Frequently Asked Questions about the Dual Prevention Pill

March 2025

Product Overview

What is the Dual Prevention Pill (DPP)?

The Dual Prevention Pill (DPP) is a single, co-formulated, daily pill containing oral pre-exposure prophylaxis (PrEP) and combined oral contraception (COC) that prevents both HIV and pregnancy. The DPP will add to the contraceptive and HIV prevention toolbox and be the first multi-purpose prevention technology (MPT) to go to market since internal and external condoms. The DPP will provide an important option for women, ideally increase uptake of HIV prevention, and could also provide evidence that governments and donors need to spur investment in other MPTs, such as vaginal rings, injectables and implants.

What is the composition of the DPP and who developed it?

Mylan (A Viatris Company) a generic manufacturer of antiretroviral drugs (ARVs) and hormonal contraceptives, is developed the first-generation DPP as a bilayer tablet containing tenofovir disoproxil fumarate (300mg) and emtricitabine (200mg) (TDF/FTC), and levonorgestrel (0.15mg) and ethinyl estradiol (0.03mg) (LNG/EE). TDF/FTC is the only oral ARV indicated for the prevention of HIV in cisgender women and LNG/EE is the most common COC in low- and middle-income countries.

The DPP will be packaged in a blister pack, similar to COC packaging (Figure 1), rather than in the pill bottles typically used for oral PrEP. This design helps address a key barrier to discreet use, as pill bottles can produce a rattling sound that may compromise privacy. Packs will contain a total of 28 tablets – 21 combination PrEP/COC tablets and 7 PrEP-only tablets (corresponding to the placebo/iron pill days of a COC regimen, which will need to be taken to maintain protection against HIV during the last week of the month/cycle). The first 21 tablets will be pink and the last 7 will be yellow to differentiate the DPP from the blue color of its generics used for treatment and as PrEP (Figure 2). It takes 7 consecutive days for the DPP to reach protective levels against pregnancy and HIV.

Figure 1: DPP packaging

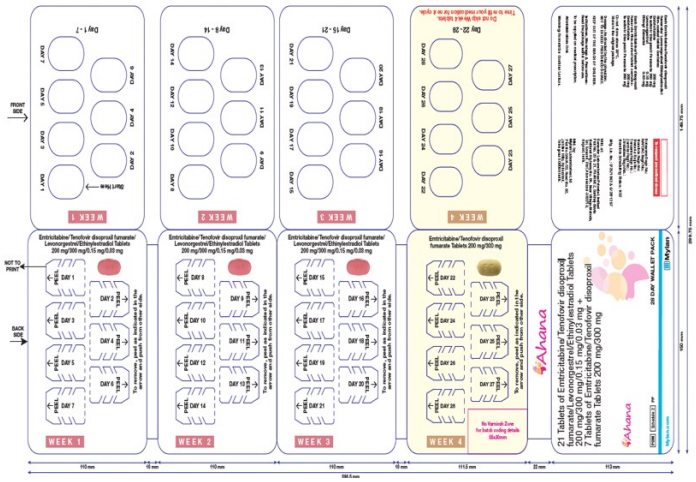


Figure 2: DPP tablet colors

The Population Council's Center for Biomedical Research, a non-profit product development partnership, is developing a second-generation DPP, a co-formulation containing LNG/EE and tenofovir alafenamide/emtricitabine (F/TAF). The timeline for development of an F/TAF-based DPP is longer term because F/TAF (Descovy®) is not currently approved for cisgender women. Gilead has completed safety and efficacy trials of F/TAF in women and intends to request approval to expand use to include cisgender women.

How effective is the DPP in preventing pregnancy and HIV?

In 2024, the DPP successfully demonstrated bioequivalence, which ensures the active ingredients in the DPP pill are absorbed in the blood at the same rate as when its oral PrEP and COC components are taken separately. This means that the DPP product is considered to have the same efficacy and safety as separate oral PrEP and COC products.

