Access Objectives

- Maximise microbicide health impact over time for women in developing countries
  - Establish evidence base to support initial introduction and later scale up
  - Situate microbicides as part of comprehensive response to HIV
  - Address components of access: availability, acceptability, accessibility and affordability
  - Mobilise partnerships: country, finance, manufacture, distribution and programme
Microbicide Access Challenges

- Timing and product profile unclear
- First-in-class product
  - No historical demand data
  - No simple analogue
  - Product use understood from trials
- Unit costs vary by formulation
- Partial effectiveness
  - Perfect use and ‘normal’ use
Microbicide Access Challenges

- Association with HIV
  - FC experience

- Gender roles
  - ‘Empowerment’ a key issued but …
  - how to include male partners?

- Demonstrating impact
  - Attribution as part of method mix
  - Dynamic HIV-prevention field
  - Time taken to show population effects
Critical Path to Access

Clinical & Regulatory
- Safety Trials
- Efficacy Trials
- Regulatory Approval
- Post-Licensure Studies
- Community Trial Engagement & Participation

Manufacturing
- Pilot Manufacturing
- Efficacy Trial Manufacturing
- Demand Forecasting & Production Planning
- Commercial Scale Production

Behavioral Research
- Trial Support & Acceptability Research
- Introduction Support Research

Delivery Research
- Operations Research
- Service Delivery Mechanisms

Policy & Advocacy
- Impact Modeling
- Mobilization of Scale-Up Financing
- Mobilization of Political Support

Marketing
- Market Research
- Branding
- Advertising
Critical Path to Access

- Sequence activities
- Need for partnerships
- *Timely* mobilisation
- Evidence for different decision makers
- Scenario planning
  - When, where and what microbicide introduced
- Manage expectations
Current Microbicide Trial Results

- Microbicide - BufferGel & PRO2000
- Microbicide - Carraguard
- Microbicide - Tenofovir Gel
- Microbicide - BufferGel & PRO2000
- Additional Next Generation?
Early-Generation Microbicides

- Data late 2007 - 2009
- No, low or partial efficacy
- Gel plus applicator-based products
- Likely prescription only
- Some contraceptive, some not
Early-Generation Microbicides

- Use needed per sex act
- Manufacturing options available
- Cost ≈ $0.5 but scale efficiencies expected
Next-Generation Microbicides

- First efficacy now and others in safety
- Various formulations
  - Gels, rings, tablets, films …
- Prescription only (at least initially)
- Don’t need to use for each sex act
- Non-contraceptive
Next-Generation Microbicides

- Manufacturing options available for lead candidates
- Unit costs vary by formulation
- Possible issue with resistance (ARVs)
Microbicide Access Assumptions

- Staggered roll-out
  - Trial countries plus first adopters

- Pilot introductions
  - Understand operational issues
  - Understand use

- Integrate as part of HIV programme
  - But position separately?
  - SRH services?

- Need to generate demand
Microbicide Access Assumptions

- Address role of gate keepers
- First impressions count
  - Select for success
  - Set realistic expectations
Why Address Access Issues Now?

- With uncertainties why address access issues now?
  - Help manage currently high expectations
  - Develop conceptual framework
  - Pilot programme approach needed for early and next generation (designs may differ)
  - Identify information needs with longer lead times
  - Identify where can learn from other products
  - Help position microbicides in a dynamic field