# Private sector delivery opportunities for the Dual Prevention Pill (DPP):

## Lessons from FP for the introduction of multi-purpose prevention technologies (MPTs)

Mitchell Warren and Kate Segal, AVAC

OCTOBER 12, 2022

# Objectives

With the Dual Prevention Pill (DPP) likely to be the first MPT available since male and female condoms, this webinar aims to:

- **Validate recommendations** for private sector delivery of the DPP with FP/SRH stakeholders
- **Surface best practices and potential barriers from the FP field** for engaging the private sector to deliver new products, highlighting unique challenges and opportunities for MPTs
- **Identify advocacy priorities and key stakeholders** to foster support for private sector delivery of HIV prevention

# Agenda

| Title | Presenter | Time |
|---|---|---|
| **Welcome and objectives** | Mitchell Warren, AVAC | 5 min |
| **What FP stakeholders want to know about the DPP:** Questions/issues from the April 2022 DPP consultation | Kate Segal, AVAC | 5 min |
| **Opportunities for the DPP in the private sector:** Findings from Kenya, South Africa and Zimbabwe | Rob Wood, Halcyon<br>Karen Webb, OPHID | 20 min PPT<br>**10 min Q&A** |
| **Lessons from country level:** Best practices for FP introduction in the private sector | Sylvia Wamuhu, PS Kenya | 10 min |
| **Innovations in service delivery:** The future of direct-to-consumer care and implications for product introduction | Chris Purdy, DKT International and carafem | 10 min |
| **Panel/Q&A** | *Panelists:* All presenters,<br>Natasha Salifyanji Kaoma, Copper Rose Zambia and FP2030 Youth Focal Point,<br>Ruth Akulu, ICWEA and AVAC Fellow<br>*Facilitators:* Mitchell Warren, Kate Segal | **30 min Q&A** |

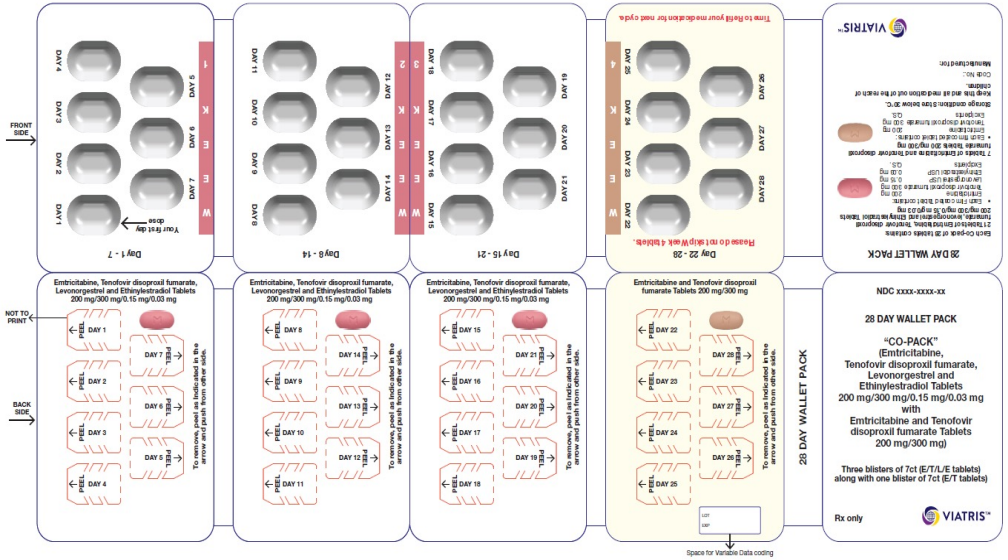
# The DPP is a daily pill for HIV and pregnancy prevention

- Viatris developing **co-formulated tablet with 28-day regimen** (TDF/FTC, oral PrEP + LNG/EE, combined oral contraception (COC))
- **Different color pills** for 21 vs. 7 days
- **Packaging will be wallet pack** with tear-off weekly sheets with instructions on them
- Pill color, packaging, brand names **validated with women**
- **Branding/secondary packaging** will have women's lifestyle feel
- Longer term, Population Council/Medicines360 to **develop F/TAF-based DPP**

**Viatris plans to file for regulatory approval with US FDA in early 2024**

*Figure 1: Proposed DPP tablet colors*


*Figure 2: Illustrative mock-up of DPP packaging by Viatris*



# What FP/SRH stakeholders want to know about the DPP

## Questions/issues from consultation with FP/SRH stakeholders in April 2022

*Will there be sufficient demand for the DPP?*

Demand for DPP **expected to be among sub-set of women who desire FP + HIV prevention**. Kenya, South Africa, Zimbabwe prioritized for early intro due to overlapping high HIV incidence and unmet need for FP, enabling environments and moderate-to-high OC use. Potential to expand to other countries with higher OC use.

