



PRITECH

Technologies for Primary Health Care

Management Sciences for Health
1925 North Lynn Street
Suite 400
Arlington, Virginia 22209

PA-ABM-220
ISA 79172

PRELIMINARY PROPOSAL
ESTABLISHING SUSTAINABLE LOCAL
PRIVATE SECTOR PRODUCTION AND DISTRIBUTION
OF ORS IN ZAIRE

A Report Prepared By:
AGMA PRINS
CAMILLE SAADE

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1. EXECUTIVE SUMMARY

Introduction

This proposal outlines a strategy to produce ORS in Zaire by a private sector food manufacturer, Cowbell, and to market this product through pharmaceutical and consumer goods outlets, currently used by PSI and Cowbell. From the marketing perspective, the project will increase demand for ORS to assure a sufficient and sustainable market for this essential health product throughout Zaire. The objective here will be to make the product available where most people buy their medication for simple illness: the market place, as well as in pharmacies and shops and in a form that will be attractive and desirable, at a price affordable to a majority of the population.

From a public health perspective the project will address the need to teach Zairian mothers how to mix and use ORS correctly within the context of an effective home management strategy which includes feeding and continued breast feeding.

Recommended Strategies

The proposed project consists of six strategies:

1.1. Activities to address regulatory concerns including the exemption of ORS from the laws applied to pharmaceutical products and the modification of the defactonational CDD policy of the PEV program so as to include ORS as a possible home fluid for the prevention of dehydration in the home.

Deregulation of ORS from the pharmaceutical classification will permit the manufacture of ORS by a non-pharmaceutical (food) manufacturer, its distribution through non-pharmaceutical channels, and its mass advertising.

It is recommended that USAID, with help from PEV, CEPLANUT, PSI and UNICEF, obtain this deregulation from the Minister of Health.

1.2. Activities to ensure the establishment of Good Manufacturing Practices (GMP) at Cowbell production facility will include plant modification as well as installation and utilization of adequate laboratory equipment by trained personnel. The full-time presence of a pharmacist may be

required during the production process. It is desirable that the deregulation agreement with the MOH include an agreement to put quality control in the hands of OZAC, the regulatory body with which Cowbell currently works for quality control of its food products.

1.3. Information gathering activities necessary to the design of an effective educational/promotional strategy and materials. Included would be: a) basic market research to clarify the current attitudes and practices of mothers (consumers), pharmacy personnel and non-pharmaceutical retailers vis-a-vis ORS, as well as toward the distribution of this product through non-pharmaceutical channels; b) basic socio-cultural research to clarify the most effective educational and promotional messages; c) pre-testing of educational materials prototypes and package design.

1.4. Educational activities to ensure the correct use of ORS by mothers. These activities will be part of an overall mothers education/ORS promotion strategy. A two phased approach is recommended: PHASE I will emphasize the correct treatment for diarrheal illness by increased consumption of fluids, continued feeding and continued breast feeding. This phase should take place prior to the launching of the ORS product. PHASE II will recommend ORS as a good choice of fluid for diarrhea and will emphasize the correct mixing and use of ORS (while continuing to instruct mothers about appropriate feeding and breast feeding during diarrhea). Both phases should continue after the commercial launching of the branded ORS.

1.5. Promotional marketing activities will be targeted to consumers, pharmacy personnel and non-pharmaceutical retailers (wholesalers as well as retailers). These promotional activities will be a component of the overall educational and promotional strategy. Messages should be in harmony with national CDD policy. Implementers will include PSI and Cowbell, for the pharmaceutical and consumer products retail channels respectively.

1.6. Evaluation activities will include a mid-term evaluation after the implementation phase and a final evaluation. In addition, periodic surveys are recommended as part of a continuing process of testing message effectiveness and adjusting educational and promotional activities as necessary.

Timing and Budget

The proposed project to establish a sustainable local private sector production and distribution of ORS in Zaire spans over a period of three years and would cost, depending on the level of communications efforts, between \$800.000 to \$1 million.

2. INTRODUCTION

A PRITECH team composed of the PRITECH Private Sector Marketing Expert, Mr. Camille Saade, and Regional Program Manager, Ms. Agma Prins, visited Zaire from 15 - 25 October, 1990 to review the feasibility of private sector production and marketing of ORS in Zaire as well as to make preliminary recommendations concerning the eventual implementation of such an effort. This was step one of a two-step process, to be followed by a second visit to design a more detailed approach if a decision was made to go ahead with the project.

