Sino-implant (II) Initiative

Background

Contraceptive implants are a highly effective, safe, long-acting contraceptive method shown to be acceptable to women worldwide. They are ideal for women with limited access to health care services, because they do not require regular resupply from a provider. Although implants are popular in developing countries, their high cost has been a barrier to uptake until recently. The Sino-implant (II) initiative is at the forefront of helping to reduce the cost of implants in resource-constrained settings.

Manufactured by Shanghai Dahua Pharmaceutical Co., Ltd. (Dahua), Sino-implant (II) is sold for about US$8 per unit under the global brand Levoplant as well as other trade names, including Femplant, Trust and Zarin. The product is composed of two thin rods, each containing 75 mg of levonorgestrel, the active hormonal ingredient. Sino-implant (II)/Levoplant is labeled for either three or four years of use, depending on the country registration.

FHI 360’s Role

With support from the Bill & Melinda Gates Foundation, FHI 360 provides technical assistance to facilitate the introduction of Sino-implant (II)/Levoplant in resource-constrained countries. Under this initiative, we:

- Act as an independent party to **assess the quality** of the product
- **Negotiate public-sector price-ceiling agreements** with distributors
- **Work with distributors to secure national regulatory approvals** of the product
- **Provide technical assistance** with World Health Organization (WHO) **prequalification**
- **Evaluate safety, effectiveness and acceptability**
- Provide technical assistance for Sino-implant (II)/Levoplant **introduction at the country level**.

Quality testing

The Dahua facility was determined to be in compliance with WHO Good Manufacturing Practices (GMP) in 2013 and was recertified in 2015. In addition to Dahua’s ongoing lot-release testing, FHI 360 performs independent, annual quality testing of the product. Results from the laboratory testing program, which began in 2008, show that Dahua demonstrates the ability to consistently produce a contraceptive implant that meets international quality standards ([http://www.fhi360.org/project/sino-implant-ii](http://www.fhi360.org/project/sino-implant-ii)).

Product registration and regulatory approvals

Sino-implant (II) has been registered by more than 20 drug regulatory authorities worldwide. FHI 360 negotiates price-ceiling agreements with distributors to ensure that the product remains affordable in the public and nonprofit sectors. Registration and procurement of the product at the country level is ongoing while WHO prequalification review is underway.
Research
Four randomized trials in China that followed more than 15,000 women using Sino-implant (II) found annual pregnancy rates to be below 1 percent. As part of the Gates-funded project and with funding from the U.S. Agency for International Development (USAID), FHI 360 and partners have since completed prospective cohort studies in Bangladesh, Kenya, Madagascar and Pakistan. More than 2,000 Sino-implant (II) users were followed for 12 months. Study results support existing evidence that Sino-implant (II) is a safe, highly effective method. In Bangladesh and Madagascar, no post-insertion pregnancies were reported, and in Kenya and Pakistan, the combined annual pregnancy rate was below 1 percent. An ongoing clinical trial in the Dominican Republic will supplement existing clinical evidence regarding the product’s effectiveness.

Product introduction and scale-up
FHI 360 provides technical assistance to governments and service delivery groups that want to introduce Sino-implant (II)/Levoplant. Information about training, clinical guidelines and other service delivery considerations can be found in the Knowledge for Health Implants Toolkit: http://k4health.org/toolkits/implants.

Strategic Impact
More than 1 million units of Sino-implant (II) have been procured so far in countries included in the initiative. Compared with the cost of procuring alternative implants during this time, these procurements represent a commodity savings of US$10.5 million for service delivery groups and donors. Sino-implant (II) units procured to date translate into more than 1.4 million unintended pregnancies, almost 3,000 maternal deaths and 175,000 abortions averted.

By increasing competition in the contraceptive implant market, the Sino-implant (II) initiative has helped expand access to affordable implants. In 2010, Jadelle, a two-rod implant made by Bayer HealthCare, was available at an average price of US$22 for international procurement groups; Implanon, a one-rod implant made by Merck/MSD, was available for US$20. Bayer lowered the price of Jadelle to US$8.50 per unit in low-income countries starting in January 2013 as part of an agreement brokered by a coalition of international partners. A year after reducing the price of Implanon to US$16.50 in 2012, Merck/MSD announced another 50 percent unit price reduction to US$8.50 in developing countries. Jadelle and Implanon/Nexplanon are now available at a price comparable to that of Sino-implant (II)/Levoplant.

Contact Us
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