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

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OUTLINE

- ✓ Sino-implant (II) Global Initiative and Platform
- ✓ Regulatory Approach
- ✓ Product Registrations
- ✓ Registration and Introduction in Latin America
 - Bolivia
 - Guatemala
 - Chile
- ✓ Key Lessons Learned & Impact

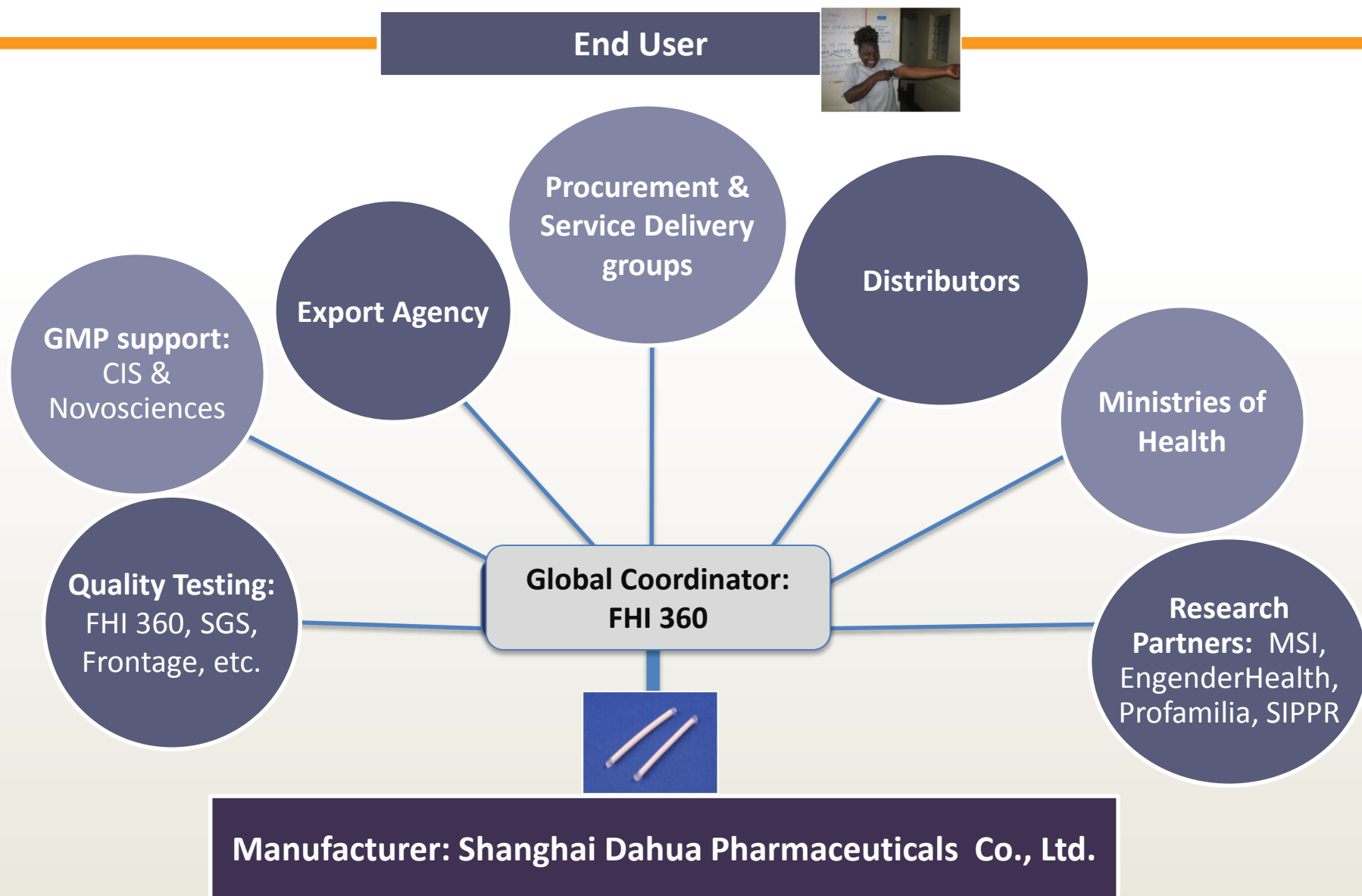
Overview of the Sino-implant (II) Initiative