*Could the DPP jeopardize progress on long-acting reversible contraceptives (LARCs)?*

The DPP will be **offered as one option in the context of informed choice**, recognizing women have different prevention needs and preferences over life course and may want to try/switch to DPP. Implementation studies important to understand optimal counseling.

*Will DPP counseling confuse providers and negatively impact FP programs?*

**DPP counseling and delivery will aim to align with OC practice**, underscoring a need to expand delivery of oral PrEP now through HIV/FP integration, task-shifting, multi-month dispensing, HIV self-testing, the private sector, and other models/channels.

# Private Sector Opportunities for the Dual Prevention Pill (DPP)

Rob Wood, Halcyon

Karen Webb, OPHID

OCTOBER 12, 2022

HALCYON

OPHID
Organization for Public Health Interventions & Development

AVAC
Global Advocacy for HIV Prevention

# Introduction and Context

## An evolution of research and opportunities for private sector delivery

**2020** → **2022**

Initial DPP Service Delivery Strategy recommended that DPP rollout **focus on the public sector**

| Phase | Years | Channels | Rationale |
|---|---|---|---|
| 1 | 2024-2025 | • Public FP/SRH clinics<br>• Public HIV clinics | **High-capacity public sector channels** most likely to be scaled & sustained after intro |
| 2 | 2025-2026 | • Pharmacies<br>• Social franchises/NGOs<br>• DICEs/Pop-specific sites<br>• Mobile clinics | As rapidly changing private sector expands PrEP channels, **Phase 2 channels show potential for impact** |
| 3 | 2026+ | • Private providers<br>• Universities<br>• Telehealth<br>• Direct-to-consumer<br>• CBD programs for FP | Phase 3 channels are **decentralized for oral contraceptives (OCs), but require policy changes to offer PrEP or in nascent stages of PrEP delivery** |

Initial service delivery assessments were reviewed to:

- **Update private sector landscaping** in Kenya, South Africa, Zimbabwe
- **Reflect growth in new PrEP delivery channels** largely in response to Covid-19, particularly pharmacies, e-pharmacies, and telemedicine
- **Include new and important PrEP pilot studies** in private sector

# Methodology and Limitations

## Methods

**1. Comprehensive desk review of available literature and data**

**2. In-country teams scoped Kenya, South Africa, Zimbabwe**
(telehealth, telemedicine, pharmacies, e-pharmacies, private provider networks, community distribution, mobile outreach)

**3. 85 key informants interviewed**

## Limitations

- Limited availability of data for some newer private sector channels
- Reluctance to share private sector data
- Lack of available data on newly expanding channels (e.g. telehealth, e-pharmacies in Kenya, South Africa)
- Non-availability of some key stakeholders

# Major Considerations for the DPP's Private Sector Potential

| Theme | Headlines |
|---|---|
| Financing | • **Data mostly unavailable** to guide DPP financing<br>• **Stakeholders concerned cost may be prohibitive** in private sector<br>• **Prices are highly variable** by country: on average, oral PrEP is 10x cost of OC<br>• **Payments for HIV services in private sector** through national health insurance schemes undefined |
| Policy and regulation | • **Cadre restrictions on PrEP and OC vary** and can be higher than WHO recommendations<br>• **Policies and regulations not in place** for newer channels |
| Coordination | • **Public-private coordination** highly variable<br>• **Private sector not intentionally invited** to participate in health sector coordination |
| Monitoring & Evaluation | • **Limited availability and use of quality data** on current uptake of OCs and PrEP in the private sector |
| Sustainability | • **Subsidies likely required**, especially in the short term, in price-sensitive markets |

# Priority Private Sector Channels for the DPP

**Pharmacies** should be prioritised for DPP rollout in all three countries. **Networked private providers** also have potential. **E-pharmacies and telemedicine** important considerations for Kenya & South Africa.

