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PREPARATORY ASSISTANCE FOR THE ESTABLISHMENT OF A PILOT PLANT FOR PHARMACEUTICALS

DP/MOZ/83/004

MOZAMBIQUE

Technical report: Potentials, Conditions and Parameters for Developing Pharmaceutical Industry in Mozambique*

Prepared for the Government People's Republic of Mozambiuqe
by the United Nations Industrial Development Organization
acting as executing agency for the United Nations Development Prgramme

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INTRODUCTION

The post-independence nationalised health policy in Mozambic has been based on a multi sectoral approach with emphasis laid on preventive medicine, nutritional education and environmental sanitation.

To ensure equitable distribution of the available inadequate health resource the nationalised health policy extends medical assistance to its 14 million (1986) population through the four integrated levels of health care institutions:

- the health posts
- the health centre
- provincial hospitals
- central hospitals

Currently the requirements of pharmaceuticals in Mozambic are met through the centralised imports by the single state company Medimoc and the humanatarian donations from international sources. The local hospitals & the 50 pharmacies (37 state owned & 13 private) produce very limited quantities of sodium benzoate expectorant, lotions and topical ointments. The oral rehydration salt plant at Beira has an installed capacity of 2 million sachet to meet an estimated 33% of country's requirement.

In recent years the hard currency expenditure on drugs consumption has progressively declined primarily due to unfavorable financial conditions. This has caused the percapita consumption drop from $1.0 in 1980 to the current level of $0.40.

The estimated population coverage has dropped from 40% to 35%. The natural calamity such as draught, acts of banditism and short falls in contry's export earnings has led to the lower population coverage in National health care system.

Recognising the inherent shortfalls of total dependence on import namely erratic health care service to the people, abrupt stockouts and excesses especially in absence of reliable data on countrys real requirement, danger of short dated & expired products reraining in market etc., the Ministry of Health has been endeavouring to promote foreign investment in a pharmaceutical formulation plant to develop a self reliant technology base in the country.

At the request of the Ministry of Health, Astra Development, AB of Sweden drew up a development plan in 1979 for the development and establishment of a pharmaceutical industry in Mozambic which indicated that parallel to the establishment of a pharmaceutical manufacturing plant, product registration, control and distribution systems of pharmaceuticals should be studied. The consulting firm finally carried out a feasibility study in 1980 for a pharmaceutical plant for manufacture and packaging of 1000 millions of tablets (33 formulations) and 2.5 million bottles of oral liquid (15 formulations) annually on one shift basis. The investment proposal was made for US$ 31 million.

The implementation of the proposal has not been effected primarily due to large investment need for a technology not immediately adaptible. The financial analysis indicated a long return on investment not commercially attractive.

The studies of Astra was followed by a WHO consultant report in December 1982. This report suggested an investment of US$8.6 million (excluding start-up and pre-project expenditure) for a pharmaceutical industry for 950 million tablets (32 products), 50 million capsules and 2.5 million bottles of oral liquid (19 products). This proposal also did not find implementation for the same reasons.

This report high lights certain critical areas in respect of potentials that People's Republic of Mozambique posses as well as the conditions and parameters for the development of a domestic industrial unit for the production of pharmaceuticals,

Potencials, Conditions and Parameters
For Developing Pharmaceutical Industry

State of the art	Intervention area	Nature of intervention	Action agency
I	II	III	IV
Skilled man -power, (estimated - 85 persons)	-Planning for short term & long term personnel needs at various levels for a domestic pharmaceutical industry, (Total estimated manning = 185 based on production program.)	Identification of the following levels of technical personnel: -Plant accountant,1 -Plant engineer, 1 -Assistant manager, 2 -Laboratory analysts, 8 -Production supervisor, 4 -Maintenance foreman, 2 -Skilled operator, 45 -Maintenance technicians, 13	Ministry of health
	-Institutional education for the identified personnels	-University education for plant engineer, plant accountant, and 2 assistant managers; Suggested school/ institute education for the rest of required personnel, OR to withdraw suitably qualified technical institute personnels engaged elsewhere for further training and development.	Ministry of health, Ministry of education, Ministry of manpower planning Ministry of health
Adaptibility of production technology	selection of adaptible dosage forms and scale up local production in phases to industrial level	Progressive development of installed technology initially with non-sterile non-penicillins namely tablet capsule,oral liquid at work--shop and/or pilot production units consistent with local conditions and capabilities.	Collaborating industry, Ministry of health.

Potencials, Conditions and Parameters

For Developing Pharmaceutical Industry

(continuation)

State of the art	Intervention area	Nature of intervention	Action agency
I	II	III	IV
Institutional capability	-Domestic educational facilities in pharmacy and pharmaceutical technology.	-Inclusion of selective theoretical courses on manufacturing technology (process flow sheets etc.) for tabletting, encapsulation and oral liquid manufacture at the pharmacy institutes in third year curriculum.	Ministry of health and Ministry of education
		-Introduction of faculty of pharmacy at the university level	Ministry of education International agencies, UN agencies
	Up-grading institutional facilities in chemical and microbiological analysis of drugs to develop laboratory technicians	-Introduction of selective drug analytical laboratory courses in the carriculum of the existing chemistry department, Edward Mondlane University.	Ministry of education and Ministry of health
		-Development of analytical capability at the National Hygeine Laboratory, Ministry of Health for chemical and microbiological analysis of vitamins and antibiotics in pharmaceutical formulations with external assistance.	U N I D O , UN agencies, Bilateral agreements.

Potencials, Conditions and Parameters

For Developing Pharmaceutical Industry

(continuation)

State of the art	Intervention area	Nature of intervention	Action agency
I	II	III	IV
		-Inclusion of microbiological analisys of drugs at the existing laboratory of the faculty of medicine, Edward Mondlane University	Ministry of education and Ministry of health
	Drug control administration and institutional frame-work	External exposure of key personnels at the policy making level on drug legislation, legal issues for drug registration, drug monitoring and control systems for future national manufacturing unit(s), licensing and certification of manufacturing units, drug information services, GMP, drug analytical requirements etc.	U N I D O / Regional co-operation/ Bilateral agreements.

Potencials, Conditions and Parameters

For Developing Pharmaceutical Industry

(continuation)

State of the art	Intervention area	Nature of intervention	Action agency
I	II	III	IV
Skill development (Domestic and external training)	Domestic in service practical training develop the skill in production, laboratory and plant maintenance.	-Optimal utilisation of the up-coming tabletting training work-shop (Beira) to develop progressively the skill for production operators and laboratory technicians in presence of external experts.	U N I D O , Ministry of health, International agencies.
		-Establishment of training work-shops by dosage form/ pilot scale production unit	U N I D O / Collaborating foreign industries
	Institutional co-ordination	Integration of the technical institute academic curriculum with the training work-shop(s)/pilot production unit to provide a predesigned limited training in pharmaceutical manufacturing technology to the pharmacy technics/agents and to the selective out comers of the industrial institute on pharmaceutical equipment maintenance.	Ministry of health and Ministry of education.
		-To utilise the nuclei of Central National Hygeine laboratory and Regional laboratory as well as training work-shop laboratory for chemical/microbiological analysis of drugs in presence of external technicians.	U N agencies/ Bilateral agreements Ministry of Health

Potencials, Conditions and Parameters

For Developing Pharmaceutical Industry

(continuation)

State of the art	Intervention area	Nature of intervention	Action agency
I	II	III	IV
	Industrial training: external	To provide trainee at key and supervisory levels to the selected external industries for training specific to the function to be performed. -plant engineer and assistant engineer, -plant maintenance fore man -production manager -production foreman -quality control manager -plant accountant -production process technicians.	U N I D O / collaborating industry/ Existing regional and sub-regional agreement.

Potencials, Conditions and Parameters
For Developing Pharmaceutical Industry
(continuation)

State of the art	Intervention area	Nature of intervention	Action agency
I	II	III	IV
Domestic complementary packaging material industries (containers, closures, printers)	Revitalisation	-Limited back-up assistance with imported primary materials for fabrication of contractual packaging materials and/or financial assistance in advance of placement of orders.	Ministry of health and Ministry of industries
	Quality Standards (Institutional co-ordinations)	-Integration with pharmaceutical quality control for a fine tuning development phase with initial small scale deliveries and periodical follow-ups.	Ministry of health and Ministry of industries
		-Vidreira glass bottle manufacturer and the Metal box screw cap manufacturer for 25mm neck size vs. cap diameter sizes.	M/S Vidreira and Metal Box, Maputo

Potencials, Conditions and Parameters
For Developing Pharmaceutical Industry
(continuation)

State of the art	Intervention area	Nature of intervention	Action agency
I	II	III	IV
Establishment of the industry and financing the project	Construction/erection, start-up, introduction of inplat multi-tier systems and procedures, technical processes manpower training.	To initiate with small scale production unit such as training work-shops by dosage form/pilot plant unit and progressively introducing new formulations, balancing, expansion and modernisation of plant capacity to the level of industry and provision of international expertise	U N I D O , collaborating foreign industry (-ies) Ministry of health.
	Credit extensions	Short term and long term bank loans, suppliers credits	International banks/ADB, World bank, National banks.
	Equity participation	Collaboration with suitable foreign industry preferably having experience in developing countries	Collaborating industry, Ministry of health, bilateral agreements.

