INCREASING ACCESS TO AFFORDABLE CONTRACEPTIVE IMPLANTS IN LATIN AMERICA: REGISTERING SINO-IMPLANT (II) IN BOLIVIA, GUATEMALA AND CHILE

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Sino-implant (II) Global Initiative and Platform

Regulatory Approach

Product Registrations

Registration and Introduction in Latin America
  - Bolivia
  - Guatemala
  - Chile

Key Lessons Learned & Impact
Overview of the Sino-implant (II) Initiative

Goal: Increase access to safe and affordable contraceptive implants in resource-constrained settings.

- Quality Assurance & Testing
- WHO Prequalification; Clinical Studies
- National Registrations
- Country Introduction & Post-marketing Studies

Funding for the Sino-implant (II) initiative comes from the Bill & Melinda Gates Foundation
Sino-implant (II) - Global Business Platform & Partners

End User

Procurement & Service Delivery groups

Export Agency

Distributors

Ministries of Health

Research Partners: MSI, EngenderHealth, Profamilia, SIPPR

Global Coordinator: FHI 360

GMP support: CIS & Novosciences

Quality Testing: FHI 360, SGS, Frontage, etc.

Manufacturer: Shanghai Dahua Pharmaceuticals Co., Ltd.
Regulatory Approach

WHO Prequalification
✓ Application accepted for review in 2010
✓ Development of CMC dossier for review
✓ 2 clinical studies in DR and China to supplement clinical data
✓ GMP inspection: Dahua achieved WHO GMP status in 2013

Global Registration
✓ Development of CTD Dossier for regulatory registrations
✓ Adapting dossier for country-level registrations; translations
✓ Preparing for multiple dossier regulatory reviews
✓ Preparing for numerous GMP inspections
Sino-implant (II) Registration
August 2014

Registered (n=26)
Malawi‡
Mali‡
Mongolia‡
Mozambique‡
Nepal*
Nigeria‡
Pakistan‡
Senegal‡
Sierra Leone‡
Uganda‡
Vietnam†
Zambia‡
Zanzibar‡

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

Under review in over 10 additional countries

†Distributed by Marie Stopes International (MSI);
‡Distributed by Pharm Access Africa Ltd. (PAAL)
* Distributed by WomanCare Global
** Distributed by DKT International
¥ Distributed by APROFAM
Sino-implant (II) Registration in Latin America
Product Registration in Bolivia

- FHI360 partnered with MSI Bolivia in 2010

- The implant was included in the National Family Planning Guidelines in 2011

- Femplant was registered in 2012

- Femplant was launched and introduced in 2013

- Since registration, 35,000 Femplant implants have been distributed
Product Registration in Guatemala

- FHI 360 partnered with APROFAM (IPPF affiliate) in 2010
- Zarin became available in 2011
- Registration was obtained in 2012
  - Additional information is required due to new regulations.
  - Full registration process is ongoing
- 25,000 implants distributed under the trade names of Zarin and Femplant
Product Registration in Chile

- WomanCare Global partnered with APROFA (IPPF affiliate)
- Simplant was registered and launched in 2013
- 10,000 Simplant implants were distributed to Chile the same year
- Inclusion in MoH guidelines and procurement list -required to enter public sector- has been initiated
Key Elements of Product Registration & Introduction - Latin America experience

- Key opinion leaders advocacy
- Stakeholder engagement
- Provider training
- Demand generation
- Market segmentation
- Outreach through community health workers and mobile health units
Impact – Latin America experience

• Expanded method mix, including implants, providing more choices to women

• Reduced economic and cultural barriers to satisfy unmet need for contraceptives

• Over 70,000 implants available, reaching low-income, hard-to-reach women
Overall Key Lessons Learned from Sino-implant (II) Initiative

- Sustainable and equitable access remains a priority
- Support to manufacturer from global coordinating entity facilitated dossier submissions, quality testing, and international introduction
- It is essential that all implant programs ensure high quality service provision, informed choice, and timely access to removals
- WHO Prequalification remains critical milestone
- Three highly effective, low-cost contraceptive implants are now available

2009:
- Sino-implant (II) is registered in Kenya. First time outside Asia

2011-2012:
- Merck/MSD reduces price of Implanon to $18

2011-2012:
- Bayer reduces price of Jadelle to $19 and then $18

2012-2013:
- Bayer and Merck/MSD lower the prices of Jadelle and Implanon to US$8.50 (volume guarantees)

2009-2013: 1 million Sino-implant (II) procured since 2009, resulting in over $10 million in commodity savings
IMPACT

1 Million implants procured

- 1.4 million unintended pregnancies averted
- Over 3000 maternal deaths averted
- Over 175,000 abortions averted

$10.5 million in commodity cost savings

Positive social return on investment
Thank you!

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