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PRODUCTION PLAN FOR THE ARAB PHARMACEUTICAL INDUSTRY IN SELECTED ARAB COUNTRIES\* •

TF/INT/77/017 TF/INT/76/030 VC/INT/76/077,

Volume one: General aspects,

Prepared for the Arab Company for
Drug Industries and Medical Appliances (ACDIMA)
by the United Nations Industrial Development Organization

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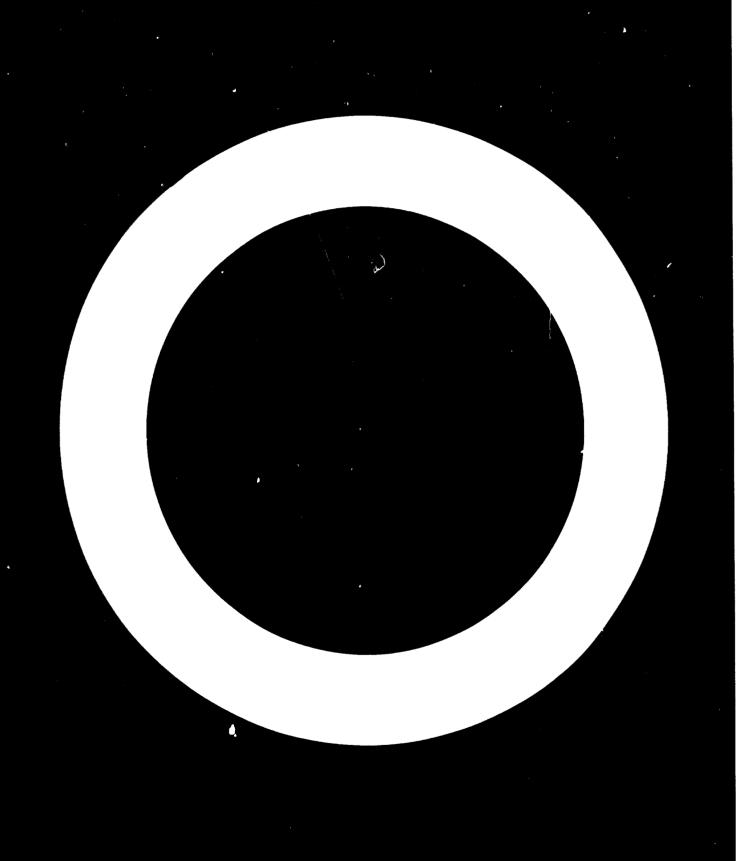
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#### SUMMARY AND RECOMMENDATIONS

#### A. <u>Introduction</u>

The United Nations Industrial Development Organization (UNIDO) jointly with the Industrial Dsvelopment Centre for Arab States (IDCAS) carried out in 1973 a survey of the pharmaceutical industry in 18 Arab countries - Algeria, Bahrain, Democratic Yemen, Egypt, Iraq, Jordan, Kuwait, Lebanon, Libyan Arab Jamahiriya, Morocco, Oman, Qatar, Saudi Arabia, Sudan, Syrian Arab Republic, Tunisia, Yemen, United Arab Emirates.

The study revealed that the pharmaceutical industry in the various countries was at different stages of development.

- (a) Countries with no pharmaceutical industry: Bahrain, Democratic Yemen, Libyan Arab Jamahiriya, Qatar, Saudi Arabia, Yemen, United Arab Emirates;
- (b) Countries with limited pharmaceutical industry: Kuwait;
- (c) Countries with pharmaceutical industries based on bulk
  materials/formulation: Algeria, Iraq, Jordan, Syrian Arab Republio,
  Lebanon, Morocco, Sudan, Turisia;
- (d) Countries with well established pharmaceutical industries based on production of bulk chemicals and materials: Egypt.

A broad list of pharmaceuticals consumed in the different Arab countries was also prepared. The consumption of pharmaceuticals in the Arab countries in 1973 was about US\$450 million per year of which those worth US\$180 million (40%) were produced bocally. The Arab countries with a population of 130 million have a large market for pharmaceuticals and wish to develop an integrated pharmaceutical industry based on bulk chemicals with the object of becoming as self-sufficient as possible.

A programme of technical assistance by UNIDO to the Arab Company for Drug Industries and Medical Appliances (ACDIMA) was discussed in May 1976 and it was agreed to prepare in detail a programme for the production of drugs, packaging materials and medical appliances. A budget of US\$248,000 was made available for this project under cost-sharing arrangement between UNIDO, and ACDIMA and the Canadian Executive Service Overseas (CESO).

A team of seventeen experts was assembled at Cairo during the period May - October, 1977 to review and evaluate the information provided by ACDIMA and collected from other sources, which would be needed for the implementation of the objectives of ACDIMA viz. the planning and establishment of pharmaceutical industries in different member countries.

This report outlines the appropriate measures and steps to be undertaken by ACDIMA in the short term and the long term for the implementation of the various projects. Industrial profiles are presented where specific recommendations for the establishment of manufacturing facilities are made.

This final report incorporates further information and analysis work requested by ACDIMA during review meetings at UNIDO Headquarters in October, November 1977.

#### B. Antibiotics

In the domain of drugs and pharmaceuticals, antibiotics constitute perhaps the most important group both from the point of view of essentiality as well as investment potential. In view of this, an analysis in depth has been carried out to assess the present requirements and projected demand pattern taking into account not only the future plans of the concerned Arab countries but the pattern of drug consumption and future trends in the developed countries. A detailed assessment has also been made of the existing facilities for basic production of antibiotics in bulk both in Egypt and Iraq as well as the availability of the requisite skills and infrastructure as also the raw materials and auxiliary materials. Based on this, a strategy has been worked out to fully utilize the existing capacities as a short term measure at least to meet part of the demand as early as feasible and to create a base for facilitating the implementation of the long term plans. As regards future, a product mix is suggested for the antibiotics plant proposed to be established. It is also suggested that facilities should be provided in the new plant for the formulation of half of the bulk drugs manufactured with a view to improve the economic viability of the new venture as well as serve as an ideal formulation plant for the Arab countries with emphasis on Qood Manufacturing Practice.

# Present: Strategy to fully utilize the existing capacities:

There exist facilities both at El Nasr P.C.Co. in Egypt as well as State Drug Industries, Iraq for the manufacture of antibiotics. However, there is no production of antibiotics in Egypt while a small quantity of Tetracycline is being produced in Iraq utilizing part of the facilities. There is a good demand for Tetracycline in the Arab countries. Apart from this, tetracycline lends itself more easily for commencing production in the available facilities in Egypt, while as indicated above, it is already being produced to a limited extent in Iraq. In the light of above, the following recommendations are made:

(i) Take up production of Tetracycline at El Nasr plant in Egypt on the basis of strain and technology available at S.D.I. plant in Iraq.

(ii) Both S.D.I. and El Nasr plants should switch over to chemical precipitation method of recovery of tetracycline in place of the current ion-exchange method, which has been a bottleneck at S.D.I. plant. This will also enable both the plants to fully utilize the available fermentation capacities and the other infrastructure.

It should be possible to implement the above measures within six months. This will also result in doubling the output of tetracycline at S.D.I. plant, Iraq.

(iii) In the field of antibiotics, the new high yielding culture strains of microbes facilitate the augmentation of production several fold in practically the same fermentation facilities by the addition of some balancing equipments to the recovery section. In view of this, it is recommended that ACDIMA may procure a high yielding strain and technology for tetracycline for use in El Nasr and S.D.I. plants-a strain which gives about 22,000 units/ml. of activity in place of one giving 9,500 units/ml. at S.D.I. plant at present.

The above measure will facilitate the production of about 85 tons of tetracycline per year at El Nasr and S.D.I. plants put together and can be implemented within the course of about one year. This compares favourably with the present requirement of tetracycline for five Arab countries - Egypt, Iraq, Libyan Arab Jamahiriya, Sudan and Syrian Arab Republic which is estimated to be about 79 tons per year.

Thus with minor investment, it should be possible to activate El Nasr plant and fully utilize the available facilities at S.D.I. plant to produce tetracycline in bulk to meet the current demand for tetracycline in the concerned Arab countries within one year. The cost of production of tetracycline is also expected to compare favourably with the prevailing international prices. The above measures will also provide necessary experience for

technicians at S.D.I. and El Nasr plants to man the proposed ACDIMA anti biotics plant.

## Future

Based on the future plans of the Arab countries to improve the National Health and the pattern of consumption of drugs and future trends in the Arab states as well as the developed countries, it is recommended that the proposed antibiotics plant should be designed to manufacture the following antibiotics:

(i) Penicillins

200 M.T. per annum

(ii) Ampicillin

66 M.T. per annum

(iii) Erythromycin

20 M.T. per annum

(iv) Pharmaceutical preparation plant to process half of the above bulk antibiotics into dosage forms ready for use as follows:

(i) Sterile penicillins

30 M.T. per annum

(ii) Penicillin V (oral penicillin) 12.5 M.T. per annum

(iii) Ampicillin

33 M.T. per annum

(iv) Erythromycin

10 M.T. per annum

The above project will entail an investment of about US\$28 million, bring a sales revenue of US\$13 million per year and a modest return of 5.2% on investment. It may take 3-5 years to implement. It should be remembered that with the discovery of new high yielding culture strains of microbes, the production of antibiotics via fermentation is not only capital intensive but highly competitve. Hence the production of antibiotics in bulk alone will hardly be viable economically. This is one of the reasons for recommending the formulation of half the bulk production to improve the profitability. Further it is advisable to take up production of three major antibiotics viz. Penicillin, Ampioillin and erythromycin in the proposed plant instead of taking more at the same time. This is also in

suggested are presently under construction in Italy, Poland and Mexico. It should be possible either to expand the production of these antibiotics or change the spectrum of antibiotics at a later stage depending on the requirements. Fortunately the fermentation facilities and utilities are more or less the same for different types of antibiotics.

The low return on investment also highlights the fact that the volume of production is not large enough to yield handsome dividends. With the increase in the scale of operations and with the acquisition of better technology, the profitability is bound to improve.

## C. Synthetic drugs

The group of synthetic drugs is next only in importance to antibiotics in terms of its essential nature as well as the quantum of investment involved. These drugs have stood the test of time and play an important role in any National Health programme. However, the production of synthetic drugs in bulk in the concerned Arab Countries is restricted only to El Nasr P.C. Co. in Egypt. Over the years, significant additions have been made to the product mix in this plant. Further, the principle of unit production is applied wherein a given set of facilities is devoted to a specific product.

An analysis of the Arab market reveals that many of the drugs are consumed in quantities not large enough to render the establishment of a separate production unit economically viable. In the result, the existing facilities are only partially utilized and surplus equipment is available at El Nasr plant as indicated in Section VIII. It is in this context that efforts are being made at El Nasr plant to take up the production of additional drugs to utilize fully the surplus facilities available. In the light of the above, the following recommendations are made for implementation on the short term basis:

#### Present

- (i) Take up the production of chemicals and drugs specified. This list is compiled on the basis of requirements in the Arab countries, the ease of synthesis, constituting therapeutic groups not produced so far in Arab countries and ensuring the utilization of surplus equipment. This recommendation also takes into account the present pattern of drug consumption as well as future trends and economic viability as a group.
- (ii) Organize working groups and requisite facilities for process development to work out process details for scale up from test tube.

bench and pilot plant scale to commercial production of known drugs required in the Arab World and for which established procedures are available in the technical literature. This is precisely the manner in which process development has been carried out in many developed countries over the years. Further the cost of technical know-how for a product required in small volume will adversely affect the economic viability of its production. It will, therefore, be more economical to invest in the facilities for process development. Fortunately the necessary skills are available at El Nasr plant and this can form the nucleus. It may, however, be necessary to provide additional laboratory space and equipment in the pilot plant. These facilities will also help adaptation to the local raw materials. The investment involved in this is in the order of US\$240,000. (iii) Initiate the construction of a multipurpose plant (1st stage) and commence production with procedures worked out by the process development group. The production of chemicals and drugs referred to in item (i) above is expected to utilize the surplus equipment. However, this would require the addition of some new equipment to balance and in some cases augment the existing facilities to meet the requirements of these drugs in the Arab countries. It is in this context that the establishment of a multipurpose plant is recommended in preference to the assembling of independent small units. The main advantages of a multipurpose plant are the flexibility of production programme, economic viability of small volume of production and amenability to the simultaneous production in a co-ordinated manner of several drugs and chemical intermediates for optimum utilization. Further, the multipurpose plant facilitates stepwise expansion at a subsequent stage. However, these advantageous features are counterbalanced by certain factors such as the requirement of equipment with more rigid specifications to provide versatility, the need for close co-ordination to facilitate parallel operation and the inevitable loss of time during transition between one product and the other. In the balance the multipurpose plant is to be preferred for the overriding benefits which will accrue. The Ist stage of the multipurpose plant is estimated to entail an investment of US\$5.7 million will bring in an annual sales turnover of US\$7.2 million and a return on investment within four years.

However, it is not desirable to establish a larger multipurpose plant without prior experience. It is rather preferable to build separate production units on a short term basis for drugs needed urgently. It is recommended that the Ist stage of the multipurpose plant be located adjacent to El Nasr plant where certain infrastructure is available and this will also require less investment. The construction of this unit is expected to take about 2-3 years.

### Future

- (i) Take up the construction of the IInd stage of the multipurpose plant. Based on the experience gained in the operation of the Ist stage of the multipurpose plant and to meet the growing needs of drugs, it is recommended that suitable additions be made to the existing multipurpose plant. The second stage unit with 20 reactors as against 12 in the first stage will entail an investment of US\$9.3 million and the expansion could be completed within one year. Subsequently new independent multipurpose plants can be established either at the same location or elsewhere.
- (ii) Take up production of some drugs, e.g. vitamins in separate new plants. As the demand for certain drugs goes up, it is desirable to take these drugs from the multipurpose plant to separate plants. An industrial profile is given for the manufacture of 65t of Thiamin hydrochloride by full synthesis in a separate new plant.

This unit will entail an investment of US\$3.24 million and will have annual sales turnover of US\$0.68 million resulting in a loss of 0.69 million. This clearly demonstrates that the production of thiamin hydrochloride can only be economically viable with a larger volume of production with a highly optimized plant layout. This also indicates that the production of similar drugs is highly competitive.

