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REPORT OF A CONSULTANCY ON  
ORS SUPPLY AND DISTRIBUTION IN NIGERIA

A Report Prepared By PRITECH Consultant:  
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During The Period:  
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TECHNOLOGIES FOR PRIMARY HEALTH CARE (PRITECH) PROJECT  
Supported By The:  
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## I. INTRODUCTION

A review of Nigerian ORS production and supply and the management of its public sector distribution was conducted by PRITECH consultant Michael Fry during March and April of 1987. This report raised several issues that will impact the future availability of ORS in the public and private sectors of the health care system. As a follow-up this author was requested to come to Nigeria and draft an outline and specifications for a U.S.A.I.D. Request For Proposal (RFP) to contract private sector involvement in production, marketing, and distribution of ORS packets.

This report has two parts: a brief review of some of the issues with recommendations and the draft for the RFP.

## II. CURRENT SUPPLY LOGISTICS RELATED ISSUES

Several issues affecting the supply logistics component of the ORT program need to be confronted and resolved before the RFP drafted in this report can be finalized and strategic planning can proceed.

### A. PUBLIC SECTOR

#### 1. ORS/SSS Policy

##### a) Observation:

- Dehydrated children are treated using ORS in the health care facilities.
- Mothers are educated in the preparation and use of SSS at the health care facility.
- Mothers are not educated in the preparation and use of ORS and are not give ORS packets at the health care facilities.
- Several persons related with the ORT program, including Dr. Sulaiman believe that the MOH should reevaluate its approach on ORS and SSS, considering factors of safety, convenience, and effectiveness. For example, are there circumstances in which it is most appropriate to give mothers ORS packets to take home from health facilities to continue diarrhea treatment?

##### b) Evaluation:

- There is general confusion over what the ORS/SSS policy is or should be. Mothers may not be receiving the optimal education regarding ORT.

- Effect on supply/logistics - A change in the policy for education and dispensing of ORS will change the demand for ORS. The lack of ORS promotion in the public health sector is resulting in a reluctance on the part of the private sector to become involved in the production, marketing, and distribution of ORS.

c) Recommendation:

- Research this issue and adopt a clear policy regarding ORS/SSS. Methods to consider are:
  - A review of experience from other countries
  - Field studies to evaluate the effectiveness of mixing and treatment with SSS vs. ORS and their acceptability (i.e. cost and ease of use) and current and potential availability.

2. Current supply of ORS

a) Observation:

- M. Fry's recent report predicts that stock levels of ORS at Oshodi warehouse will soon be depleted.

600ml - December 1987

6 liter - July 1987

Lead time for procurement has been approximately 3-6 months.

b) Evaluation:

- Supplies of ORS will soon run out. This will have an impact on the entire ORT program.

c) Recommendation:

- Identify a supplier and funding and initiate the appropriate procurement immediately considering projecting distribution and program expansion.

3. ORS supply and distribution - short term

a) Observation:

- There is a lack of planning and coordination in the current ORS supply system and ORS is not being distributed in adequate quantities to some states, LGAs, and health facilities.

- The ORS supply and distribution is at least partially integrated with EPI.
- Many health care workers are not aware of the availability of ORS or the methods for obtaining it.

b) Evaluation:

- ORS distribution through the EPI supply system appears to be a reasonable approach but needs strengthening.

c) Recommendation:

- Enlist a local or international supply/logistics specialist to review the current distribution system from the level of procurement to dispensing and set a plan for improvement to include training of health workers. Medium to long-term distribution plan should take into account progress by states in setting up essential drug programs.

4. ORS Supply and Distribution - Long Term

a) Observation:

- State governments are currently experiencing difficulty in supplying ORS and many other essential drugs to the health care facilities. One of the problems is that funds are being spent on nonessential drugs such as anti-diarrheals.
- The state governments are currently and will continue to be the primary source of drug supply to the public sector.
- There is currently a plan to develop the essential drug programs at the state level. Revolving drug funds are a component in this plan.

b) Evaluation:

- The state drug procurement and distribution systems has the potential to be an important long term method of ORS supply.

c) Recommendation:

- Training and education of the state government drug committees should include planning for ORS supply.