TABLES

2. - CURRENT CONSUMPTION & EXPENDITURES

2.1 Populations

The current population level of 14 million has an annual growth rate of 2.6% and is expected to rise to million by the year 2000.

2.2 Consumption Level

The pharmaceuticals are imported in 11 dosage forms. The consumption of pharmaceuticals in Mozambic is primarily determined on the quantity available through import and donations.

The growth in consumption volume and product spectrum in 1985 over 1982 is illustrated in table 01 by dosage forms. The imported volume & cost of imports in 1983 to 1985 is indicated in table 02 for eight dosage forms. The consumption of pharmaceuticals by product in 1984 and 1985 is presented in table 03.

Table 01

Trend of Drug Consumption by Dosage Form

	No. of Products		%	Vol. of consumption <Million Units>		%
	1982	1985	growth	1982	1985	growth
-Tablets	125	70	<44>	383.60	169.60	<56>
-Capsules	14	9	<36>	19.20	13.50	<31>
-Oval liquids	26	6	<77>	1.69	0.17	<90>
-Ointment : topical	25	2	<92>	2.44	0.10	<96>
Opthalmic	4	2	<50>	1.31	0.61	<53>
-Sterile liquid	99	25	<75>	2.39	0.61	<75>
-penicillin injectables	5	4	<20>	2.43	2.62	8

< > means negative growth, figures rounded to nearest whole figure.

Table 02

Import Volume & Cost by Dosage Form, 1983-1885

Dosage Form	1983 Quantity	1983 Cost Meticais	1984 Quantity	1984 Cost Meticais	1985 Quantity	1985 Cost Meticais
	Figures in Millions					
-Tablets	233.32	75.82	343.72	50.23	169.63	64.58
-Capsules	7.38	19.24	16.88	18.61	13.50	8.41
-Oral liquid	1.15	17.95	0.79	10.15	0.17	0.37
-Injectables :						
Penicilines (powder-vials)	4.21	41.18	0.18	2.74	2.62	21.08
Non-Penicicilins (liquid-ampoules)	2.19	5.17	2.45	7.63	0.61	4.92
-Ointments:						
Topicals (tubes)	1.37	23.40	1.03	11.28	0.10	0.32
Ophthalmic (tubes)	0.11	1.04	0.36	1.30	0.61	3.04
-Penicillin Granules (syrup/suspension)	0.29	0.52	-	-	0.002	0.29

-The range of expenditures for tablets is 30-40%, topical ointments 8 - 12% and oral liquid 5 - 8% of annual pharmaceutical expenditures (1983-1985). Among 20~25 varieties of the topical ointment (30 to 50 tons) imported, the anti infective agents are predominant.

Table 03

Consumption of Pharmaceuticals, by Product 1984/1985

Products	Consumption Volume x 1000			
	1 9 8 4		1 9 8 5	
	Import	Donation	Import	Donation
I - Tablets:				
Clorfeniramina, 4 mg	750	1001	1047	2200
Voltaren	25	-	-	-
Fenilbutazone, 200 mg	-	528	-	3507
Indometacin, 25 mg	-	19	851	1
Probenicid, 500 mg	75	5	106	-
Dralazina, 25 mg	195	-	-	34.75
Guanetidina, 25 mg	50	-	-	-
Metildopa, 250 mg	-	1767	350	61.5
Reserpina, 0.25 mg	218	218	-	20
Digoxina, 0.25 mg	-	8034	1112	2305
Dimetilpolissiloxano	400	-	-	-
Cimetidina, 200 mg	25	-	-	-
Hidroxido de Aluminio	9860	35	2150	4.1
Bisacodil, 5 mg	3182	16	3187	-
Difenoxilato de Ataopina	434	-	270	-
Metoclopramida, 10 mg	634	20	-	1.978
Metilegometrina	36	301	324	15.4
Aminofilina, 100 mg	10500	1229	5000	23.5
Terbutalina	480	-	480	200
Amilorido	810	480	2350	-
Clortalidona, 50 mg	1780	-	845	2499
Furosemida, 40 mg	-	118	220	20
Ácido Nalidixico, 250 mg	386	-	-	-
Cotrimoxazol, 400/80 mg	8676	2084	7150	1255.7
Cloroquina, 250 mg	27439	59814	30060	329
Mebendazol, 100 mg	5620	27044	2000	2453
Metronidazol, 250 mg	500	87	10	1148
Praziquantel, 600 mg	810	11	-	-
Ethambutol, 400 mg	645	-	1300	1754
Isoniazida Tialetazona	-	1299	-	692.5
Pirazinamida, 500 mg	1512	-	-	1003

Consumption of Pharmaceuticals, by Product 1984/1985

(Continuation)

Products	Consumption Volume x 1000 1984 Import	1984 Donat.	1985 Import	1985 Donat.
I - Tablets:				
Quinestrol	31	-	-	-
Metil Prednisolona	274	-	-	-
Prednisolona	1989	-	5000	2001
Sacarina, 20 mg	-	-	6.6	-
Acido Ascorbico	5020	468	-	76.1
Axeroftol (Vit.A)	200	-	-	-
Complexo B	7250	2279	-	364.92
Multivitaminas	-	4282	20	3237.6
Piridoxina (Vit.B6)	64	-	200	-
Sal Ferroso, 200 mg	23212	413689	7500	1775.03
Sal Ferroso & Acido Folico	15000	-	500	907
Butil Escopolamina	-	25	41162	102.96
Neostigmina, 15 mg	50	-	-	-
Ergotamina E Cafeina	84	-	-	-
Propanolol, 40 mg	100	-	500	-
Acido Acetilsalicilic	197055	84653	30650	9607.16
Paracetamol, 500 mg	-	111	1400	37.36
Carbamazepina, 200 mg	156	-	-	-
Fenobarbital, 100 mg	1060	20	1600	-
Fenobarbital, 15 mg	524	-	-	-
Amitriptiline, 25 mg	208	2	-	-
CA Risoprodol, 350 mg	100	-	-	-
Clorpromazine, 100 mg	350	135	-	-
Prometazine	131	1	402	3.76
Clordiazedoxido, 10 mg	352	17	-	-
Diazepam, 2mg	800	250	1535	-
Diazepam, 10 mg	3420	40	-	3.76

Consumption of Pharmaceuticals, by Product 1984/1985

(Continuation)

Products	Consumption Volume x 1000			
	1 9 8 4		1 9 8 5	
	Import	Donat.	Import	Donat.
II - Oral liquid:				
Clorifeno, 60 ml	20	-	-	-
Co-trimoxazol, 60 ml	22	0.225	-	0.163
Sodium Benzoate 125 ml	480	-	-	5.60
Chloroquin Phosphate, 75 ml	60	5	10.5	-
Chloroamphenicol Palmitate 60ml	60	2.2	15.50	14.8
Caulina pectina, 100 ml	20	-	-	-
Definoxilate, 100 ml	60	-	-	-
Ferrous Sulfate	-	0.13	-	62.5
Miltivitamin, 100 ml	17.5	0.55	-	2.4
Pepsin & Paneveatin, 140 ml	1.4	-	-	-
Vitamin B-Complex, 100 ml	17.5	0.34	-	8.0
Chloropheniramine, 150 ml	20	-	-	0.35
Polaramin	-	0.96	-	-
Piperazine, 100 ml	-	2.7	-	0.23
III - Capsules				
Amoxacilina, 500 mg	2920	1484	2015	290.4
Ampicilina, 500 mg			75	10
Clorafenicol, 250 mg	1314	1510,4	904	818.1
Eritromecina, 500 mg	320	11	-	304.74
Fenoxilmetil Penicilina 500mg	780	216	340	10
Tetracilina, 500 mg	12219,8	-	6509	156.17
Rifampicina, 300 mg	-	1659.6	588	5
Rifampicina, 150 mg	-	203	41	1207
Levodopa & Benzerazoda	-	528	90	-
Assooxazil Penicilli	-	-	120	1
Axeroftal (Vit.A)	-	-	-	20

Consumption of Pharmaceuticals, by Product 1984/1985

(Continuation)

Products	Consumption Volume x 1000			
	1 9 8 4		1 9 8 5	
	Import	Donat.	Import	Donat.
IV - POWDER VIALS: INJECTABLE				
Ampicilina, 500 mg	20	70	10	7.61
Isoxazolil Penicilina, 500 mg	306	-	-	-
Penicilina, 10 mu	-	1006	150	88.164
Penicilina Procaina, 3 mu	72	717	-	19.85
Estrepromicina, 1 g	-	6124	2200	665.026
Benzathin Penicillin	-	-	50	54.674
Cefalosporina, 1 g	-	-	52	-
Kanamicina, 1 g	-	-	-	35.844
V - AMPOULLES				
Definidramina, 50 mg/5 ml	755	-	-	-
Metoclopramida	832	7	-	0.02
Metil Ergometrina	-	13	-	0.036
Ocitolina	-	-	-	6.6
Aminofiline	1152	-	0.4	0.1
Furosemida	-	111	-	-
Gentamicine, 80 mg/2 ml	255	56	6	-
Gentamicine, 20 mg/2 ml	-	-	4	30.5
Cloroquine	24	25	41	1.94
Quinine	206	1	-	20.2
Prednisolone	28	-	-	0.01
Progesterona	15	-	-	0.067
Fitonadiona, 1 mg	874	-	-	0.5
Hidroxicobalamine	360	28	-	0.382
Atropine	51	1	-	0.01
Butilescopolamine	-	165	55	0.1