- (iii) Collaborate with producers of organic intermediates to assure uninterrupted supply at low cost of important raw materials.
- (iv) The offers of certain firms for the production of some drugs have been analyzed to assess the economic viability.
- (v) The offer for a multipurpose plant is annexed to serve as a guideline for evaluation of similar offers. This plant entails a capital investment of US\$0.7 million for an annual production of 200 tonnes.

### D. Formulations

An assessment has been made of the present status of pharmaceutical formulation plants and pharmaceutical storage facilities in Egypt, Iraq, Kuwait and the Sudan and recommendations are given for improved quality assurance and production capacity. The existing pharmaceutical formulation plants in the Arab countries produce only 50% of the Arab countries pharmaceutical needs. The forecast based on current annual production dollar volume indicates that approximately 35 formulation plants capable of an annual production of US\$35 million should be built to provide approximately 44% of the Arab countries' pharmaceutical needs by 1935. In view of this, it is recommended that ACDIMA may take the following measures:—

- a) Create a master marketing plan and select the dosage form mix that would be produced under the ACDIMA label.
- b) Create joint ventures with Arab countries and non-Arab countries.
- c) Establish formulation plant profiles and construction projections.
- d) Plan the location of formulation plants in the Arab countries.
- e) Establish standards of good manufacturing practices for its manufacturing plants.
- f) Advise on the feasibility of regional bulk buying where applicable.
- g) Establish a comprehensive integrated training programme for its initial and future plant personnel. These are broadly classified for implementation on a short term and long term basis as follows:

  Present:
- (i) ACDIMA should establish contact with existing pharmaceutical industry to initiate the formulation and production of a limited group of products under ACDIMA's label and according to ACDIMA's GMP.

This will result in increased and efficient utilization of existing plants and equipment, introduction of ACDIMA's name and products to the Arab market and setting an example for improved G.M.P. and other capabilities in these companies.

- (ii) Include a high priority programmed co-operation with the existing pharmaceutical (private and public sectors) manufacturers to utilize to the maximum the capabilities and capacities of the existing plants.
- (iii) ACDIMA should undertake a long term (five year and ten year) projections to establish market trends and the fulfilment of health needs of the Arab countries.
- (iv) Introduce formal training programme in processing and packaging operations to maximize efficiency of labour personnel.
- (v) All plants should study the feasibility of implementing two shifts in all formulation plants. This will result in an increase of approximately 30% over and above present production.

#### Future

- (i) Set up a feasibility study for establishing one or more soft gelatin manufacturing plants.
- (ii) Develop at once a formulation plant devoted solely to the manufacture LVP's, SVP's and other sterile products (with the exception of biologicals). It is strongly recommended that the formulation plants should not include a parenteral operation in conjunction with tablets, liquids, ointments, etc. Such a plant will entail an investment of US\$6.4 million and have an annual turn over of US\$15.0 million.
- (iii) Set up a totally integrated hard gelatin and powdered capsule operation (i.e. the manufacture of both the empty shells and filled capsules).

This plant will involve an investment of US\$7.0 million.

- (iv) Establish model formulation plants which do not contain parenteral, capsule (Hard and soft), powders and granules operation. Tablets, liquids, ointments and creams and suppositories will be manufactured in this unit. A typical plant will entail an investment of US\$4.8 milion.
- (v) Set up animal feed and veterinary premixes plants and veterinary pharmaceuticals formulation plants. The basic plant layouts and cost projections used in the human manufacturing (without parenterals) operations are applicable in these cases too.
- (vi) Establish facilities for packaging and labelling from bulk finished product where it would not be feasible to construct a formulation plant due to small population, lack of technology, difficulty of accessibility, etc.
- (vii) The location of new plants should be complementary to improving existing plants and recommendations are made on suitable locations.

## E. Veterinary formulations and packaging

Next in importance to the formulations for human use are veterinary formulations. The Arab Company of Livestock Development declared in August 1976 is an integral part of a master plan by the Arab community, through the Council of Arab Economic Unity to create industrial complexes within the Arab countries to become economically independent of other nations while serving the needs of Arab countries.

Most forms of veterinary medicines can be carried out using the same facilities which are used in the production of human medicines. The construction of a separate entity for the processing and packaging of veterinary products will, therefore, depend on what products are actually needed. However, the information on the actual requirements of veterinary formulations in all the concerned Arab countries is not available except for some scarty data relating to Egypt, Oman and Iraq. In the absence of complete data, an attempt has been made to survey a typical plant manufacturing formulations for human use to assess the feasibility of utilizing the available facilities for veterinary formulations. A plan is also given as a long term measure for the establishment of a pharmaceutical-veterinary formulation plant.

#### Present

(i) A survey of C.I.D. formulation plant in Assuit, Egypt has been conducted for carrying out dual operations to produce both pharmaceutical and veterinary medicines in the same entity. This plant at the present time is only being utilized at about 30% of its available floor space. Veterinary medicines can be processed using the existing equipment after overhauling. Suggestions are given for making suitable alterations in the existing unit with a view tô process animal feed products as well as crop chemicals.

(ii) The above survey highlights the numerous possibilities for the utilization of the existing formulation units in the Arab countries used in the production of human medicines for the manufacture of most forms of veterinary medicines.

#### Future

(i) A plan is given for the establishment of a pharmaceutical-veterinary formulation plant having the following annual capacity (8 hours shift)

Products	Capaci ty
Tablets (compressed and coated)	250 - 300 M.
Hard Gelatine capsules	100 - 150 M.
Soft Gelatine capsules	50 - 60 M.
Liquids (syrups and suspensions etc.)	30,000 L.
Ointments - creams	150,000 kg.
Suppositories	required for sale

The above plant will entail a total estimated cost of US\$2.0 million. Guidelines are laid down for plant construction. A separate entity may be constructed for antibiotic processing and packaging and necessary equipment to operate this facility provided. This recommendation is also in line with G.M.P. guidelines. The estimated capacity as indicated above can be doubled by working two 8 hour shifts with very few changes in the internal design.

(ii) Instead of building a multitude of complete formulating plants (small and large) in every area concerned, it is suggested that a "unit" of a pharmaceutical plant, one for each country may be built viz. one entity to produce tablets and pack where there is a high demand for tablets and very few liquids.

#### F. Fermentation products

Historically speaking, fermentation is perhaps one of the age old processes known to man. Most of the antibiotics and several nutritional supplements, enzymes, organic acids and solvents are products based on fermentation. A cheap form of fermentable carbon is essential for an economically viable fermentation industry and in the case of much of the Arab countries, this is the sugar in molasses. In those areas rich in oil, the potential exists for the use of methane and other n-paraffins as the carbon source, but these sources are also potentially more expensive than molasses. There is an adequate supply of molasses both of cane and beet origin for the establishment of fermentation industries, although it is not evenly distributed geographically. The largest supply (Egypt) is not at present fully utilized at home, two thirds being exported to

Europe while one comes across in some other countries molasses being discharged into the Nile posing serious pollution hazard.

A list of products which could be made by fermentation in the Arab World is given together with an indication of the Technology involved. It is necessary to assess in each case the ourrent requirements, the forecast for the next ten years and the economics of production. The latter becomes all the more important in view of the fact that some of these products are also made by the synthetic route.

## Present

Ethanol, acetic Acid and Enzymes are currently being manufactured in Egypt and possibly other Arab countries. It is recommended that the possibility of augmenting these capacities be considered.

#### Future

As a long term measure it is recommended that the production of citric acid and feed yeast be taken up based on fermentation and utilizing molasses.

(i) Citric Acid: Based on the information available, the consumption of citric acid in the Arab countries is expected to be 2,000 tons per annum in 1980 according to ACDIMA. However, the actual quantity planned for import by Egypt in 1977 is only 304 tons. Apparently this is for drug use only. If non-drug use is considered, the consumption figure may be much higher. In view of this, an industrial profile is presented for a production of 3,000 tons per annum of anhydrous citric acid. Based on a shallow tray fermentation process, the estimated cost of production compares favourably with the current market price. The capital cost for buildings and equipment will amount to US\$2.0 million.

The factors which have to be investigated before establishing the actual plant have been highlighted. These include the assessment of actual requirements in view of the wide disparity between the figure projected by ACDIMA and the actual imports into Egypt in 1977. The suitability of came molasses has to be evaluated by the collaborator in view of the sad experience of India where production could not materialize for years with cane molasses possibly due to the presence of inhibitors such as trans-acotinic acid. In fact, the foreign collaborator developed the process with the use of beet molasses in Europe and cane molasses could not be used as a substitute in the Indian plant. Fortunately there is availability of beet molasses in some of the Arab countries. In view of the developments in the field of petro-chemicals, the economics of fermentation using molasses vis a vis methane is to be investigated. Similarly the relative economics of using the traditional shallow tray process as against the deep tank method has to be worked out.

## (ii) Feed Yeast:

Yeast is a product which can be produced in all the molasses producing areas of the Arab countries which has a sufficient value in utility that a market exists for all that can be produced. This will also meet the distal objective of ACDIMA to raise the health level of all the Arab people. Moreover this must be done at a period of history when population pressure will make a shortage of protein so necessary for good health for many people most probable. Yeast has the capacity to some degree to alleviate both protein and vitamin deficiencies. If all the available molasses is converted into yeast, on the average of 0.75g. of protein are available to each person per day in the Arab countries.

Fodder yeast is presently being manufactured in Egypt using cane molasses. The desirability of establishing a model plant for the production of dried yeast for use as protein concentrate for both animals and humans has been emphasized. For animals, yeast will be incorporated into the feed rations. For humans it is suggested that it be incorporated into a basic food such as flour.

A modified industrial profile is presented for yeast. The plant entails an investment of about US\$3.25 million. The different aspects to be considered before actually embarking upon such a project have been outlined.

As regards fodder yeast, the product currently manufactured in Egypt is experted to Europe. There is no competitive protein concentrate in Egypt. So this production can be expanded.

Before taking up the manufacture of food yeast for humans the acceptability aspect should be thoroughly gone into. This is particularly so in view of the serious set back suffered by an experimental plant set up in West Indies for the manufacture of food yeast as the local population did not like its taste.

### G. Opotherapeutics

There is a large cattle population in the Arab countries particularly in Sudan. The formation of the Arab Company of Livestock Development in August 1976 is an integral part of a master plan by the Arab community to create industrial complexes for attaining self sufficiency. It also highlights the priority which the Arab countries accord to the development of livestock.

Arab countries some old and some new with modern facilities. The byproducts from these slaughterhouses constitute a valuable source for essential drugs, enzymes and chemicals. However, there is no production of these important drugs and chemicals in any of these countries. In view of these, a detailed survey has been carried out of the various slaughterhouses in Egypt, Iraq, Saudi Arabia, Sudan and Strian arab Republic based on which recommendations are made for implementation on a short term as well as long term basis.

#### Present

- (i) Insulin: As regards by products from slaughterhouses, insulin is the most important. Diabetics need this drug to survive. Insulin is the only medicine for more difficult cases of diabetes mellitus. The raw material for the production of insulin is pancreas of the animals from the slaughterhouses except that from sheep and goats.
- (a) As a first step the formulation of imported insulin into dosage forms ready for use is recommended for reasons of economy. A start can be made in Egypt and Iraq to be subsequently extended to Sudan and Syrian Arab Republic.

- (b) Develop the Bioassay method of testing insulin in the State Drug

  Control Laboratories in Traq, Sudan and Syrian Arab Republic to check the
  imported as well as locally produced insulin.
- (c) Organize the collection and deep freezing of pancreas from slaughterhouses. For this purpose, the slaughterhouses should be provided with deep freezer units. Till adequate quantity of pancreas becomes available for taking up commercial production of insulin, the frozen pancreas can be exported for which there is a good market.
  - (ii) Catgut: Expand the catgut manufacturing facilities at Nile Co. in Cairo to process the entire quantity of sheep intestines from slaughterhouses in Egypt for export. Also collect sheep intestines in Sudan for the above expansion programme.
  - (iii) Blood: Use the blood from all slaughterhouses in Egypt, Iraq,
    Sudan and Syrian Arab Republic as fodder for animals such as blood meal.
  - (iv) Pilot Plant: Organize laboratory and pilot plant scale experiments on the extraction of insulin, isolation of heparin, preparation of rennet in Egypt, Iraq and Sudan. The facilities required for these will entail an investment of about US\$50,000.

## **Future**

(i) Insulin: For a viable production of insulin, there should be at least 200 tons of pancreas per annum. The limitation on the use of pancreas of sheep such as allergic factor and the low yield of insulin should be investigated and the proportion in which sheep pancreas can be used along with cattle or camel pancreas has to be worked out before the feasibility of establishing a plant for the commercial production of insulin can be considered. The world resources of pancreas are limited and as such the possibilities of import have to be explored before hand since pancreas of the

requisite quality available at present in the Arab countries is not adequate to support a viable production - 90 tons as against 200 tons required.

Keeping the above factors in mind, plan for the establishment of an insulin plant in Egypt or Iraq preferably the latter.

- (ii) Requirements of rennet, catgut, heparin, blood plasma and albumin and blood meal in Arab countries are to be worked out in order to assess the need to establish manufacturing facilities for the same.
- (iii) Organize the processing of plasma and albumin from blood in Baghdad and Khartoum.
- (iv) Plan for the erection of plant facilities for rennet in El Nasr Co., Cairo.
- (v) Build a new catgut factory in Sudan.
- (vi) Carry out feasibility studies for the production of heparin.

## H. Economical aspects of medicinal plants

Plant Kingdom constitutes a very significant source of important drugs, chemicals and essential oils. The Arab countries are very rich in vegetable resources, which can be exploited for industrial purposes. Because of wide variety of climatic and soil conditions, all types of medicinal plants of tropical, sub-tropical, temperate and mediterranean region can profitably be cultivated in one or the other Arab country.

A close study of the available information on medicinal plants indicates that 21 species of medicinal plants occur in 13 Arab countries. Out of these only 10 can be considered to be of use as raw material for a modern pharmaceutical industry. Amongst these, according to a scientific survey carried out, only six of the plants are available in sizeable quantities and that too from wild sources. There are eight other plants which are either found growing wild or have been cultivated on an experimental scale, but the available quantity is small. Analysis of the available information indicates that phytochemicals and crude extracts from medicinal plants are used extensively in different Arab states. About 20 pure chemicals and more than 80 crude extracts are found to be used in formulations marketed in the Arab countries.

