO prequalification.</i></p> <p>Ethinylestradiol/Desogestrel tablets: combined oral contraceptive (August 2013) <i>This is the first generic prequalified for this formulation.</i></p>

Current Members

- **China Resources Zizhu Pharmaceutical Co. Ltd.**, based in China, has activities in pharmaceutical development, manufacturing and marketing in domestic and foreign markets. The company manufactures emergency contraceptives, combined oral contraceptives, misoprostol and a range of Active Pharmaceutical Ingredients (APIs).
- **Cipla Limited**, headquartered in India, is one of the world's largest generic pharmaceutical companies with a presence in over 170 countries. Cipla manufactures a wide range of products, including emergency, combined oral contraceptives and misoprostol.
- **Famy Care, Ltd.** is an India-based pharmaceutical company that focuses on family planning and reproductive health care products. Famy Care's product range includes oral contraceptives, emergency contraceptives, progesterone-only contraceptives, injectable contraceptives and intra uterine devices.
- **HELM AG**, headquartered in Germany, works in cooperation with international partners to develop active pharmaceutical ingredients, generic pharmaceuticals and medical products. HELM's main reproductive health product is the DMPA injectable contraceptive produced by Fresenius Kabi South Africa.
- **Naari AG** is a Swiss Pharmaceutical company focused on female health with an emphasis on hormones. Naari produces fermentation intermediates, Active Pharmaceutical Ingredients and Finished Dosage Forms supported by in house R&D in each domain. The company's current portfolio consists of hormonal contraceptives and APIs, as well as other niche generics.
- **PT. Tunggul Idaman Abdi**, based in Indonesia, produces injectable contraceptives in two product categories – a monthly injectable and a quarterly injectable/DMPA. Additionally, PT. Tunggul produces oral contraceptive tablets and emergency contraceptive pills.
- **Shanghai Dahua Pharmaceuticals Co., Ltd.** is a Chinese pharmaceutical company that produces the Sino-implant (II), a 2-rod contraceptive implant. Dahua's manufacturing facility was specifically designed and built to meet China's Good Manufacturing Practice (GMP) standards.

Additional Resources

For more information on the role of generic manufacturers, visit: www.conceptfoundation.org and www.rhsupplies.org. The Concept Foundation serves as the coordinating partner of GEMS. GEMS also functions as a Caucus within the Reproductive Health Supplies Coalition (RHSC), a global partnership of public, private and non-governmental organizations working together to ensure that all people can choose, access and use affordable, high-quality reproductive health products.