Sino-implant (II): Scale-up of a Low Cost, Highly Effective Contraceptive Implant

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Dahua has proven track record in China, Indonesia and a number of FP 2020 countries

- Established in 1991; current plant built in 2003
- Manufactured 2-rod implant since 1996
- NPFPC and CFDA authorized manufacturer of family planning products
- WHO GMP certified – 2013; re-certified – 2015
- Over 10 million units distributed globally to date
  - Initial focus on domestic market
  - Expanded to sub-Saharan Africa starting in 2009
- Member of RHSC’s Generic Manufacturers Caucus since its inception

Dahua is at the forefront of helping to increase access to affordable, high-quality implants.

- Partnered with FHI 360 since 2007 and CHAI since 2014 with support from the Bill & Melinda Gates Foundation

NPFPC: National Population and Family Planning Commission;
CFDA: China Food and Drug Administration
Dahua's product Sino-implant (II) has been registered in more than 25 countries

Registered under multiple trade names: Zarin, Femplant, Trust
Dahua has made significant investments towards achieving WHO Prequalification

**Investment in facilities, HR and contract services**
- Facility improvements
- Human resources
- Contract services

**GMP for pharmaceutical products**
- 2004 China GMP
  - re-inspected in 2009 and 2013
- 2013 WHO GMP
  - re-inspected 2015

**Existing and ongoing research**
- Review of 15 published studies demonstrated that Sino-implant (II) is highly effective:
  - Over 15,000 women in 4 randomized trials using Sino-implant (II) for up to 5 years
- Additional clinical data requested by WHO: new studies in the Dominican Republic and China ongoing

**Experience in the field:** Pre-/post-marketing studies in four countries* of over 2500 women support existing evidence that Sino-implant (II) is a safe and highly effective method

*Bangladesh, Kenya, Madagascar, and Pakistan
Dahua is committed to quality, price and market benefit, and aims to contribute to family planning programs worldwide by enhancing access to implants.

- Under review with WHO Prequalification group—additional clinical data requested; clinical trial in Dominican Republic ongoing
- Dahua conducts lot-release testing
- Independent lot-release testing conducted by Swiss-based company, SGS
- Independent quality evaluation conducted by FHI 360 since 2008

- Committed to affordable pricing to procurement agencies/donors for IAP markets
- Price ceilings negotiated with distributors by FHI 360

- Dahua entry increases competition within IAP markets, increases supply/access to LARCs
- Shorter lead times (4 to 6 weeks vs. more than 6 months for incumbents)
- Sustainability - Dahua is committed to the contraceptive implant segment
- Seasoned Global Market Manager is onboard to align with global market needs
Thank you!

Please contact us:

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