B. PRIVATE SECTOR

1. Policy

a) Observation:

- Other than policy statements in the National ORT Promotion Plan, the FMOH has not actively confronted the private sector issues of:
  - o Sales of anti-diarrheals
  - o Non-WHO formulas of ORS (Flavoring, other ingredients, and volume)
  - o Recognition of ORS
- Prescription vs. OTC classification is still to be determined.

b) Evaluation:

- These private sector issues can significantly impact the ORT program.

c) Recommendation:

- The FMOH needs to confront these issues, adopt a policy, and incorporate it into ORT program planning and promotion.

2. Private Sector Involvement in the ORT Program

a) Observation:

- Private sector pharmaceutical companies have been involved in the sales of oral rehydration type products in Nigeria for several years.
- Local manufacturers have expressed an interest in becoming involved in the ORT program. They have hesitated to proceed because of the FMOH ORS/SSS policy and low profit margin in ORS packets as opposed to their other nonessential products.

b) Evaluation:

- The private sector is a vital and effective force that if properly directed can be instrumental in achieving the objectives of the ORT program.

c) Recommendation:

- Review all options for the use of private sector

resources in accomplishing the objectives in the ORT program. Consider cost, feasibility, and program impact. Plan an approach for enlisting their involvement. Some options are:

- Import duty waiver on ORS raw materials and machinery.
- Promote private sector involvement in a coordinated effort with the FMOH in the ORT program.
- Private practice health care provider and retailer training.
- National marketing campaign.
- Enact legislation against nonessential products.

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DRAFT

REQUEST FOR PROPOSAL (RFP)

TITLE: NIGERIAN PRIVATE SECTOR ORAL REHYDRATION SALT (ORS) PROJECT

FUNDING PERIOD: \_\_\_\_\_ to \_\_\_\_\_

FUNDING AGENCY: United States Agency for International Development

SUBMIT PROPOSALS TO: \_\_\_\_\_

CLOSING DATE FOR PROPOSALS: \_\_\_\_\_

BUDGET: N/A

THE CONTENTS OF THIS RFP ARE:

BACKGROUND

SUPPLY/LOGISTICS RELATED OBJECTIVES

ESTIMATES OF ORS REQUIREMENTS

PRODUCT SPECIFICATIONS

QUALITY CONTROL OF THE FINISHED PRODUCT

PRODUCTION PREMISES

COMPONENTS OF THE PROPOSALS

1. BACKGROUND

The National ORT Program Promotion Plan was formulated in September 1985. A CCCD project for Nigeria was developed in 1985/86 and approved in the latter half of 1986. One of the components of the CCCD project is the strengthening of diarrhea case management. A significant portion of this component is planned for ORS supply management. Experience from programs in other countries has shown that the most successful strategy for assuring widespread availability of ORS packets is through a coordinated effort between the public and private sector distribution systems. The Ministry of Health believes that the private sector can plan a significant role in the goals of a sustained program by building a base for local production and distribution with a combined marketing, education and communication campaign consistent with the national ORT policy. U.S.A.I.D. is in support of the FMOH objectives by offering funding for this project and requesting an innovative proposal from the private sector for achieving the following supply/logistics related objectives.

II. SUPPLY/LOGISTICS RELATED OBJECTIVES

1. Improve the availability of low cost ORS packets for the Nigerian public through private sector marketing and distribution to all potential outlets including pharmacies, patent medicine stores, and private hospitals and clinics.
2. Increase utilization and improve proper use of ORS through at private sector information, education, and communication campaign funded through the proceeds of the sale of ORS salts.
3. Assure sustainability of the project by building a base for local production of ORS.
4. Standardize ORS packets in the public and private sector.
5. Provide a supply of ORS packets to the public health care sector to be distributed by the EPI program.
6. Manage the project in accordance with the contractors policies and procedures, Federal government regulations, national ORT program objectives, and U.S.A.I.D.'s terms and conditions.

III. ESTIMATES OF ORS REQUIREMENTS

Estimates of ORS requirements depend upon the FMOH policy of dispensing and education of ORS packets and private sector promotion.

