Sayana® Press: Pilot introduction and evaluation

BACKGROUND
Injectable contraceptives are among the world’s most popular methods for preventing pregnancy, offering women safe and effective protection, convenience, and privacy. Sayana® Press, a new formulation and presentation of Depo-Provera®, offers the potential to improve contraceptive access for women worldwide.

Sayana Press is a three-month, progestin-only injectable contraceptive product packaged in the Uniject™ injection system, a small, prefilled, autodisable device. It contains 104 mg of depot medroxyprogesterone acetate (DMPA) and is administered via subcutaneous injection.

Sayana Press has the potential to improve injectable contraceptive access by increasing the ease, safety, and reach of non-clinic delivery through means such as community-based distribution and social marketing. While Sayana Press currently is not labeled for self-injection, in the future it may offer women more control over their use of contraception through home or self-injection.

COMMITMENT TO INCREASING ACCESS
In July 2012, the London Summit on Family Planning launched a new coordinated effort to ensure that voluntary family planning services reach an additional 120 million women and girls in the world’s poorest countries by 2020. More than 150 leaders from donor and developing countries, international agencies, civil society, foundations, and the private sector pledged their support to improving access to family planning information, services, and supplies.

As part of this event, public and private partners announced plans to reach women in sub-Saharan Africa and South Asia between 2013 and 2016 with up to 12 million doses of Sayana Press. The Sayana Press pilot introduction partnership includes the Bill & Melinda Gates Foundation, the US Agency for International Development (USAID), the United Kingdom’s Department for International Development (DFID), the United Nations Population Fund (UNFPA), Pfizer Inc., and PATH.

PROJECT OVERVIEW
As a result of the Summit on Family Planning commitment, PATH and partners are supporting pilot introduction of Sayana Press in Bangladesh, Burkina Faso, Niger, Senegal, and Uganda. Country introduction activities are expected to begin in the first quarter of 2014. Plans are under way to make Sayana Press available through normal delivery channels in the public, NGO and commercial sectors. The project’s evaluation component will generate information that builds upon the evidence base for decision-making about whether and how countries can include Sayana Press in family planning programs in the future. The pilot introduction units of Sayana Press are being procured by donors involved in the Summit on Family Planning.

This pilot introduction will complement small-scale Sayana Press acceptability studies and operational
assessments completed in Senegal and Uganda in 2013. These studies generated information concerning the acceptability of Sayana Press among clients and a range of health care providers, including community-based workers.

**PROJECT OBJECTIVES**

The pilot introduction partners share the goal of including Sayana Press in family planning programs to help address the unmet need for contraception. Sayana Press is expected to increase contraceptive access and reach new users rather than replace the intramuscular presentation of DMPA, which is being used successfully in a number of delivery settings.

The project will evaluate the product's impact on expanding access to injectables for new users, improving contraceptive continuation rates, and reducing service-delivery costs. The evidence generated will enable governments, nongovernmental organizations, donors, and procurers to make informed purchasing and programming decisions regarding inclusion of Sayana Press in the family planning method mix.

**PROJECT COUNTRIES AND DELIVERY CHANNELS**

In each participating country, PATH is working closely with the ministry of health and key partners including UNFPA, USAID, nongovernmental organization service delivery partners, and social marketing groups to identify appropriate family planning product delivery channels for Sayana Press pilot introduction. The product will be introduced through several non-clinic family planning delivery channels, such as community-based distribution, outreach, and social marketing. Whether or not country partners continue to provide Sayana Press after the pilot introduction phase, PATH will work with partners to help ensure that systems are in place to give women access to other injectable products for continuity of service.

**PRODUCT REGISTRATION**

Sayana Press has been approved by regulatory authorities in the European Union. Country-level regulatory approvals are in place in three of the five pilot introduction countries, with all five expected to be approved in the first quarter of 2014.

*Sayana Press was approved in the European Union via procedure number UK/H/0960/002UK/H/0960/002. The UK was the Reference Member State. A Public Assessment Report is available at the Heads of Medicines Agency website and the MHRA webpage: www.mhra.gov.uk/home/groups/par/documents/websiteresources/con126147.pdf