| | Scoped delivery channels | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | D2C channels | | | | | | Indirect to consumer/access through a third party | | | |
| | Pharmacy | E-pharmacy | Telehealth | Tele-medicine | Community distribution | Mobile outreach | NGO | FBO | Private network clinics | Social franchise networks |
| **Kenya** | | | | | | | | | | |
| **South Africa** | | | | | | | | | | |
| **Zimbabwe** | | | | | | | | | | |

| Inclusion Criteria | Description |
|---|---|
| Policy and regulation | Are supportive policies and regulations in place? |
| Public-private coordination | Is there ongoing dialogue between the private sector channel and the government? |
| M&E | Are M&E systems in place for sharing of data? |
| Supply chain | Is there a stable supply chain system between government and private sector channel? |
| Financing | Are there financing or subsidy systems in place or that can be learnt from? |
| Feasibility | Could the DPP easily be rolled out through this channel? |
| Scalibility | Does this private sector channel have the ability to reach many users across the country, rural and urban segments? |

**Legend**

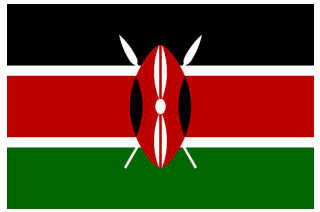
- High potential and recommended channel for delivery in the near-term
- Medium potential and not recommended as a near-term delivery channel
- Currently low potential and not immediately recommended channel

# Recommended Channels: Kenya

**Pharmacies** are the top priority private sector channel, followed by **e-pharmacies**, as policy changes and PrEP pilot studies open up opportunities.

| Channel | Key points |
|---|---|
| Pharmacies | • **>6,500 registered pharmacies** nationally<br>• **Government supports** pharmacy-based model for PrEP delivery<br>• **PrEP pilot studies** in pharmacies ongoing<br>• **Artificial intelligence (AI)** used to verify HIV self-testing (HIVST) for PrEP dispensing<br>• **Maisha Meds** platform offers subsidized FP<br>• **Telehealth integration** such as Aviro Pocket Clinic for HIVST counselling |
| E-pharmacies | • **Growing entry point** for SRH/HIV services<br>• **Discreet and accessible** 24/7<br>• **Distribute key products** at some scale<br>• **Pilot study on virtual care model** for PrEP delivery with MyDawa starting imminently |

# Recommended Channels: Kenya



**Networked private providers** established and trusted networks for FP and HIV services.
**Telehealth** a key entry point for service provision.

| Channel | Key points |
|---|---|
| **Networked private providers** | • **~600 franchised clinics** countrywide, including rural areas<br>• **Strong relationships** with MoH<br>• **Growing networks of private providers** offering lower-cost services; some becoming more involved in PrEP delivery<br>• **Additional delivery channels are integrated** into private provider networks, including telemedicine |
| **Telehealth** | • **Most platforms do not dispense** but are key entry point<br>• **Rapidly growing sector**, with ~40 providers with country-wide reach (up from 10 in 2020)<br>• **High demand for FP, STI and HIV services**, such as PEP and PrEP, particularly on weekends<br>• **Telehealth apps** (e.g., MOSAIC user journey tool, Aviro Pocket Clinic) support users and providers from decision-making to service delivery support |

# Recommended Channels: South Africa

**Pharmacies** highest potential for the DPP since approval of PIMART. **Telemedicine** and **networked private providers** also significant potential to rollout the DPP.

| Channel | Key points |
|---|---|
| **Pharmacies** | • **>4,700 registered pharmacies**<br>• **Rollout of PIMART and expanded FP scope of practice** allow pharmacist initiation of PrEP/OCs<br>• **Pilot pharmacy PrEP studies** to support rollout of PIMART and explore safety, efficiency and willingness to pay |
| **Telemedicine** | • **Online platforms allowing virtual consultations** between providers and clients<br>• **Widely accessed and rapidly growing market**, accessible countrywide |
| **Networked private providers** | • **3,000 providers**<br>• **GP Care Cell pilot** between private providers and National Health Insurance (NHI) Scheme<br>• **Southern African HIV Clinicians Society online training modules** for PrEP; other online training modules available |

# Recommended Channels: Zimbabwe

**Pharmacies** show highest potential for the DPP in Zimbabwe although likely to remain in Phase 2.

| Channel | Key points |
|---|---|
| **Pharmacies** | • **>900 countrywide**, urban and rural<br>• **No prescription required** for OC<br>• **Community Pharmacies Association (CPA) engaging MoH** on task-shifting for PrEP initiation to pharmacists |
| **Networked private providers** | • **Wide geographic reach** and focus on low-income high density urban areas and rural areas<br>• **Provide integrated FP/HIV services**, including PrEP<br>• **Models linked with community health workers and peer navigators**, e.g., PSH, CeSHHAR connect facility and community distribution |
| **Public-private partnership (PPP) models** | • **PPPs are strategic objective** of current USAID/PEPFAR TASQC program with OPHID support<br>• **Pilot projects for ART will generate lessons** that can be used in scale-up of PrEP or rollout of the DPP<br>• **De-medicalization of OCs** and distribution of MoH commodities through private sector successful |