The PRITECH visit was preceded by two other consultant visits. The first of these was completed by a Project SUPPORT team in March of 1989. This team reviewed a number of possible local producers, including the para-statal, Laphaki, a number of pharmaceutical producers including PROMED, and some local food producers, including Cowbell, a company which currently produces and distributes packets of milk powder, fruit drinks and baby cereal. The SUPPORT team concluded that Laphaki, although technically capable of producing sufficient ORS to meet local demand, was unable, at present, to produce sufficient ORS to meet even public sector needs due to production and management problems, further exacerbated by the inability of the MOH, through the PEV program, to pay for the requisite packets. In addition, Laphaki is legally barred from sale to the private sector. The SUPPORT team found the pharmaceutical producers were interested primarily in production of a relatively higher priced product aimed at the pharmaceutical sector and reflecting the high mark-ups of this sector. Of the potential producers reviewed, only Cowbell appeared to be interested in the production of a high volume, low mark-up product accessible to the majority of Zairians. The primary constraint on the potential production of ORS by Cowbell appeared to be the government classification of ORS as a "drug" and the consequent legal restrictions on its production by a non-pharmaceutical producer, its distribution through non-pharmaceutical channels and the advertising of a brand name product through the mass media.

A second consultation visit occurred from 2 - 5 May, 1990, by John Tomaro, working for USAID/S&T/Health. Tomaro designed a strategy for local private sector production and distribution of ORS based on a partnership between Cowbell, Population Services International (PSI), a USAID contractor responsible for the introduction, promotion and sales of contraceptives in the private sector in Zaire, and USAID. USAID would provide a one-time grant of \$200,000 to PSI, who would in turn provide a loan of \$75,000 at 9% interest per year for a period of three years to Cowbell. The remaining \$125,000 would be used by PSI to finance promotional activities for ORS. Cowbell would use the loan to upgrade its production facilities to meet Good

Manufacturing Practices (GMP) standards for pharmaceutical production. The loan would be repaid to PSI in ORS packets. PSI would also purchase additional packets from Cowbell "at a preferred rate" for sale through pharmaceutical channels. Cowbell would distribute its product through consumer goods channels which now distribute other Cowbell products. Tomaro also suggested that a coordinating "working group" be established to "ensure that private sector activities are complementing GOZ efforts". This group would be composed of the major private and public sector groups involved in CDD and ORS and serve to review promotional activities, share distribution and sales figures and exchange information on quality control measures. The group would have an advisory rather than a policy-making role.

The proposal described in this paper is an expansion of the proposals submitted by the previous consultants. The proposed strategy seeks to address both public health and marketing concerns. As a social marketing effort, the main objective of the project is to dramatically increase access of a large proportion of the population to a key ingredient (ORS) in the good home management of diarrheal illnesses, while ensuring correct use of this product as part of effective treatment by most families. Correct use of ORT for the home management of diarrhea includes not only proper mixing and administration of ORS but also adequate feeding during and after diarrhea and continued breast feeding.

It became evident in the course of the PRITECH visit that, while there is reason to believe that there is adequate demand to justify a local private sector ORS production and that available local channels provide a much needed opportunity to significantly increase access to this product, it is also highly probable that the majority of Zairian mothers, while they may have heard of ORS, do not know how to use it correctly. This reality suggests the need for a well planned educational effort prior to and concurrent with the marketing promotion effort. It also underlines the need for a collaborative effort between private and public sectors in order to meet the goals of the project.

1. KEY ISSUES FOR SUSTAINABLE MARKETING OF ORS

3.1. Need for a collaborative effort between private and public sectors

De facto national CDD case management policy as implemented by the National PEV/CDD Program to date has been to limit the use of ORS to the treatment of dehydration in health facilities, while recommending the use of home available fluids (including SSS) for the prevention of dehydration in the home. This fact has several very important implications and consequences:

3.1.1. The private sector marketing of ORS as a recommended home fluid for the prevention of dehydration does not correspond with current national CDD policy. Prior to commercial distribution of ORS, a clear national policy including ORS as one possible home fluid to prevent dehydration should be established by the PEV/CDD program.

3.1.2. Attempts by the public sector program to educate mothers to mix and use ORS correctly as a home remedy for diarrhea have been limited, at best. Data from coverage surveys completed by the PEV program in 1988 in 20 sites throughout Zaire show that mothers' reported use of ORS to treat diarrhea varies between 0% and 73%, with 15 sites reporting use rates of under 30%. It is not clear whether these "users" represent mothers who received their ORS at health facilities at the time of their initial visit. Another 1987 PRICOR survey reported that in three sites, only 50% of mothers who received ORS at 19 health facilities received instruction on how to mix and administer ORS. In the same survey only 21% of community health workers interviewed cited ORS as a treatment for diarrhea.

Limited knowledge of correct use of ORS coupled with wide distribution could lead to disillusionment with this product by mothers who found that it did not meet their expectations after incorrect use. A further possible consequence is that some children could suffer adverse effects (even death) from consuming hyper-concentrated solutions if their mothers mixed the packets with too little water.

3.1.3. There are at present no local educational materials to educate mothers in the correct use of ORS. Appropriate materials would educate mothers in the importance of fluids and feeding (and breast feeding) for treating diarrhea at home, present ORS as a possible home fluid, teach correct mixing and use of ORS, and recommend referral to health facilities when necessary. Commercial promotion materials (including package instructions) are mostly product oriented and may not be best suited to getting educational messages across in a consistent manner. Public sector education and private sector promotion should complement and reinforce each other to increase awareness, knowledge and skills, as well as demand. Collaboration of the MOH would not only make possible brand name advertising - a powerful way to increase demand - but would also create possibilities for low-cost education through the mass media (a private market survey in Lubumbashi and Kisingani showed that, in those areas, 68% of the population watched television occasionally while 74% sometimes listened to radio).