#### Present

Some kind of phytochemical industry exists only in Egypt and Iraq. The industry which is well developed in Egypt can be broadly classified as 'Aromatic plant industry' producing essential oils, and oleoresins used in perfumery, cosmetic and food flavours, and 'medicinal plant industry'. There is only one industrial unit in Iraq for processing medicinal plants. However this plant has an idle capacity of about 80%.

In view of above it is recommended that ACDIMA may help the existing units in Egypt and Iraq to utilize their idle capacity for the production of crude extracts for all Arab countries.

#### **Future**

- (i) Set up an organization to process existing raw materials as well as for producing medicinal plants on a commercial scale.
- (ii) Both the processing as well as cultivation units should carry out applied research and development to produce important vegetable drugs for internal consumption and control.
- (iii) Take steps to start drug farms in Egypt (1,000 acres), Sudan (1,000 acres), Syrian Arab Republic (200 acres) and Iraq (200 acres) to start working on research on cultivation and commercial production of medicinal plants. No Arab country has a good source of steroidal sapogenins, Ergot alkaloids, pyrethrins and menthol. Hence proper species of plants used for production of these chemicals have to be introduced in order to grow adequate quantities of these raw materials to sustain an industry. These constitute a high value low volume drugs of essential nature used as antiarthritic, antiinflammatory and oral contraceptives.
- (iv) Establish a production unit to take up the processing of senna leaves and pods, liquorice roots, ammi majus seeds and henbane leaves in the first stage of the project. Considering the current use of vegetable drugs in the world, the health needs of the Arabs, the export potential and the availability of raw materials in different countries, 19 different plant drugs which include pure chemicals, essential oils and crude extracts are considered important for production in the new unit.

## I. Pharmaceutical centre

A stage has been reached when there is urgent need to establish a pharmaceutical centre attached to ACDIMA. The requirements of drugs and pharmaceuticals in the fields of antibiotics, synthetic drugs, opotherapeutics and medicinal plants have been assessed. Areas have also been identified for taking measures in these fields on short term as well as long term basis. The sources of technology have been located. The time is, therefore, ripe for establishing a pharmaceutical centre for follow up action on all the recommendations and to evolve a strategy to implement various measures in a co-ordinated manner. In this centre, laboratory and pilot plant facilities will be provided for the testing of raw materials, evaluation of technologies and filling in the gaps, working out the process details for scaling up to commercial production and for training personnel.

The pharmaceutical centre will be equipped to take the process from test tube, bench scale and pilot plant to commercial production.

A broad organizational set up and a brief description of the relative functions are given in figure I.

Figure I. Organizational set-up of pharmaceutical centre

Porments til on	Chemical Purification	Multipurpose Plant (Synthetic drugs)	Medicinal Plants	Opothera- peutics	Microbiological laboratories	Chemical laboratories	Formulation & and packaging	
1	Research and Development Product Deve	do.	Cell for evaluation of E	Chemical Engineering design	Training			

## a) Fermentation:

This unit will be equipped with facilities for conducting fermentation studies of different types in shake flasks, laboratory fermentors and pilot plant fermentors. The fermentation processes for the production of antibiotics, enzymes, nutritional supplements and organic chemicals can be evaluated in this unit. The tetracycline producing culture strain of microbes recommended for introduction in El Nasr and S.D.I. plants can be tested in this unit. The cultures for citric acid and yeast can also be evaluated. Similarly this unit will facilitate biological testing of local raw materials for their suitability.

## b) Chemical Purification:

This section is primarily meant for the recovery and chemical purification of antibiotics, enzymes, drugs and chemicals produced in the fermentation process. There will be facilities for most of the unit operations, such as filtration, evaporation, ion-exchange, distillation, crystallization, centrifugation and drying. This will enable the evaluation of the chemical purification recommended for tetracycline as a short term measure.

## c) Multipurpose Plant:

This unit is primarily meant for synthetic drugs. This is a versatile plant for carrying out different types of organic synthesis. This will facilitate the evaluation of the processes developed in the process development unit as well as the technological processes suggested by the collaborators.

#### d) Medicinal Plants:

Facilities are provided in this section for processing medicinal and essential oil plants. The equipment comprises units for extraction, filtration, evaporation, distillation, crystallization and drying. This will also facilitate the evaluation of medicinal plants recommended for their

suitability for commercial exploitation.

## e) Opotherapeutics:

This section will facilitate the processing of by products from the slaughterhouses for assessing their suitability for industrial production of insulin, pancreatin, heparin, rennet, catgut and blood plasma. There will be facilities for deep freezing, extraction, concentration, crystallization and freeze drying. This will enable the evaluation locally available byproducts recommended for use in commercial production.

## f) Microbiological laboratories:

These will serve the needs of fermentation section as well as quality control of products at various stages. Facilities will be available for handling antibiotic producing microbes.

## g) Chemical Laboratories:

These laboratories will be all purpose type useful for in process control as well as quality control at various stages of production in different sections.

## h) Formulation and Packaging:

Facilities will be provided for preparing formulations for human use as well as veterinary formulations and plant protection drugs. This unit will facilitate the development of formulations to meet the local conditions of climate, handling and storage.

### i) Research and Development and Product Development:

This is primarily a process development unit to work out detailed processes for known drugs for evaluation in the pilot plant as a prelude to taking up commercial production. Facilities in the fields of microbiology, mycology, organic chemistry, biochemistry, physical chemistry, analytical chemistry will be provided.

A good reference library will be attached to this. There will also be facilities for product development to evaluate the formulae suggested by the collaborators as well as develop new formulations to suit local conditions and needs.

## j) Cell for evaluation of Technology:

This cell will enable ACDIMA to evaluate the different technologies offered by the collaborators to facilitate a final acceptance of any given offer. Patent literature will be available to the cell. They will be in touch with current developments in the drug and pharmaceutical industry.

# k) Chemical Engineering Design:

This section will provide designs for the fabrication or procurement of equipments, establishment of new plants or the expansion of the existing manufacturing units. This will liaise between the pilot plant and the main plant in the transfer of technology.

## 1) Training:

There will be a special cell for training various categories of personnel for the new manufacturing plants being established by ACDIMA.

The above pharmaceutical centre will entail an investment of about US\$1.0 million and will take 2-3 years for completion.

## J. Medical appliances

Medical Appliances constitute an important segment in any National Health Programme and this is so in the Arab countries. The emphasis in all these countries is on child and mother care, preventive action in combating diseases, effecting qualitative improvements in the existing hospitals and dispensaries and the elimination of the regional imbalances with respect to availability of reasonable medical care facilities. The production programme for the new medical appliance units, will therefore, have to fit in with the Government plans to provide reasonable medical facilities to a large cross section of the population. The units should also be versatile enough to provide comprehensive range of products to the medical services.

Considering the multiplicity of medical appliances, designs, makes and specifications, the different levels of health care prevalent in the Arab countries and paucity of data, it is well nigh impossible to correctly assess the current requirements of medical appliances in the Arab countries. One yard stick suggested by ACDIMA in this connection is to multiply the current imports into Egypt by a factor of 3 to work out the total demand of medical appliances in the Arab states in 1980. Simultaneously an analysis of the National Health programmes, the levels and types of health services proposed at different points, the disease pattern in the Arab States and the measures being taken to combat the same has been carried out to project the demand for medical appliances. Based on these forecasts, the medical appliances, instruments and equipments have been classified. The available technical infrastructure in the region has also been taken into account. In the light of above, it is recommended that the medical appliances industry be developed in the following manner:

- i) Simple designs of the commonly used appliances for preventive and curative aspects of medical care should be taken up for production in the initial stages. Such products should facilitate qualitative improvements in health services in rural and semi urban areas, where there is need for improvement.
- ii) Steps should be taken simultaneously to develop certain essential technical infrastructure within ACDIMA in order to prepare for erection and commissioning of equipment, production and marketing of medical appliances.
- iii) The production units should have functional layout and be versatile enough to include in the production programme, a wide range of products within the same range of technology.

  On the basis of above it is recommended that the following units be taken up for production in the Arab countries:

#### a) Clinical Thermometers:

The need for setting up a manufacturing base for clinical thermometers is paramount as this is one of the basic requirements of any programme of medical care and health service. It is recommended that units can be commenced with a capacity of 2 million thermometers per year and additional capacities added to take this up to 6 million pieces per year. This does not involve automation. The latter can be considered only when the minimum installed capacity is 10 million pieces per year going up to 50 million. A unit with a capacity of 2 million pieces per year will entail an investment of US\$600,000 will have an annual turnover of US\$1 million and will bring in a return of 30% on the investment.

#### b) Light engineering complex:

Based on a detailed analysis, a combined project profile for the following products has been worked out as the production processes and

technology are similar in nature and since the establishment of individual production units would not be economical:

- a) Surgical instruments including dental equipment.
- b) Hospital appliances
- o) Blood pressure apparatus and stethascopes.

In view of the wide range of specifications and designs of the above products, the design preferences in the Arab countries and the more popularly accepted international specifications have been considered. The rated capacities, the quantum of investment, the annual turnover and the return on investment are given below:

Medical	Annual		Annual	Return on
Appliance	Capacity	Investment	Turnover	Investment
		In US	<u>8000</u>	
Stethosoope	18,900)			
Blood pressu	re )			
apparatus	10,400)	236.5	7483.5	21%
Hospi tal	)			
appliances	51,390)			
Surgical				
Instruments	300,000	415.3	571.0	14.2%

#### o) Microscopes:

Based on the demand potential and current level of development of industry in this field in the concerned Arab countries, there is a big demand for microscopes which is in the order of about ten thousand microscopes of various types which is currently met by imports. In the product mix, other commercial consumer products of similar technology such as overhead projectors have been included to form a second line of production and fill in the possible gaps in the demand to maintain a

steady profitability. This project will entail an investment of US\$1.9 million at a capacity of 9,500 pieces per year, will have an annual sales turnover of US\$1.3 million and bring in a return of 17.5% on the investment.

### d) Electronic complex:

# (i) Electro cardiograph:

Electro cardiographs are used in the catheterisation laboratory, coronary care units and for diagnostic applications in cardiology. The estimated annual demand at present stands at 3,350 E.C.G. machines per year going up to 8,600 machines after a decade. It is recommended that a general purpose machine which would meet almost all the routine clinical requirements be taken up for manufacture. This project with an annual capacity of 3,000 pieces will involve a capital investment of US\$521,000, will bring in a sales turnover of US\$2.6 million and 20.5% return on investment.

# (ii) Hearing Aids:

Hearing aid is used to overcome the deficiencies of different types of hearing losses. The annual requirement of hearing aids. in the concerned Arab countries has been estimated to be 6,000 pieces going up to 16,000 pieces. The unit with an annual capacity of 5,000 numbers will entail an investment of US\$106,000 will have an annual sales turnover of US\$230,000 and bring in 30.2% return on investment.

#### e) Laboratory Equipment:

1) PH meter: PH meter is a direct reading instrument for precise and accurate measurement of PH and millivolts. With different types of electrodes, it can be used for the measurement of PH

- of blood and biological measurements etc. The unit with an annual capacity of 2,300 pieces will require an investment of US\$308,500 is expected to have annual sale value of US\$508,000 and result in a return of 27.6% on investment.
- 2) Spectrophotometer: A composite unit for the manufacture of spectrophotometers UV type, spectrocolorimeters and flamephotometer amounting to 2,550 numbers per year will entail an investment of US\$1.2 million, will bring in annual sales turnover of US\$2.2 million and 34.5% return on the investment.
- Balances: In medical applications, the balances are required for weighing adults and infants. The table balances and analytical balances are required for weighing substances in the laboratories. Three models of electronic balances using digital display and the fourth one for very high resolution one pan auto-mechanical type are recommended for production. The composite project requires an outlay of US\$674,000, will have annual sales volume of US\$1.9 million and bring in a return of 31.6% for an annual production capacity of 11,000 numbers.

# f) X-Ray Film:

As a first step towards making available large quantities of medical x-ray films, it is proposed to take up manufacture of this by importing the ocated film in semi-finished form and converting in the Arab states. Such a project will save valuable foreign exchange and will form a nucleus for the establishment of an integrated photographic complex in the future. This is precisely the manner in which this industry developed in other countries. This unit will entail an

investment of US\$1.65 million for a capacity of 5 million sq.m. per year, result in an annual turnover of US\$2.38 million and a return on investment of 36.30%.

# g) Tool Room:

It is recommended that a compact self supporting tool room be established exclusively for the development of medical appliances.

# h) Medical Appliances repair Workshop:

There is immediate need for the organization of a small self supporting repair workshop for the electronic based medical and laboratory equipment to serve the ourrent needs as well as to function as the after sales service unit for ACDIMA's electronic medical equipment. This will also be useful for training the service engineers.

#### K. Overall management

The subscribed capital of ACD IMA is US\$200 million. The acitivites of ACDIMA cover practically all the facets of drugs, pharmaceutical and medical appliances industries. Further, ACD TMA is also keen to establish these industries with a sense of urgency. In view of this, it is highly necessary to create an infrastructure to provide a suitable base to enable ACDIMA to undertake these projects in a co-ordinated manner and within a short span in a business like manner. It is in this context that important aspects such as Management, Quality Management, Procurement and Distribution, Education and Training of Personnel have been studied in order to assess the present situation in the Arab countries and recommend measures for implementation to achieve the main objectives of ACD IMA both on a short term as well as a long term basis. Similarly the requirements of antibiotics and synthetic drugs have been assessed and projections made based on which recommendations for the creation of production facilities have been made. With a view to utilize the existing facilities fully, the surplus facilities available both at El Nasr plant in Egypt and S.D.I. plant in Iraq have been identified.

The salient points and recommendations are described below: -

#### 1. Management

An efficient organizational structure and the application of modern management techniques are vital to achieve the lofty aims enunciated in the constitutive provisions of ACDIMA. Organization charts are given for the senior level of management. The job description is given in each case. The basic concepts of this organization structure are:-

- (1) Centralization of the project function.
- (2) One point of responsibility for each of the basic functions.
- (3) Relatively easy measurement of managerial performance.

- (4) Relatively easy centralization of controls.
- (5) Allows short "line" with separate but strong advisory services.
- (6) Only seven people report to the Managing Director.