# Recommendations: all countries



| Channel | Recommendations for the DPP |
|---|---|
| Pharmacies (all) | • **Engage with pharmacy networks** to increase interest in providing the DPP<br>• **Include pharmacies in national PrEP dialogue and planning processes**<br>• **Support advocacy with national government** for pharmacy-based PrEP delivery<br>• **Support ongoing task-shifting** policy development to include new channels<br>• **Advocate for PIMART** to be reinstated (on hold due to pending court case) (South Africa)<br>• **Advocate for inclusion of DPP training module** into PIMART training (South Africa) |
| E-pharmacies (Kenya) | • **Support e-pharmacies and MoH** to engage more on the delivery of PrEP to pave way for DPP<br>• **Advocate for progressive eHealth Bill** to become law |
| Networked private providers (all) | • **Partner with country medical associations** and other cadre-specific associations<br>• **Address provider bias** by piloting VCAT and client-centred care training<br>• **Partner with cadre-specific associations** to increase support for PrEP and DPP through private sector network<br>• **Advocate for PrEP and DPP inclusion** in national health insurance (Kenya and South Africa) |
| Telehealth (Kenya only) | • **Work with Kenya Medical Practitioners and Dentists Council** and others to gather data on telemedicine providers<br>• **Include telehealth sector in national dialogues and planning processes** to increase support from government<br>• **Advocate for progressive eHealth Bill** to become law |
| Telemedicine (South Africa) | • **Work with Africa Telehealth Collaboration, Health Professions Council of SA** to gather data on FP/HIV services<br>• **Support discussions with public sector** to update 2014 telemedicine guidelines/regulations |
| PPP models (Zimbabwe) | • **Closely follow PPP models** for lessons learnt<br>• If PPPs show promise, **consider supporting specific PPP pilot models** of integrated FP/PrEP delivery |

# Conclusion and Next Steps

## Greater and more immediate opportunities for private sector channels to deliver the DPP than was previously found

- **Private sector advances:** Advances in policies and pilot models for pharmacy delivery of PrEP and rapid growth of telehealth models in Kenya and South Africa have increased private sector opportunities for the DPP
- **Phase 1 private sector delivery is possible:** Pharmacies and private provider networks that were previously recommended for Phase 2 delivery offer potential to be introduced earlier
- **However…**for the DPP, willingness-to-pay and pricing models need to be clarified and better defined for clearer recommendations to be developed. End-user validation also required for recommended channels
- **Definitive recommendations by end 2022:** Planned DPP private sector delivery strategy aims to address many such concerns, with recommendations on which private sector channels can be introduced in Phase 1

# Discussion

- What models or channels do you see as having the most promise for the DPP?
- What recommendations would you suggest prioritizing, based on your experience with FP delivery in the private sector?
- What recommendations would you add or de-prioritize?
- Are there particular stakeholders that you would recommend engaging?
- What areas do you see as requiring further research?

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# Lessons from country level: Best practices for FP introduction in the private sector – Kenya

Sylvia Wamuhu, PS Kenya

October 12, 2022



# PS Kenya's FP Implementing Models

## Social Marketing

- Pharmacies
- The general trade

## Social Franchising

- Tunza Health Network
- Over 400 health clinics

# PRODUCT

- Brand name needs to be funky and should aim to kill any potential stigma around the product
- Packaging: Make it attractive and convenient e.g., to carry around in a handbag, wallet, pocket
- Ease the journey for repeated visits to the pharmacy or clinic; you can have different SKUs
  - 1 cycle pack
  - 3 cycle pack
- Quality: This is very important; use reputable manufacturers and keep testing the product in-country; minimize side effects
- Easy to use:
  - Avoid complicated instructions: keep it simple and to the point
  - Provide various channels for instructions e.g. for HIV-self-test kits we have Instructions both on product packaging and a link to YouTube for demonstration videos