Can the DPP prevent other sexually transmitted infections (STIs)?

No, the DPP does not prevent other STIs. It only protects against HIV. As with other forms of PrEP, to reduce the risk of acquiring other STIs, it is recommended to use additional prevention methods, such as condoms.

What opportunities does the DPP offer?	What are the potential risks to successful DPP introduction?
Simplified Research: The DPP combines two previously approved products, bypassing the need for a separate, large clinical trial to demonstrate safety and efficacy.	**Providers may be reluctant to offer the DPP because it feels like an added burden,** requiring additional training for the delivery of oral PrEP and adaptation of counseling approaches for a combined product. The DPP may also bring out biases that some providers hold, such as the perception it could encourage younger women to have sex.
Potential for Accelerated Product Introduction: DPP introduction builds on the foundations and lessons learned from contraceptives, oral PrEP and ongoing planning for next-generation products. In turn, future MPTs are likely to build on the regulatory, delivery and financing lessons generated from DPP introduction and scale-up. Strengthening HIV and family planning (FP) linkages and platforms for the DPP could ready health systems for other MPTs.	**With a single manufacturer for the DPP initially,** supply security and affordability may be an initial concern of governments and could deter procurement in favor of separate oral PrEP and COC. Market shaping should be explored to expand the number of manufacturers in line with demand and to improve the value-for-money in commodity procurement.
Potential Catalyst for HIV/Sexual and Reproductive Health (SRH) Integration: The DPP may foster integration of HIV prevention and SRH services and systems, needed to deliver a dual-indication product. Evidence indicates FP and oral PrEP have higher uptake when they are delivered together.	**Bridging historically siloed HIV and FP programs to deliver an MPT is challenging,** given separate HIV/FP budgets and supply chains. Introducing a product with HIV prevention to both the current HIV prevention and contraceptive method mix will require more intentional coordination. Growing commitment, momentum and mechanisms for integrating HIV prevention and SRH services can improve coordination across departments to facilitate DPP introduction.

What opportunities does the DPP offer?	What are the potential risks to successful DPP introduction?
Potentially Broader Donor Base: As donor resources for HIV prevention and FP are increasingly limited, the DPP may attract a wider range of funders interested in creative, integrated HIV and SRH interventions to support introduction and scale. This may provide a buffer against vulnerabilities to US funding shifts and cancellations, which could impact both HIV prevention and FP.	**Governments and funders may face trade-offs** as they plan to invest in rolling out new prevention products, like the dapivirine vaginal ring (DVR), injectable cabotegravir (CAB) and injectable lenacapavir (LEN), which could impact resources available for the DPP.
Potential to Address Challenges with other Prevention Products: One pill instead of two makes the DPP more convenient – possibly motivating women to sustain adherence and effective use – and it expands choice for women who want to reduce their risk of both unintended pregnancy and HIV. There is a higher acceptance of contraceptives among women while oral PrEP continues to face stigma and acceptability issues. Combining products offers the chance to reach users with a product they feel meets their overall HIV prevention and SRH needs. End-user perspectives on the DPP can also influence the development of future MPTs.	**The DPP may face risks related to uptake and effective use,** as both oral contraceptive pills and oral PrEP have high rates of early discontinuation, and awareness of oral PrEP is low in many settings. In some channels, injectable contraception is the most common FP method, which may limit demand for the DPP as an oral pill.

Potential Users of the DPP

Who is likely to use the DPP?

The DPP will likely be indicated for all women of reproductive age unless they have contraindications for COC or PrEP use. Country governments will decide on priority populations for introduction based on multiple considerations, including the current contraceptive landscape, populations at highest risk for HIV, and populations that prefer oral formulations, among other factors. The DPP would likely be best suited for a select population but would not replace oral PrEP.

Will the size of the DPP be a barrier to uptake and use?