It is suggested that the scope of the existing Technical Committee be widened to include a thorough technical and economic survey of existing units in locations where new plants are proposed to be set up to highlight problems concerning power supply, water, steam and industrial effluents, which are peculiar to the developing countries. As the ACDIMA projects take shape, it is necessary to create separate organizations for each of such units. An organization chart is also given for such a unit.

Priorities for making initial appointments are indicated.

#### 2. Quality management

#### PRESENT:

- (a) ACDIMA should appoint a Director of Quality Management (QM).
- (b) Written standards should be prepared for (i) plant design as related to QM and (ii) operating methods of control, applying to all types of production to be undertaken by ACDIMA.
- (c) The above standards should be used for a complete assessment of the existing or projected operations, so as to devise corrections.
- (d) A beginning should be made on a 5-10 year plan for a full complement of standards for materials and products including raw materials, packaging material and finished product.

#### FUTURE:

ACDIMA should establish a Pharmaceutical Centre according to the following guidelines:

- (a) The centre should be aimed for maturity in 10 years.
- (b) It should prepare and update industry standards on a continuous basis and publish them.
- (c) It should conduct industry intelligence and liaison.
- (d) It should maintain laboratories to supplement or complement any already existing.
- (e) It should have facilities for training for different levels of function.

# 3. Procurement and distribution

#### FUTURE

#### A. PROCUREMENT

- (1) Procurement unit should be established within the ACDIMA
  Secretariat responsible for the co-ordination and procurement
  of all goods and services relating to ACDIMA and other Government
  Purchasing agencies headed by a Director of Procurement.

  The unit may comprise a Contracts Section, a Purchasing Section
  and a Data and Service Unit.
- (2) The Procurement Unit should establish methodologies and procedures to cover current and future transactions.
- (3) The Director of Procurement should be a member of Technical Committees for Project Studies.
- (4) The Procurement unit should maintain liaison with National Agencies engaged in procurement and importation.
- (5) This unit should initiate studies to develop the common basis for the requirements of the various procurement agencies.
- (6) ACDIMA should establish, where possible, facilities for the consolidated bulk purchasing of common items and in the first instance, pharmaceutical raw materials. For example, an off-shore purchasing office or subsidiary can be established in a location such as London for centralized procurement of combined common requirements.

#### B. STANDARDIZATION

(1) ACDIMA may make efforts to reach agreement on essential items of common need, standardize specifications on pharmaceutical raw materials, pharmaceutical finished products and packaging materials, taking into account the work done by international organizations.

Standardization of pharmaceutical production machinery and laboratory equipment concerning formulation plants may also be carried out.

#### C. DISTRIBUTION

(1) ACDIMA should evaluate the existing channels of distribution, and determine the most suitable channels - either existing selected channels or create new channels and organize separate channels for the areas listed above.

#### D. DATA AND STATISTICS

(1) ACDIMA should establish an economic research unit to assemble and make available data on current production, planned production, distribution costs and selling prices for items listed above with respect to all Arab countries.

#### E. MARKETING

(1) ACDIMA may undertake the import and marketing under its own brand names of selected items of medical supplies and equipments of common use as a complementary scheme to its production programme.

#### F. MISCELLANEOUS

- (1) ACDIMA may augment the present organization to oreate a strong multidisciplinary approach.
- (2) ACDIMA may establish levels of remuneration equal to the best prevailing rates in the Arab countries to obtain the best qualified staff and achieve a geographical approach.
- (3) ACDIMA may maintain liaison with UN Agencies
- (4) ACDIMA may seek technical co-operation from developing countries such as Greece, Hungary, India, Mexico, Spain, Turkey and Yugoslavia. ACDIMA may also develop contacts with developed countries for technology supplies and equipment.

- (5) ACDIMA should assist in improving the existing production in Arab Countries to encourage inter-Arab production and distribution.
- (6) ACDIMA may enlist the support of the Ministries of Health and Industry to achieve an integrated development of pharmaceutical Industries. The form of protection to be given, the incentives such as tariffs, import duty concessions, and tax benefits preferential treatment to local produce may be examined for implementation, as the case may be.

#### 4. Education and training of personnel

- (a) That an in-depth study be undertaken of the curricula of Faculties of Pharmacy in the Arab countries in comparison with the curricula of faculties in other countries with a view to remove imbalances in the courses.
- (b) That an immediate upgrading of facilities and equipment in Faculties of Pharmacy be commenced.
- (c) That special attention be given to courses on Industrial Pharmacy in the curricula, in close co-operation with the Pharmaceutical Industry.
- (d) That the governments institute a careful study of manpower in Pharmacy and establish a five year forecast.
- (e) That university enrolment in the future be governed by the figures in the forecast.
- (f) That in the establishment of new pharmaceutical industries a sound system of management be introduced.
- (g) That in new and existing pharmaceutical industries serious consideration be given to achieving proper proportion of university graduates who could each contribute their own particular expertise to the company.
- (h) That specialized training facilities be provided for the training of technicians for the pharmaceutical industry.
- (i) That personnel from the pharmaceutical industry play an' important part in the training programs for these technicians.
- (j) That high priority be given in the Arab countries to the training of sufficient skilled trades - people to meet the growing demands of the industry.
- (k) That pharmaceutical industries employ as much mechanization and automation as possible in order to increase production and efficiency.

#### 5. Requirements of antibiotics and synthetic drugs

Based on statistics and data on production, imports, exports and consumption of antibiotics and synthetic drugs in five Arab countries, the requirements of the same were computed. These countries are Egypt, Iraq, Libyan Arab Jamahiriya, Sudan and the Syrian Arab Republic. From these figures, a forecast of consumption in 1979 and 1985 is made which can be used as a base for production plans. A forecast has also been made by ACDIMA for 1980.

The weighted average of the increase in population in all Arab Countries from 1980 - 85 is 14.5%. According to ACDIMA estimates, per capita consumption will increase by 70% in the same period; this figure reflects the growing use of a greater number of drugs beyond the spectrum

made taking this aspect into account. Drugs consumed in quantities below one metric ton have not been included for economical reasons.

#### SOURCES OF DATA

- (1) Report on "Arab Pharmaceutical Consumption and Industries" furnished by ACDIMA.
- (2) UNIDO report on "Production plan for the Arab Pharmaceutical Industry in selected Arab countries to supply jointly the total Arab market VC/INT/76/077 revision 4, 11 July, 1977.
- (3) Annual tenders for the procurement of drugs as invited by Egypt, Iraq, Libyan Arab Jamahiriya, Sudan and Syrian Arab Republic.
- (4) Periodical chemical statistics, furnished by the data processing centre, El Goumhouria, Cairo representing the supply planning calculations for the requirements of the Public Sector and private sector plants and institutions in Egypt.

- (5) Production programmes of the plants of El Nasr P.C.Co., Egypt and S.D.I., Iraq.
- (6) Procurement plan of KIMADIA, Iraq.
- (7) Procurement plan of Directorate Genoral of Medical Supplies and Medical Store, Baghdad, Iraq.

# 6. Surplus facilities available at El Masr P.C. Co., Egypt and S.D.I., Iraq

According to a survey of the facilities available for the production of antibiotics at El Nasr P.C.Co., Egypt and S.D.I., Iraq, surplus facilities are available. These include a number of equipments suitable for the production of antibiotics and synthetic drugs and spare capacities of utilities. The surpluses are the result of partial utilization of fermentation facilities at both the plants. The equipments are in reasonably good condition and in the case of utilities, they are being used by rotation and form part of regular maintenance programme.

#### I. Introduction

#### A. Project background

### (i) ACDIMA:

The Arab Council for Economic Unity decided in February, 1970 to add "Pharmaceutical Industry" to the industries to be co-ordinated among the member states. The Council approved in December, 1971 the establishment of an Arab Company to undertake the activities, which would extend the capability of the existing companies. A symposium for Arab industrial co-ordination and co-operation in the field of the manufacture of pharmaceuticals was held in January, 1974 in Tunis. The discussions in the symposium highlighted the fact that the pharmaceutical industry should be regarded as one of the vital and strategic industries directly related to the health of individuals and having conspicuous priority in the fields of socio-economic development. Although industry was established in ten Arab States, it has covered only 40% of the total needs of the Arab world. Further, the industry related mostly to the formulation of pharmaceuticals, where the production depended essentially on imported raw materials and requisites. In any case, this industry would not be in a position to cope with the ever increasing demand of drugs during the next ten years. This would naturally require the establishment of facilities for the production of raw and basic materials, which in its term would entail large investment and provision of the necessary technical know-how. On the anology of Trans-National Companies, the need to mobilize the resources of the entire Arab World was recognized in order to achieve integration in this industry.

In the light of the above, the symposium recommended the study of the feasibility of establishing an Arab joint company for the manufacture and marketing of pharmaceuticals with the following aims:-

(a) The production of pharmaceutical raw materials (by fermentation or synthetically) needed by this industry.

- (b) The production of pharmaceutical products to cover the needs of the Arab and other markets, thus adding to the possibilities of the already existing national projects without contradicting their activity.
- (c) The production of packing materials needed by this industry, as well as some medical appliances.

The Council for the Arab Health Ministers approved in February, 1975
the establishment of the proposed company. The Arab Council for
Economic Unity approved in June, 1975 the establishment of the Arab
Company for Drug Industries and Medical Appliances - ACDIMA. Its capital
stands at sixty million Kuwaiti Dinars (US\$ 200 million). The Company's
deed of partnership was signed on March 6, 1976. The partners are the following
thirteen Arab States:-

- (1) Democratic Yemen
- (2) Egypt
- (3) Iraq
- (4) Kuwait
- (5) Libyan Arab Jamahiriya
- (6) Palestine
- (7) Qatar
- (8) Saudi Arabia
- (9) Sudan
- (10) Syrian Arab Republio
- (11) Tunisia
- (12) United Arab Emirates
- 13) Yemen
- It was decided that the central office and the Headquarters of the Company would be in Cairo.

According to the statute of the company, the latter in agreement with the Governments concerned and the other institutions, would undertake all activities in the field of the production and marketing of pharmaceutical raw materials, medical products, intermediates and medical appliances and apparatuses. It might carryout, in particular, the following:-

#### In the field of Production

- 1. Production of pharmaceutical chemicals.
- 2. Production of extracts, active ingredients and oils from medicinal and aromatic plants.
- 3. Production of biological products from whatever source.
- 4. Production of packing materials.
- 5. Production of medical appliances and apparatuses.
- Production of human and veterinary pharmaceuticals and food additives.
- 7. Contribution with the Arab states in the development of drug industries on a national level.

#### In the field of Research

The Company would conduct the necessary scientific studies and researches for the development and amelioration of what is existing, creating new active materials and keeping pace with scientific progress in this field, besides giving care to training with the aim of creating suitable cadres in the Company's activities.

#### In the field of Marketing

- 1. Importing intermediate materials and commodities, devices of production related to the Company's activities.
- 2. Marketing the company's products within the Arab countries and exporting what is surplus to its requirements.
- Establishing and securing the means of transport and storage and supporting and concommitant services.
- 4. Possessing, registering and disposing of the trade marks of the company's products.

Amongst the constitutive provisions, it is stated that the company shall exercise its activities in conformity with commercial principles following the practice adopted by the private sector's companies.

The Company decided to study the following projects. Each project would be carried out in the light of its "feasibility study", which comprises quality and quantities of products the form which the project would take, its economic aspects and the sate where it is to be set up:Pharmaceutical Raw Materials

#### (a) Fermentation Products

Penioillin Salts
Streptomycin salts
Tetracycline compounds
Latest antibiotics
Citric Aoid
Tartario acid
Vit. C
Vit. B<sub>4</sub>

# (b) Synthetic Products

Chloramphenicol oompounds
Salicylate compounds
Sulphonamides
Anthelmintic and antiparasitio chemicals and anti-tuberculosis medicines
Paramaebe
Tranquilizers

#### (o) Biological Products

Sera and vaccines plasma substitutes and blood derivatives

# (d) Production of extracts of natural origin

Extracts of medicinal and aromatic plants.

Animal extracts such as hormones, biological tissue extracts, gelatine and surgical threads and catgut, animal by products in general.

#### Other products

Pharmaceutical products and cosmetics

Production of children's food and milk

Production of veterinary medicines and food additives

Production of medical glycerine

### Medical appliances and equipments

Production of ampoules and injection vials

Production of cardboard
Thermometers
Microscopes
Blood pressure apparatus
Electro cardiograms
Stethoscopes and hearing aids
Factory for X-ray films
Dental requisites
Laboratory equipment
Plaster bandages

#### Pharmaceutical packing materials

Neutralglass

Production of metal tubes
Production of gelatine capsules
UNIDO-ACDIMA

UNIDO jointly with IDCAS carried out in 1973 a survey of the pharmaceutical industry in the Arab countries. This study was carried out in 18 different Arab Countries - Algeria, Bahrain, Democratic Yemen, Egypt, Iraq, Jordan, Kuwait, Lebanon, Libyan Arab Jamahiriya, Morocco, Oman, Qatar, Saudi Arabia, Sudan, Syrian Arab Republic, Tunisia, Yemen and United Arab Brirates.

The study revealed that the pharmaceutical industry in the various countries was at different stages of development.

- (a) Countries with no pharmaceutical industry: Bahrain, Democratic Yemen, Libyan Arab Jamahiriya, Qatar, Saudi Arabia, Yemen, United Arab Emirates.
- (b) Countries with limited pharmaceutical industry: Kuwait.
- (c) Countries with pharmaceutical industries based on bulk materials/formulation: Algeria, Iraq, Jordan, Syrian Arab Republic, Lebanon, Morocco, Sudan, Tunisia.
- (d) Countries with well established pharmaceutical industries based on production of bulk chemicals and materials: Egypt.

A broad list of pharmaceuticals consumed in the different Arab countries was also prepared. The consumption of pharmaceuticals in the Arab countries in 1973 was about US\$450 million of which those worth US\$180 million (40%) were produced locally. The Arab states with a population of 130 million have a large market for pharmaceuticals and wish to develop an integrated pharmaceutical industry based on bulk chemicals with the object of becoming as self-sufficient as possible.

A programe of technical assistance by UNIDO to the Arab Company for Drug Industries and Medical Appliances was discussed in May, 1976 and it was agreed to prepare in detail a production programme for the production of drugs, packaging materials and medical appliances.

