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ORS PRODUCTION AT THE PHARMACIE CENTRALE

DE TUNISIE

A Report Prepared by PRITECH Consultant:  
STEVE J. FABRICANT

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TABLE OF CONTENTS

	<u>PAGE</u>
I. INTRODUCTION . . . . .	1
A. Purpose of Visit . . . . .	1
B. Background . . . . .	1
II. ORS PRODUCTION STATUS . . . . .	1
A. Production Quantities . . . . .	1
B. ORS Sachet Size . . . . .	2
C. Private Sector Production . . . . .	2
III. IMPROVED ORS PRODUCTION . . . . .	2
A. Technical Specifications . . . . .	2
B. Production Costs . . . . .	3
C. Donor Contributions . . . . .	3
IV. RECOMMENDATIONS . . . . .	3
APPENDICES . . . . .	7
Appendix 1: Three Scenarios for 1-Liter Sachets	
Appendix 2: Principal Contacts	

## I. INTRODUCTION

### A. Purpose of Visit

The purpose of this visit was to assess the economic and technical constraints to increasing the quality and quantity of ORS in Tunisia, especially by the Pharmacie Centrale de Tunisie (PCT).

### B. Background

The technical conditions reported after a visit to PCT in 1984 remain largely unchanged. PCT is seriously limited by an old and inappropriate dosing/filling/sealing machine. As a result, the maximum output is low; because of the need to produce two-500 ml sachets, the cost is high and the quality of the sachets is inconsistent.

Since 1984, trials have been run using citrate with Aerosil; although problems of deterioration have been reduced, it is still necessary to granulate the ORS mixture to achieve accurate filling with the volumetric doser used. The present cost of production is now given as 99 millimes (M) or US \$0.12 (1000 M = 1 Tunisian dinar [TD] = US \$1.17).

## II. ORS PRODUCTION STATUS

While these technical problems can certainly be resolved with a new machine, which would at the same time reduce the production cost, several other related issues have been raised.

### A. Production Quantities

A relationship between the amount of ORS needed for Tunisia and the "profitability" of production has been recognized. It is usually considered uneconomical to use an automatic machine to produce less than two million sachets per year, although, in fact, the practical effect is that, for smaller quantities unit costs become elevated due to the fixed costs of production and the amortization costs of the equipment. It has been very difficult to estimate the true future demand for ORS in Tunisia. At present, combined public and private sector distribution probably does not exceed 600,000 (liters) per year (UNICEF donation plus PCT production). Increased promotion of ORT in the public sector through the Catholic Relief Services/USAID project could increase demand considerably, but the effect will be very sensitive to the actual policy toward home solutions, the comprehension of the mothers, and the distribution of the ORS sachets. Demand through private pharmacies could increase as well, but will also depend strongly on MOH policy toward the use of alternative anti-diarrheal drugs, and the profit available to

pharmacies through the sale of ORS. Demand could also be increased through export of ORS to neighboring countries, but this will depend in large part on donor agencies with the capability and interest to arrange this. Taking all the preceding into account, one may say with comfort that a minimum demand for one million liters per year could exist within the next few years.

#### B. ORS Sachet Size

The second issue concerns the size of ORS sachets to be produced and used. In my opinion, there is a high degree of risk that the 1-liter sachet will be mixed in water measured with a 740-ml bottle rather than a 1-liter bottle, resulting in hyperconcentration with its attendant danger to the child. The adoption of a 200-ml sachet has been proposed as a remedy to this problem, but this also presents problems. The parameters of this issue are well known, and a careful study should be made to determine the one best sachet size for Tunisia. This decision will in turn affect the decision about local production since an alternative low-cost source of 750-ml or 200-ml sachets may not be available, making the local production of either of these sizes relatively more attractive.

#### C. Private Sector Production

The possibility of ORS production in the private sector was not investigated due to lack of time. Even though several Tunisian firms have been organized for drug production since 1984, it seems unlikely any would be interested in producing a low-cost ORS even if the MOH or UNICEF were to guarantee purchase of a certain quantity.

### III. IMPROVED ORS PRODUCTION

#### A. Technical Specifications

If the decision to move ahead with increased ORS production at PCT is affirmative, the following matters will have to be addressed:

1. A dosing/filling/sealing machine of appropriate specifications from a manufacturer approved by PCT should be supplied. A new mixer and several accessories will also be needed. The need for other equipment can be further studied by an expert from UNICEF/WHO. The cost of this equipment will be \$60,000 - 70,000.
2. The PCT will have to construct work areas for ORS batch preparation and for sachet filling. The cost of this "boxage" will be approximately TD 12,000 for 20 M<sup>2</sup> (\$14,000).