An oral contraceptive pill (OCP) is much smaller than oral PrEP. The first-generation DPP will be a larger pill for COC users due to the PrEP component, but the size is about the same as oral PrEP (TDF/FTC). A DPP with F/TAF could be about 1/3 the size of the TDF-based DPP and could expand the market for women who find the TDF-based tablet too large.

What are the potential side effects of the DPP?

The World Health Organization (WHO) and the US Centers for Disease Control and Prevention have affirmed that there are no drug-drug interactions between oral PrEP and COC and that oral PrEP and COC can be "safely taken together." Oral PrEP and COC share similar common side effects, such as headache and nausea, while rarer side effects for each differ. Evidence on PrEP and COC demonstrates that concerns about side effects are major drivers of discontinuation for both products.[1, 2, 3, 4] As such, clear provider messaging on side effects and side effect management will be crucial for supporting effective use.

What happens in cases of missed doses, and what steps should be taken after to maintain protection?

If a DPP pill is missed, it should be taken as soon as possible, even if that means taking two pills in one day. However, no more than two pills should be taken in a single day. Missing pills can increase the risk of pregnancy and HIV acquisition, so taking the pill at the same time each day is recommended for consistent protection.

Will women on longer-acting contraception, including injectable contraception, be able to switch the DPP?

Approaches for offering the DPP to end users will ultimately be determined by national guidelines, informed by WHO recommendations. Initial consultations suggest that the DPP may be offered to women as one option among other FP and HIV prevention products to support expanded choice. In line with standards from HIV prevention and FP programs, it will be critical to ensure that women are be provided with sufficient information about trade-offs between various methods to be able to make an informed choice on the product that is right for them. No single product will work for all women. If a woman is no longer satisfied with her current method or is interested in switching to the DPP, she should have the option to do so.

Would the DPP be recommended for breastfeeding women?

The first-generation DPP contains both estrogen and progesterone and, therefore, is not recommended for women who are breastfeeding. However, given the heightened risk of HIV in the post-partum period, developers are considering a formulation that would combine PrEP with progesterone-only pills (POPs) that women could use post-partum and during breastfeeding.