In addition to teaching mothers, public and private sector collaboration is needed to assure modification of current government regulations to allow for the production and distribution of ORS through non-pharmaceutical channels as well

as to make sure that GMP are followed in the production of ORS.

3.2. Need for local private sector production and mass distribution of ORS

Currently ORS is distributed exclusively through health care facilities and pharmacies. Pharmacies are located primarily in urban areas, carry imported ORS products targeted primarily at the wealthy and tend to recommend other more expensive, less appropriate products (anti-diarrheals, antibiotics) in preference to ORS.

Only 26% of the total national population (40% in urban areas, 17% in rural areas) has access to health services. PEV currently estimates that it has about 3-4 months worth of ORS supplies in the pipeline. It is not unlikely that public sector ORS supplies will decrease. Managerial and financial problems at Laphaki (which has produced an average of only 288,000 packets per annum-see annex 1) seem to be worsening. PEV continues to struggle with its "revolving fund" to purchase Laphaki output. Donations of imported packets (UNICEF, USAID) have partially compensated for insufficiencies of local packet production. However, these packets come in a one liter pack size which is different from the locally produced 750 ml size packet. Private sector production and distribution would increase the probability that health facility patients requiring ORS could obtain it even when the public health system was unable to supply it.

As pointed out by the Project SUPPORT team, there is little information available on the total volume of ORS supply and demand in Zaire. However rough estimates suggest that the actual supply is far inferior to demand. Total volume of ORS sales through the private sector pharmaceutical channel was estimated by CIBA-GEIGY, the largest distributor, at 1,000,000 packets per year. The national PEV program, primary distributor of ORS to both public and non-commercial private sector health facilities, reports a distribution of 1,419,000 packets from January - October (inclusive) of 1990. Accepting CIBA-GEIGY's estimate of 1,000,000 commercial packets and guesstimating another 500,000 packets from other sources (mission hospitals, smuggling, other health programs), total availability of ORS can be estimated at a maximum of 3,500,000. Zaire's population of 33,000,000 includes approximately 7,000,000 children under five years of age. Studies have estimated an average of 5 episodes of diarrhea per child per year. Three packets of (750 ml.) ORS are required per episode. If even one episode per child were correctly treated, the country would need 21,000,000 packets of ORS per year. According to SUPPORT, PEV estimates its current demand at 4-5 million packets per year. Private sector demand has been estimated at 7-8 million packets by one pharmaceutical producer.

There may be as many as 8 different ORS products (ranging from effervescent tablets in 120 ml dosages to packets for 500 ml. and 1 liter) on the market. Widespread commercialization of a single brand name ORS which follows national standards and sells at an affordable price would help eliminate some of the confusion generated by the diversity of available products.

An informal and rapid "market survey" in Kinshasa revealed that, in both pharmacies and the ubiquitous market drug stalls, a variety of costly and dangerous products are being sold as a diarrhea treatment for children. In the market, a tablet of tetracycline, Imodium or other "anti-diarrheal" can be obtained for 50 - 100 Zaire (equaling about 200-400 Z per "treatment dose"). A 1989 survey conducted by the SUPPORT team revealed ORS products in pharmacies ranging in price from 90 - 800 Z per treatment dose (1989 prices). PEV estimates actual cost of packets to mothers at health facilities at between 100 - 200 Z. Under those circumstances, a packet of ORS at 180 - 250 Z (the current Cowbell retail price estimate) would be competitive price-wise and a safer alternative to other commercially available products.

Diarrheal disease is still among the top three causes of morbidity and mortality in Zairian children. The AIDS epidemic will probably continue to effect these figures as diarrhea is one of the principal symptoms of AIDS. ORS and food is an effective treatment for all diarrheas.

STRATEGIES

4.1. Obtaining Regulatory Approval

As mentioned above, deregulation of ORS to permit production and distribution of ORS by a non-pharmaceutical company is a necessary condition precedent to the implementation of this project. There is some concern that this deregulation may be difficult to achieve. Several potential partners in the project including PSI and CEPLANUT felt, however, that they may be able to help in procuring the necessary agreements from the MOH. The PRITECH team recommends that USAID proceed through regular government channels, enlisting the support of other potential intermediaries (including those mentioned above as well as the director of the PEV/CDD Program, and UNICEF) as necessary, to obtain the required exemptions from the pharmaceutical regulations for ORS. Full concurrence and participation of appropriate government authorities will prove invaluable at later stages of project implementation. Lack of such agreement may result in later blockage of key project activities.

Another important preliminary step will be the development, with the PEV/CDD program, of an official national policy for

diarrheal case management which clarifies the role of ORS as an acceptable home fluid for the prevention of dehydration. Such a policy will serve as a solid base for the development of appropriate educational messages and materials as well as a motivator for the wholehearted participation of public sector health personnel in the implementation of the strategy.