A budget of US\$248,000 was made available for this project under cost-sharing arrangement between UNIDO, ACDIMA and the Canadian Executive Service Overseas (CESO).

#### B. Objectives

Prior to the establishment of pharmaceutical industries in different countries, ACDIMA would like to work out a production programme in detail as follows:

#### PHASE I:

# Pharmaceutical and Medical Appliances Industrios

A: Based on the pharmaceuticals consumed (Human and Veterinary)
according to the IDCAS report updated by ACDIMA, which includes quality
and quantity of drugs, generic names, chemical composition, raw materials,
form of presentation, therapeutic indication, where manufactured,
technology, packaging materials and medical appliances used and other
relevant information, the list would cover the following groups:-

<u>Human</u>		Veterinary
Antibiotios	Enzymes	Antibiotics
Sulfas	Vitamins	Anthelmeutics
		Dermatological
Anti-leprosy	Anti-depressants	
Anti-diabetics	diuretics	Chemotherapeutios
Anti-malarials	anti-epileptics	Minerals,
		Food Additives
Anaesthetics	Vaccine, Sera	
Analgesics, antipyretics	Miscellaneous drugs	
Barbiturates	Citric acid	
Hormones	Tartaric acid	
Drugs of Vegetable and		
Animal origin		

#### Packaging Materials

- 1. Gelatine capsules
- 2. Glass (vials, ampoules, bottles)

#### Medical Appliances

- 1. Thermometers
- 2. Blood pressure apparatus

#### Packaging Materials

- 3. Aluminium foils
- 4. Plastic containers
- 5. Disposable bags (PVC)
- 6. Metallic Tubes

### Medical Appliances

- 3. Stethescopes and hearing aids
- 4. Microscopes
- 5. Electro-cardiograms
- 6. Dental requisites
- 7. Laboratory equipment
- 8. Plaster bandages
- Factory for
   7-Ray films.

Accordingly, a team of 15 pharmaceutical experts was assembled at Cairo during the period May - October, 1977 to review and evaluate the information provided by ACDIMA and collected from other sources, which would be needed for the implementation of Phase II. This information would include the assessment of the following:-

Natural rescurces such as botanical, animal and minerals which are of interest to the pharmaceutical and packaging industry. Existing manufacturing facilities, pharmaceuticals, packaging materials, technical capabilities and sources of technology in the relevant participating Arab Countries.

Existing training facilities for managerial personnel, medical engineer, chemical engineer, pharmacist, chemist and technicians for the pharmaceutical and packaging sectors.

#### PHASE II+

# Project Proposals for Pharmaceuticals

- (a) Short-term (Priority)
- (b) Long-term

# (a) Short-term objectives

(1) On the basis of the information collated in Phase I, it was decided to formulate project proposals for the following groups:-

# (i) Human

### (ii) Veterinary

### Basic product material

Formulation and

packaging

(a) Antibiotics

Antibiotics

(b) Vitamins

Anthelmeutics

(c) Anti-tubercular

Dermatological

(d) Citric acid

Chemotherapeutics

(e) Tartaric acid

Minerals

(f) Preparation based on animal by-products

Food Additives

(g) Medicinal plants

# (iii) Packaging Materials

- (a) Hard gelatine capsules
- (b) Pharmaceutical glass (vials, ampoules, bottles, droppers)
- (2) It was also decided to prepare industrial profiles for each of the above mentioned products.
- (3) Appropriate measures were to be recommended for drug legislation, registration, quality control, as well as procurement and distribution system for the above mentioned drugs.
- (4) Appropriate measures were also to be recommended for training required skilled personnel.

#### (b) Long term objectives

1. The team of experts was to explore the possibility of mammacturing the following remaining products locally.

#### (i) Human

(ii) Veterinary

1. Sulfa

1. Antibiotics

2. Anti-leprosy

2. Anthelmeutios

#### Human

- 3. Anti-diabetics
- 4. Anti-malarial
- 5. Anaesthetics
- 6. Analgesics
- 7. Anti-pyretics
- 8. Hormones
- 9. Enzymes
- 10. Anti-depressants
- 11. Anti-histamines
- 12. Diuretics
- 13. Anti-epileptics
- 14. Vaccine and sera

#### Veterinary

- 3. Dermatological
- 4. Chemotherapeuticals
- 5. Minerals
- 5. Food Additives

### (iii) Paokaging Materials

- 1. Aluminium Foils
- 2. Plastic containers
- 3. Disposable bags (PVC)
- 4. Metallic Tubes

(3) Taking into consideration of the above aspects, the team of experts
was to recommend appropriate measures and steps to be undertaken
by ACDIMA for the implementation of the projects.

# Medical Appliances and Equipment

#### Definition

The term "Medical Appliances and Equipment" will include Instruments, Appliances and Equipment directly used for preventive, diagnostic and ourative purpose by physicians and surgeons in clinics and hospitals.

Besides the information collated in Phase I, it was decided to collect additional information as follows:

1) Identification and classification of various types of Medical Appliances and Equipment (Human and Veterinary) used in the Arab countries at different levels of Medical Services, in terms of overall technology, keeping pace with the plans of the countries.

Classification was to include the following groups: -

# a) General Medical Appliances and Equipment

To include all appliances and equipment required in clinics and general hospitals depending upon available common services.

# b) Specialized Medical Appliances and Equipment

To include all appliances and equipment for different functional specialization in various branches of medicine and surgery.

- c) Laboratory Equipment
- 1. Used in clinics and hospitals as auxiliary to diagnostic services.
- 2. Assessment of annual demand during the past five years for each of the major items and projections for the next ten years, with particular reference to the following:
  - a) thermometers
  - b) Blood pressure apparatus
  - c) Stethoscopes and hearing aids
  - d) Nicroscopes
  - e) Electro-cardiograms
  - f) Dental requisites
  - g) Laboratory equipment
  - h) Plaster bandages
  - i) Factory for X-ray films
- 3. Exploring the export potential to neighbouring countries.
- 4. Evaluation of the existing facilities especially for items mentioned in item 2 above.
- 5. Identification of areas where potentially usable facilities are available in Arab States which could be pooled and areas where technology in full is to be acquired.
- 6. Recommendation of Sources of Technology according to appliances and equipment identified in item 1 above.

- 7. Preparation of overall industrial profiles for each of the items identified under item 2 above.
- 8. Suggestion of appropriate measures for training required skilled personnel.
- 9. Establishment of a suitable marketing organization in those countries where production is suggested and effective oc-ordination of all the projects by ACDIMA.

Accordingly a team of two experts was assembled at Cairo during the period July-September, 1977 to carry out the activities specified above. After completion of their mission in Egypt and other Arab Countries, the experts returned to India and in co-operation with a local team of experts prepared industrial profiles for the items mentioned under 1 above.

#### II. MANAGEMENT

#### A. Summary

An efficient organization structure and the application of modern management techniques are vital to achieve the lofty aims enunciated in the constitutive provisions of ACDIMA. Organization charts are given for the senior level of management. The job description is given in each case. The basic concepts of this organization structure are:-

- (1) Centralization of the project function.
- (2) One point of responsibility for each of the basic functions.
- (3) Relatively easy measurement of managerial performance.
- (4) Relatively easy centralization of controls.
- (5) Allows short "line" with separate but strong advisory services.
- (6) Only seven people report to the Managing Director.

It is suggested that the scope of the existing Technical Committee be widened to include a thorough technical and economic survey of existing units in locations where new plants are proposed to be set up to highlight problems concerning power supply, water, steam and industrial effluents, which are peculiar to the developing countries. As the ACDIMA projects take shape, it is necessary to create separate organizations for each of such units. An organization chart is also given for such a unit.

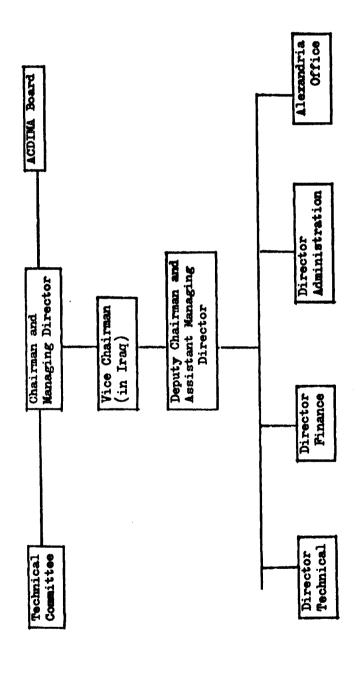
Priorities for making initial appointments are indicated.

#### B. Introduction

With efficient organization structure and modern management techniques, the performance of ACDIMA can make this enterprise a source of pride in the Arab countries. The Organization proposals elaborated below rely on a division of work under traditional "technical" and "commerical" headings rather than into decision making units directly geared to the objectives of the Company. The recommendations take into account "the Company's General Policy", "The Constitutive Provisions of ACDIMA", "The Company's Statute" and the "Deed of Partnership".

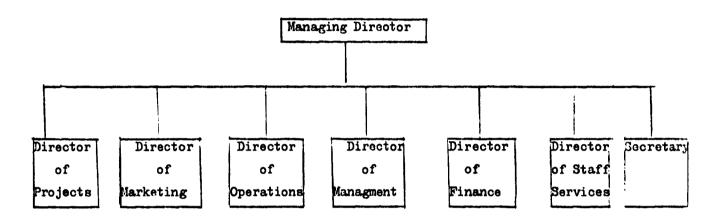
The existing organization setup is given in figure II and the recommended organization structure at senior level of management is given in figures III, IV and V. As the ACDIMA projects take shape, it is necessary to create separate organizations for each of such units. The recommendation in respect of a manufacturing unit is given in figure VI. The Job Description is outlined in each case. The Organization structure for sub-units in Quality Management is given in the report on Quality Management and that for procurement and contracting unit in the report on Procurement and Distribution.

Figure II. ACDIMA organization chart - present set-up



#### C. Recommendations - senior level of management

Figure III. ACDIMA - suggested organization chart (senior management)



The basic concepts of this organization structure are:

- 1. Centralization of the Project function.
- 2. One point of responsibility for each of the basic functions.
- 3. Relatively easy measurement of managerial performance.
- 4. Relatively easy centralization of controls.
- 5. Allows short "line" with separate but strong advisory services.
- 6. Only seven people reporting to the Managing Director. Managing Director who will probably also be Vice-Chairman will be free to assist the Chairman in working at a high level internationally to create a favourable climate for ACDIMA.

# MANAGING DIRECTOR (JOB DESCRIPTION)

- 1. Supervise his seven subordinates to ensure that clear short term goals are established within the operating guidelines and that performance is measured regularly.
- 2. Ensure that every Manager clearly understands the operating guidelines.
- 3. Ensure adequate delegation of responsibility so that each subordinate can do his job and couples this with adequate centralized controls to alert him promptly of any significant failures.
- 4. Approves or obtains approval for the ten year master plan and any changes thereto.
- 5. Approves the basic strategy for execution of each project.
  Approves or carries out negotiation of any major contracts.
- 6. Approves, separately:
  - (a) detailed plans and specifications for
  - (b) financial commitment for major projects.
- 7. Ensures that good management principles are followed in ACDIMA (attached).
- 8. Provides Project Director with information on the basic attitudes and objectives of each participating nation as related to ACDIMA's field.
- 9. Selects and appoints his seven immediate subordinates. Approves other managerial appointments.
- 10. Inspires loyalty and enthusiasm throughout ACDIMA. Every employee should be willing to train his own replacement.

- 11. Reviews organization, management practices and communications of ACDIMA and initiates and approves changes.
- 12. Ensures that every participating organization is clearly aware of ACDIMA policies (operating guidelines) and organization.

  Ensures that each participating organization appoints adequate and appropriate counterparts for rapid and direct flow of information to and from ACDIMA experts.

It is recommended that the Managing Director attend a course in General Management such as the four week course of The American Management Association:

#### MANAGEMENT PRINCIPLES:

- 1. Separation of work into units of responsibility which:-
  - (a) are functionally reasonable.
  - (b) can establish clear objectives.
  - (c) can make meaningful internal decisions.
  - (d) have skill and resources to achieve goals.
  - (e) whose results can be measured.
  - (f) are clearly defined.
- 2. Shorten the "line" (Few layers of management)
- 3. Advisory and support functions arranged to advise and inform the short "line".
- 4. Reporting system that reveals deviation from plan. Each manager to have his own clear, short term goals consistent with ACDIMA plans, with regular measurement of performance.
- 5. Rapid response to changes in the problem. (good feedback)
- 6. Enthusiastic contribution by all employees (willingly train own replacement).
- 7. Recognition of merit.
- 8. Planning with participation by those who must carry out the plan.
- 9. Constant review and adjustment of the management system.

10. Constant review and adjustment (system analysis) of communications and recording within ACDIMA and with participating organizations.

As a guide, a copy of the Management Handbook published by the American Management Association and similar publications from other countries using advanced management techniques may be consulted.

# DIRECTOR OF PROJECTS (JOB DESCRIPTION) REPORTS TO MANAGING DIRECTOR

- Supervises preparation of ten year master plan of projects with priorities and seeks approval of the plan and any changes as needed.
- 2. Decides for each project in descending order of priority best method, in principle of planning and execution.
- 3. Assigns appropriate planning functions within his group.

  Initiates or requests appropriate negotiations with external partners or supervises negotiations by planning manager.
- 4. Co-ordinates detailed planning to ensure completion on schedule.
- 5. Obtains final approval of plans.
- 6. Initiates and or co-ordinates execution of project until in full operation and taken over by permanent management.

# DIRECTOR OF MARKETING (JOB DESCRIPTION) REPORTS TO MANAGING DIRECTOR

- Compares availability of products within ACDIMA's field to needs and determines, on priority basis where sales, advertising, public relations, warehousing and transportation activites need to be improved.
- 2. Advises project manager and participating organizations of his findings and encourages action.
- 3. Volunteers to assist participating organizations in execution of his recommendations.
- 4. Recommends (to project director) direct action by ACDIMA where needed, including establishment of branches.
- 5. Executes (and/or operates) approved plans (4) above with co-operation and approval of participating organizations and operations manager.
- 6. Seeks out and defines export opportunities and offers assistance to participating organizations or acts for them in negotiating with foreign buyers, documentation and shipment of exports.

