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Documenting and Institutionalizing New Product Introductions

Lessons from the AFFORD Health Marketing Initiative

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This presentation outlines and documents the steps for introducing new health care products by a USAID funded project in Uganda. Although some of the steps may seem obvious, some of the requirements are very specific in nature and it has been a good learning experience for AFFORD introducing 8 new products in a span of 24 months, which is a unique experience for most social marketing programs.

- AFFORD Health Marketing Initiative
- Product introduction process
- Case studies
- Lessons learned

This presentation has four sections:

1. An overview of the AFFORD Health Marketing Initiative
2. A description of the AFFORD product introduction process
3. Case studies on two AFFORD product introductions
4. A summary of lessons learned

Objectives

- Increase accessibility, availability and affordability of basic health products and services through private sector partnerships
- Empower communities and families to manage their health effectively through integrated marketing and communication activities
- Establish indigenous, sustainable health marketing organization: Uganda Health Marketing Group (UHMG)

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This slide describes the three objectives of the AFFORD Health Marketing Initiative in Uganda.

AFFORD Areas of Intervention

<p>Child Survival</p>  	<p>Family Planning</p> 
<p>Malaria</p> <p>LLINs ACTs</p>	<p>HIV AIDS</p> 

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This slide presents AFFORD’s intervention areas of products. AFFORD products target four areas of intervention: Child survival, family planning, HIV/AIDS, and malaria. This slide shows the product categories and branded products for each area of intervention. Not all brands and products are supported directly by AFFORD. For example, in the case of ACTs for malaria treatment, AFFORD helps to create demand for existing private sector products. The products, by area, are:

1. Child survival: Low-osmolality ORS co-prescribed with zinc sulfate tablets; water purification tablets
2. Family planning: Two low-dose oral contraceptives, progestin-only oral contraceptive, injectable contraceptive, and standard-days method cycle beads
3. Malaria: Long-lasting insecticide treated nets and artemenisin-combined therapy (ACTs)
4. HIV/AIDS: Two condom brands, Cotrimoxazole, acyclovir and multivitamins with antioxidants

- Targeting distinct segments in four intervention areas
- Creating a family of products for Ugandan consumers
- Segmenting within categories
 - Example: Multiple oral contraceptives positioned to distinct segments based on socio-economic level and reproductive stage
- Portfolio for UHMG sustainability
 - Subsidized products
 - Full cost-recovery products
 - Margin generating products

This slide summarizes AFFORD's product strategy. AFFORD's strategy is to offer a diverse array of products to meet distinct needs in each of the four intervention areas, and create a family of basic health products for Ugandan consumers. Within product categories, AFFORD is also segmenting markets, for example, by offering different types of oral contraceptives for different socio-economic segments, and even a progestin-only oral contraceptive for breastfeeding women. AFFORD also aims to create a product portfolio that has subsidized products (using donated commodities), break-even/cost recovery products that will sustain themselves at least with respect to commodity procurement, and finally, products that produce a small margin for the UHMG.

- More products than most social marketing programmes
 - In under three years:
 - 10 new products
 - 3 re-launches
- Direct management of procurement and introduction
 - New brands owned by UHMG
- Sourcing commodities from commercial suppliers

With this product strategy, AFFORD has had a major product introduction challenge, as the programme is offering a larger and wider range of products than is typical of many social marketing programmes. In less than three years, AFFORD will have introduced ten new products and re-launched three. The AFFORD team has elected to directly procure many of these new products and manage most aspects of the introduction process, in part because of the brand ownership by UHMG. And finally, AFFORD is utilizing commercial suppliers for the new products, a factor that in itself presents some unique introduction challenges.

AFFORD New Product Introduction Process

- Predicting introduction steps
 - Critical deliverables
 - Key decisions
 - Responsibilities
 - Internal
 - External
- Managing introduction processes
 - Sequential and parallel
 - Time
 - Resources
 - Personnel
 - Money

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With these strategies and challenges in mind, AFFORD mapped out predicted product introduction steps and processes. It was by comparing planned introduction steps and processes with actual experience that AFFORD has identified challenges and learned how to cope with them to achieve its results.

- 1) Market and Product need assessment
- 2) Defining the product (*brand name, packaging, form - tablet, liquid, powder*)
- 3) Pretest defined product (*acceptability of attributes, name*)
- 4) Product introduction business plan
- 5) Sourcing of product (*local, international, traded vs. contract manufactured*)
- 6) Obtain waiver from USAID if non-U.S. source
- 7) Start process of product development (*estimate requirements, negotiate price, develop product and pack designs*) with identified source
- 8) Submit product registration dossier and product samples to National Drug Authority (NDA), register trade mark

The next two slides list the basic new product introduction steps, in sequential order. The listing in sequence does not fully capture the interdependent nature of certain steps, or the long lead times of some steps. It is also important to remember that some of these steps are basically within the project's control, while other steps are largely outside of the project's control.