A. PUBLIC SECTOR DISTRIBUTION

600ml = 2.5 million packets per year increasing to 6 million packets per year (over the next 3-5 years)

6 liter packets = 60,000 packets per year increasing to 80,000 packets per year (over the next 3-5 years)

Delivery points: EPI warehouse at Oshodi and Kano

B. PRIVATE SECTOR DISTRIBUTION

600ml = increasing to 15-18 million packets annually

IV. PRODUCT SPECIFICATIONS

A. COMPOSITION OF O.R.S.

The WHO approved ORS - citrate formula adapted to the Nigerian standard volumes of 600ml and 6 liter:

|                             | gm/600ml     | gm/6 liter    | %            |
|-----------------------------|--------------|---------------|--------------|
| Sodium Chloride             | 2.1          | 21.00         | 12.55        |
| Trisodium Citrate dihydrate | 1.74         | 17.40         | 10.39        |
| Potassium Chloride          | 0.90         | 9.00          | 5.38         |
| Glucose, anhydrous          | <u>12.00</u> | <u>120.00</u> | <u>71.68</u> |
| Total                       | 16.74        | 167.40        | 100.00       |

B. QUALITATIVE SPECIFICATION OF INGREDIENTS

1. Quality Certificate

For each batch a detailed analytical quality certificate with reference to the ordered standard must be supplied with the goods.

2. Quality assurance/test procedures

After receipt of the ingredients, they should be placed in a quarantine area. Ingredients may be transferred to the final storage place in the warehouse only after the quality control laboratory has analyzed each batch of the supplied material and released it for production. The analysis should include at least testing for identification, purity, and assay.

Sodium Chloride: within limits set by I.P., 3rd ed., Vol. 2(p.189)

Trisodium Citrate dihydrate: within the limits set by I.P., 3rd ed., Vol 3

Potassium Chloride: within the limits set by I.P., 3rd ed. Vol. 2(p.163)

Anhydrous Glucose: "oral grade" quality within the limits set by I.P., 3rd ed., Vol.2(p.135)

C. SHELF-LIFE OF THE FINISHED PRODUCT

The finished product will have a minimum shelf-life of two years under environmental conditions common in Nigeria.

D. PACKAGING MATERIAL

1. ORS for Public Sector Distribution

The individual dose pack for 600ml of ORS will consist of two unprinted low density polythene bags, one for the whole of the ORS mixture and the second to hold together the first bag containing ORS and the printed insert. Both bags will be hermetically sealed and conform to the following specifications:

|                                  | <u>Approximate<br/>size of bag</u> | <u>Min gauge of<br/>plastic</u> |
|----------------------------------|------------------------------------|---------------------------------|
| Inner bag containing ORS dose    | 65mm X 100mm                       | 0.04mm                          |
| Outer bag holding ORS and insert | 70mm X 120mm                       | 0.05mm                          |

Printed insert - This insert will be specifically designed for packets used in the public health care distribution system. It must be designed in a way that the public sector packet will not be confused with the packet to be sold in the private sector. The label content will include composition, instructions for use, illustrations, manufacturing date, expiration date, and batch number.

Plain white board collecting boxes will be used that will contain 50 packets. Ten of these collecting boxes (500 packets) will be contained in a corrugated shipper of sufficient strength to withstand extensive transport throughout Nigeria. These transport cartons will be secured by adhesive tape and suitably labelled indicating contents, batch number, and expiration date.

The 6 liter packets are intended for use in large clinics and hospitals. Therefore one single low density polythene bag for the whole ORS mixture with labeling on the polythene may be substituted for the double bag method described for the 600ml packet. The label content will include composition, mixing instructions, manufacturing date, expiration date, and batch number. The polythene, collecting boxes, and corrugated shipper will be of the same quality as described for the 600ml packets. A minimum of five collecting boxes will be used to contain a maximum of

50 bags in a corrugated shipper similar in size to the one described for 600ml packets.

2. ORS for Private Sector Distribution

The packaging for the ORS packets for private sector distribution must be easily differentiated from the packets for public sector use to prevent the sale of FMOH packets on the private market. (ex. product name, logo, print color, etc.).

The label content must be consistent with the national ORT message and policy.

The manufacturer may vary from the packaging specified for the public sector packets while keeping in mind the objective of providing a low cost ORS product.