3. Further technical assistance in specifying chemical and packaging materials, in initiating production, and especially in quality control can be provided by the donors involved with the project (UNICEF and PRITECH). (It has been noted that Good Manufacturing Practices are not followed in the PCT plant in general and, while the PCT's Laboratories are well-equipped and staffed, some changes in Quality Control procedures may be desirable for ORS production.)

#### B. Production Costs

Detailed estimates of production costs with new equipment and some other changes are shown in Table 1. The essential points are that present packaging material costs can be decreased, and the use of a more efficient packaging machine at a high annual level of output will reduce the unit-cost impact of fixed costs. Even at relatively low levels of production of ORS, costs will be close to that of the least expensive imported products and foreign exchange costs for the PCT will be much lower (Table 2).

#### C. Donor Contributions

In addition to providing the production equipment, donor agencies can further encourage local self-sufficiency by providing raw materials for an initial period and by guaranteeing the purchase of a part of the PCT production. Several scenarios are presented in Appendix 1 to illustrate how all of the parties concerned (MOH, PCT, UNICEF, CRS) can benefit.

### IV. RECOMMENDATIONS

The following actions will be necessary to pursue the objective of ORS production at PCT.

1. A field study of container availability and of mothers' knowledge, attitudes, and practices (KAP) should be carried out. The cost of producing a 200-ml cup should be studied, including an analysis of the present wastage associated with the 1-liter sachet. The pros and cons of 200-ml or 750-ml sachet should be assessed in light of the KAP study results.
2. At the same time it is important to clarify the policy of the MOH regarding home solutions so that the CRS project can estimate the effects of its education campaign on the demand for ORS sachets.

TABLE 1

	Present PCT production using citrate 1,100/hour @ 150,000/yr.	New Machines for 1-liter sachets 2,400/hour		New Machines for 750-ml sachets 2,400/hour		New Machines for 200-ml sachets 3,200/hour	
		@ 500,000/yr	@ 1,000,000	@ 500,000/yr	@ 1,000,000	@ 2,000,000/yr	4,000,000/yr
Chemical Materials	36 (1)	31 (2)		23 (2)		6.2	
Packaging Foil	21	10 (3)		9 (3)		5.0 (3)	
Cartons	2	2	-	2	-	3.0 (7)	
Direct Labor	11	9 (4)		8 (6)		4.5	
Indirect Costs (Variable)	<u>9 (8)</u> 79 M.*	<u>9</u> 61 M.	<u>61 M</u>	<u>9</u> 51 M	<u>51 M</u>	<u>4.5</u> 23.2 M	<u>23.2 M</u>
Indirect Costs (Fixed)	<u>20 (8)</u> 99 M	<u>12</u> 73 M	<u>9</u> 70 M	<u>12</u> 63 M	<u>9</u> 60 M	<u>6.0</u> 29.2 M	<u>4.0</u> 27.2 M
Depreciation of New Assets (5)	<u>-0-</u>	<u>8</u>	<u>4</u>	<u>8</u>	<u>4</u>	<u>4</u>	<u>2</u>
Production Cost	99 M	81 M (2)	74 M (2)	71 M (2)	64 M (2)	33.2 M	29.2 M
Equivalent Cost per liter ORS	99 M	81 M	74 M	94 M	85 M	166 M	146 M

**NOTES:** (1) Includes flavor, alcohol, Aerosil  
 (2) Could decrease 3 M. with cheaper citrate  
 (3) Using locally-made Al-complex  
 (4) Granulation eliminated  
 (5) TD 70,000 equipment/10 years  
 TD 15,000 plant/20 years allocated 50% to  
 ORS for 1-liter and 750-ml, 100% for  
 200-ml.

(6) Fewer batches need to be prepared and  
 tested.  
 (7) 10 per pack, 40 packs per carton  
 (8) Divided arbitrarily from PCT data.

\* 1000 M = US \$1.17 (Sept. 1986)

TABLE 2

COST COMPARISONS

A. 1-LITER ORS SACHETS

	<sup>1</sup> PCT Present	PCT Future <sup>1</sup>		UNICEF/ WHO	Ciba Geigy Servipharin
		500,000/YR	1,000,000/YR		
Foreign Exchange Cost to PCT (CIF) <sup>2</sup>	59 M*	39 M	35 M	68 M	99 M
TOTAL UNIT COST	99 M	81 M	74 M	68 M	99 M

B. 750-ML SACHETS

	PCT Future <sup>1</sup>		Ciba Geigy
	500,000/YR	1,000,000/YR	
Foreign Exchange Cost to PCT (CIF) <sup>2</sup>	31 M	27 M	Not available
TOTAL UNIT COST	71 M	64 M	