Consumption of Pharmaceuticals, by Product 1984/1985

(Continuation)

Products	Consumption Volume x 1000			
	1 9 8 4		1 9 8 5	
	Import	Donat.	Import	Donat.
Adrenaline	47	-	-	0.1
Lidocaine & Adrenalina	312	1	-	0.005
Lidocaine 40 mg/2 ml	25	-	-	-
Promethazine	15	28	-	-
Hidrocortisone 100 mg/ml	-	-	-	205.475
Diazepam 10 mg/2 ml	-	-	-	11.309
VI - TOPICALS				
A) **OINTMENTS** :				
Mentol & Salicilato de Metilo	150	-	-	0.7
Heparinoide	785	-	-	-
Corticoide & Acido Salicilico	726	-	-	-
Tetracillina	350	-	-	-
Camphora	-	-	-	1
B) **CREAMS** : (up = 40,000 Tub)				
Corticoide	4527	-	-	-
Corticoide & Antibacte	35635	-	-	-
Clotrimazol	582	-	-	-
C) **LOTION** (X1,000's)				
Hexacloreto de Benze	375	-	-	8997
VII - OPHTHALMIC				
A) **Ointment**				
Tetracycline	6876	114	356	24650
Cloranfenicol	248016	-	216	10719
VIII - EAR				
Clorobutanoc & Benzocaine	-	-	530	-
Fenazona & Procaina	-	-	-	4

Consumption of Pharmaceuticals, by Product 1984/1985

(Continuation)

Products	Consumption Volume x 1000			
	1 9 8 4		1 9 8 5	
	Import	Donat.	Import	Donat.
IX - NOSE				
Fenilefrine 50 mg/10 ml	43	25	-	-
Fenilefrine 25 mg/1 ml	37	-	-	-

Tablets in volume of 50,000 units or less which are deleted: meclizina // colchicina // nitroglicerina // inda pamida // quinidina // verapamil // norgestrel e etinilestradiol // ketoconazol // praziquantel // bromocriptina // clomifeno // estrogenio equinos conjugados // etinil estradiol // medroxiprogesterona // noretisterona // norgestrel // levotiroxina // metmazol // prodiltiouralilo // triodotironina // calcio // acido focico // nicotinamida // acetazolamida // atropina // isoprenalina // metilfenidato // etossuccimida // primidona // valproato de sodio // petidina // flvfenazina // tioridazina // trifluo perazina.

2.3 Estimated Local Production

The estimated consumption through local prodution of one oral formulation and few topical formulations of ointments & lotions are presented in table 04. The local productions are confined in country's three central and seven provincial hospitals as well as fifty pharmacies in urban areas.

Table 04

Estimated Local Production, 1984 & 1985

Dosage forms	Units	1984	1985
- Expectorant (sodium benzoate)	L	13,124	67,230
- Ointment (topical)	Kg	30,261	113,962
- Lotions (topical)	L	50,710	593,887

- LVP production in local hospitals is not considered.
- In adition to the above indicated product forms, the antidiarrhocal oral rehydration salt has been produced / to the extent of 0.585 million and 2.354 million sachets in 1985 and 1986 respectively. The estimated country requirements is 6 millions sachets.

The magnitude of local production of pharmaceuticals is dependant on importable raw material availability.

Abreviation : L = Litres

2.4 Evolution of expenditures

2.4.1 There is almost a progressive decline in import expenditures for pharmaceuticals in 1980 to 1985 primarily due to financial constrains. The evolution of expenditure is illustrated in table 05.

Table 05

Evolution of Import expenditures

Year	Expenditure US $ x 1000	Index	% National Health Budget
1980	9,638.8	100	Unavailable
1981	11,848.4	123	21.92
1982	8,721.9	90	16.30
1983	6,164.8	64	12.01
1984	4,370.6	45	16.06
1985	5,321.8	55	23.16

2.4.2 The Study on the consumption and expenditures of pharmaceuticals based on disease pattern identify the top 12 therapeutic groups.

Table 06 illustrates the results indicating that between 1980 to 1984 there is no major swing in consumption cost by therapeutic group or in medical condition and that the three therapeutic groups, namely aetiotrophic-nervous system topical represent between 65% to 70% of the value of the annual consumption of drugs in the country.

Table 06

Consumption-Cost by Therapeutic Group

	% Expenditure	
	1980	1984
-Antibiotic, Antiparasitic	45.6	49.5
-Topicals	11.0	13.8
-Nervous System, Somatic	7.3	10.6
-Respiratory	4.2	6.6
-Hoematinic/Blood Volume	1.7	4.4
-Electrolyte, Acid-base balance	5.8	3.2
-Immunologic	4.6	1.5
-Nutrition	1.4	3.0
-Hormonal & Antagonists	1.2	0.9
-Diuretic	2.1	0.9
-Digestive	3.9	2.0
-Genital	0.7	1.5
-Aetiotrophic Drugs -Nervous System -Topical -Nutrition -Digestive System	69.2	78.6

2.5 - Donations

In recent years humanitarian donation of pharmaceuticals supplemented import short falls substantially. In 1985, 39 foreign countries and international organisations have contributed in donations 98.4% in medicines and 1.6% in materials. The total value of donations is US$1022 million, the five principal sources 35.7% donated by Italy, 8.4% by RDA, 8.0% Norway, UNICEF 5.1% and Lutheran Federation 5.5%.

The quantity of tablets received through donations is 40 million in 1983, 39.1 million in 1984 and 39.3 million in 1985.

The donations constitute an integral part of NHS and it passes through a planning phase at the Ministry of Health so as to complement the imports.

The trend of donations value as percentage of overall consumption cost is indicated in table 07.

Table 07

Trend of Donations Received

Donations versus consumption Cost

US$ X 1000

	1982	1983	1984	1985
Donation	257	635	1,324	1,560
Consumption	8,722	6,164	4,370	5,321
% of consumption	2.95	10.30	30.29	29.33

2.6 - Expenditure by Utilising Sector

The acquisition of pharmaceuticals & the efforts for equitable distribution of the limited resource is illustrated in table 08. The split of expenditures are indicative of coverage of vast mass of population in rural sector who utilises the network of health units in NHS sector in apparant detriment of the urbanised population using the pharmacies.

Table 08

Import Expenditure Per Utilising Sector

Year	Import Expenditure 000's MT	N H S 000 MT	%	Pharmacies 000 MT	%
1983	307 580.2	153 811.8	50.0	153 768.4	50.0
1984	232 491.0	183 215.8	78.8	49 275.2	21.2
1985	275 152.3	223 660.9	81.3	51 491.4	18.7

2.7 - Magnitude of Future Funding Requirements

The estimated future funding requirement for pharmaceuticals in the country is projected for the years 1988 to 1992. It is indicated below:

Out Line of Funding Requirements (1)
Millions US $ (2)

	1988	1990	1992
Estimated Expenditures	19.33	24.67	31.32

The values are dimensional and calculated based on the assumptions of population growth and an average percentage growth over the current cost of imported drugs. This should be viewed in its proper perspective as the present import cost of medicine in Mozambic is one of the lowest one can experience.

The export possibilities has been excluded.

However, the market size can be termed as fair & have a reasonable growth rate.

(1) Source: Medicines:Requirement & Funding (August 1986)
Department of Pharmaceutics
Ministry of Health, Peoples Republic of Mozambic

(2) Exchange rate: Identical (1986), 40 MT = $1 USD

3 Most Regulary Necessary Products

3.1 General

It was found difficult to identify the most regularly necessary products based on current consumption level only. This is because of swing from year to year in product-mix to utilise the available sub-optimal fund to maximise health care service to the population. Historical consumption data were useful in the selection process as well as for long range projection of the identified pharmaceuticals. Besides the studies by SIDA/UNICEF on the estimation of essential drug requirements based on morbidity data/patients attendance (Mozambic, 1985) has also been consulted.

3.2 The selection is made based on the following principles:

- these are consumed in very large quantities
- the products are essential drugs in the National Formulary of Peoples Republic of Mozambic, and
- essential as defined by WHo (L'utilisation des medicaments essentials - serie de Rapports techniques-722), 1985
- important therapeutic group coverage
- import cost

3.3 A total of 45 products in 8 dosage forms consisting of 24 tablets, 6 capsules, 7 oral liquids, 3 topical ointments, 2 liquid injectables, 1 each of sterile penicillin powder, opthalmic ointment and granular syrup. Please refer to table 09 for regularly necessary.

