### Multipurpose Prevention Technologies:

### Aligning Investments in R&D, and The Critical Path to Introduction

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### Why Develop MPTs?

1. To meet women’s multiple SRH needs in one product
2. To achieve efficiencies in cost of delivery of prevention products
3. To leverage existing delivery channels to achieve higher levels of prevention product uptake and demand

### Developing Target Product Profiles (TPPs) for MPTs

- **Why a TPP?**
  - To identify key attributes/parameters for MPT products that would lead to the highest potential public health impact (i.e., prioritization)
  - To guide product development and donor investment strategies

  **Initiative for MPTs (IMPT) TPP Working Group Process:**
  - Solicited expert review from domestic and international SRH researchers on ideal and minimally acceptable thresholds of product attributes / parameters
  - Surveyed US, African and Indian providers as to priority attributes for MPTs:
    - 593 US providers who are members of the Association of Reproductive Health Professionals (U.S.-based)
    - 289 African providers attending the 2011 International Conference on Family Planning in Dakar, Senegal
    - 34 Indian providers attending the Regional Conference on MPTs in New Delhi, India (Dec 2012)
  - Consolidated consensus views

#### Key Attributes of MPTs:

- **Indications:**
  - HIV & Pregnancy
  - HIV & STI
  - HSV, HPV, BV
  - STI & Pregnancy

- **Dosage Forms:**
  - Sustained release
  - Topical over oral
  - On demand over daily

- **Product Related (e.g.):**
  - 40°C storage
  - 36-month shelf life
  - Concealable presentation

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### Complexity of developing MPTs

#### INDICATION

- Pregnancy
- HIV
- HSV
- HPV
- Other STIs
- Other Indications

#### MECHANISM OF ACTION

- Barrier
- Probiotic
- Anti-Microbial
- Anti-Viral
- Anti-Fungal
- Other

#### DOSAGE & ADMINISTRATION

- Oral Daily
- Vaginal Topical
- Systemic Sustained

- Other

#### FORMULATION & DELIVERY

- Vaginal gel
- Vaginal film
- Vaginal tablet
- Vaginal ring
- Non-IVR device
- Implant
- Injection

#### Critical Attributes Considered:

- Indications
- Target Population
- Efficacy
- Adherence
- Route of Administration
- Dosage Form & Schedule
- Side Effects
- Storage Conditions
- Reversibility
- Other Health Benefits
- Contra-indications & precautions
- Use by age / marital status
- Product Production (i.e. cost, etc.)
- Access: Potential & Restrictions (selling?)
- IP Status
- R&D Costs
- Time to Market
- Product Cost
- Product Presentation
- Packaging
- Shelf Life
- Disposal/Waste

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### TPP Input from SRH Researchers
Conclusions from the MPT TPP process:
Although challenging, it is possible to identify general development priorities and product design targets for MPTs.


SAWG MPT Pipeline Prioritization Process:
- Assembled comprehensive list of MPT-related products/components
- Evaluated based on development feasibility, and number per product type (e.g., MOA, chemical class, dosage form)
- Compared to general TPP findings
- Evaluated based on per other criteria
- Accessed expertise from SRH field

SAWG MPT Prioritization and Gap Analysis: General Summary:
- Top Priorities
  - Suite of product types:
    - On-demand formulations
    - Vaginal rings
    - Long-acting injectables
  - Active Pharma. Ingredients (APIs): ARVs for HIV
  - STI-specific APIs
- Long term R&D needs
  - STI-specific APIs
  - Non-ARV based HIV prevention
  - Lactobacillus-based products
  - Non-hormonal contraceptives
  - Novel on-demand product configurations

Process Priorities:
- Consensus on development objectives across donors and developers
- ID single leads through common R&D pathways using TPPs specific to product types
- Coordinated investment and collaborative development
- Pooling of capacity, expertise, and other resources between MPT R&D partners
- Early and proactive engagement of regulatory authorities

SAWG Members
- Donor Representatives: BMGF, DFID, NIH/NIAID, NIH/NICHD, NIH/OAR, USAID
- Regional Representatives: Africa, China, India, IMPT Coord. Committee

SAWG MPT Prioritization and Gap Analysis:
- Outside the SAWG Scope:
  - Study-section type review of specific MPT products or component products and technologies
  - Recommendations on funding for specific products or technologies

2. MPT Regulatory Approval

2. SAWG

2. MPT Regulatory Approval
1. Which of the combined indications is the primary?
2. Is the product drug+drug or drug+device?
3. Are the product components already approved, or experimental?
4. Is the product delivery mode topical or systemic?

Although specific regulations will vary with each MPT type, these four basic questions will guide the regulatory approval process:

- **Will the product be effective?** (and some sense of how well in an understandable format)
- **Will it cause harm?**
  - (to me, my partner, my baby if I’m breastfeeding)
- **Will it jeopardize my future fertility?**
  - (will I be able to get pregnant in the future, if I want to?)
- **Will it disrupt my relationship with my partner?**
  - (issues of trust, pleasure, secrecy, social cost)

Across Products, Geographies and Time, Women Want to Know…

**FP/RH Product Considerations for MPTs:**

- General Characteristics:
  - Over-the-counter (OTC) vs. by prescription (Rx)
  - Skilled clinician involvement vs. limited or none
  - User-controlled vs. user-independent
  - Coitally-dependent vs. coitally-independent
  - Local vs. systemic effects
  - Different durations of action / effectiveness
  - Discreet vs. known use (by partner, family, etc)

- Medical monitoring
- Rx only (at least initially)
- Provider / service delivery type
  - Capacity for periodic HIV testing
  - Scalability
- HIV testing as gateway for use
- Adherence, and counseling about partial effectiveness
- Effects of different formulations and delivery modes on the potential for ARV drug resistance
- User and partner knowledge, attitudes, perceptions and practices will ultimately drive success – or failure

Thank you!