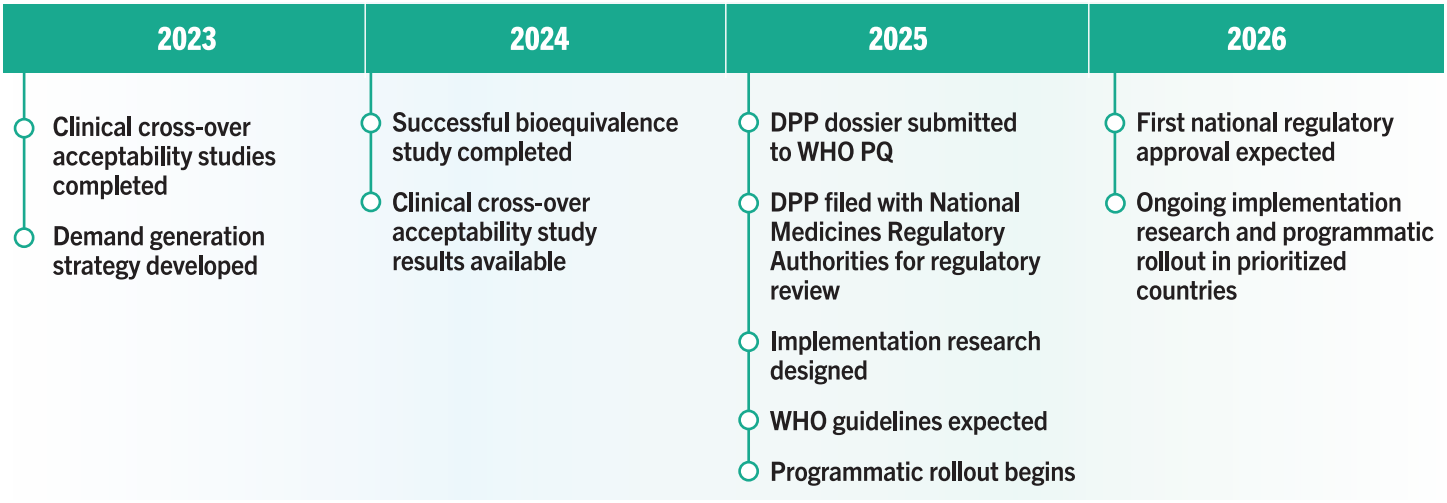
Market Preparation and Introduction

Regulatory Process and Evidence Generation

What is the planned regulatory pathway and when might the DPP be available?

With successful bioequivalence results, Viatris submitted the DPP dossier to WHO Pre-qualification (PQ) in January 2025. The WHO has indicated that it plans to issue guidelines for the DPP in 2025. In parallel with WHO PQ review, Viatris will seek registration with national regulatory authorities in countries with a high HIV burden/ incidence and moderate-to-high oral contraceptive use.

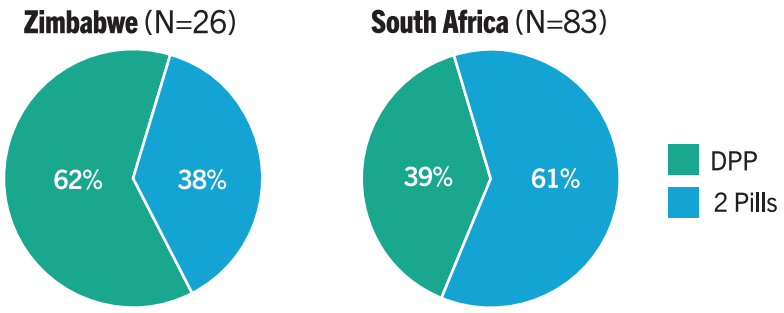
Figure 3: Key milestones for DPP development



What studies have been conducted to generate evidence on the DPP?

Clinical cross-over acceptability studies were conducted to compare adherence, acceptability, and preference using an over-encapsulated DPP compared to two separate PrEP and COC tablets taken separately. Participants consisted of 96 women aged 16-40 in South Africa and 30 women aged 16-24 in Zimbabwe who were current COC users, but most had never used PrEP before. Participants in both countries found the DPP acceptable. In Zimbabwe, the DPP was preferred, while in South Africa, two separate pills were favored (Figure 4). Expanding prevention options to include the DPP could potentially increase demand for prevention products overall. Key considerations for DPP uptake and use include the pill size and packaging of the DPP, as well as the need for counseling and support to ensure effective use. DPP acceptability studies also collected data about women's experiences with side effects. Most participants in Zimbabwe reported no side effects from the DPP, while some in South Africa experienced side effects that bothered them.

Figure 4: Preference for the DPP vs 2-pill regimen in Zimbabwe and South Africa acceptability studies



Human-centered design (HCD) research was conducted with end users, male romantic partners and healthcare providers in Kenya, South Africa and Zimbabwe in order to better understand women's motivators, barriers and behaviors and how people who are significant in their lives may influence their beliefs or decisions around uptake and use of the DPP. This research helped identify the DPP user journey and shape DPP demand generation and marketing approaches (Figure 5).

Figure 5: DPP prototype campaign concepts based on HCD research findings

Are there any studies that will be conducted to generate more evidence for DPP?

HIV Prevention Trials Network (HPTN) 104 will be a multi-site study to evaluate adherence to Viatris's co-formulated DPP compared to PrEP and COC taken separately among 300 women ages 16-39 in 3-4 sites in sub-Saharan Africa. The study is expected to begin in 2025, and findings will help to inform introduction and counseling strategies for the first-generation DPP once available.