# DIRECTOR OF OPERATIONS (JOB DESCRIPTION) REPORTS TO MANAGING DIRECTOR

- 1. Operates ACDIMA plants according to ACDIMA policy and to highest international standards of quality and efficiency, and within budget.
- 2. Strives to achieve profitable operation consistent with ACDIMA policy.
- 3. Recommonds appropriate alterations improvement, expansions, etc. of plants under his jurisdiction as needed, consistent with ACDIMA policy.
- 4. Appoints or replaces management and staff as necessary in ACDIMA plants.
- 5. Provides consulting service for new ACDIMA for other owners as they approach completion so as to ensure smooth take-over by owners.
- 6. Takes over staffs and operates new projects intended to be managed and operated by ACDIMA.
- 7. Assists in training personnel for new projects by providing on job training to an extent that does not interfere unduly with current operations.

# DIRECTOR OF QUALITY (JOB DESCRIPTION) REPORTS TO MANAGING DIRECTOR

- 1. Creates and seeks approval for standards of international grade for:-
  - (a) Production and quality control methods.
  - (b) Raw materials.
  - (o) Finished products.
- 2. Compares standards with reality and develops a feasible program with priorities and timing for upgrading present performance toward the objectives established above.
- 3. Seeks approval for above.
- 4. Encourages and assists appropriate action by participating organizations.
- 5. Administers the ACDIMA Award of Excellence and assists (so that awards are made or withdrawn) as appropriate, by an outside body created for the purpose.
- 6. Seeks support (as needed) from governmental authorities of member countries for his recommendations through the chairman and ACDIMA board member concerned.

Please refer to the elaboration of this function in the report on Quality Management.

# DIRECTOR OF FINANCE

- 1. Acts as custodian of assets of ACDIMA including financial, real estate, trademarks, investments, contracts, charter etc.
- 2. Prepares short and long term plans for surplus financial assets and debts to achieve maximum return or minimum cost.
- 3. Makes available funds as needed, according to approved budgets or according to contract for operations, projects etc. as appropriate.
- 4. Manages all relations with banking and financial institutions.
- Provides all legal services as needed including advice on all contracts, trademarks and financial commitments.
- 6. Examines financial performance reports of ACDIMA and of each ACDIMA manager compared to budget. Makes appropriate recommendations to each manager and to General Manager.
- 7. Same as 6 for each organization in which ACDIMA is an investor.
- 8. Same as 6 for other participating organizations on request.
- 9. Assumes responsibility for the following functions through an office manager-Comptroller. (These services should include advising or supplying participating organizations as well as providing the services for ACDIMA).
  - (a) Records and library
  - (b) Computer or data processing services including meeting meeting requirements Staff Services Manager
  - (c) Accounting:-

Performance compared to budget for each Manager.

Accounts Receivable.

Accounts Payable

#### Payroll

- (d) Insurance coverage as needed for assets.
- (e) Personnel management including employee records, employee benefits.
- (f) Travel arrangements including company automobiles.

# DIRECTOR OF STAFF SERVICES (JOB DESCRIPTION) REPORTS: TO MANAGING DIRECTOR

- 1. To establish, supervise and monitor the performance of consultants to support and simplify the other functions of ACDIMA and, as appropriate, those of participating organizations.
- 2. To ensure that this expertise is prepared and freely offered in form and amount of detail precisely as needed.
- 3. To ensure constant upgrading of the services under his jurisdiction. Designs and provides direct, approriate channels of communication (in both directions) between his experts and appropriate persons in participating and other organizations.
- 4. To organize his department by discipline as follows:-
  - (a) Market Intelligence (Product and raw material Managers).
  - (b) Technology and research Intelligence (Medical-Academic-Industrial).
  - (o) Purchasing, movement of incoming goods.
  - (d) Manpower and Training.
  - (e) Quality Control.
  - (f) Management Consultant.

## SECRETARY (JOB DESCRIPTION) REPORTS TO MANAGING DIRECTOR

Serves as Secretary to the ACDIMA Board of Directors. Assists
Chairman in planning, managing and recording Board Meetings, General
Assembly Meetings, transport, accommodation and reception of board
members and official guests. Keeps stock records, minute book and ensures
compliance with ACDIMA statute and Deed of Partnership.

#### TECHNICAL COMMITTEE

At present there is a Technical Committee represented by major units and the concerned Ministries. It is suggested that this committee may also carry out a thorough technical and economic survey of an existing pharmaceutical plant or chemical or chemical based plant in each of the suggested locations of plants proposed to be set up by ACDIMA. This sorutiny will highlight problems concerning the following vital areas:-

- (1) Electric Power, the power shutdowns or fluctuations inload.

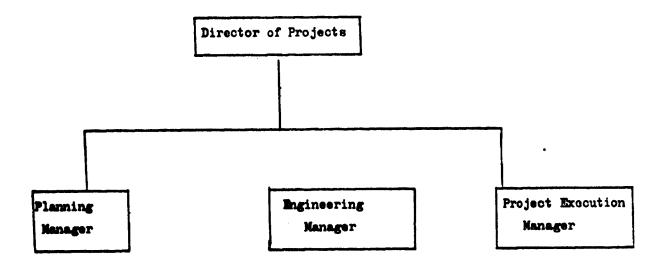
  Power supply resources in developing countries usually have insufficient capacity to cope with demands in hot weather, for ventilation, refrigeration and chilling water plants. There are also frequent shutdowns of power which result not only in all operations coming to a halt but many semi-processed products being destroyed.
- (2) Water, its availability, treatment required to make it useful in industry. Rivers dry up during the hot season when supply of water becomes soarce. In order to maintain continuity of supply of water in these regions it will be necessary to build special storage systems as well as to provide complex water chilling and recirculation systems that results in additional expenses and increases the capital cost of the project as also the running costs.

- (3) Steam, fuel supply for its generation.
- (4) Industrial effluents their treatment and disposal. Effluent from pharmaceutical factories need some preliminary treatment at the plant and subsequent biological treatment after mixing with town effluent to bring about bio-degradation of toxic chemicals before they can be discharged into irrigation systems. These installations are complex and costly when there is no possibility of adequate dilution when the rivers dry up.

The results of such a scrutiny will determine to a considerable extent, the feasibility of a pharmaceutical enterprise being established and profitableness of its operation and competitiveness of its products. Here it will also have to be borne in mind that Capital Costs including machinery, equipment and building costs have risen steeply and the incidence of depreciation on capital will be much more in newly established plants, compared to those already in operation in the country or outside, which are at present meeting the demands. Such incidence reduces the competitiveness of the finished products and may have to be subsidised or protected if they have to find a market.

#### D. Recommendations - projects unit

Figure IV. Organization chart for projects unit



#### PLANNING MANAGER (JOB DESCRIPTION)

#### REPORTS TO DIRECTOR OF PROJECTS

- 1. Consults experts within ACDIMA to obtain data on:
  - (a) needs in each participating country present and future.
  - (b) availability of raw materials in each participating country.
  - (c) quantity and cost of available products in each participating country.
  - (d) manpower resources available in each participating country.
  - (e) basic attitudes and objectives of each nation.
- 2. Analyse the above data and establish projects which conform to ACDIMA policy in sufficient detail to show:-
  - (a) capital required
  - (b) imports replaced
  - (c) additional benefits (need and justice)
  - (d) location
  - (e) expected employment (by discipline or skill)
  - (f) priority within ACDIMA master plan
  - (g) time needed to complete
- 3. Upon approval of master plan and priorities, recommends basic approach to each project as to ownership, whether partners are to be involved in planning or execution or management etc. (Consultation with project execution manager and engineering manager).
- 4. Upon approval to proceed with detailed planning:-
  - (a) Initiates (or requests initiation of) negotiations as appropriate.
  - (b) Assigns appropriate planning functions within his group, requests assistance from engineering manager.
  - (c) Ensures that detailed planning, ready for execution is completed on schedule.
- 5. Seeks approval of final plan.
- 6. On approval transfers responsibility for ACDIMA's role in execution of the project to execution manager.

#### ENGINEERING MANAGER (JOB DESCRIPTION)

#### REPORTS TO DIRECTOR OF PROJECTS

- 1. Advises planning manager on facilities needed for each project.
- On approval, and based on approved priorities, prepares detailed drawings and specifications for buildings and equipment.
- 3. If partners are involved in design, co-operates with them according to terms of agreement.
- 4. Provides consulting service to existing and operating projects (on approval and according to plan) to maximise or to increase ospacity or to increase efficiency.
- 5. Provides consulting service to project execution manager.

## PROJECT EXECUTION MANAGER (JOB DESCRIPTION) REPORTS TO DIRECTOR OF PROJECTS

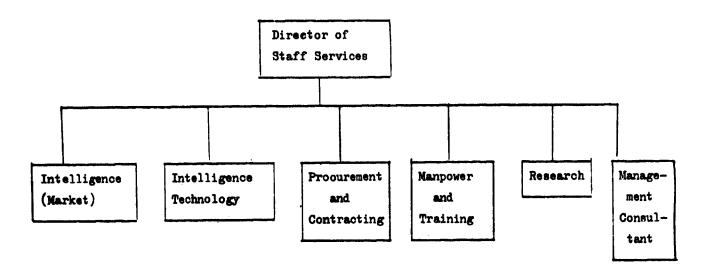
- 1. Investigates and makes recommendations on best strategy for execution of each project.
- 2. On approval becomes responsible for all measures needed to bring project into full operation in hands of permanent management, according to approved time schedule and within budget.
  NOTE:

May involve working with partners and/or owners, and/or contractors and/or providing for project management.

- 3. Reports monthly (?) on progress to:
  - (a) Director of Projects
  - (b) Planning Manager
  - (c) Owners of Project
- 4. Co-operates with owners (or with ACDIMA Operations Manager) and ACDIMA management consultant and training manager to ensure availabilities when needed of permanent management and work force to ensure smooth take over on schedule of complete, functional facility.
- 5. Responsibility ends when owners are satisfied.

#### E. Recommendations - staff services

Figure V. Organization chart for staff services unit



### MARKET INTELLIGENCE MANAGER (JOB DESCRIPTION) REPORTS TO DIRECTOR OF STAFF SERVICES

Develops and Maintains:-

- 1. Expert knowledge within each product group (for each country) of:
  - (a) current and ten year forecast for state of supply compared to need and relationship of imports to local supply.
  - (b) competition, marketing methods, market shares, packaging, pricing and future plans if possible.
  - (c) significant trends in foreign areas.
  - (d) attitudes of users and how and why buying decisions are made.
  - (e) effect of economic situation (present and future) on demand.
- 2. Expert knowledge of raw materials which are or might be needed or used including ourrent and future expectations.
- 3. Knowledge of the efficiency of distribution of each product group within each participating country. Detect failures in making products freely available where needed in a just manner.
- 4. Make appropriate recommendations.

#### NOTE:

Recommend that this vital function be carried out through product experts and raw material experts, each limited to a single product or small group of products. Each must either travel freely or set up direct, high quality sources where needed.

Examples: Antibiotics, Parenterals, Prosthetic Appliances etc.

#### TECHNOLOGY INTELLIGENCE MANAGER (JOB DESCRIPTION)

#### REPORTS TO DIRECTOR OF STAFF SERVICES

- Maintains up to date knowledge of technology needs and developing needs of ACDIMA and participating organizations.
- 2. Seeks out as needed, a precise knowledge of world-wide technology (in our field) and keep up to date.
- 3. Monitors appropriate technology centres or sources of special interest to ACDIMA and participating organizations (in and beyond Arab World) including competitors where possible.
- 4. Offer recommendations as appropriate to managers in ACDIMA and participating organizations on request.

#### PROCUREMENT AND CONTRACTING MANAGER (JOB DESCRIPTION)

#### REPORTS TO DIRECTOR OF STAFF SERVICES

- 1. Consults ACDIMA Experts and develops and recommends programmes for purchasing on a consolidated or group basis of items in ACDIMA's field including finished goods, raw materials and intermediates.
- 2. Seeks approval of participating organizations directly.
- 3. Executes approved plans and takes all appropriate action to ensure delivery when and where needed.
- 4. Maintains knowledge of sources and costs of machinery and equipment as needed by ACDIMA planners.
- 5. Purchases, arranges delivery on schedule of all equipment and supplies needed for approved projects when ordered by project execution manager.
- 6. Upon written request by participating organizations, advises them or acts for them in purchasing of finished goods, raw materials, equipment and supplies.
- 7. On request, and when approved, advises on or negotiates contracts for construction of facilities or installation of equipment.

Please refer to elaboration of this function in report on Procurement and Distribution.

#### TRAINING AND MANPOWER MANAGER (JOB DESCRIPTION)

#### REPORTS TO DIRECTOR OF STAFF SERVICES

- . 1. Maintains a plan for manpower needs based on ACDIMA's long term and short term projects, subdivided by discipline and training needed, and location.
  - 2. Maintains a precise knowledge of present and expected availability of manpower on the same basis.
  - 3. Establishes training needs.
  - 4. Compares training needs with available training facilities.
  - 5. Recommends a detailed training programme including:
    - (a) on-job training using present facilities of partioipating organizations.
    - (b) alterations in size or content of presently available programmes in educational or other institutions.
    - (c) foreign training of selected individuals or temporary importation of foreign experts, if necessary.
    - (d) Establishment by ACDIMA of training facilities or courses where necessary.
  - 6. Executes approved programmes.

#### RESEARCH MANAGER (JOB DESCRIPTION)

#### REPORTS TO DIRECTOR OF STAFF SERVICES

- 1. Compares research activities within the Arab countries to unfilled needs, based on advice of ACDIMA experts.
- 2. Recommends programmes to, and encourages execution by available Arab institutions.
- 3. Develops detailed programmes for direct execution by ACDIMA alone or in co-operation with Arab or foreign partners (where necessary).
- 4. Executes approved programmes and reports on progress and results to General Manager and encourages action by participating organizations to utilize results.

#### MANAGEMENT CONSULTANT (JOB DESCRIPTION)

#### REPORTS TO DIRECTOR OF STAFF SERVICES

- 1. For new projects, recommends size and type of management structure; prepares recommended organization chart and job descriptions.
- 2. Assists in selection and training of managers for approved projects so as to encourage availability of competent management when required.
- 3. Advises ACDIMA managers regarding organization development and management and control of their departments. Conducts analysis of management practices, organization and systems of ACDIMA. Recommends training and/or management development programmes.

