

Update on the Status of USAID's HIV/AIDS Microbicides Program

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Overview

What's going on at USAID?

What do these changes mean?

What changes will there be in the portfolio?

What is happening with tenofovir gel?

Under New Management

As of January 1, 2011

- Management of microbicides portfolio moved to the Office of HIV/AIDS (OHA)
- Two additional positions are being recruited
 - Senior Science advisor – Selected
 - Product Introduction Specialist – Recruiting

Why this move?

● PEPFAR

With greater focus on HIV/AIDS over the last 8 years we need to integrate microbicides research with the broader US government response. The Microbicides agenda has remained separate from PEPFAR activity and these barriers need to come down.

● CAPRISA 004

The results of this trial have changed the focus of the microbicides efforts from R&D to R&D AND Product Introduction.

Therefore the USAID microbicides portfolio will address the urgent need for planning and strategies for product introduction.

This will bring a new set of players to the table (more on this later)

Changes in the USAID microbicides portfolio

- We don't expect any increases in funding for microbicides in FY2011. The budget is uncertain
- **In order to support the tenofovir gel introduction, funding will need to shift from other areas – most likely product development**

Changes in the USAID microbicides portfolio

- In Early April we will conduct careful and well informed reviews of each partner's portfolio to be sure we maintain a sound pipeline of products and supportive activities while assuring enough resources for the product introduction effort.
- These reviews will be conducted jointly with USG and BMGF colleagues.

Tenofovir Gel

- FACTS Trial
- Advisory committee
- Introduction Strategy

Tenofovir Gel - 1

FACTS Trial

- A confirmatory trial of 1% tenofovir gel using the same dosing regimen as CAPRISA 004.
- The South African Government will be the largest funder of this trial.
- USAID has been asked to participate
- NIH protocol review just completed and USAID will be communicating its final decision with the investigators this week.

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Advisory committee

- Working out details with general counsel regarding standing advisory committees
- Has not prevented us from seeking advice from individuals
- We will be seeking more consultations in the weeks to come.

Tenofovir Gel Introduction Strategy

- Thanks to

- Martha Brady (Population Council)
- Wendy Taylor (USAID)
- Lee Claypool (USAID)

Aims of the strategy

- Provide a broad roadmap for product introduction
- Not a USAID strategy – a USAID proposal
 - Focusing on the interval between completion of a trial and the introduction of the product
 - Undertake initiatives to identify the practical steps to bring a microbicide product to market and maximize its impact
 - Inform future product introduction efforts – beyond tenofovir gel

Assumptions

- Early products will be partially protective
- Early products will Require prescription, at least initially
- Research at the clinical, user, and health systems levels essential
- Product roll out will be influenced by the number of purposes it has
- Regulatory process will differ significantly between countries
- Regulatory process will be slow without manufacturer and stakeholder resources and interest

Assumptions

- The first counties to adopt a product are likely to be those where clinical trials took place
- Initial availability will be limited due to facility based distribution and adoption will be slow – based on similar experiences (e.g. FC and MC).
- Normative agency support will be critical
- Public sector pricing agreements will be different from the private market price.
- Newer products exiting the pipeline (i.e. rings or PrEP) may alter optimized introduction plans
- Many many others

Global and National Level Strategies

- Aggressive initiatives will be needed at both levels to ensure timely roll out of product
- These must be complementary and reinforcing

Global Level Strategy – 5 Initiatives

- Create an Microbicide Access and Introduction Working Group
 - Deliverables and Timeline: Working Group established in the second half of 2011 and functioning thereafter.
- Streamline support for regulatory, licensure, manufacturing, and financing needs
 - Deliverables and Timeline: Defined with implementation experts, in early 2011 in South Africa, with identification of key parties, priorities, and first-year timeline.
- Design and Implement a Microbicide Readiness Assessment Tool
 - Deliverables and Timeline: Tool developed in 2011, tested in two high-priority pilot countries in 2012, and available for application in other countries thereafter

Global Level Strategy – 5 Initiatives

- Develop an operations research agenda for introduction and delivery
 - Deliverables and Timeline: A Global-Level generic operations research plan designed in 2011 and commenced in late 2011 or early 2012.
- Adapt cost modeling for Microbicides as an intervention for HIV prevention.
 - Deliverables and Timeline: The adaptation and pilot demonstration of this model can be completed in 2011

National Level Strategy - 5 initiatives

- Support the development of national policies on the use of microbicides
 - Deliverables and Timeline: Draft introduction plans in two pilot countries will be completed by the end of Year 2012.
- Support the development a comprehensive communications, advocacy, and demand creation strategy
 - Deliverables and Timeline: Draft Communications and Advocacy Plan developed by the middle of 2012 in two pilot countries.
- Support development of a national introduction plan and OR agenda
 - Deliverables and Timeline: Draft Introduction Plan and Operations Research Agenda developed during 2012 in two pilot countries.

National Level Strategy - 5 initiatives

- Support application of costing tools for policy development and program planning
 - Deliverables and Timeline: Draft Costing Tool can be applied in two pilot countries during 2012.
- Support licensure, programmatic, and logistics planning
 - Analysis of national regulatory requirements
 - Market, manufacturing, and distribution strategies
 - End user surveys
 - Others
 - Deliverables and Timeline: Objectives and priorities tailored for the particular national-level circumstances in two pilot countries in 2011.

Let's spend a moment in the weeds: the "to-do" list

- Get the scientists out of the room
- "Neither the elegance of the science nor the strength of the effect predict the ease of implementation." David Stanton 2009
- Identify the regulatory requirements for licensure
- Establish protocols for counseling, dispensing, follow up testing, referrals
- Conduct demand forecasting
- Conduct new market appraisals: pricing, packaging, competing and complimentary products, users' experience with the product etc.
- Conduct a gender analysis

- Identify appropriate product outlets
- Identify supply mechanisms and logistics systems needed
- Identify suppliers/manufacturers, if manufacturing is in country establish process to assess GMP
- Train providers and distributors in client counseling, education, dispensing, follow up and referral
- Get the scientists back in the room:
 - Operations research post licensure
 - Post marketing surveillance for adverse events, resistance, effectiveness etc.

How will USAID accomplish all this?

- USAID will seek broad input and partnership for this strategy
- We will work closely with our USG and International Partners as well as private sector partners
- Short term: USAID will turn to its current implementing partners to carry out much of this agenda
- In the long term: the portfolio will be realigned to better meet new USAID goals

Next Steps in the next 6 Months

Benchmark

- Finalize decision regarding FACTS 001
- Internal OHA recruitment completed
- WHO/UNAIDS/USAID Convene tenofovir gel implementation planning meeting in South Africa

Anticipated Dates

- End of March
- End of April 2011
- June 2011 (tentatively)

Summary

- The USAID microbicides portfolio and management are realigning in order to better integrate with the global response to the epidemic and to respond to major achievements and opportunities in product development.
- The current budget environment coupled with the need to take on new activities will require a close examination of funding priorities.
- USAID proposes an aggressive strategy for product introduction and seeks your input and advice.

Thank You

Time for questions