3.4 In respect of import of oral liquid, the dosage form that is prefered for children, has been substantially curtailed due to cost reasons.

A total of 778,000 bottles in 11 formulations were imported in 1984, at the expenditure of US$330,408. In addition donation accounts for 10,093 bottles in 9 formulations and 15,600 bottles of penicillin granular suspension (Phenoxy methyl penicillin & ampicillin) value US$5495. In the long range projection only those products are indicated which were imported or received through donations in quantities only excess of 200 bottles, this has eliminated 5 products. For details of oral liquid imports and donations (1984 & 1985) refer to table 10 and 11 respectively.

Table 09. Products identified as Most Regularly Necessary

1. Tablets	mg/tablet
Acetyl salicylic acid	500
Alumium hydroxide	500
Ascorbic adic	50
Aminophilline	100
Bisacodyl	5
Butyl scopol amine	10
Chloroquin	250
Contrimoxazol	400,80
Chorpheniramina	4
Amilorido	5
Diazepam	2
Diazepam	10
Furesemida	40
Ferrous Sulfate,Folicacid	200,0.25
Isoriazid	100
Methyldopa	250
Metronidazol	250
Mebendazol	100
Phenylbutazone	200
Paracetamol	500
Propanolol	40
Prednisolone	5
Praziquantel	600
Sulfadiazme	500

2. Capsules	mg/capsule
Ampicillin	250
Amoxycillin	500
Vitamin B-Complex	-
Multivitamin	-
Tetracycline	250
Rifampicin	300

3. Non-Ste/liquid.	mg/5
Chloroquin syrup	50
co-trimoxazol	200,40
Paracetamol	120
Ferrous sulfate	135
Expectorant	100
Mebendazol syrup	100
Multivitamin syrup	

Pen. oral suspension	mg/5ml
Ampicillin	250
Sterile liquid	**Ampole/2ml**
Chloroquin	250mg
Lidocaine with adrenaline	40mg 0,2m
Penicillin injectable	**units/vial**
Procain penicillin	3ml
Opthalmic Ointment	**3.5g/tube**
Tetracycline	1%
Topical Ointment	**20g/tube**
Benzoie acid+Salicylic	6%, 3%
Menthol, Methyl salicylate	1%, 3%
Benzoate, benzyllindane	1%

Table 10

Oral Liquid: Import Volume & Cost

Product	Quantity X 1000		Cost X 1000 MT	
	1984	1985	1984	1985
- Chlorpheniramine	20		450.5	
- Chloroquin phosphate	60	10.5	749.9	30.13
- Caulina pectina	20		435	
- Clomifeno	20		203	
- Co-trimoxazol	22		1199	
- Chloramphenical	60	.545	1830	.33
- Multivitamin	17.5		275.6	
- Vitamin B-complex	17.5		257.3	
- Pepsin and paneveatin	1.4		130	
- Sodium benzoate	480		6346.8	
- Defenoxilato	60		1305	
- Propiliodona susp.		.108		0.10
- Sub-total	776.4	11.153	13182.1	30.5

Table 11

Oral Liquid: Donation Volume & Cost

	Product	Quantity bottles		Cost Meticais	
		1984	1985	1984	1985
-	Chloroamphenicol	2,200	14,825	33,000	250,000
-	Ferrous sulfate	129	62,500	1,702	3,255
-	Co-trimoxazol	225	163	3,330	460
-	Chloroquin	5,000	416	59,000	600
-	Piperazin 50ml	2,667	23	104,946.5	4,800
-			740		1,700
-	Multivitamin syrup	548	1,210	9,754.4	45,000
-	" drops		1,225		
-	Vitamin B-complex	340	80,870	59,000	36,000
-	Erythromycin susp.		113		4.1
-	" drops		100		2
-	Polaramina	961		2,016	
-					
	Sub-total	12,070	162185	272,749	341,821

3.5 Long Range Projection:

3.5.1 The market growth is projected taking into consideration the population growth and the current 35% coverage of the population in the national health care system. An average yearly percentage growth has been applied to the products which again not same for all products. The quantities thus arrived at for the period 1988 to 1994 is presented in table 12.

As compared to some other developing countries the requirements are quite low and should be considered as minimumn requirement.

The oral liquid requirement in 1988 is calculated as 3.13 million bottles and this appears to be on lower side primarily due to unavailability of a reliable base line current consumption figure.

3.6 Consumption of the identified Most Regularly Necessary Products

3.6.1 The consumption level of the most regularly necessary products in 1982 and 1985 is illustrated in table 13.

The identified tablet, capsule and oral liquid products constitute 78.7% to 98.0% of the annual consumption of the three dosage forms in 1982 and 1985, refer table 14.

Table 14: Consumption of the identified tablet, capsule and oral liquid products in 1982/1985

Identified products	% of Annual Dosage-form Consumption	
	1982	1985
tablet	86,4	90,0
capsule	84,5	96,0
oral liquid	78,7	83,9

Table 12

PROJECTION OF PHARMACEUTICAL PRODUCTS MOST REGULARLY NECESSARY IN THE NATIONAL MILIEU

PRODUCT	STRENGTH	PROJECTION			
I. TABLETS (million pieces)	mg/TABLET	1988	1990	1992	1994
1. Acetyl salicylic acid	500	242	293	354	429
2. Aluminium hydroxide	500	12	15	18	21
3. Ascorbic acid	50	9	10	11	12
4. Aminophylline	100	12	15	18	21
5. Bisacodil	5	10	12	14	17
6. Butyl scopolamine	10	9	10	11	12
7. Chloroquin (150mg base)	250	265	350	427	512
8. Co-trimoxazole	480	36.3	44	53	64.3
9. Chlorpheniramine	4	11	11.3	12	13
10. Amiloride	5	4	9	11	13
11. Diazepam	2	12	15	18	21
12. Diazepam	10	8	10	14	16
13. Furosemide	40	6	7	9	11
14. Ferrous sulfate+folid acid	200	173	249	301	365
15. Isoniazid	100	6	8	10	12
16. Methyldoped-L	250	2.25	2.25	2.39	2.53
17. Metronidazol	250	4.41	4.86	5.36	5.91
18. Mebendazol	100	31	48	59	71
19. Phenylbutazone	200	12	15	18	21
20. Paracetamol	500	8	10	14	18
21. Propanolol	40	1.06	1.13	1.19	1.27
22. Sulfadiazine	500	3.18	3.38	3.59	3.8
23 Prednisolone	5	3.18	3.38	3.59	3.8
24 Praziquantel	600	26	35	42	51
TOTAL TABLETS		906.38	1181.3	1422.1	1719.61

Table 12

PROJECTION OF PHARMACEUTICAL PRODUCTS MOST REGULARLY NECESSARY IN THE NATIONAL MILIEU

	PRODUCT	STRENGTH	PROJECTION			
II.	CAPSULES(PEN+NON-PEN) (X million pieces)	mg/capsule	1988	1990	1992	1994
1.	Ampicillin	250	11	12	13	15
2.	Amoxycillin	500	32	42	56	73
3.	Vitamin B-complex		24	29	35	43
4.	Tetracycline	250	17	20	25	30
5.	Multi-vitamin		2.87	3.16	3.48	3.84
6.	Rifampicin	300	3.53	3.89	4.29	4.73
	Sub-total		90.4	110.05	136.77	169.57

PROJECTION OF PHARMACEUTICAL PRODUCTS MOST REGULARLY NECESSARY IN THE NATIONAL MILIEU

	PRODUCT	STRENGTH	PROJECTION			
	III.NON-STERILE LIQUID (X 1000 L)	(mg/5ml)	1988	1990	1992	1994
1.	Chloroquin syrup	87.5	66	87	116	153
2.	Co-trimoxazole	240	20	26	35	46
3.	Chloramphenicol palmitate	125	22	32	43	58
4.	Ferrous sulfate	135	60	73	80	107
5.	Expectorant	100	66	86	116	163
6.	Mebendazol syrup	100	33	43	53	53
7.	Multivitamin syrup		46	53	61	76
	Sub-total		313	400	504	642

Table 12

PROJECTION OF PHARMACEUTICAL PRODUCTS MOST REGULARLY NECESSARY IN THE NATIONAL MILIEU

	PRODUCT	STRENGTH	PROJECTION			
	IV. PEN ORAL GRANULE:SYRUP/SUSP X 1000 bottles	mg/unit	1988	1990	1992	1994
1.	Ampicillin	250	331	437	578	765
	-STERILE LIQUID (Mg/5ml) X 1000 ampules					
1.	Chloroquin	250	1322	1749	2313	3059
2.	Lidocaine with adrenaline	40	908	1098	1329	1608
	Sub-total		2230	2847	3642	4667
	-PENICILLIN POWDER INJECTABLE X 1000 vials					
1.	Procain penicillin	3 mu	6000	6600	7500	8000
	-OPTHALMIC OINTMENT X 1000 tubes					
1.	Tetracycline	1%	1150	1322	1455	1600
	-TOPICAL OINTMENT X 1000 tubes	20-G/TUBE	10460	12294	14784	17334
1.	Menthol+Methy/salicylate	1%+3%	440	484	506	534
2.	Benzoicacid+salicylicacid	6%+3%	330	363	761	406
3.	Benzoicacid of benzylinoane	1%	385	424	445	467
	Sub-total		1155	1271	1334	1401