Figure VI. Organization chart for manufacturing unit

#### F. Priorities for making initial appointments

It is suggested that the Director of Projects be appointed first and that the Project Execution Manager be appointed at the same time. Engineering and design services can be obtained by contract during this initial phase, and a rapid start on one or more projects should be possible.

Following this, the Market Intelligence function should be established (Director of Staff Services, Market Intelligence Manager and one or more Product Managers). This should quickly improve the quality of information available to the Director of Projects.

The Director of Finance and Secretary should probably come next in order to provide internal support services of high quality.

Beyond this stage, it is suggested that priorities be determined by the developing situation. A Director of Operations will not be needed until ACDIMA needs to staff and manage a manufacturing or distribution unit. The Director of Quality Management can be added independently of other activities. The urgency of the Marketing function (Director of Marketing) will depend on studies by the Market Intelligence Manager.

#### III. QUALITY MANAGEMENT

#### A. Summary

#### PRESENT:

- (a) ACDIMA should appoint a Director of Quality Management (QM).
- (b) Written standards should be prepared for (i) plant design as related to QM and (ii) operating methods of control, applying to all types of production to be undertaken by ACDIMA.
- (c) The above standards should be used for a complete assessment of the existing or projected operations, so as to devise corrections.
- (d) A beginning should be made on a 5-10 year plan for a full complement of standards for materials and products including raw materials, packaging material and finished product.

#### FUTURE:

ACDIMA should establish a Pharmaceutical Centre according to the following guidelines:

- (a) The institute should be aimed for maturity in 10 years.
- (b) It should prepare and update industry standards on a continuous basis and publish them.
- (c) It should conduct industry intelligence and liaison.
- (d) It should maintain laboratories to supplement or complement any already existing.
- (e) It should have facilities for training for different levels of function.

The report outlines a plan, to be completed in a 10 year period, for ACDIMA to follow in achieving a full Quality Management function, both to control its own operations, as they become established and to give leadership to all member countries in their pharmaceutical and related industries. The measures recommended for the present include the appointment of a Director of Quality Management, preparation of standards and assessment of existing manufacturing operations based on the latter with a view to bring them to the International Standards. The establishment of a Pharmaceutical Centre by ACDIMA is recommended for implementation as a long term measure.

#### B. Present situation

#### (a) Director of Quality Management

ACDIMA should appoint a Director of Quality Management (QM). The objective is to embark on a 8-10 year program of quality management in ACDIMA operations in particular and in the industry of the ACDIMA Countries generally, in order to enable ACDIMA to become an influence of first importance in maximum development of the industry. It is also necessary to effect a reconciliation of government policies in the ACDIMA countries respecting drugs and to complement or supplement governmental control or quality. The Director of QM reports to the Chief Executive of the Company and maintains liaison with the heads of other functions such as manufacture, marketing and research and development, while exercising control in certain areas to the extent necessary.

#### (b) Preparation of written standards

ACDIMA should prepare as early as feasible, written standards, covering (a) plant design as related to QM and (b) operating methods of control, applying to all types of production to be undertaken by ACDIMA. Requirements of these standards should cover design and workmanship for

buildings and equipment, methods of control of manufacturing, packing, raw materials, as well as records, laboratory, training and health of personnel, housekeeping and storage and distribution.

#### (c) Review of existing facilities to devise corrections

Standards should then be used for a complete assessment of existing or projected operations, so as to devise corrections. Of particular urgency will be attitudes and habits of workers at all levels. A survey of the state of Quality Control in pharmaceutical manufacturing in the ACDIMA countries indicates an urgent need of improvement to bring the quality to the accepted international standards. It is therefore, necessary for ACDIMA to achieve a full Quality Management function, both to control its own operations, as they become established, and to give leadership to all member countries in their pharmaceutical and related industries. It is most important that in any ACDIMA projects, QM principles be built in from the outset, with the aim that each should be a model plant, in both construction and operation.

#### (d) Standards for materials and products

A beginning should be made on a 5 to 10 year plan for a full complement of standards, starting with the more important items. A standard must be prepared for each item, whether raw material, packaging material or finished product, (including labelling and packaging). See appendices I and II.

In the case of manufactured products standards, the QM Director will work for the development, as needed of complete master manufacturing orders, designed to ensure and record the correct completion of each step of manufacturing and control. These should be used in all ACDIMA operations and urged in all other plants.

As the portfolio of standards grows, it should be made accessible to all manufacturing and all governmental control bodies within the ACDIMA world.

Laboratories: The QM Director should study all laboratories within his sphere of influence and determine their suitability, in the light of the standards to be applied. As ACDIMA plans or establishes further manufacturing plants, he will design and install the QM system for each.

#### C. Future development

#### The ACDIMA Pharmaceutical Centre

This institute should be aimed for maturity in 10 years. It should be the vehicle by which ACDIMA takes and holds a position of leadership and influence in the Arab countries in the field of pharmaceuticals. Its functions and facilities should be as detailed below. Its development and management should be the task of the Director of QM.

#### (1) Industry Standards

A facility should be maintained for the continued preparation and updating of standards and their publication. This would take the form of a secretariat. It would convene voluntary groups of advisers and provide all secretarial services. It would maintain a library of standards and publish indexes and reports.

Itmight also contain a reference library as needed to complement or supplement existing services, possibly in collaboration with R and D.

Advisory groups should consist of expert representatives of research, QM, production, marksting, the professions and others, as suited to each case. Groups should be of minimum numbers and limited to those who can make a definite technical contribution.

These classes of subjects for standards should be recognised in the group structure.

Raw materials, packaging materials, labels, intermediates. Finished products, in form for shipment.

Manufacturing and QC practices and records.

Building design as related to Good Manufacturing Practice

Labelling, marking and inserts

Conditions of storage and distribution.

Although the international compendia will be used a great deal as references in the standards, the use of such references alone is quite inadequate for completeness.

#### (2) Industry Intelligence and Liaison

A staff group of QM should:-

- (a) Keep up-to-date knowledge of world advances in standards and controls.
- (b) Monitor the performance of ACDIMA operations and others in the ACDIMA countries.
- (o) Provide assistance to all operations in meeting standards and dealing with problems.
- (d) Establish a Board of Advisers on the use of the ACDIMA Award of Excellence and assist the Board with information from intelligence work.
- (e) Administering a system of personnel exchange and training among the ACDIMA organizations and in the larger industry.
- (f) Advising concerning government controls and legislation.
- (g) Maintain a system of "Vendor ratings" for suppliers, such as used in many North American industries.

#### (3) Laboratory Facilities

Laboratories should be maintained to supplement or complement any already existing, for the purpose of:-

- (a) Assisting in the standards work by checking test methods for feasibility and precision and to set tolerances; comparing methods of test for speed, precision and cost.
- (b) Maintaining special testing facilities such as may be beyond

the scope or budget of individual plants. One such problem is the examination of degradation products in drugs as part of the work of assessing shelf life.

- (c) Advising and assisting the industry on lab facilities to meet standards.
- (d) Providing testing services to company or plant research and development programs.

#### (4) Staff Qualifications and Training

#### Levels of Function:

#### Senior Quality Management

Supervision of major units or activities, including standards of work, lab. direction, senior intelligence and liaison.

Alternate for Director

#### Intermediate Staff:

Supervision of line workers in local plants' QM units.

Take most decisions on acceptance/rejection of products and deal with manufacturing units.

Difficult analyses in lab

Preparation of routine or special reports

Assistance to Senior personnel

#### Workere:

Sampling as instructed Routines in lab. Care of samples Report to Intermediates

#### Levels of Training

#### Senier:

Professional in Chemistry, Pharmacy, Medicine, Microbiology, with or without engineering.

Special or post-graduate training in:

Quality control principles

Theory of Measurements

Statistical Quality Control, including classification of defects and inspection by attributes.

Data processing and related skills

Sanitation engineering

Business Administration; report writing

#### Intermediate:

Technical School in Chemistry, Pharmacy, Microbiology

A degree of knowledge in the fields listed for seniors

On-the-job training

#### Workers:

High School or Technical School to Grade 12 Aptitude in mechanix and mathematics Thoroughness, accuracy, alertness On-the-job training

In-House training for all ranks might include:
Knowledge of Pharmacopoeias

Knowledge of Inspection procedures

Knowledge of government policies and others such as:
WHO

FDA

Canadian 74-GP-1 Studies in interpersonal relations

#### D. General

#### (a) Government Policies Harmonization

There appears to be no basic diversity in the drug control methods of the various ACDIMA countries. Most of them follow the more developed pattern of the Egyptian. A considerable degree of uniformity is desirable and over the long term will tend to establish itself. Attempts to hasten the process are often faced with disappointment. These statements are echoes of those made at the WHO seminar.

Harmonization of governmental methods should be an aim of the QM Director. In the effort he will be all the more successful if his own program succeeds. In fact, a fully operative ACDIMA program of Quality Management, having a strong influence in the industry, would tend to reduce the necessity for increasingly elaborate and costly government programs, each to a large extent duplicating the others.

#### (b) List of Essential Drugs

The work of reducing the large list of drugs now being used and produced, already begun, should continue, using advice such as advocated for the industry standards in the Pharmaceutical Centre. With such groups of experts the selection of essential drugs could have regard to such factors as changes in the practice of medicine, occurrence of diseases, chemical technology and dosage form development.

#### Appendix I

#### DEFINITION AND COMPONENTS OF QUALITY MANAGEMENT

#### Definition of quality management

QM is an executive function of the company directed at maintaining the high level of product quality established as company policy. It deals with all operations, activities, facilities and policies which relate to quality of product.

#### Components of quality management

Plant, Facilities, Maintenance.

These have quality implications and must be subject to quality management.

Manufacturing standards:

All manufacturing is conducted according to standard procedures laid down by QM and capable of being checked as to compliance by clearly described means. This includes requirements for raw materials and all the conditions of manufacturing.

#### Manufacturing Control:

Each person engaged in manufacturing follows the prescribed procedures according to fully detailed, written instructions and maintains the required conditions. His work is verified by a second person, both attesting in writing.

#### Quality Control:

In each manufacturing plant there is a Quality Management unit, distinct from manufacturing or marketing and responsible only to top management. Its function is to ensure that Manufacturing Control is working and for this purpose may, whenever it doesns it advisable, examine the procedures or equipment, sample materials, apply any desired tests or even stop operations.

QH may establish "resident staff" in any operating facility.

#### Laboratories:

QM may use its own or any laboratory services, if they are judged to be suitable.

#### Finished Products:

QM may withhold from finishing, packaging or further processing any material if it considers the action warranted. It may inspect batch yields. It has authority to deal likewise with all manufacturing, handling and storage conditions related to the product in any stage.

#### Records:

QM ensures that all manufacturing and control is suitably recorded and attested in writing by operators, and that all tests applied are correctly performed and recorded so as to be readily useable during a future period established for records.

#### Labelling:

QM ensures that labels are controlled and excess quantities disposed of.

This applies also to all other containers and packaging material carrying information or batch numbers.

#### Samples:

QM ensures that control samples are retained for the necessary period in the prescribed conditions.

#### Product Stability:

QM audits the company's estimation of shelf life and ensures that, where appropriate, data on degradation products are obtained and recorded.

#### Self-Inspection:

ON conducts periodic inspections of facilities, conditions and methods of manufacturing and control, and prepares reports to all concerned indicating action to be taken. It also ensures that such action has been taken.

#### Recall of Products:

QN ensures a system of complete recall and traceability of materials, operators and equipment.

#### Personnel Training:

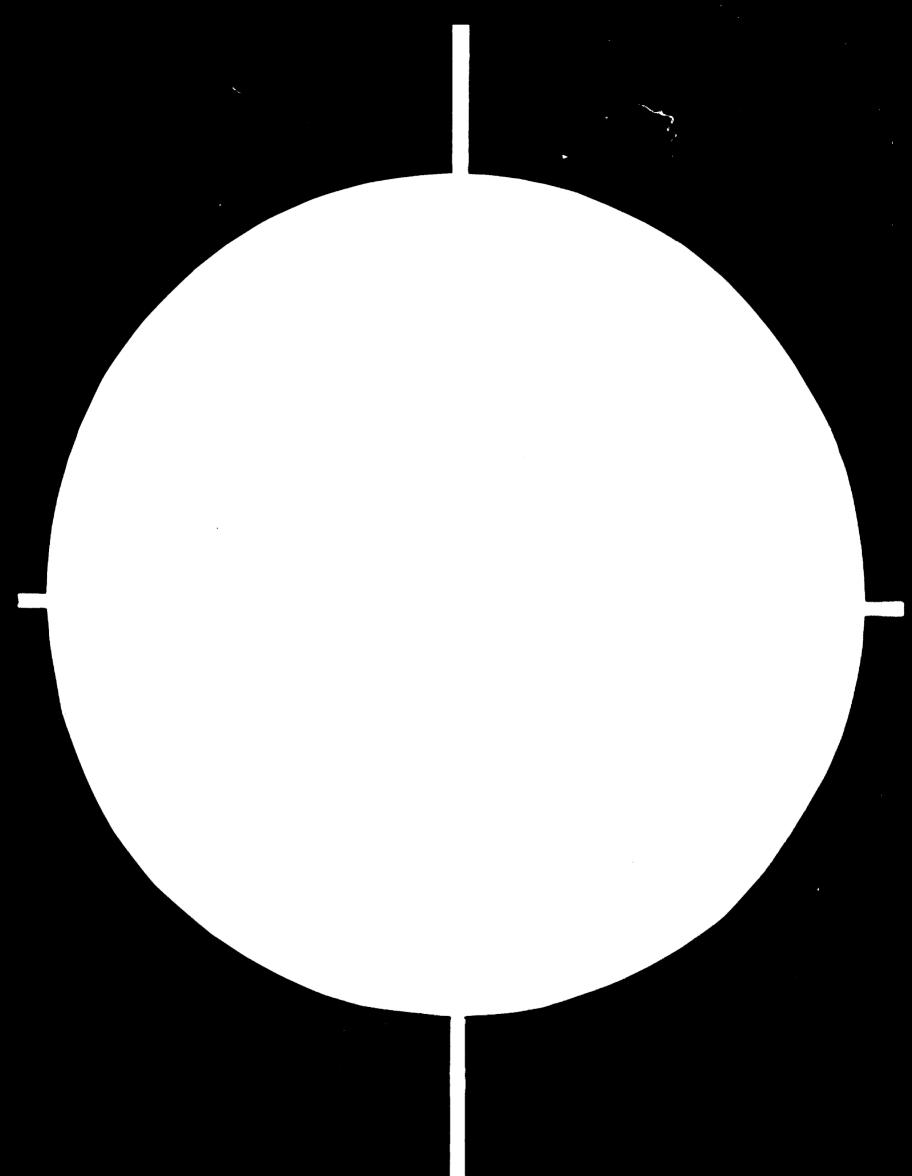
QM undertakes to ensure understanding by each worker, at all levels, of the principles and practice of QC as applied to his own job, and at the higher levels, of the whole QM program, using any suitable means, including job rotation.