- 9) **Develop Marketing Plan** (*brand communication, distribution & pricing strategies; launch activity plan*)
- 10) **Develop and pretest materials**
- 11) **Obtain approvals for promotional materials**
- 12) **Place orders for product procurement** (*after NDA approval*)
- 13) **Organize launch**
- 14) **Train sales team and distributors on new product**
- 15) **Distribute product prior to launch**
- 16) **Launch** (*advertising, press release, etc.*)

This slide is a continuation of the product introduction steps.

AFFORD Market & Product Needs Assessment

- Identify market gap/need/opportunity (*research - desk review, field survey, FGDs*)
- Identify product that will satisfy the need
- Define the product (*composition, technical specs, dosage form, packaging*)
- Select ad agency
- Develop brand name, pack design

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The next seven slides provide more detail regarding the more general steps outlined in the previous two slides.

AFFORD Product Introduction Business Plan

- Define market and environment
- Define product life cycle stage in the market
- Identify possible commodity suppliers
- Estimate sales (Volume and revenue for at least 3 years)
- Define pricing (*product cost recovery, full cost recovery, subsidized, etc.*)
- Define brand strategy (*own brand, manufacturers brand, over branding*)
- Determine launch feasibility

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AFFORD Sourcing & Approval of Product

- Identify quality suppliers currently manufacturing the defined product
- Initiate discussions with prospective suppliers
- Provide all technical specs, branding requirements estimated volumes and seek responses
- Negotiate terms and conditions including pricing
- If source is outside of U.S., prepare waiver application for USAID approval
- Sign MOU or contract with supplier

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On this slide the non-U.S. source waiver is highlighted because it turned out to be a critical step.

AFFORD Product Registration with NDA

- With manufacturer, prepare registration dossier per NDA product registration guidelines
- Submit registration dossier with product samples and necessary fees
 - If the manufacturer's facility is not approved by NDA, necessary fees have to be paid to get the facility approved by NDA
- On approval of the facility by NDA the product will be registered and permission will be granted for importation into Uganda

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Registration of products by NDA Uganda follows certain guidelines that need to be adhered to. Even if a manufacturing facility has the most stringent approvals like USFDA, MCC, MCA, TGA this facility has to be first inspected and approved by NDA Uganda before the product is registered and permission is granted for importation and marketing

AFFORD Brand Marketing Plan

- Develop and finalize marketing plan (*define the 4 P's, target audience, marketing strategy*)
- Obtain internal approval of marketing plan
- Develop advertising and promotional materials
- Pretest materials (*adverts, communication materials, promos, visuals etc.*)
- Finalise artwork and materials based on pre-test results

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These are a list of activities that run parallel to other launch preparation activities

AFFORD Approval & Production of Materials

- Ensure promotional materials are approved by relevant authorities (*NDA, MOH, USAID*)
- Request bids for print materials and advertisement production
- Select suppliers and prepare contracts
- Ensure quality and on-time production
- Finalise media plan and schedule

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AFFORD Training Program & Launch

- Develop training program for sales team, distributors, providers
- Prepare technical and promotional training materials
- Start product distribution and training
- Launch the product

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Development of a training program and materials for various targets within the organisation as well as for external training are very critical steps in ensuring that the correct and consistent messages and strategies are disseminated

- Original plan: Introduce the product in December 2006
- Introduction process began in February 2006
- Supplier was identified and negotiations finalised by May 2006
- Applied for USAID product source waiver in July 2006
 - Simultaneously prepared documents for NDA approval, developed draft designs for the pack, brand names were pre-tested
- Waiver approval received January 2007
 - Other steps were dependent on waiver approval: Final procurement agreement, product procurement, final NDA submission
- Product was launched in June 2007

The next two slide present brief case studies on two products introduced by AFFORD in the past 18 months. We'll focus on the aspects of each case that illustrate key lessons learned about our product introduction processes. AquaSafe is AFFORD's point of use water purification tablet. It was successfully introduced in the second quarter of 2007. Through the Aquasafe introduction process we dealt with some challenges that helped us learn lessons that we have applied to other introductions. First, although Aquasafe is not a pharmaceutical product, we had to submit a new product registration dossier to the Ugandan NDA. This submission required fully packaged samples with the proposed brand name and all product information. Providing fully packaged samples required completing the preceding steps first – that is, identifying, testing, and selecting the brand name and all associated packaging and packaging materials, based on research with Ugandan consumers. When we realized this we had to double-back a bit and de-couple the brand and packaging related research and deliverables from the other consumer research deliverables. This allowed us to submit fully packaged samples to the NDA, knowing that the packaging and other aspects of the product materials might still be changed prior to final production. Second, we also learned a lot about managing the USAID requirement that non-U.S. products receive a waiver. We identified a non-U.S. company as the best product source, and so prepared a source procurement waiver to our funder, USAID Uganda. The review and approval of the waiver took longer than we anticipated. Throughout, we learned what steps were more or less within our control, and which ones depended on outside reviews and decisions. We were able to get the product into the market quickly once the regulatory and procurement issues were resolved.