C. 200-ML SACHETS

	PCT Future <sup>1</sup>		Ciba Geigy	Egypt CID <sup>3</sup>
	2,000,000/YR	4,000,000/YR		
Foreign Exchange Cost to PCT (CIF) <sup>2</sup>	10.2 M	8.2 M	Not available	38.3 M
TOTAL UNIT COST	33.2 M	29.2 M		38.3 M

(1) Without factory profit

(2) Includes chemicals and depreciation

(3) Production cost = Egyptian pound (E.L) 0.36 + 20% profit + 20% I + F

\* 1000 M = US \$1.17 (Sept., 1986)

3. If a decision to use 200-ml or 750-ml sachets is reached, the absence of inexpensive alternatives would seem to favor local production. In the event the 1-liter size is retained, the economic advantages (although significant foreign exchange will be saved) would be less important than the benefits to the PCT in terms of self-sufficiency and increased capacity for sachet production. Should a decision be reached to proceed with enhanced local production, the visit of an expert from UNICEF/WHO CDD program will be required to work on a technical level with PCT. If this visit takes place in early 1987, production could start by early 1988.
4. MOH should add to its drug budget an amount needed to assure purchase and distribution of ORS as UNICEF donations are phased out.

## APPENDIX 1

### Three Scenarios for 1-Liter Sachets

#### Scenario A: (For 1-liter sachets, but could work for any size)

- PCT purchases all materials for 1 million sachets (43 M/sachet).
- UNICEF provides \$60,000 in equipment for PCT.
- UNICEF buys 500,000 sachets from PCT at cost (74 M) for donation to MOH.
- PCT sells 300,000 to CRS for 85 M (15% profit).
- PCT sells 200,000 to private pharmacies for 85 M.  
(Probable retail price 120 M.)

#### Results:

- UNICEF in effect pays 8% above UNIPAC prices (\$.08 = 68 M) for sachets donated to MOH, but thereby assists in establishing local production.
- PCT profits TD 5,500, but has to spend TD 31,000 in foreign exchange for materials.
- CRS pays 8% above UNIPAC but 10% below current U.S. price.
- Tunisia gets ORS with packet designed to suit local needs, and the flavor and color preferred.

### Scenario B:

- UNICEF provides equipment to PCT.
- UNICEF donates chemicals for 500,000 sachets (25 M/sachet = \$15,000) and provides chemicals for another 500,000 on reimbursable basis to PCT, paid in foreign exchange (\$15,000).
- PCT buys foil and cartons printed locally and produces 1 million sachets. Additional production costs total 43 M per sachet.
- UNICEF buys 500,000 sachets for 39 M as donations to MOH to cover all production costs except depreciation.
- PCT sells 500,000 sachets to CRS and private distributors for 85 M.

### Results:

- UNICEF has paid a total of 64 M (39 + 25) for sachets to donate, as against 68 M landed price from UNIPAC.
- PCT pays TD 12,750 in foreign exchange (not including depreciation) and gains a profit of TD 8,500 on sales to CRS and private distributors.
- Tunisia gets locally designed sachet, etc.

### Scenario C:

- UNICEF provides donation of \$60,000 in machinery to PCT in 1987.
- UNICEF provides chemicals for 1,000,000 sachets (\$30,000 CIF) per year to PCT. This is equal to CIF cost of 385,000 UNICEF sachets. The donation of chemicals is equivalent to 25 M per sachet. (UNICEF would have donated 500,000 sachets per-year 1988 to 1990)
- PCT buys foil, cartons locally: 12 M/sachet.
- PCT makes 1 million sachets: 31 M/sachet, production cost including depreciation.
- PCT sells 500,000 to MOH for 43 M/sachet.
- PCT sells 300,000 to CRS for 85 M/sachet.
- PCT sells 200,000 to private pharmacies for 85 M/sachet.

### Results:

- UNICEF has provided 500,000 sachets to MOH at the equivalent cost of 375,000 sachets. Saving of \$100,000/year pays off investment in six years.
- PCT profits TD 21,000 from sales to CRS and private pharmacies.
- CRS saves two cents per sachet under USAID cost.
- MOH pays 25 M less than UNIPAC cost, starts to assume cost of ORS by itself. Pays in TD, not foreign exchange.

APPENDIX 2

Principal Contacts:

Dr. Sidhom, DSSB

Dr. Zouheir Fekih, DSSB

Dr. Ali Naas, PCT

Dr. F. Ben Hammouda, PCT

Dr. K. Boukef, PCT

Dr. Hizaoui, PCT

SIEK Aluminum, Ksar Sied-Tunis

Dr. M. Mansour, CRS

Dr. J. Vermillion, USAID

Mr. H. Lakhdar, USAID

Mme. Nefissa Zerdoumi, UNICEF

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