Table No. 13

Consumption of the Most Regularly necessary Products

The consumption of the identified most regularly necessary products in 1982 and 1985 is indicated below:

	Milligram / Tablet	Consumption 1982 x1000	Consumption 1985 x1000
A: Tabletes			
1. Acetyl salicylic acid	500	98,590.02	40,257.16
2. Aluminium hidroxide	500	5,625	2,150
3. Ascorbic Acid	100	6,593	76.1
4. Aminophylline	100	4,500	5,023.5
5. Bisacodyl	5	12,254.2	3,187
6. Butylscopolamine	10	8,410	41,264.96
7. Chloroquin phosphate	250	140,840	30,389
8. Co-trimoxazole	400+80	79,762	8,405.7
9. Chlorpheniramine	4	2,653	3,247
10. Amelirido	5	176	2,350
11. Diazepam	2	4,202	1,535
12. Diazepam	10	1,000	3.76
13. Furesemide	40	3,204	240
14. Ferrous sulfate + folic acid	200+0.25	39,365	1,407
15. Isoniazid	100	5,967	12
16. Methydopa-L	250	477	411.5
17. Metronidazol	250	307	1,158
18. Mebendazol	100	455	4,453
19. Phenylbutazone	200	8,180	3,507
20. Propanolol	40	455	500
21. Prednisolone	5	300	7,001
22. Paracetamol	500	2,263.6	1,437.36
23. Praziquantel	600	3,402	-
24. Sulfadiazine	500	2,040	-

Table No. 13 (Cont.)

	mg/capsule	Consumption 1982 x1000	Consumption 1985 x1000
B: Capsules			
1. Ampicillin	250	5.150	85
2. Amoxicillin	500	116	2305.4
3. Tetracycline	500	10.792	6665.1
4. Rifampicin	300	2.18	593
5. *Vitamin-B Complex	-	6867.6	364.9
6. *Multivitamin	-	22.295	3257.6
		7024.017	13271
C: Oral Liquid : Bottles 100 ml	mg/5ml		
1. Chloroquin	200+40	160	.25
2. Co-trimoxazol	200+40	12	.163
3. Chloramphenicol Palmitate	125	46.6	30.275
4. Expectorant	250	303.2	5.592
5. Ferrous sulfate	135	70.1	62.5
6. Multivitamin	-	395	1.225
7. Vitamin-B complex	-	120	8.087
		1106.9	108.092
D: Penicillin Oral Granules: Bottles			
1. Ampicillin	250	791	-
E: Sterile Liquid (SVP) Ampoules	mg/amp.		
1. Chloroquin	250	120	42.94
2. Lidocaine with adrenalline	40,0.02	235	.005
F: Sterile Pen. Powder: Vials			
1. Procaine Penicillin	3 mu	1.01	19.85
G: Ophthalmics: Ointment	3.5g/tube		
1. Tetracycline		9.055	380.65
H: Topicals : 20 g/tube			
1. Benzyl benzoate	1%	15	-
2. Tetracycline		7709	-
3. Menthol and Methyl salicylate	1% + 3%	265	.7

* Actual consumption as tablet

4. - DOMESTIC PRODUCTION OF THE IDEN IED PHARMACEUTICALS

4.1 - Production parameters:

4.1.1- The identified dosage forms vary in complexity of production technology. Table 15 indicates the relative ranking of the dosage forms in descending order of complexity of manufacturing technology and current GMP requirements.

Table 15 - Descending order of complexity of manufacturing technology of the dosage forms

1 - Sterile penicillins

2 - Sterile liquid, Opthalmics

3 - Oral penicillin and non-penicillin granules

4 - Topical ointments, Creams, lotions

5 - Tablets coated

6 - Tablets <uncoated>

7 - Oral liquid, Capsules, Topical powder

4.1.2- Plant working conditions

- Net working days: 229
  (calendar days per year less week-ends, national holidays, one month annual leave / plant shut down)
- Working time per day: Man & Machine
  . Net working time per worker: 7 hours per day
  (stay time 9 hours less 1 hour lunch, 0.5 hour tea and 0.5 hour changing in & out)
  . Net machine running time: 6.5 hours per day

4.2 - In order to make the demand on production capacity discernible, the projected requirements 1988-1994 of the identified pharmaceuticals (table 12) are exploded in terms of key manufacturing steps (magnitude indicators) by dosage form. The estimated throughputs on one shift per day basis is shown below in table 16.

Table 16 - Magnitude of Plant Loading for Domestic Production of the Identified Pharmaceuticals.

(I) - Tablets & Capsules:

Steps	Units	1988	1990	1992	1994
- Tablets	Million	938	1,219	1,473	1,781
Capsules (1)	pieces	90.4	110.1	136.8	169.6
- Total blend	M.tons	514.2	664.7	805.0	975.1
- Mixing/day	M.tons	2.34	3.02	3.74	4.43
- Tabletting (300,000 tab/day)	No.of tablet Press	14	19	22	27
- Coating (50Kg/shift)	No.of days	290	350	420	510
- Coating Pan	pieces	9	13	15	19
- Encapsulation per day	000's pieces	452	550	684	848

(II) - Oral liquids:

- syrup/suspension emulsion	Million bottles	3.13	4.00	5.03	6.48
- Compounding/day	Litres	1,575	2,000	2,525	3,250
- Packaging (fill-label-pack)	Pieces per minute	45	56	70	90

(1) For calculation purposes only the penicillin and non-penicillin capsules are combined.

(III). Ointment:

- The three topical ointments selected are required in 23 tons in 1988 and 28 tons in 1994. These are on lower side.
- Topical ointments are not studied in detail as the Ministry of Health has an on-going project in Maputo with OXFAM/EEC for an annual production capacity of 60 tons for a wide range of 14 formulations. The start-up is foressen in 1988.
- The sterile opthalmic ointment blending requirement is 144 Kg per day in 1988, climbes to 200 Kg in 1994.

(IV). Oral granules

The estimated annual processing requirements of ampicillin granules for suspension,

Key steps	Units	1988	1990	1992	1994
- Blending / Granulation	M. ton	14.9	19.6	25.7	34.4

(V). Sterile penicillin

- Fill-Label-pack	000's Vial per shift	296	340	374	411

This requirement of sterile penicillin packing is high and not possible to produce in one industry even with mechanised asceptic operation. The technology is complicated for local production.

conclusion:

- The overall conclusion is that the magnitude of the production requirements is too high for a single industry demanding high speed automated technology and the needed multiplicity of the manufacturing technology for the wide spectrum of products is not immediately adaptible. There is a need for stepwise development and in the process the primary considerations should be laid on,-

    - adaptibility of technology
    - selection of relatively simple non-sterile dosage forms and phasewise introduction of products
    - availability of potencial domestic production inputs
    - GMP requirements

4.3 -Phasing of dosage forms for local production

The following table 17 illustratres the suggested phasing of the local production of pharmaceuticals.

Table 17.

Phasing of production of pharmaceuticals.

Administered form (Arranged in ascending order of complexity)	Progressive introduction of the dosage form — Phasing					
	I	II	III	IV	V	VI
. Non-sterile:						
Tablets/Capsules/Oral liquid	***					
Topicals			***			
Oral penicillins				***		
. Sterile:						
Non-Penicillin					***	
Penicillins						***

4.4 - Production program:

4.4.1 -Three non sterile dosage forms, namely tablets, capsule and oral liquid are suggested to be produced in the pharmacentical industry. The rationale of the suggestion is the relatively simple manufacturing technology. The products are selected based on the criteria illustrated in 3.2 and that these are among the identified most regularly necessary products.

Table 18 indicates the planned products and quantities - tablets 250 millions, capsule 25 million and oral liquid 1.85 mollion bottles to be produced locally.

The quantities approximately equates to the need of 3 to 4 pharmaceutical plants to meet 1988-1990 requirements of the country in the three dosage forms, namely tablets, capsules and oral liquid.

4.4.2 -Although the spectrum of 15 tablet, 4 capsule and 7 oral liquid formulations are included in the production program, refer table 18, certain products may be delected and more volume of the same product to be included as an alternative for ease of technology adaptability, need of the country and economic considerations. In this sense the volume is indicative of the magnitude of the throughput envisaged.

4.4.3 -The next dosage forms suggested to be introduced into the expanded plant in phases are the topicals.

4.4.4 -Production of oral penicillin containing products namely ampicillin, amoxyllin capsules / granules has been phased out later in the chronogram (refer 4.3) due to the rigid GMP requirements controlling the operation and the operators to ensure that non-pen products are not contaminated by penicillin, the complexity of technology and construction designs (HVAC/ventillation/utilities) as well as operation and maintenance of a pen plant within a plant (dedicated space and equipement), the separate penicillin plant being expensive.