Implementation research will be designed in collaboration with governments and partners and initially be conducted in Kenya, South Africa, Zambia and Zimbabwe, across urban and rural settings and among different segments of women to evaluate acceptability, impact, cost-effectiveness and feasibility. Innovative, sustainable, and scalable delivery platforms will be prioritized.

How will communities be engaged in the development and rollout of the DPP?

Since 2020, an advisory group comprised of country and regional civil society advocates, as well as end users, including young women, has regularly engaged with DPP product developers and researchers to input into product development, research, and introduction plans. They have provided input on the HPTN 104 study design, DPP branding and have represented the advisory group at conferences and meetings. They are now implementing projects focused on raising awareness of the DPP and engaging stakeholders in Uganda, Malawi, South Africa, Zambia, and Zimbabwe, among other activities.

Early Introduction

Which regions are being considered for the introduction of the DPP?

Current introduction planning efforts are focused on Kenya, South Africa, Zambia and Zimbabwe, where there is higher HIV burden, moderate-to-high OC use, unmet need for FP, and enabling environments. In addition, Viatris plans to file for regulatory approval with several other countries in sub-Saharan Africa, as well as in other low- and middle-income countries in Asia, Latin America and the Caribbean, and Europe with higher OC use and HIV prevalence.

With high LARC use among women in sub-Saharan Africa, why are product developers introducing the DPP as a daily oral pill?

Oral contraceptive use in the region has been generally stable over the years, and in some places has increased,[5] indicating there is a segment of women who may prefer the flexibility of short-acting contraceptives that are immediately reversible and user-controlled. Zimbabwe, for example, has high OC use and has scaled up oral PrEP, showing potential for successful DPP introduction.

Why might it make sense to introduce the DPP in South Africa, even though the use of OCPs is not common?

Although the use of OCPs is not common in South Africa compared to other modern contraceptive methods (e.g., injections and implants), a market sizing study by the Population Council estimates that South Africa has the highest number of potential DPP users within the region among the countries evaluated.[6] It found that given South Africa's large population size, the number of HIV-negative OC users who could potentially convert to the DPP is high. South Africa also has a large number of estimated HIV-negative condom users and women with an unmet need for FP. Moreover, South Africa is rapidly scaling up oral PrEP,[7] which could tap into a new population of oral PrEP users who are also interested in pregnancy prevention.

How will country-level leadership be engaged to lead introduction planning?

Country entry engagements in Kenya, South Africa, Zambia, and Zimbabwe are in progress with HIV prevention and SRH stakeholders to identify priority needs and opportunities for the introduction and integration of the DPP, particularly in terms of funding and policies for delivery. Focal areas for assessment include (1) Stakeholder Engagement & Adoption, (2) Planning & Budgeting, (3) Supply Chain Management, (4) Delivery Platforms, (5) Uptake and Effective Use, and (6) Monitoring, Evaluation and Learning. As part of this engagement, DPP introduction roadmaps are being developed in collaboration with Ministries of Health. Existing frameworks such as MOSAIC's Value Chain Situation Analyses and the CHAI HIV New Production Introduction Toolkit provide tools and resources to help evaluate, plan and execute introduction.

What are considerations for DPP introduction alongside other PrEP modalities?

While the DPP is likely to be introduced in parallel with the DVR, CAB, and LEN, these new products do not provide contraceptive benefits – a concern that is top-of-mind for many women. The DPP, therefore, may offer an additional benefit to these other PrEP products and may appeal to certain women at certain times in their lives. While the DPP contains a shorter-acting oral PrEP pill – which might be a barrier for some users compared to the DVR or injectable PrEP – this combination offers the earliest opportunity to assess if uptake and effective use of biomedical HIV prevention increases with an MPT formulation.

Service Delivery

What service delivery channels are most appropriate for the DPP?

