Using an Innovative Public-Private Partnership Model to Increase Access to Affordable Implants: Lessons Learned from the 5-Year Sino-implant (II) Initiative

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RHSC Membership Meeting
The Power of Partnerships
Dahua’s Global Business Platform with Current Partners

Manufacturer: Shanghai Dahua Pharmaceuticals Co., Ltd.

Global Coordinator: FHI 360

Distributors: MSI, PAAL, DKT, WCG, APROFAM, Progyne

Ministries of Health

Research Partners: MSI, EngenderHealth, Profamilia, SIPPR

End User

Procurement & Service Delivery groups

Export Agency: S2

GMP support: CIS & Novosciences

Quality Testing: FHI 360, SGS, Frontage, etc.
Overview: Sino-implant (II) Initiative

Shared Goal:
To increase access to highly effective, low-cost contraceptive implants in resource-constrained settings

Funding for the Sino-implant (II) initiative comes from the Bill & Melinda Gates Foundation
Ongoing product quality evaluation

- **Lot-Release Testing:** Every Sino-implant (II) lot tested by Dahua and independent, internationally recognized company (SGS)

- **Annual Evaluation:** API, metal impurities, sterilization residue, endotoxins, cytotoxicity, and package integrity

  2008-2012: Product met all international quality standards evaluated

  - **CpK Analysis** of three test parameters (dissolution, content and tube thickness) showed manufacturing process is stable & well-controlled
  - **Explant study** compared levonorgestrel in Sino-implant (II) rods removed after different periods of use to published data for Jadelle
WHO Prequalification Process Ongoing

• Application compiled and submitted to WHO by Dahua with technical assistance from FHI 360
• Application accepted for formal review in Oct 2010
• Process includes clinical dossier review, CMC dossier review, and GMP inspection
• Additional clinical data requested; studies in the Dominican Republic and China ongoing

WHO GMP Status Achieved Jan 2013
• Dahua determined to be operating in compliance with WHO Good Manufacturing Practices (GMP)
**Sino-implant (II) Registration Status**

**Sept 2013**

Registered under multiple trade names: Zarin, Femplant, Trust, Simplant

<table>
<thead>
<tr>
<th>Registered (n=25)</th>
<th>Under review in over 10 additional countries</th>
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<tr>
<td>Bolivia†</td>
<td>†Distributed by Marie Stopes International (MSI);</td>
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<td>Burkina Faso†</td>
<td>‡Distributed by Pharm Access Africa Ltd. (PAAL)</td>
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<td>Cambodia†</td>
<td>* Distributed by WomanCare Global</td>
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<tr>
<td>Chile*</td>
<td>** Distributed by DKT International</td>
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<td>China</td>
<td>¥ Distributed by APROFAM</td>
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Bolivia†, Burkina Faso†, Cambodia†, Chile*, China, Ethiopia**
Over 2,500 women enrolled across four studies: Bangladesh*, Kenya, Madagascar, and Pakistan
- Findings contribute to understanding of safety profile
- Desire from Ministries of Health for local data
- Research partners: EngenderHealth, MSI
- Funding from USAID and Gates Foundation

Studies completed with 12 months of follow-up data available. Key findings:
- Bangladesh & Madagascar: no pregnancies
- Kenya & Pakistan: pregnancy rate below 1%
- Insertion problems rare
- High satisfaction and continuation rates
- 1 Serious Adverse Event (SAE) reported that was possibly related to product: pregnancy in Kenya was ectopic
1 Million units distributed since 2009 in countries supported under project

According to the MSI Impact Calculator:
• 1.4 million unintended pregnancies averted
• Over 3000 maternal deaths averted
• Over 175,000 abortions averted

In addition, units translate into
• $10.5 million in commodity cost savings*

Savings mean that an additional 1.3 million units of Sino-implant (II) could have been purchased

*Impact is estimated based on distribution of 1,000,100 units. Savings are based on a price of US$8 per unit for Sino-implant (II), assuming the alternative would have been to purchase Jadelle. The average price for Jadelle was US$24 in 2009, US$22 in 2010, US$19 in 2011, US$18 in 2012, and $8.50 in 2013 according to information from the RHSC (www.rhsupplies.org).
Contraceptive Implant Prices 2009-2013: Changes Since Global Introduction of Sino-implant (II)

2009: Sino-implant (II) registered in Kenya under trade name Zarin; first registration outside of Asia

2011-2012: Under agreement with partners, Merck/MSD reduces price of Implanon to $18/unit, with retro-active reduction to $16.50 when volume thresholds reached in Dec 2012

2011-2012: Bayer HealthCare reduces price of Jadelle to $19/unit and then subsequently to $18/unit

2012-2013: Bayer HealthCare and Merck/MSD lower the prices of Jadelle and Implanon to US$8.50 per unit as part of volume guarantees

2009-2013: Over 1 million Sino-implant (II) units procured in countries under Gates initiative since 2009, resulting in over $10 million in commodity savings

Key Milestones

2009-2010 prices based on weighted averages from RH Interchange in Kenya, Ethiopia and Sierra Leone.
2011-2013 prices from RHSC and press releases issued by the manufacturers
Key Take-Aways and Lessons Learned (1 of 2)

✓ Three highly effective, low-cost contraceptive implants are now available
  o Dahua played direct role in this effort by being the first to market with a low-cost (<US$9/unit) contraceptive implant

✓ Support to Dahua from global coordinating entity facilitated dossier submissions, quality testing, and international introduction

✓ WHO Prequalification remains critical milestone
  o Process lengthy and costly; ongoing technical assistance will be required

✓ For all implant programs, ensuring high quality service provision, informed choice, and timely access to removals is essential
  o Will require commitment and involvement of multiple partners
Sustainability remains priority
- Southern manufacturers may not have capacity for all activities including product registrations and renewals. Partnerships important moving forward
- Size of total implant market unknown
- New landscape may require modified business model for Dahua

The UN Commission on Life-Saving Commodities for Women and Children recognizes that to strengthen quality and ensure accessibility, it is essential that “at least three manufacturers per commodity are manufacturing and marketing quality-certified and affordable products.”
Under New Contraceptive Technology Innovation Initiative, Strengthening and Building Strategic Partnerships is Priority

GOAL: To develop strategically important, long-acting contraceptives with a strong focus on global partnerships to ensure access to affordable and acceptable quality products for those most in need.
Thank you!

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