4.2. Upgrading Production to GMP Standards and ORS Product Improvement

4.2.1. ORS PRODUCTION ISSUES

If a consumer goods company such as Cowbell produces ORS, MOH approval will be needed. Approval is linked to the ability of Cowbell to meet GMP quality standards. Upgrading to GMP means redesign of production line/flow, investment in laboratory equipment and trained personnel and adopting the practices necessary to document the production and quality control steps. Cowbell will need a loan to modify conditions at their plant prior to beginning to produce ORS. The Cowbell management believes these modifications can be achieved quite rapidly, within three months of project approval. Technical assistance will be required to help them meet these requirements, however. In addition, Cowbell may be required by the MOH to engage a full-time pharmacist to monitor production of ORS, at least during the actual time of such production. Cowbell management did not perceive this to be problematic, but the details will have to be worked out. Finally, in the regulatory environment of Zaire, it would be considerably less costly to Cowbell if an agreement could be reached with the MOH that the government body overseeing the compliance to quality standards would be the same one now in charge of monitoring Cowbell's food production activities, OZAC. However, we need to confirm with MOH that OZAC has the capabilities or the potential to undertake the quality control responsibilities for what is currently a pharmaceutical product.

PRITECH and ST/Health recommend that Cowbell's capabilities to meet and maintain GMP quality standards in ORS production be carefully assessed. To this end, we are proposing that an expert in ORS production be added to the follow-on team in January 1991; this expert will examine the feasibility of quality control at Cowbell and assess the monitoring capabilities of OZAC.

Initially, the low volume of ORS sales will not justify a full-time mixing or packaging machine. ORS will be produced at a rate of 500,000 packets/week (three shifts). Estimated first year needs are 1.5 million. This quantity can be produced in 3 weeks. This means that the same machines used to mix and package ORS will be used the rest of the year to mix and package other Cowbell products, at least until the volume of demand

justified the full time use of these machines for ORS production alone. Necessary cleaning and sterilization procedures will have to be carefully reviewed. A related issue is that of staff assigned to ORS production. Cowbell currently uses day laborers in addition to its full-time employees at periods of high production. If ORS production requires labor with a different level of training than is necessary for food products, specific staff may have to be assigned to ORS production when this is in process. These issues can only be clarified and resolved with expert technical assistance

4.2.2 PRODUCT RELATED DECISIONS

All ingredients and packaging material for the ORS product will have to be imported to Zaire. Although Cowbell is already importing packaging and most raw materials for its food products, this raises concerns in an environment where foreign exchange is increasingly difficult to obtain. However, local sugar can be substituted for anhydrous glucose by doubling the quantity. Cowbell is already crushing local sugar for use in its other products and reports no problems with excess moisture. However, the decision to use local sugar for ORS implies a larger package size as well as pre-production testing for osmolarity, stability, taste and shelf life.

It is likely that flavoring will enhance the acceptability of the product to children who have diarrhea but are not yet severely dehydrated, thus making it more likely that mothers will continue to purchase ORS for home use. What are the price implications of this (probably very little)? The choice of appropriate and acceptable flavoring for a product to treat diarrhea will have to be determined through preliminary market research and taste testing.

There has been some discussion about the possibility of producing two different products: one for sale through food channels, the other for the pharmaceutical sector. The PRITECH team agrees with Cowbell that a single brand of ORS should be marketed by both PSI and Cowbell. This would strengthen the impact of product promotion activities and reduce consumer confusion by focussing attention on a single product. Glucose/Sugar based ORS could be followed by a cereal based product (currently undergoing clinical trials by WHO) at a later date.

It has been agreed by all parties that the final product should be packaged to be mixed in 750 ml. of water, following national CDD policy. In addition, the package should provide pictorial mixing and usage instructions comprehensible to illiterate mothers and in concordance with national CDD guidelines. If possible, the message should include information about feeding as well as fluid intake. Sufficient pretesting of these

instructions is essential.

4.3 Gathering Needed Information on Target Audiences

There appears to be a general dearth of information key to the development of an effective promotional and educational strategy concerning ORS/CDD. Some basic, rapid but appropriate, research will be required prior to comprehensive strategy design. Two types of information are needed:

4.3.1. Information concerning the market potential for ORS including:

- * A better estimate of actual ORS availability and demand,

- * An understanding of the acceptability to mothers, wholesalers and detailers, of the sale of a "health" product at non-pharmaceutical points of sale including general consumer goods shops and market stalls specializing in small consumer goods articles (eg. powdered milk, matches, etc.) Zairians generally purchase medication at pharmacy shops or from market vendors ("tables") specialized in pharmaceuticals. Will they purchase ORS from non-pharmaceutical outlets? Will the sale of ORS through such channels in Zaire make it a less "valid" medicine in the eyes of the people? Will non-pharmaceutical wholesalers and retailers be willing to carry such a product?