# PROMOTION – CONSUMERS

## Consumers

- Not allowed to promote Femiplan range of products because they are ethical e.g., OCs
- Can promote the behaviour but not mention the brand
  - Community engagement
  - Radio spots
  - Social media
- It is a major shift for consumers….
  - Market the behaviour aggressively and mention … *for further information contact your doctor;* consumers need to understand the product, where to find it…
  - Expect myths and misconceptions around the new product; focus on the benefits until they stick in the consumer's mind
  - Your campaigns on adopting the behaviour should be so cool to also kill the stigma that may be associated with the product
  - Localize your communication for people to associate with it

*Through the private sector distribution chain. **#PSKenya** makes it easier for women in Kenya to access oral contraception (pills) thus empowering them to have control of their **#SRHR**. **#Femiplan***


*With a HIV Self-test kit, you can easily get to know your status discreetly and conveniently anytime **#HIVST***

# PROMOTION – PHARMACIES AND HEALTH FACILITIES

## Health Facilities / Pharmacies

- Health Care Providers are critical for pushing the product to consumers
- The product can be promoted to the health care worker in any way –put up posters, leave behind product information leaflets, flyers etc..
- Provider behavior change is important:
  - Shifting from short term to long term FP methods took time and a lot of trainings and sensitization were done to change this
  - Success of the DPP in the market will highly depend on the Health care workers' buy-in of the product
  - Need to conduct trainings, CMEs, sponsorship of relevant stakeholder events, exhibitions
  - At facility / pharmacy level, have champions, TOTs, mentorship sessions etc...
  - Collaborate with the health care providers' bodies e.g., Nursing council, Clinical officers' council, Kenya Medical Association
- Products can get stuck at pharmacies; what is the incentive for e.g., pharmacies to promote / sell the product?
  - Higher profits?
  - Quality? New technology?
  - More customers?

# PLACE

- Wide availability of product is key for easy access – both traditional, e-pharmacies and telemedicine
- PS Kenya distribution chain: Distributors (10) – wholesalers – retail pharmacies - consumer
- E-pharmacy: HIV self test kits - Over the counter
  - 80% Physical pharmacies
  - 20% e-pharmacy (MyDawa, Kasha, Jumia) – provides confidentiality
  - PS Kenya sells to these channels and then the products follow the e-platforms normal selling process – like for any other drug
- Femiplan is a prescription and low value product – thus very low sales go through the e-platforms (also added cost due to delivery costs)
- Pharmacies also have their own e-pharmacies/online platforms, therefore e-sales could be higher
- Regular supplies very important, avoid stock-outs

# PRICE

- Kenya is price sensitive
- Depending on the target market – there might be a need to subsidize the cost
- For Example: HIV test kits: With subsidy sales were high; @ USD 2.5 about 5,000 kits a month, dropped the price to USD 1.5 and sales went up to about 9,000 per month; currently USD 6.2 (no subsidy) selling 1,200 per month
- Consider the current price of OCs and Oral PrEP as stand-alones
- Average margin for products sold in pharmacies is about 33%
- Consider 15% for distributors

# REGULATION

- Pharmacy and Poisons Board (PPB) is the regulator
- Key stakeholders: National Aids and STIs Control Program (NASCOP); Division of Reproductive and Maternal Health (DRMH), Pharmaceutical Society of Kenya, Kenya Pharmaceutical Association, Kenya Medical Association, Nursing Council, Clinical Council etc.…their endorsement is critical
- Need a pharmacist in house – to guide on the requirements and to be the PPB contact
- Products needs to be registered in country – pharmacist critical here for registration, meeting regulations and getting permits
- Pharmacist critical for Pharmacovigilance: Any adverse events captured in the markets; must develop a pharmacovigilance process; this is a new combination therefore very critical to gather feedback
- Communication materials including posters need to be approved by PPB

*THANK YOU*

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# The DPP at ICFP 2022

## Join us to learn more about the DPP and a future with MPTs!

| Date | Time | Session | Presentation | Organization |
|---|---|---|---|---|
| **Tuesday, November 15** | 10:15-11:35am | Ushering in a New Era of Choice for Comprehensive SRH and HIV Prevention: How new FP and HIV product introduction is shaping markets | All | AVAC, FP2030, PATH, SEMA Reproductive Health |
| | 2:40-4:00pm | Innovative data sources to improve monitoring and decision making | Dual or Dueling? Review of HIV and FP M&E Systems to Inform Introduction of MPTs | CHAI |
| **Wednesday, November 16** | 10:15-11:35am | Innovations in contraceptive technologies to better meet user and system needs | The promise of the DPP: Engaging Health Care Providers in Development and Introduction | Population Council |

# Thank you!

## Private sector opportunities for the DPP