While a variety of service delivery channels and health worker cadres are trained to deliver OCPs, because the DPP contains oral PrEP, it will need to be delivered in settings where trained providers are authorized to prescribe and monitor oral PrEP. Public-sector FP, HIV, and primary healthcare clinics are potential channels for early DPP introduction. Expansion of differentiated delivery models for oral PrEP, including mobile and community-based models, show potential for diversified channels and cadres for the DPP in the future.

An analysis found that in the private sector, pharmacies and networked private providers show high potential for the DPP in Kenya, South Africa and Zimbabwe. E-pharmacies, telehealth and telemedicine models that offer HIV prevention products are growing in Kenya and South Africa, which could increase access to the DPP, particularly for adolescent girls and young women, who may prefer to seek services outside of health facilities.

How will delivery of the DPP balance HIV testing and prescribing requirements with the more decentralized approach to OCP delivery?

In many countries, OCPs are available over the counter and delivered by diverse cadres in a variety of delivery settings, including through pharmacy and community-based channels. By contrast, current oral PrEP policies typically require a prescription, initiation by a trained provider and HIV testing every three months. Since the DPP contains oral PrEP, DPP users will likely need to follow oral PrEP testing and prescribing requirements. Recent expansion of differentiated and self-care approaches to oral PrEP delivery, including multi-month dispensing and HIV self-testing, as well as delivery of oral PrEP in FP clinics and private sector channels, show an encouraging move towards aligning oral PrEP and OCP delivery. Preparing health systems for the DPP could open up additional channels for oral PrEP, in line with where women prefer to access services, and accelerate PrEP/FP integration.

Cost and Funding

Will the DPP be affordable?

The cost of the DPP has not yet been confirmed. However, modeling conducted in South Africa, Zimbabwe and Kenya indicates the DPP has the potential to be cost-effective and cost-saving in populations at substantial HIV risk, and it is likely to be a cost-effective alternative to oral PrEP among users in need of contraception. Product developers will aim to ensure that the DPP costs as close to oral PrEP and COC separately as possible, recognizing that these products tend to be highly subsidized. Donors and governments can look to subsidize DPP costs in order to make it available for free or very low cost to users. As the DPP scales up, the price is likely to decline.

What are considerations for manufacturing the DPP?

TDF/FTC is available at scale volumes, but the DPP is different because it will contain hormones for contraception. For this reason, the DPP must be manufactured at hormonal contraceptive facilities. Viatris will be the initial manufacturer of the DPP with sufficient manufacturing capacity to supply 250,000+ women per year with the DPP. Viatris could potentially increase DPP volumes further by exploring collaborations with additional suppliers to develop the DPP.

Who is funding the development of the DPP?

DPP development and market introduction planning efforts to date have been supported by the Children's Investment Fund Foundation (CIFF), Gates Foundation, US Agency for International Development (USAID), National Institute of Mental Health, Catalyst Global, and the HPTN.

Why should funders consider investing in the DPP?

The DPP will be rolled out sooner than any other MPT, presenting a learning opportunity that can inform all MPTs in the pipeline that will be introduced in the future. Even as other products are approved (e.g., LEN), there is likely a market for the DPP as a short-acting prevention product. With HIV incidence alarmingly high among women and girls, coupled with a critical unmet need for contraceptives, the DPP presents an opportunity to address these challenges by offering an additional prevention choice. As a combined product, it also paves the way for the integration of HIV and SRH services, a solution urgently needed in many settings. In an increasingly resource-constrained landscape, where PEPFAR and USAID will play more limited roles, the DPP would be a valuable investment to enhance accessibility and improve health systems efficiencies.

For inquiries, updates and resources on the development of the DPP, please visit https://www.prepwatch.org/products/dual-prevention-pill/.

Acknowledgments

This document was developed in partnership with HIV prevention and SRH stakeholders.

About the DPP Consortium

The DPP Consortium is coalition of organizations, including AVAC, CHAI, Population Council, and Viatris, that are implementing market preparation and introduction activities for the DPP. These efforts are currently supported by CIFF, the Gates Foundation, and the HPTN.

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