AFFORD Case Study



- Original plan was to introduce the product in September 2007
- Introduction process began in August 2006
- Suppliers were identified and negotiations finalised October - December 2006
- Applied for USAID product source waiver in July 2006
 - Simultaneously prepared documents for NDA approval, developed draft designs for the packs brand names were pre-tested
- Waiver approval received January 2007
- NDA registration through the two different companies took longer than expected: NDA approval received June 2007
- MOH had a close and ongoing role because a new treatment policy was involved
- Product ready for launch December 2007
- Product launched in February 2008 by MOH & AFFORD/UHMG

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Many of the issues highlighted for Aquasafe were similar for our second case study product, but still our second case study highlights some unique product introduction issues. Here we were introducing a new formulation of ORS along with zinc sulfate tablets, for childhood diarrheal disease management. Starting in early 2006 AFFORD laid the groundwork for a close collaboration with the Ugandan Ministry of Health Child Health Division in anticipation of future introduction of these products. The use of the new formulation of ORS and zinc sulfate for childhood diarrheal disease management requires changes in Ugandan MOH treatment policies and guidelines. It also implied a potential cost impact for the MOH if the products were eventually to be used as well as private sectors. On the NDA side, we learned that a truly new product, in this case zinc sulfate for diarrheal disease management, can be ahead of the regulatory system. At the time of initial registration, the NDA had zinc sulfate classified as a food supplement and registered it as such. However, by the time of the final dossier review, zinc sulfate had been added to the NDA's essential drugs list as a pharmaceutical product. Although the content of the dossier did not change, this change in context caused some additional reviews, and delays, in our introduction process. However, in the end we were able to resolve issues with the MOH and NDA. In the case of the MOH we were given approval for introduction in the private sector initially while the MOH considered a strategy for wider adoption. The NDA gave us approval to move forward, once they reached agreement with the manufacturer to inspect their facility. The net result was that a launch we had originally expected in July 2007 was fully ready in December 2007, with the products officially launched in February 2008. AFFORD's biggest lesson was the importance of establishing ongoing communication with the MOH particularly because the new products had implications for treatment policy. We also learned again how to develop clear guidance from the NDA regarding the requirements for new product registration, in this case, the requirement that manufacturers inspected if the product is classified as a pharmaceutical.

AFFORD Lessons Learned

- Identify suppliers that comply with recognized stringent regulatory authority to reduce delays in USAID waiver approval
- Clarify all NDA requirements prior to submission of registration file
 - Example: NDA must inspect factories of new suppliers of pharmaceutical products
- Streamline internal approval processes to reduce delays

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This slide offers a summary of the three key areas of learning for AFFORD concerning new product introductions.

AFFORD Lessons Learned

- Create new product team at start with a new product team leader
- Determine critical path for the launch
- Launch dates are moving targets: Weekly meetings to review progress help map out changing landscape
- Responsibilities must be shared among the team and not left to the team leader



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What are big lessons learned by AFFORD about product introduction? First, we have come to understand that launch dates are moving targets, and that this is as normal in social marketing as well as in private industry. Look at the Boeing Airplane Company, one of only two major aircraft makers in the world. Boeing recently announced more delays in the delivery of the 777 aircraft, with test flights to take place in June rather than March of this year, and the first delivery of aircraft in early 2009 rather than late 2008. And how many times has Microsoft announced a delay in the introduction of an updated version of its Windows software? At the same time, we have also learned how essential it is to keep the power and energy behind a product introduction – the internal team leaders must continue to regroup and refocus the introduction even as circumstances change and launch dates are revised.

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Lessons Learned

- Plan sequential and parallel activities
 - Have a tight grip on internal activities that can be controlled
 - Constantly follow up on external activities (*NDA, MOH & USAID approvals*)
- Realistically estimate timelines for specific activities (*research, pre-tests, internal approvals*)
- Realistically estimate the capacity and skills of ad agencies



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Finally, we have been continually reminded of the value of identifying sequential versus parallel activities, as well as those processes over which we have more or less control. Realistic time and capacity planning is also essential.

Most important, AFFORD is learning how to best streamline its own internal management, review, and approval processes, so that we reduce the extent to which our own processes contribute to delays. We do not want to say that “we have met the enemy, and he is us.”

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Lessons Learned

- Creating and tracking a plan is useful, even when plans change
- Make dependent processes clear
 - delivery lead time and responsiveness of suppliers
 - ad agency response, internal reviews, revisions
 - waivers and regulatory approvals – NDA, MOH USAID
- USAID and AFFORD gaining experience
 - Learning more about commercial procurement
 - Important to document processes
 - Learning curve identifies potential roadblocks in future introductions
 - Helps build leadership and management skills

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Still, having a plan that can be tracked is very useful for management, even when plans change continuously. We have identified those processes that are most likely to cause other steps to be delayed, those being (1) establishing final agreements with suppliers and factoring in delivery lead times; (2) realistically managing the time required to get designs and materials from ad agencies, and then reviewing and revising them; and (3) obtaining approvals from USAID, the MOH, and the NDA for their respective inputs.

AFFORD and USAID are gaining experience in this new approach to social marketing, especially where commercial suppliers are used.

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Thank you!

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