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



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

Sino-implant (II) - Global Business Platform & Partners



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

Registered (n=26)

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

**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

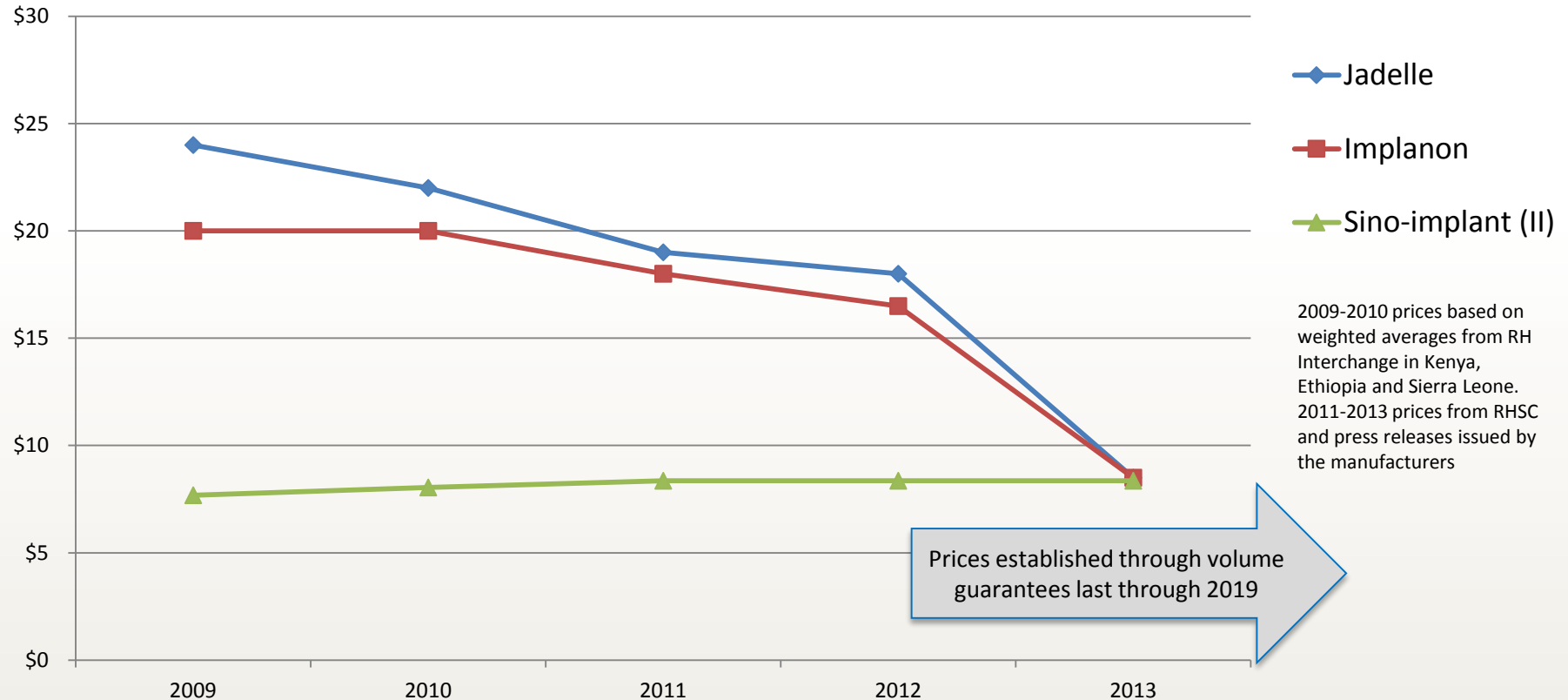
- Expanded method mix, including implants, providing more choices to women
- Reduced economic and cultural barriers to satisfy unmet need for contraceptives
- Over 70,000 implants available, reaching low-income, hard-to-reach women



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

Contraceptive Implant Prices 2009-2019: Changes Since Global Introduction of Sino-implant (II)



Key Milestones

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

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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