- * An understanding of pharmacists', retailers' and consumers' current beliefs and attitudes about ORS as a diarrhea treatment, especially in comparison with competing products. Also a better understanding of families' willingness to pay for ORS (at what price?) and retailers' actual pricing practices. While specific retail mark-ups are legally established, it is generally acknowledged that these are often not closely followed by vendors.

- * Clarification of consumers' attitudes and preferences in flavoring for "medicines" for children.

4.3.2. Sociocultural information concerning mothers' beliefs and attitudes toward diarrheal diseases and their perception of appropriate treatment.

Stan Yoder's 1989 research in Lubumbashi, for example, showed that mothers there traditionally identified 5 different diseases of which diarrhea was an important symptom. They believed that ORT was an appropriate treatment for only one of these: "kuhura" or "simple acute diarrhea". Treatment strategies for the other four diarrheal illnesses included applying mixtures of ashes and palm oil to the fontanelle, suppositories of various

kinds, herbal baths, and so forth. Educational messages recommending ORT for "kuhura" would simply reinforce mothers' erroneous belief that this treatment was not appropriate for other types of diarrhea. "Sunken fontanelle disease" (lukunga), probably diarrhea with dehydration, was not treated as diarrhea by giving ORT, but was specifically treated by rubbing herbal remedies on the fontanelle area, indicating that the children most in need of ORT were least likely to receive it. Given the cultural diversity of Zaire, this type of information should be gathered in other major cultural zones prior to the design of educational or promotional messages.

Another area that needs clarification concerns mothers' worries concerning the consequences of diarrhea. While most mothers certainly want the diarrhea to stop, this may not always be their only or first concern. As already indicated, for some types of diarrheal illnesses, their concern focusses primarily on other signs (eg. the sunken fontanelle in the case of "lukunga", the redness of the anus for "kilonda ntumbo"). Even for "kuhura", mothers may be more concerned about the child's weakness and listlessness or loss of weight than about "dehydration" which is a relatively foreign concept. Mothers are more likely to want to use ORS and ORT if it is presented to them as a medication which addresses their real concerns about their child with diarrhea rather than if it is associated with a concept that is currently probably not generally well understood.

Once educational and promotional messages have been agreed upon, both the messages and the prototype materials incorporating those messages have to be field tested prior to finalization.

4.4. Educating the Target Audiences

Educational activities should target mothers, health personnel, pharmacists and their assistants, wholesalers and retailers. The first concern must be that these target groups understand that ORT (liquids + food + breast feeding) is the best "medicine" for all diarrheas, and that this combination not only shortens the duration and decreases the severity of the diarrhea but also combats the negative consequences of diarrhea. In addition, mothers should be informed that other medications are not only unnecessary but possibly dangerous for their children. Promotion of ORS, and especially of a brand name ORS product, for the home fluid for diarrhea should be a secondary concern.

A multi-media, multi-channel, integrated approach will be most effective at getting these messages across. The use of television, radio, wall posters, billboards, mothers' leaflets, popular theater and other available resources is encouraged. The best strategy would draw on the resources of all the partners. Cowbell has access to excellent graphic artists and

has a very good rapport with the television station in Kinshasa. PSI also has access to graphic artists and visual materials production specialists as well as to radio. SANRU has experience with community level health education including popular theater. PEV has an IEC department and has worked with health personnel in the area of health education. The MOH can facilitate low cost access to the mass media for health education.

The education strategy should be one component of an overall, integrated health education/ORS promotion strategy so that one will reinforce the other.

4.5. Segmented approach to Distribution and Promotion of ORS

Locally produced ORS will be distributed and promoted through two channels:

- 1) consumer products outlets, through Cowbell and
- 2) pharmaceutical outlets, through PSI.

In addition, PSI should explore means to promote and distribute the ORS through health facilities linked to large industrial facilities (eg. the mining companies) and those run by missions and other private sector and non-profit organizations who are not currently supplied by Laphaki. PSI may also be able to promote ORS through women's and other community based organizations, especially in Kinshasa.

The ORS distributed through Cowbell and PSI will be an unsubsidized product, in the interest of strengthening the long-term sustainability of the effort. Cowbell believes that high volume demand will keep the price competitive in the consumer products sector. Legal mark-ups in the pharmaceutical sector are higher than in the non-pharmaceutical sector, but free market competition should keep the price low enough to be within the reach of many, probably most, Zairians. With the steadily worsening economic conditions in Zaire, it is possible that this commercial ORS will not be within reach of the poorest urban inhabitants as well as of cash-poor rural families. At the same time, the retail per-packet price currently estimated by Cowbell: 18 - 20 US cents (at 1000 Z to 1 US \$) in shops and markets, 20 - 25 US cents in the pharmacies, is not very different from the reported actual ORS cost to mothers at government health facilities: 10 - 20 US cents. It is posited that the poorest families will benefit from educational activities teaching the use of home fluids and feeding and may benefit from subsidized public sector ORS for the treatment of dehydration in health facilities. Pricing issues should be further investigated prior to the market launch of the Cowbell product (see "Information Gathering" above).