Table 18

PROPOSED PRODUCTION PROGRAM

A. TABLETS

PRODUCT	DOSE (mg/Tab)	QUANTITY (millions)
Acetyl salicylic acid	500	95
Aminophilline	100	10
Paracetamol	500	10
Isoniazid	100	5
Isoniazid + Thiocetazone	300 + 150	5
Amilorido	5	5
Mebendazol	100	10
Co-trimoxazol	400 + 80	15
Chloroquin	150 (base)	55
Furesemida	40	5
Biscodyl *	5	5
Ferrous sulfate+Folic acid*	200+0.25	15
Diazepam	2	5
Diazepam	10	5
Phenylbutazone*	200	5
- plain tablet	-- 225 millions	
- Coated tablet *	-- 25 millions	

	DOSE (mg/capsule)	QUANTITY (millions)
B. CAPSULES		
Tetracycline	500	15
Vitamin B-Complex	-	5
Rifampicin	300	3
Rifampicin	150	2
- Capsule size No. '0'	- 15 millions	
- Capsule size No. '1'	- 8 millions	
- Capsule size No. '2'	- 2 millions	

C. ORAL LIQUID

Product	Dose (mg/5ml)	Quantity bottles 000's
- Chloroquin, 100 ml	50 (base)	250
- Co-trimoxazol, 100 ml	200+40	250
- Expectorant, 100 ml	250	500
- Mebendazol, 100 ml	100	100
- Paracetamol, 100 ml	120	100
- Multivitamin, 100 ml	-	500
- Ferrous sulfate 100 ml	135	150

Bottles, 100 ml - 1.85 millions

4.5 -PRODUCTION TECHNOLOGY

4.5.1 -Formulations:

The products indicated in the production program table 18 comprise a variety of formulations for tablets, capsules and oral liquid dosage forms. Since pharmaceutical formulations are composed of multiple components, the source of procurement of materials, type of equipment used and the technics followed in the process of manufacture influence a great deal in ultimate product stability. Therefore, it is necessary that each product formulation should have been developed, established and well-studied for stability and pharmacological parameters before its commercial scale manufacture is initiated in a new manufacturing facility.

4.5.2 -Process flow:

The overall production process flow from raw materials to finished goods passes throgh a number of sequential manufacturing and packaging steps such as, approved material dispensing -> Mixing -> Granulation -> Compression -> Coating -> Subdivision & Packaging. The flow for oral liquid manufacture is: Mixing -> Filtration -> Subdivision -> Packaging.

The methods of handling and transportation in the plant is recommended to be largely manual.

4.5.3 -Manufacturing technology:

To manufacture the proposed volume of tablets, capsules and oral liquid, the following is the estimated loading at certain key steps of manufacture foreseen:

		Processing load per day	
	Units	Mixing	Granulation
Tablets:	Kg	983	609
Capsules:	Kg	90	-
Oral Liquid:	L	1000	-

- The tablet compression requirement including slugging rate per day is 1.60 million units and encapsulation of 110,000 units.

- The tablet manufacture embrace multitude of technology - direct compression, dry granulation, wet mass (aquous/solvent) granulation and film coating technics. The daily output required is large enough and dictate the necessity of high speed tablet press.

- Microdose products:

  In order to ensure that the finished product fulfills certain criteria specified in international pharmacopea, each manufacturing process should be developed individually. Prior to manufacture of the two microdose products, namely Amilorido, 5 mg ,Bisacodyl, 5 mg and Furesemida, 40 mg tablet included in the production program, process validations should be established at 'mixing' and tablet 'compression' stages to ensure that the finished products conform to specifications.

4.5.4 -Packaging technology:

-In principle, simple, largely manual adaptation of technology and preferential use of indigenous materials are the overwhelming considerations in favour of the use of plastic or glass jars for bulk packing of tablets and capsules. The subdivision for multiple pack is suggested by weighing and/or by use of perforated plastic trays.

-Sophesticated, expensive blister packers and strip packing machines offer improved product presentation but puts the country to unlimited commitment to imports of high in-put technology with the use of PVC, Al-foil which are not suggested.

-Cost considerations (1986) of local HDPE jars for multiple packs of tablets/capsules are substantially favorable over the glass jars tin containers.

4.6 - Indigenous Production Inputs:

4.6.1 - Raw materials:

Water and sugar are locally available. The present local production of sugar does not meet pharmaceutical specifications. To comply with the specifications, the locally produced brown sugar will have to undergo further purification process in local sugar industries. Municipality supplies of water quality is not potable at all points of use and supply is erratic. Self contained reliable well water is suggested.

4.6.2 -Packaging materials (Indigenous):

The following types of packaging materials are envisaged:

Production	Type of packaging materials
-Tablets/Capsules	-Plastic or glass jars with lids
-Oral liquid	-Non-parenteral soda-lime glass bottles, metal screw caps, labels and hard board boxes.

4.6.3 -The survey studies made on the complementary industries suggest that the plastic, glass, printing, cardboard box and metallic closure industries around the city of capital Maputo and the port-city of Beira are potential sources which directly or indirectly use imported basic and intermediate materials. Due to large dependence on foreign inputs and other associated industrial problems almost all of these ancilliary industries are however presently under-utilized. VIDRIERA glass factory has a large & impressive base since pre-liberation days and produce glass bottles for drinks and other commercials consumer goods. Metal Box (UK based) is engaged mostly in fabrication of metallic containers and closures for packing, domestic and industrial products. Except Metal Box all of these packaging materials industries are state owned.

4.6.4 -The presence of quality control department in these industries are either insufficient or non-existent. The overall technical manpower base is thin and spare parts are limited. Some sort of revitalising support should work as a big incentive to these ancilliary industries to ensure continuity of supplies and in quantities required.

- One common condition for the local suppliers/manufactrers is that a formal agreement and back-up assistance in terms importable basic materials or financial shall be required.

4.7 -Co-ordination activities:

4.7.1 -Much of the local packaging input-supply technical bottlenecks however can be minimised by integration of pharmaceutical quality control with local suppliers, coordination of institutional activities and scale-up of deliveries only in phases. As there is no competition in the domestic market among the local suppliers for improvements in quality a fine tuning time lag in the development process is foreseen especially for the required volume of the deliveries for the envisaged pharmaceutical industry.

4.7.2 -The container-closure suppliers especially the glass & metal cap manufacturers will need mutual horizantal coordination efforts via pharmaceutical industries to upgrade the quality of their imported input materials and processing technics to manufacture finished goods within the specified tolerances.

4.8 -Production Packsizes:

4.8.1 -The suggested Packsizes are as follows:

Dosage form	Recommended Packaging material	Packsize
Tablets	Jar	1000-3000/Jar
Coated tablets	Jar	100-3000/Jar
Capsules	Jar	500-1000/Jar
Oral liquid	Glass bottle, 100ml	2x40/shippers
Oral liquid	PVC Jars, Litre	5-6 cardboard chippers

4.8.2 -Bulk Packs: Oral liquid

-Selective oral liquids and tablets (excluding the vitamin formulations) can be bulkpacked in litres & multiples of thousand respective for dispensing only in hospitals, through acceptable parameters of hospital pharmacy GMP practices. The three central hospitals have necessary infrastructure.

5. -QUALITY CONTROL:

-The production program suggested for a pharmaceutical industry includes product-mix requiring a fully developed laboratory with advance analytical technics. The demand on the functional capability level is high.

-The quality control facilities would embrace:

-in-process control.

-analytical controls involving physico-chemical, chemical and micro-biological testings for incoming raw-, packaging materials and finished goods, stability testings, etc.

-environment control, field complaints, returns, investigation of manufacturing variances, etc.

In-process control:
Well trained in-process inspectors of adequate technical capacity are required to monitor and control various stages of production processes that need statistical sampling, conspicuous process validations, documentation and data analysis.

-conclusion:

The development of the required level of quality control technical capability among the nationals for industrial scale domestic pharmaceutical unit is an institution building process to be attained only in phases.

6 - MANPOWER

6.1 - Requirement

6.1.1 - General

The manpower requirement is dependant on the volume of production and also the technology installed. However in principle the following categories of personnel shall be needed:

- Management/Administration
- Technical & supervision
- Skilled Process Operators
- Clerical
- Semiskilled and warehouse personnell

The age limit for the key personnel is about 30-35 years while at operators level 25-30 years.

6.1.2 - The total number of personnel estimated for the production requirement is 185. The split is:

- Management Level	-	7
- Technical & Supervision	-	18
- Plant Maintenance	-	15
- Skilled Process Operators	-	45
- Semiskilled	-	89
- Clerical	-	15

6.1.3 - In table 19 the details of the personnel requirement, education, experience and the trainning needs have been mapped out.

