



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



SHANGHAI DAHUA
PHARMACEUTICALS CO.,LTD

- 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



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Dahua's product Sino-implant (II) has been registered in more than 25 countries

Registered under multiple trade names: Zarin, Femplant, Trust

Registered (n=26)

Bolivia [†]	Fiji [†]	Malawi [‡]	Senegal [†]
Burkina Faso [†]	Ghana [†]	Mali [†]	Sierra Leone [‡]
Cambodia [†]	Guatemala [¥]	Mongolia [†]	Uganda [‡]
Chile	Indonesia	Mozambique [‡]	Vietnam [†]
China	Jamaica	Nigeria [†]	Zambia [‡]
Dem Rep. of Congo [†]	Kenya [†]	Pakistan [†]	Zanzibar [‡]
Ethiopia ^{**}	Madagascar [†]		

Under review in over 10 additional countries

[†]Distributed by Marie Stopes International (MSI);

[‡] Distributed by Pharm Access Africa Ltd. (PAAL)

^{**} Distributed by DKT International

[¥] Distributed by APROFAM



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!

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