ORS promotion activities should be targeted at pharmacy wholesale and retail personnel and consumer products wholesale and retail personnel as well as at consumers. These promotional activities should aim to educate the target populations regarding the advantages of ORS over competing products, the role of proper nutrition in the treatment of diarrhea, the proper preparation and use of the product (including specific advise to mothers about what to do if the child refuses to drink, vomits or if the diarrhea does not stop within three days). It should be remembered that the most likely point of contact of the consumer is not the pharmacist or shop owner but the sales clerk or pharmacy assistant. These are thus key target audiences for trade promotional activities.

Promotional activities should be segmented according to each target audience and incorporated into an overall education/promotion strategy.

4.6. Evaluating the Strategy and Expanding ORS Nationwide

Nine months after the product launch, a mid-term evaluation should assess the impact of project activities on ORS accessibility, cost of ORS to mothers, demand for ORS, sales volumes, mothers' and distributors' attitudes toward ORS and knowledge of correct preparation and use and other issues related to project effectiveness and sustainability. An evaluation specialist should design the evaluation strategy during the preparatory phase of the project so that adequate baseline data can be collected for later comparison. The outcome of the mid-term evaluation should lead to a decision to continue (or not) to the national expansion phase of the project as well as to modify specific strategies, if necessary. Prior to the mid-term evaluation it is expected that those responsible for educational and promotional activities will conduct simple periodic surveys (once every three months) to assess the effectiveness of their messages and materials. A final evaluation will take place one year after the national expansion of the program.

5. STRATEGY PHASES

The strategy consists of three phases:

5.1. A preparatory phase during which regulatory and legal concerns will be addressed, market research and other preliminary studies will be conducted and educational and promotional materials will be designed and produced. Depending on availability of resources, both human and financial, this phase can be expected to take between 6 and 12 months.

5.2. An implementation Phase I during which the educational and promotional activities will be launched and the product subsequently distributed primarily to the regions of Kinshasa and Lubumbashi. The purpose of this phase will be to test the strategy from both an educational and a marketing perspective. A mid-term evaluation at the end of this phase will lead to a review of the strategy and an expansion of activities to the rest of Zaire. This phase is expected to last between 9 and 12 months.

5.3. An implementation Phase II which will consist of the expansion of the project to the rest of Zaire. This phase is expected to last approximately one year.

Total project duration is estimated at three (3) years from the beginning of implementation.

6. KEY PLAYERS AND THEIR ROLES

This project is a collaborative effort between different players in the public and the private sectors. Many organizations and institutions are involved. To be successful, working relationships will have to be established among the partners, perhaps in the form of a coordinating committee. At the same time, a dedicated person must be designated to ensure coordination of the different activities and to manage day-to-day implementation. This individual, ideally a neutral "program coordinator", will also need to take responsibility for organizing activities which do not fall within the purview of one of the collaborating partners. Such activities might include the design of market research, the design of an overall education/promotion strategy (possibly working with a consultant specialized in this area), the preparation of evaluation plans and activities. Short-term technical assistance may be required to assist Cowbell with necessary plant modifications, to assist in the design of an overall communications (education/promotion) strategy including materials design, to design market and social research and to prepare evaluation activities.

Partners in the program include:

6.1. The Ministry of Health, specifically the PEV program, CEPLANUT and the Direction of the Pharmacy. Responsibilities of these departments of the MOH will include:

* Facilitating declassification of ORS as a product subject to pharmaceutical regulations concerning production, distribution and name brand advertising by a non-pharmaceutical company, yet verification of the manufacturer's compliance to GMP,

- * Revision of the national CDD policy to include ORS as a possible recommended home fluid for prevention of dehydration,

- * Coordination of the development of an educational and promotional strategy, specifically in terms of message content,

- * Implementation of mother education activities in the public sector health facilities,

- * Identification of public sector training needs (if any) to implement necessary education activities and development of an approach to meet these needs, if required.

6.2. Cowbell, the manufacturer, whose responsibilities will include:

- * Plant modification to comply with GMP,

- * Manufacture of sufficient quantities of ORS to meet demand,

- * Distribution of their ORS product through non-pharmaceutical channels,

- * Promotion of ORS via mass media: television, billboards, etc.; trade promotion to retailers; inclusion of appropriate educational messages in the promotional materials in conformity with MOH policy; appropriate packet design,

- * Facilitation of the process of materials development for the public sector educational strategy.

6.3. PSI, whose responsibilities will include:

- * Distribution of the Cowbell product through pharmaceutical channels,

- * Management of the USAID loan to Cowbell,

- * Development/production and distribution of educational materials for pharmaceutical personnel, of point of sales materials for consumers and of radio promotional spots. These should be coordinated with Cowbell and follow MOH guidelines in terms of message content,

- * Assistance with public sector education, especially in Kinshasa, using existing contacts and networks,

- * Mobilization of large private sector companies or governmental industrial facilities such as GECAMINES,

SONATRA, etc. to use ORT in their health facilities and to distribute the Cowbell product, where appropriate,

- * Mobilization of non-commercial private sector health services (eg. mission health facilities) to use and promote ORS and obtain their supplies from either the PEV program or from Cowbell rather than external sources,

- * Planning and conducting of periodic surveys to assess the effectiveness of the educational and promotional activities...perhaps in partnership with SANRU.