V. QUALITY CONTROL OF FINISHED PRODUCT

Generally, the manufacturing of the ORS should follow the WHO guidelines from GMP as outlined in the official records of the WHO, No. 226, 1975, annex 12.

In process checking of physical properties must be performed by operators on the dosing machine while priority is given to rapid testing of the finished product in the main quality control laboratory.

A. PHYSICAL PROPERTIES

1. Net Weight (standard does for a solution of 600ml)

Limits ORS - Citrate 15.9 - 17.6gm (95-105%)

Check ten packets every 15 minutes:

Weigh the full packet and deduct the tare weight to give net weight of contents

If one or more packets exceed the limits:

check an additional 100 packets

If four or more packets of the 100 exceed the limits:

reject the quantity produced since the previous check or weigh every packet produced since the previous check

2. Labeling

Check ten packets every 15 minutes for completeness and legibility of the label.

If two or more packets are unacceptable:

reject the quantity produced since the previous check or check every packet produced since the previous check

3. Seal

Check ten packets every 15 minutes for visual acceptance

4. Appearance of Product

A white crystalline powder, odorless

5. Appearance of Solution

Dissolve entire contents of one packet in 600ml of water. The solution should be clear and colorless or should have only a faint yellow stain.

6. PH of Solution

Check the PH of the solution prepared in 5. above with a PH meter. It should be within the range 7.0 - 8.8.

B. CHEMICAL COMPOSITION/IDENTIFICATION

1. Melting Behavior

Heat gently a small quantity of the test substance: it melts. The melt first becomes yellow, then brown and an odor of burning sugar is perceptible. On ignition, the melt swells, then ignites and chars.

2. Assay

Random samples of the packed finished product should be taken and analyzed for uniformity. The content of each packet should comply with the given requirements. The concentrations and acceptable limits, calculated for the standard weight of 16.74gm of ORS - citrate dissolve in 600ml of water are as follows:

|           |              |                                    |
|-----------|--------------|------------------------------------|
| Na+       | 89.5 mmol/L  | Limits: 83.2-94.0 mmol/L (93-105%) |
| Cl-       | 80.0 mmol/L  | 74.4-85.6 mmol/L (93-107%)         |
| K+        | 20.1 mmol/L  | 18.7-21.5 mmol/L (93-107%)         |
| Citrate-3 | 9.9 mmol/L   | 9.2-10.6 mmol/L (93-107%)          |
| Glucose   | 110.0 mmol/L | 103.2-118.8 mmol/L (93-107%)       |

VI. PRODUCTION PREMISES

The production premises and manufacturing process should comply with Good Manufacturing Practices.

The main requirement will be to ensure prevention of cross contamination with other pharmaceutical products produced in the same facility, prevention of mix-up with other chemicals, and cleanliness in general.

The production room shall have both room air filtration and point source extraction as well as dehumidification to about 60% Rh. Comfort cooling is desired to about 25 degrees centigrade.

The premises shall include the following rooms and facilities:

warehouse for raw and packaging materials

warehouse for finished products

cleaning facilities for incoming goods

room for sieving, weighing and mixing

cubicle for washing equipment

room for dosing and sealing

room for finished product packaging

in-process quality control laboratory adequately equipped to perform all necessary testing of ingredients and finished product

toilet, showers and changing room for operators

## VII. COMPONENTS OF THE PROPOSAL

### A. THE PROPOSAL SHOULD CONTAIN:

1. Background information of the potential contractors current involvement and capabilities in areas relevant to the objectives of this project.

- Organizational structure
- Management and supervision
- Raw materials procurement
- Production equipment and capacity
- Distribution network
- Market/population coverage
- Information, education, and communication

2. Plan for the project design

- Organizational structure
- Human resources input
- Management and supervision
- Raw materials procurement
- Production equipment and capacity
- Distribution network
- Market/population coverage

Information, education, and communication  
Income generation  
Use of income generated  
Subcontracting  
Retail price for private sector packets  
Variation on any component in this RFP

3. Costing/budget

Contractors margin  
Start-up support required  
Diminishing long term support required

4. Constraints and possible solutions

B. CRITERIA FOR EVALUATION

Impact on health care and the success of the ORT program

Feasibility and sustainability of the project

Current success and capability of the firm(s) in related areas

Cost budget