TABLE 19

MANNING REQUIREMENT, EDUCATION AND TRAINING NEEDS

FUNCTIONAL LEVEL	N:PERSON.	EDUCATION & TRAINING NEED	REMARKS
A - KEY PERSONNEL:			
- Plant Manager	1	University Graduate in Pharmacy/ Science	Training abroad, in service english language
- Production Manager	1	University Graduate in Pharmacy + Experience in industry	Training abroad & in service, & english language
- Quality Control Manager	1	University Graduate in Chemistry + Experience Industry	Training abroad, in service english language
- Plant Accountant	1	University Gtaduate in Economies +Training	In service / abroad
- Plant Engineer	1	University Degree in Mechanical Engineering + Training	Training abroad & in service
- Production Planing & Inventory Control Manager	1	9 Years School, 3 Years Technical Institute, Experience	In service training (1)
- Personnel Welfare & Industrial Relations Manager	1	9 Years School, Experience	Retired ex army man, in service training
B - SECRETARIAL	4	Professional	
C - PRODUCTION:			
- Assistant Production Manager	1	University Grad. or Pharmacy Technics &Long Experience in Industry	Training abroad, in service training
- Supervisor / Forecan	4	9 - Years School, Industrial Training	Training abroad & in service (1)
- Skilled Operators	45	6 - 9 Years School, Industrial Training	In service training / training at Beira Work-shop
- Semiskilled Operator	40	4 Year school	In service training (1)
D - QUALITY CONTROL:			
- Assistant QC Manager	1	Pre-University & University Graduate, training-industry	All aspects of qual.control training abroad & in service
- Laboratory Analyst	8	9 Years School, 3 Years Chemical Institute & Training	Laboratory train. chemical (1) phisical & biological analyses
- In-Process Inspector	4	6 - 9 Years School, Training	In service training , training at Beira work-shop (1)
- Laboratory Attendant	2	4 Years School	---
- Sampler	1	4 - 6 Years School, training	In service training, training at Beira workshop

TABLE 19 (cont.)

MANNING REQUIREMENT, EDUCATION AND TRAINING NEEDS

FUNCTIONAL LEVEL	N:PERSON.	EDUCATION & TRAINING NEED	REMARKS
E - ENGINEERING AND MAINTENANCE:			
- Maintenence Foreman	1	9 Years School, 5Years Industrial Institute, Intensive Training-Ind.	Industrial training abroad & in service
-Utility Foreman	1	9 Years School,5Years Industrial Institute,Intensive Training-Ind.	Industrial training abroad & in service
-Mechanic / Technician	11	6 Years school, 5 Years Industrial Institute-Training	In service training
-Electrician	2	6 Years school, 5 Years Industrial Institute-Training	In service training
F - FINANCE & ACCOUNTS			
- Budget & Cost Control Office	1	9 years school, commercial instituite	In service training
- Clerical	6	4 years school, 5 years commercial school	In service training
G - PRODUCTION PLANNING & INVENTORY CONTROL:			
-Warehouse Supervisores	2	6 - 9 Years School, 3 Years Tech. Institute	In service training (1)
- Pharmacist	1	9 Years School , 3 Years Institute	In service training (1)
-Semiskilled Operators (Loader, Unloader,Piccker-Packer)	18	4 Years School (1)	
- Mediasc, PPIC & Co-Ordinator	2	6 - 9 Years School, Trainin--Industry	In service training (1
H - PERSONNEL WELFARE & INDUSTRIAL RELATIONS:			
- Clerical	3	6 Years School	
- Receptionist	1	6 Years School	
- Site House Keeping & Security	9	6 Years School	Ex-army man
- Miscellaneos: -Drivers -Stewards/cook -Messenger -Cleaner, Laundry	10	4 Years School	
TOTAL PLANT	185		

(1) Part of personnel requirement available training from the pharmacy technicians, agents and auxilliaries (ref. table 20) currently engaged elsewhere.

6.2 - Availability:

6.2.1 - In principle and present the availability of manpower for the different levels of requirement is scarce in Mozambic. The sectoral requirements are centrally planned and since pharmaceutical plant needs trained personnel of various disciplines a long term planning is suggested for education, training and development.

6.2.2 - The current and near-future availability of certain category of national presonnel with pharmacy / pharmaceutical education is indicated in table 20. Many of the personnel are engaged in different professions .eg. hospital pharmacy, NHS, etc. in the country and some of them can be withdrawn and made available for pharmaceutical plant. This is inadequate for multiplicity of the industrial scale operational need.

- Key personnel: The critical key personnel are plant engineer, quality control manager and plant accountant who are not readily available and has to be developed.

- Supervisory level: Three persons are identified as trainee with acceptable professional profile, 2 for production and 1 for quality control who completed preliminary training on tabletting technology and laboratory analysis preparatory to the practical work-shop training at Beira. There is shortage of plant utility and maintenance foreman and technicians who may be identified from the industrial institute for further pratical training & development.

- Laboratory analysts for physical, chemical and microbiological analysis, sampler, in-process inspectors are to be developed in phases from small scale operations.

To overcome the important constrain of manpower a development sheme according to the suggestions indicated in table - 19 should be initiated for various levels of personnel including 45 skilled operators.

Table 20: Availability of Pharmacy Personnel

The following table illustrates the availability of national personnel in Mozambic in 1986 in Pharmacy cadres:

Pharmacy Personnel with Institutional Education

Category	Institutional Education	Availability 1986
- University graduate <Pharmaceutical science>	- Five years of university studies in Cuba with initial pre-university studies in Mozambique.	3(a)
- Pharmacists	- 1 national teaching at pharmacy institute - 3 foreign nationalgin in 2 hospitals & 1 laboratory	4
- Pharmacy Technicians (b)	- Nine years school + three years in Pharmacy institute.	56
- Pharmacy Agents	- Six years school + 2 years in Pharmacy institute	87
- Pharmacy Auxiliaries	- Four years school + 1 year pharmacy institute.	201

<a> - An additional 3 nationals are studying at the universities in GDR and Brazil, expected to return by 1990. Two more are at planning stage.

<b> - For production and laboratory supervisors, 3 pharmacy technicians received preliminary training (phase-I) as preparatory for the training at Beira Work-shop.

6.3 - Job enrichment / Internal Training

In order to enrich the job among the production and quality control personnel, the system of job rotation should be an integral part of in-plant manpower development programs.

Internal Training programs on specific topics such as GMP, personal hygeine, safety practices at work as well as programs to improve capabilities, awareness, operational flexibility of the work-force and systems of measurement of performance with consequential rewards and punishments should be built-in into the industry.

7. INSTITUTIONAL FRAMEWORK AND CAPABILITIES

7.1 - Institutional Mechanisms of Drugs Administration:

7.1.1- The department of pharmaceutics, Ministry of health, is the core of the institutional mechanisms for regulations and control of pharmaceuticals in Mozambique. In absence of any pharmaceutical industry in the country, the present drugs import control is confined to imports of the 323 formulations of essential drugs under generic names embodied in the fourth revision of the "National Formulary of Medicaments". The department is assisted by the 7 member "National Drug Technical Advisory Council" to regulate the imports and for administering routine works there is a pharmaceutical industrial group (GIF) at the Ministry which has a thin base. Medimoc, the state company imports all pharmac-euticals centrally in close co-ordination with the department of pharmaceutics, Ministry of Health, in a cost effective system.

7.1.2- There is no formal legal regulations for registration of pharmaceutical products or use of trade names in Mozambique. In order to establish a local pharmaceutical industry through collaboration with an experienced foreign industry a formal procedure should be developed in due coarse. However, as the joint venture is foreseen to be established at the poblic sector and that the products to be manufactured are included in the essential drugs list in National Formulary of Medicament no difficulty however is foreseen immediately in getting the formal health registration. The Ministry of Health prefers the use of generic names for product to be produced in Mozambique. There is however no patent laws to protect new products or processes.

Certain agreements on these broad legal issues should be necessary for the future collaborating industries to operate in Mozambique.

7.2 - Drug testing laboratory:

7.2.1- Due to limitations of human, financial and technological resources the country has not yet been able to establish a drug testing laboratory. An attempt to develop certain chemical testing facilities and skills is however under way at the National laboratory for water and hygeine at the Ministry of Health with external assistance. The base is yet embryonic but encouraging. The unavailability of these resources led the National control system to least pre-market screening and no post market surveillance of the wide spectrum of imported pharmaceuticals. This short fall is significant. A phase wise build-up of a national drug testing laboratory is needed to eusure control of subpotent, misbranded or adulterated drugs.

7.2.2- In order to overcome this important technical constrain in the country, it is suggested that man power is identified for education in chemical institute as applicable for further practical laboratory training at the,

- -Work-shop laboratory at EMOFAR, Beira
- -National laboratory for Water & Hygeine at the Ministry of Healt, Maputo
- -Regional laboratories

The suggested means is a horizontal transfer towards a self reliance. In addition, specific external assistance (including sub-regional co-operation) shall be needed for phase wise development of adequate nationals in drug quality control.

7.3 - Institutional education in pharmacy

7.3.1- Education has been assigned first priority after independence. The pharmacy education is confined within the institute level as there is no professional education in pharmacy offered at the university level in Mozambic. The present system allows development of technicians of different levels after completion of different school years, as stated in table 20.