6.4. SANRU, Sante pour Tous, and other broad-based non-governmental health programs who will participate in:

- * Development and production of necessary educational materials for the public sector,

- * Realization of necessary socio-cultural research, materials testing, communications impact monitoring,

- * Provision of a "home" for the project and the "project coordinator" or technical assistance (SANRU).

6.5. USAID will be responsible to:

- * Work with others (PEV, CEPLANUT, PSI, UNICEF) to obtain deregulation of ORS from the Minister of Health,

- * Arrange appropriate financing and agreements with Cowbell, PSI and other partners,

- * Facilitate the establishment of collaborative and cooperative arrangements between the various partners, especially those funded by USAID,

- * Monitor the continuation of appropriate quality control measures at Cowbell,

- * Assure availability of adequate technical assistance where necessary,

- * Phase out importation of packets for the public sector as a measure to reinforce demand for locally produced ORS,

- * Assure adequate program evaluation.

6.6. UNICEF can contribute to this effort by:

- * Helping to facilitate deregulation of ORS by the MOH,

* Participating in a review of the ORS supply strategy for the public sector (with PEV, USAID, WHO ?),

* Assisting in the production of public sector ORS promotional and educational materials.

* Phase out importation of packets for the public sector, and allocate resources towards reinforcing local manufacturing (primarily through Lafhaki if feasible).

6.7. PRITECH may be able to contribute to this project by performing a coordination and technical assistance role.

7. ACTION PLAN FOR THE ORS PRIVATE SECTOR PROJECT

The following preliminary calendar of activities is predicated on three basic assumptions:

* that a detailed project strategy has been finalized and approved by USAID/ Kinshasa by January, 1991,

* that funding to implement this strategy has been approved and made available by USAID by that time, and

* that a suitable "project coordinator" has been located and hired by March, 1991 at the latest.

ACTIVITY	RESPONSIBILITY	DEADLINE
7.1. <u>PREPARATORY PHASE</u>		
7.1.1 Seeking Approval		
7.1.1.1 Develop and send to USAID/Zaire preliminary proposal for ORS classification as a non-drug (medicinal food)	PRITECH/Wash D.C.	12/90
7.1.1.2 Discuss proposal with PEV and incorporate their input for gaining ORS deregulation	USAID/PEV	12/90
7.1.1.3 Obtain approval for ORS deregulation from MOH and other government bodies	USAID/Unicef/PEV and other partners	1/91
7.1.1.4 GO Decision for local manufacture of ORS by Cowbell	USAID	1/91

7.1.2 Production Planning

7.1.2.1	Provide T.A. on production and quality control to upgrade Cowbell to GMP standards	PRITECH/T.A.	2/91
7.1.2.2	Confirm Feasibility of local sugar mix	Cowbell/PRITECH T.A.	2/91
7.1.2.3	Finance and implement plant modifications at Cowbell	PRITECH/USAID/Cowbell	3/91
7.1.2.4	Finance and equip Quality Control plant at Cowbell	PRITECH/USAID/Cowbell	4/91
7.1.2.5	Ordering of raw material	Cowbell	3/91
7.1.2.6	Ordering of packaging material (pending final label design)	Cowbell	9/91
7.1.2.7	Stability test for first batch	Cowbell/PRITECH T.A.	8/91
7.1.2.8	Production of ORS in its final pack	Cowbell	12/91

7.1.3 I.E.C. Planning

7.1.3.1	Update national CDD Policy including ORS as a home solution	PEV/PRITECH T.A.	1/91
7.1.3.2	Develop preliminary education and promotion strategy	ORS coordinating Committee / PRITECH T.A.	1/91
7.1.3.3	Develop preliminary marketing plan	PSI/Cowbell / PRITECH T.A.	2/91
7.1.3.4	Identify information needs and develop market research objectives	PSI/PRITECH / Cowbell	2/91
7.1.3.5	Appoint market research agency, design methodology, conduct study, analyze results	Market Research Agency (ZAT ?)	5/91
7.1.3.6	Finalize promotion and creative strategy	PRITECH/PSI / Cowbell	6/91

7.1.3.7	Develop and test messages, materials, labelling	PRITECH/PSI/ Cowbell/PEV/ SANRU	9/91
7.2. <u>IMPLEMENTATION (PHASE I)</u>			
7.2.1 Launch of Educational Campaign			
7.2.1.1	Media and face-to-face educational campaign to build awareness on home treatment of diarrhea through fluids + breast feeding + food	PEV/Unicef/ SANRU/Cowbell	9/91
7.2.1.2	Introducing the message about specific fluids i.e. ORS	as above	11/91
7.2.1.3	Distribute mothers' leaflets/posters on home treatment showing ORS mixing through health centers, NGOs, etc.	as above	9-12/91
7.2.2 Marketing Launch of ORS			
7.2.2.1	Filling distribution pipeline in: pharmaceutical channels; food channels	PSI/Cowbell	1/92
7.2.2.2	Launch of pharm promotion to pharmaceutical personnel	PSI	2/92
7.2.2.3	Launch of advertising to consumers and retailers	Cowbell	2/92
7.2.2.4	Evaluation of ORS marketing/ education in Kinshasa and Lubumbashi	Cowbell/PSI/ USAID/PRITECH	9/92
7.3. <u>IMPLEMENTATION (PHASE II)</u>			
7.3.1	National expansion of activities	all partners	12/92- 12/93
7.3.2	Final evaluation	USAID/PRITECH	12/93

