Sayana® Press Injectable Contraceptive: Planning for Introduction

December 2012

Formerly known as depo-subQ provera 104™ in the Uniject® injection system, Sayana Press is a registered trademark of Pfizer, Inc.
Product information and evidence
What is Uniject™?

- **Developed by PATH**
- **Made by BD (Becton, Dickinson and Company)**

**Used with:**
- Hepatitis B vaccine
- Oxytocin
- Tetanus toxoid
- Cyclofem

**In these countries:**
- Bolivia
- Brazil
- China
- Egypt
- Guatemala
- India
- Indonesia
- Vietnam

**Single dose**
**Prefilled and sterile**
**Non-reusable**
New technology: Sayana Press

Current standard
DMPA IM 150

- 150 mg DMPA.
- Delivered every 3 months.
- Glass vial with syringe.
- Intramuscular injection.
- 1” needle.
- Site: deep muscle tissue.
- 99% contraceptive efficacy.
- Depo-Provera® brand: Pfizer, Inc.
- Generic equivalents: various manufacturers.

New technology
Sayana Press

- 104 mg DMPA.
- Delivered every 3 months.
- Prefilled in Uniject.
- Subcutaneous injection.
- 3/8” needle.
- Site: subcutaneous fat.
- Equivalent contraceptive efficacy, safety, and side effects.
- Pfizer Inc. product: patent until 2020.
What are the benefits of Sayana Press?

**Features**
- Single, exact dose, all-in-one presentation
- Subcutaneous injection

**Benefits**
- Reduced weight and volume
- Non-reusable
- Simplified injection procedures
- Easier to transport and store, less waste to dispose
- Improved injection safety
- Simpler, shorter training
- Eliminates mismatch of syringe/vial supplies

**Value**
- Increased acceptability and use by lower-level health care workers
- Uniquely suited to home and self-injection
Overview of pilot introduction initiative
Partnership for introduction of Sayana Press

London Summit on Family Planning, July 2012

- Family Planning Summit’s goal is to ensure family planning services for additional 120 million women and girls in the world’s poorest countries by 2020.
- Pilot introduction of Sayana Press announced at the Family Planning Summit.¹
- Goal to provide modern contraception to an additional three million women with Sayana Press.
- Current funding partners: DFID, UNFPA, USAID, Bill & Melinda Gates Foundation.

Pilot introduction of Sayana Press

- Deliver 12 million units in 5-7 countries in Sub-Saharan Africa and South Asia from 2013 through 2016.
- Strong evaluation component to assess the ability to:
  - Generate new users.
  - Improve contraceptive continuation.
  - Reduce service delivery costs.
- Evaluation results will be used by donors and governments to inform decisions about use of Sayana Press.
- Pilot introduction countries:
  - Country identification driven by evaluation objectives, donor priorities, and country government agreement.
  - Possible countries include: Burkina Faso, Niger, Senegal, Kenya, Uganda, Pakistan and Bangladesh.
Country stakeholder considerations

- Understanding of information needed by governments and donors to make future procurement decisions.
- Government agreement to pilot introduction.
- Product registered in country before pilot introductions begin (or waivers if delay in registration).
- Country partners implement service delivery:
  - Government programs, including CBD and CHW
  - NGO programs
  - Social marketing
  - Commercial sector
- Identify pilot introduction sites with unmet need for injectables:
  - Locations where delivery using Sayana Press could expand access for women and/or reduce costs.
Back-up
**Current Sayana Press studies**

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<thead>
<tr>
<th>Current studies</th>
<th>What we will learn</th>
<th>Country context</th>
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</thead>
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<tr>
<td>Acceptability studies</td>
<td>Compared to DMPA-IM, how acceptable is Sayana Press to users?</td>
<td>Uganda, Senegal</td>
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<tr>
<td></td>
<td>Compared to DMPA-IM, how acceptable is Sayana Press to CBD and clinic providers?</td>
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<td>How well does the training prepare providers to administer Sayana Press?</td>
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<td>Operational assessments</td>
<td>Compared to DMPA-IM, what are the logistical pros and cons of Sayana Press for clinics and CBD programs?</td>
<td>Uganda, Senegal</td>
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<td>What does it cost and how long does it take to train providers?</td>
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### Sayana Press regulatory pathway

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<td>Pfizer received provisional MHRA (European) approval.</td>
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<td>Pfizer completes final MHRA requirements:</td>
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<td>• Online training materials produced and approved.</td>
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<td>• Certificate of Pharmaceutical Product with marketing statement from</td>
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<td>Belgian regulatory authorities.</td>
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<td>• Final MHRA approval in place.</td>
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<td>Pfizer prepares/submits country registration dossiers.</td>
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<td>Cascade of country regulatory approvals.</td>
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January 2013