The institute in Maputo offers a 3 year coarse and three other institutes at provincial level offer 2 years coarse one each in Maputo, Beira and Nampula.

The level of education is elementary in nature and primarily directed towards basic education on essential drugs , galenicals - syrup e topical ointments preparation in pharmacies in the third year curriculum.

7.3.2- Except for limited positions in industrial unit the institute level of education is not directed towards adequate technical education for creating manpower base for pharmaceutical industries. The possibilities of initiating limited but appropriate coarse and laboratory works under the existing chemistry department at the Edward Mondlane Universaty as an initial step to establish a separate pharmacy faculty to meet future marpower needs of the pharmaceutical sector has been discussed at the Ministry of Health with immediate favorable response.

External assistance for foreign university education for certain key personnels and assistant managers is suggested.

7.4 - Maintenance Facilities/Work-shops.

The single central maintenance work-shop under the Ministry of Health is located in Maputo. Their primary engagement is in repair and maintenance of hospital machineries and equipment, air conditioners, vehicles etc.

Reliable external maintenance facilities are scarce.

In absence of adequate infrastructure for local fabrication of spares, tools and trained maintenance personnel the emphasis on self contained well equipped work-shop is a precondition for industrial scale pharmaceutical production unit in the country.

7.5 - Drug distribution network.

7.5.1- Until 1985 the Ministry of Health has been directly controlling the drug distribution in Mozambic. With assistance of Italy in a long term project (1985-1990) the Ministry of Health is up grading the network through decentralisation of the administrative system and the drug storage facilities.

The distribution responsibility is shifted to Medimoc, the state company importing the drugs.

The country has been unevenly served with 2 regional warehouses at Maputo for the southern region covering 3 provinces and at Beira for the central and northern region of the country covering 7 provinces.

In order to improve the accessibility to drugs for the northern region the regional warehouse at Beira is split through the up-grading of the provincial ware house at Nacala to the level of regional warehouse. The regional storage facilities in respect of geography of the country and the population distribution is thus rationalised.

The plan for the three regional warehouses namely Maputo, Beira and Nicala will serve an estimated 3.83 million population in Maputo city, Gaza & Inhambane, 4.82 million population in Sofala, Manica, Tete & Zambesia and 4.57 million population in Nampula, Cabo-delgado and Niassa provinces respectively.

The transportation system is also planned to be improved for the land routes. Due to security reasons accessibility through the land routes has certain limitations hindering drug distribution to 3 provinces in the country

7.5.2- The layout of the distribution net work of NHS is briefty as under:

A.	Regional Warehouse Nos.3	- Procures, stores & distributes to the provincial warehouse - Distributes to health institutions in the area
B.	Provincial Warehouse Nos.11	- Receives drugs from regional warehouses & stores - Distributes to the district level storage facilities & health institutions
C.	District Storage Facilities Nos.110	- Distributes drugs to health centres & community health workers.

- In addition, Medimoc directly serves 37 pharmacies under the state company, FARMAC with the imported pharmaceuticals.

8 . Conclusion & Recomendations

8.1 - Production Program

Based on the complexity of pharmaceutical manufacturing tecnology the of the three non-sterile dosage forms, namely capsule and oral liquid is suggested to be initiated in the first phase. The analysis of he indentified pharmaceuticals indicates, the magnitude for local production requirement is too large to adapt in a single industry in respect of the required tecnology, manpower and supporting infrastructure. The size of an industry in the order of a production volume of 250 million tablets, 25 million capsules and 1.85 million bottles of oral liquid comprising 15 tablet, 4 capsule and oral liquid formulations are suggested.

The product - mix may however be altered to the advantage of adaptibility or production of the same product in larger quantities rather than wide spectrum of products is an alternative.

Further, the indicated level of pharmaceutical production facility is suggested to be attained only in phases, progressively adding new cappacity to the on - going small scale operation. This will permit development of domestic complementary packaging material industries, technical manpower for production, quality control & plant maintenance progressively.

8.2 - Pontencial Domestic Productions Inputs

At present no raw material except water is available locally.

- Among the packaging materials studied PVC & HDPE plastic jars, polythene bags, glass bottles, aluminium serew caps, tin containers, card board boxes, labels and cartons can be sourced locally.

  The plastic jars are suggested for tablet and capsules and the brown bottles for the oral liquid. The sample bottles were free of detectable defects. The glass bottles meet USP NP grade.

  Labels, cartons & card board boxes were found to be of acceptable quality.

- These pontential local industries need some rehabilitative and revitalising support. Acceptance of orders for the pharmaceutical industry is subject to extension of assistance either financial or by supplying the processing materials.

- To meet the specifications of pharmaceutical packaging materials the need for co - ordination of institutional activities is fore seen. The fine tuning development phase of these industries has to be achieved progressively through initial small scale deliveries integrated with pharmaceutical quality control.

8.3 - Production Technology:

The technology that is adaptible in mozambic should be influenced by the selection of machineries. Semiautomatic machines in man-machine combination for manufacturing and bulk packing in jars by simple weighing is suggested for prodution technology. Two types of packagie are suggested - usual market packs and hospital packs.

The provincial and the central hospitals inherit the infrastructure necessary for subdivision of bulk pack of tablets, capsules and oral liquid and it is suggested that in addition to bulk packs of tablets and capsules the non-vitamin oral liquid formulations are packed in litres for dispensing in hospital pharmacies.

8.4 - Institutional Co-ordination Activities

A number of co-ordination activities are foreseen as a pre-condition to the overall achievement for the establishment of a pharmaceutical production unit in Mozambic.

These national co-ordinating agencies are:

- Ministry of Education and Ministry of Manpower Planning: identification of the required personnel and placement in various institution for education/training.
- Ministry of Health and Ministry of Industries: nature of assistance and its magnitude as a pre-condition by the domestic packaging material suppliers, (complementary industries) development need of suppliers as integrated with pharmaceutical quality control.
- Ministry of Health and Ministry of Education: introduction of pharmaceutical analysis in the curriculum of the chemistry department, Edward Mondlane University and at the chemical institutes,

- Department of Pharmaceutics, Ministry of Health and Department of National Hygeine Laboratory for Food and Water (central & regional): in using premises for horizontal transfer of the laboratory analytical technics of drug analysis for the preliminary training of the selected nationals as laboratory analysts.

- Vidreira glass industry and the Metal Box: the need for horizontal co-ordination between these two manufacturers is foreseen to ensure the precision of containers and closures.

8.5 - Man Power:

- Plant manning: A total of 185 personnel is estimated for the pharmaceutical industry. This includes 18 technical & supervision, 45 skilled operators. In order to meet this requirement of personnel for pharmaceutical sector it is suggested that, - an effective long term planning is made for education and subsequent training initially at work-shop/pilot plant level,

- National planning for formal university education for a plant engineer, assistant plant engineer, assistant production manager, assistant quality control manager and a plant accoutant followed by industrial training is suggested.

- On return of the nationals from abroad on copletion of university education in GDR and Brazil towards 1988-1990 further specialised externel industral trainning should be planned.

- Manpower development in quality control functions is institution building process.

- The ptential action agencies on the state of the art are, the Ministry of Health, UNIDO/UN agencies,

bilateral agreements & the sub-regional accord (April 1981) among Mozambic, Madagascar, Mauritius and Seychelles, regional co-operation among SADCC countries.

8.6 - Progressive Build-up of National Pharmaceuticals Industry

In order to build-up industrial level of pharmaceutical operation in Mozambic it is suggested that suitable embryonic work-shops for the non-sterile oral & topical dosage forms are established in phases in the existig buildings as rennovated/remodelled to meet pharmaceutical requirements. The work-shop facilities by the dosage forms should enable technical manpower development as well as the domestc packaging material manufacturers.

The next phase is the transfer of work-shop tecnology to the industry via the pilot/sub-commercial size production unit with progressive expansion and introduction of new capacity.

All plant construction and expansion works should be supervised by international experts.

8.7 - Collaboration with Foreign Industry

In order to establish, operate and maintain a pharmaceutical industry the collaboration with a suitable foreign industry with experience in developing countries at the public-private or public-public sector should contribute most favorably in regard to:

- industrial training for both plant management and technical personnel at various levels
- acquisition of suitable machineries and transfer of the adaptible technology,
- adaptation, development & integration of technical management and administrative systems,
- assistance in plant construction, installation of machineries, start-up and maintenance of the plant facilities
- development of local complementery industries for packaging materials

8.8 - Drug Control Administration

In order to strengther the existing drug administration apparatus at the Ministry of Health for future sectoral need it is suggested that an exposure be planned of the person(s) at the policy making level to the health authorities in a foreign country to upgrade the functions and responsabilities that is foreseen to be necessary with the establishment end growth of domestic pharmaceutical industry(ies). It is suggested that among others the following areas should be covered during external training:

- establishing quality control standards, safety, efficacy and WHS's policy on quality control
- establishment of regulatory laws / drug legislation
- registration of pharmaceuticals
- drug monitoring
- G.M.P'S
- licensing and certification of manufacturing units