8. PRELIMINARY BUDGET

The following is a very approximate budget estimation to give an idea of the order of magnitude of the funding required for this project as described above.

Funding for PSI/Cowbell (as per J. Tomaro proposal)	\$200,000
Long term T.A. ("Dedicated person"/project coordinator) (2 years)	\$250,000
Short term T.A. (10 person-months)	\$150,000
Educational/Promotional materials/Media activities	\$200-400,000
TOTAL	\$800,000-1,000,000

ORS PACKETS IN ZAIRE PUBLIC SECTOR

Year	Packets Produced Locally	Packets Imported	Total Packets
1980	0	390000	390000
1981	80000	490000	570000
1982	195000	380000	575000
1983	310000	640000	950000
1984	205000	2270000	2475000
1985	280000	370000	650000
1986	54000	3050000	3104000
1987	602580	0	602580
1988	564400	87400	651800
1989	307000	200000	507000
Annual Average	288664	787740	1076404

Source: PEV/LMTE

LIST OF CONTACTSCiba Geigy

66 Ave. Lt Colonel Lukusa
Kinshasa - tel 24202

Mr. André Schoepfer
économiste, chef de région
division pharmaceutique

Cowbell

6078 Ave. des Entrepôts
Kingabwa - tel 77702

Mr. Trevor Watkins
Directeur Général
Mr. Paul Rose
Directeur de Marketing
Mr. Nguisana - Chimiste, chef
de production

Laphaki

Ave. des pharmacies
Kinshasa

Mr. Baketa
Directeur - pharmacien

Population Services
International

(PSI) Avenue Kasavubu
Kinshasa

Mr. Jay Drosin
Directeur
Mr. Carlos Ferreros, ex-
Directeur

PEV/LMTE

28 Ave. de la Justice
Kinshasa - tel 31106

Dr. Musindé - Médecin Directeur
Mme Bipendu - Pool coordination
Mr. Issa - pharmacien
Dr. Mutombo wa Mutombo
coordinateur LMD (met in
Wash. D.C.)
Mme Karen Wilkens - conseillère
technique - CDC

CEPLANUT

Dr. Banea
Directeur

UNICEF

Ave. de la Justice
Kinshasa - BP7248

Dr. Bruno Martin
Conseiller projet de Santé
Dr. Jules Grand-Pierre
Conseiller projet de Santé

Ministère de la Santé Publique
Troisième Direction -
Pharmacie, Médicaments et
Laboratoires 36, Ave. de la
Justice
Kinshasa

SANRU

75, Ave. de la Justice
BP 3555 Kinshasa
tel 34480-30121

Upjohn

Pharminaport/ndolo
BP 894 Kinshasa

USAID

Mr. Charles Johnson
Mr. Arnold Lessard

Mr. Ray Martin
Mr. Chris McDermott
Mr. Utshudi Lumbu

Mr. Banzola Kundi Kinungi
Pharmacien Inspecteur,
Directeur Chef des Services
Mr. Ngunza, Chef de division
production et importation
des médicaments

Dr. Bongo Beni
Chef de division supervision
technique et planification
Mr. Munkatu Mpese
Anthropologue, Chef de
division études et
recherches opérationnelles

Mr. Sita Tuala
Pharmacien, superviseur des
ventes

Mission Director
Private Sector Technical
Advisor
Chief HPN
Health Officer
Pharmacist, Project Officer

SOW AND TIMING OF NEXT PRITECH VISIT

Proposed dates: January 7-18, 1991

Proposed consultants: Agma Prins/Camille Saadé/Humberto Zardo

SCOPE OF WORK

As a follow-on to the first PRITECH consultancy from October 15-25, 1990, to work with USAID/Kinshasa and potential collaborating partners to finalize the strategy and budget for the proposed Private Sector ORS Production and Marketing project. This will include the following tasks:

- * To review the preliminary strategy document with the proposed partners to confirm their interest, clarify and seek more detailed information on available resources and constraints, incorporate their ideas where appropriate and clarify the role of each collaborating organization according to the available resources.
- * Based on these discussions, to redraft the proposal in more detail. This revised proposal would then be reviewed, as possible, with potential partners to assure their concurrence.
- * Working with PSI, Cowbell, USAID and other partners, to clarify, detail and finalize a budget proposal for the project.
- * Examine the feasibility of quality control at Cowbell and assess the monitoring capabilities of OZAC.