#### Personnel Health:

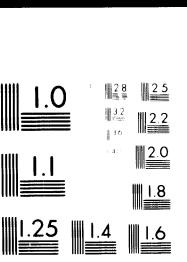
Off ensures that anyone with a condition of health which is not consistent with quality of product is excluded from operations on the product.

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MICROCOPY RESOLUTION TEST CHART

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#### Appendix II

#### CONTENT OF A PRODUCT STANDARD

#### Specifications for:

Each raw material

Intermediate stage(s) of manufacture, when required.

Each process described as to method, conditions, precautions, yield, packaging, labelling.

Finished product as to physical state, finish, packaging, labelling, control procedures, acceptance criteria, such as test results with tolerances, shelf life, conditions of handling and storage.

Other requirements if necessary

For brevity or convenience some of the above requirements are often given by reference to well-known compendia or other standards, if these are accessible to those who need to use them.

#### IV. PROCUREMENT AND DISTRIBUTION

#### A. Summary

This report relates to the procurement and distribution of pharmaceuticals and medical appliances by existing organizations in Egypt and to the present and future execution of similar functions by ACDIMA. It also covers ACDIMA'S current activities and its future involvement in the procurement of Services and goods, also the distribution and marketing of the latter. Based on the conclusions arrived at, specific recommendations have been made. The most important relate to the establishment of a procurement and contracting unit and and an economic research unit within the ACDIMA secretariat.

#### Procurement

- (1) Proourement unit should be established within the ACDIMA
  Secretariat responsible for the co-ordination and procurement
  of all goods and services relating to ACDIMA and other Government
  Purchasing agencies headed by a Director of Procurement.
  The unit may comprise a Contracts Section, a Purchasing Section
  and a Data and Service Unit.
- (2) The Procurement Unit should establish methodologies and procedures to cover current and future transactions.
- (3) The director of Procurement should be a mamber of Technical Committees for Project Studies.
- (4) The Procurement unit should maintain liaison with National Agencies engaged in procurement and importation.
- (5) This unit should initiate studies to develop the commonality of requirements of the various procurement agencies.

(6) ACDIMA should establish, where possible, facilities for the consolidated bulk purchasing of common items and in the first instance, pharmaceutical raw materials. For example, an offshore purchasing office or subsidiary can be established in a a location such as London for centralized procurement of combined common requirements.

#### Standardization

(1) ACDIMA may make efforts to reach agreement on essential items of oommon need, standardize specifications on pharmaceutical raw materials, pharmaceutical finished products and packaging materials, taking into account the work done by international organizations.

Standardization of pharmaceutical production machinery and laboratory equipment concerning formulation plants may also be carried out.

#### Distribution

(1) ACDIMA should evaluate the existing channels of distribution, and determine the most suitable channels - either existing selected channels or create new channels and organize separate channels for the areas listed above.

#### Data and statistics

(1) ACDIMA should establish an economic research unit to assemble and make available data on current production, planned production, distribution costs and selling prices for items listed above with respect to all Arab countries.

#### Marketing

(1) ACDIMA may undertake the import and marketing under its own brand names of selected items of medical supplies and equipments of common use as a complementary scheme to its production programme.

#### Miscellaneous

- (1) ACDIMA may augment the present organization to oreate a strong multidisciplinary approach.
- (2) ACDIMA may establish levels of remuneration equal to the best prevailing rates in the Arab countries to obtain the best qualified staff and achieve a geographical approach.
- (3) ACDIMA may maintain liaison with UN Agencies
- (4) ACDIMA may seek technical co-operation from developing countries such as Greece, Hungary, India, Mexico, Spain, Turkey and Yugoslavia. ACDIMA may also develop contacts with developed countries for technology supplies and equipment.
- (5) ACDIMA should assist in improving the existing production in Arab Countries to encourage inter-Arab production and distribution.
- (6) ACDIMA may enlist the support of the Ministries of Health and Industry to achieve an integrated development of pharmaceutical Industries. The form of protection to be given, the incentives such tariffs, import duty concessions, and tax benefits preferential treatment to local produce may be examined for implementation, as the case may be.

#### B. Procurement

- 1. The procurement of goods and services is vitally important to ACDIMA's current and future activities. Procurement has two distinct but inter-related roles to perform within ACDIMA. First is with respect to the establishment of new production facilities or assistance to existing manufacturing plants for pharmaceuticals packaging and medical appliances. The second role is that of assistance in the purchase of supplies and materials for distribution and consumption within the ACDIMA member states.
- The oreation of production facilities involves the establishment 2. of source data for equipment, expertise and technology; the invitation of proposals; their evaluation in conjunction with technical, financial and management personnel; the formulation of contracts for feasibility studies, technical management and turnkey contracts; and the administration and prosecution of these contracts until their successful conclusion. The establishment of pharmaceutical and medical appliance industries depends importantly on the transfer of technology, which in itself requires identification of the most appropriate and economical sources, and the procurement of the goods and services, on the basis of which the technology is implanted and becomes operative within its new setting. The efficient procurement of services, or the negotiation and conclusion of contracts for the required services, is an essential element in the realization of ACDIMA's objectives. The value of goods and services to/procured for new plants and facilities in the immediate future amounts to \$150 - \$ 200 million.
- 3r. The second role of procurement in ACDIMA is to assist the existing national agencies in the ACDIMA member states, who are presently responsible for the provision of pharmaceuticals and medical appliances. This function is carried out by Government organizations in all member countries except Saudi Arabia and the Gulf States. The total current value of overseas purchasing amounts to approximately \$ 950 million.

- 4. No organizational unit yet exists within ACDIMA to fulfil the above-mentioned twin roles. Their execution requires the establishment of a Procurement Unit to co-ordinate op-going transactions and deal with future matters relating to the acquisition of goods and services, both for the implementation of ACDIMA's own production programme and to assist the national purchasing organizations in the procurement of their requirements from within the Arab states and from other countries.
- The procurement unit must be headed by a person of the widest experience and the highest integrity. His primary qualifications should be in purchasing and contracting. In addition he must have a good working knowledge of the industrial sectors concerned, i.e. pharmaceuticals, packaging and medical appliances; and he must be familiar with both the Arab countries and global sources of supply. His appointment must be an equivalent level to the heads of the departments for Administration, Finance and Technical= Affiars, with whom there must be continuous co-ordination and co-operation; the level must also be such as will enable him to deal effectively with the heads of the importation and Purchasing Departments in the national agencies of the ACDIMA member states.
- 6. The Procurement Unit will require effective staff support at all levels and the necessary facilities for efficient communication within ACDIMA, with the ACDIMA member states and with international sources of goods and services.
- 7. In the light of foregoing conclusions, itis

#### RECOMMENDED

R.1) a Procurement Unit to be established within the ACDIMA Secretariat responsible for the co-ordination and procurement of all goods and services relating to both the ACDIMA production programme and to provide support and operational services to the various national Government purchasing offices;

- R.2) the unit to be headed by a Director of Procurement of the highest qualifications, appointed at an appropriate staff level and with sufficient delegation of authority to effectively carry out the responsibilities of the unit;
- R.3) The procurement Unit to responsible to the Office of the Deputy Chairman and Assistannt Managing Director, at the same time maintaining close working relationships with the Technical Department;
- R.4) The procurement Unit to initially comprise three sections;
  (a) a Contracts Section concerned primarily with the procurement of services for the ACDIMA production programme;
  (b) a Purchasing Section to assist the national purchasing organizations in the member states; and (c) a Data and Service unit to acquire and maintain source material for services and equipment, also to provde general olerical services;
- R.5) The Procurement Unit to be so staffed and equipped as to permit it to deal efficiently and rapidly with the functions for which it is responsible.
- 8. Concurrently with the organization of a Procurement Unit a Work Programme should be established taking into account the priorities.
- 9. First priority calls for the formulation and adoption of proposals, the issue of tender, the adjudication of awards, the formalization of recommendations to the ACDIMA Management Board; and the adoption of forms of contract with appropriate terms and conditions. The procedures should be established with two objectives: to facilitate and accelerate the decision-making process in purchasing and contracting transactions; and to establish and maintain the highest code of ethics in the execution of these transactions. Good Procurement Policy (GPP) is of equal importance as Good Manufacturing Practices (GMP) are to the pharmaceutical industry.

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Early action is required to fill in the current information gaps regarding procurement operations in the various member states. The information in this report relating to the Egyptian system should be amplified and continued to cover the other member countries. Regular liaison must be maintained with the various national procurement organizations to learn their procedures, the nature and volume of thier activities, the problems which they have overcome and the difficulties which continue to exist. Sepcial effort should be applied towards identifying and quantifying the requirements of the various countries which are common to each other. Infomation regarding current imports of pharmaceutical raw materials into Egypt have been provided in the appendix. Similar information relating to the other member states should be obtained by visits to and discussions with the officers responsible for procurement in the national organizations.

In implementation of these conclusions relating to the Working Programme for the Procurement Unit, it is.

#### RECOMMENDED

- R.6) First priority in the Working Programme of the Procurement
  Unit to be given to the establishment of methodologies and
  procedures to cover current and future transactions for the
  procurement of goods and services related to ACDIMA projects,
  with the objectives of accelerating decision-making relating
  to current proposals and at the same time providing the
  guidelines for Good Procurement Practices to cover both
  present and future transactions.
- R.7) In the implementation of procurement and contracting procedures, the Director of Procurement to be a member and take active part in the Technical Committees for project studies, as provided for in the Company's general policies.
- 12. The next stages of work to be undertaken by the Progurement Unit involves assistance to the National Procurement Agencies in the ACDIMA member states, in connection with which it is

#### RECOMMENDED:

- R.8) Liaison to be initiated and maintained with the officers responsible for procurement and importation in the National Agencies with the object of organizing the periodic exchange of information regarding procedures, prices and current problems.
- R.9) Studies to be initiated to develop the <u>commonality</u> of requirements of the various procurement agencies:

  the items, volumes, ordering frequencies, degree of conformity of specifications for pharmaceutical raw materials, for packaging supplies, for finished drugs and for medical appliances, with particular reference to essential and large volume items.
- 13. The appendix listing the principal pharmaceutical raw materials being imported into Egypt indicates many products of significant tonnages coming from world sources, subject to competitive, sometimes volatile, price conditions. Many, if not the majority of these products are also being purchased by the other ACDIMA countries engaged in the formulation of pharmaceutical products. The fact that most ACDIMA member states are obtaining these items under Government bulk-purchasing arrangements indicates an awareness of the economics of scale in consolidated purchasing. The economies of scale and the leverage of large-volume purchasing would be further exploited if the various national purchasing agencies were to combine and take joint procurement action on their larger volume requirements of common items. The object of the studies referred to in R.9 above would be to develop the extent of the potential combined volumes.
- 14. If the combined, common requirements were to be purchased by ACDIMA, there would be additional advantages: Firstly, ACDIMA can import materials free of duty according to its statutes, whereas imports into Egypt for example, are subject to customs duties. Secondly, national purchasing is often restricted by annual budgetery provisions and in the case of some countries by the availability of foreign exchange, meaning delayed ordering, slow payments and higher prices. These latter situations would not apply to ACDIMA purchases.

Furthermore ADCIMA would be in a position to negotiate long-term, openend contracts based on total estimated requirements, on the basis of which the national purchasing organizations, or ACDIMA acting on their behalf could draw quantities as and when required. Long-term contracts also afford potential for advantageous price arrangments.

- 15. The concept of combined purchasing may not be implementable in the first instance to all member countries but already at an early stage ACDIMA would be in a position to offer bulk-purchasing arrangements to some of its member states, particularly those in the most need of assistance.
- 16. Bearing in mind the many advantages of inter-Arab consolidated purchasing, it is

### RECOMMENDED

- R.10) Based on the studies referred to in R.9 above, ACDIMA to give early attention to the possibility of establishing and offering to organizations in the member states, facilities for the consolidated bulk purchasing of common items; and that first priority be given to pharmaceutical raw materials.
- 17. In the early stages of organizing inter-Arab centralized procurement, the activities should be carried out by Purchasing Section in the ACDIMA Procurement Unit. With expanded operations, ACDIMA should consider alternative organizational arrangements, such as the creation of a separate ACDIMA purchasing agency, and to the consideration of an alternative site at Cairo. The successful operation of a large scale central purchasing organization depends importantly on an efficient comminications infrastructure, which is not presently the case in Egypt. There would also be advantages in allocating the office site close to its main sources of supply which are in Europe (which would not handicap contacts with the Americas and Asia). An office in Europe would facilitate the possibilities of using, initially at least, the purchasing assistance which can= be offered by WHO and by UNICEF through the latter's European Supply Office in Geneva. With respect to middle to longer term planning, it

### RECOMMENDED

- R.11) ACDIMA through its Procurement Unit to consider the establishment of an off-shore Purchasing Office or subsidiary organization in such a location as London, Paris Geneva or Vienna, for the centralized procurement of combined common requirements of the ACDIMA member states.
  - C. Standardization, specifications and essential items
- 18. The standardization of products, together with the formulation of standards specifications for the item concerned, form part of the broad strategy for the development of an industrial sector. Specifications provide the clear language by which procurement and distribution can be rationalized. Its development may take many years, money and personnel but in the early stages as well as the longer term it will significantly reduce costs and increase efficiency in the production, purchasing warehousing and distribution of supplies and equipment.
- 19. Pharmaceuticals and medical appliances constitute two sectors in which there is great scope for the elimination of duplications and the reduction of equivalents. The Egyptian government and others have demonstrated how 40,000 products in world drug use can be reduced to a few thousands or a few hundreds. Similar results can be obtained with medical appliances. Provision must always remain for special orders to meet special requirements but in its assistance to member states, ACDIMA should concentrate on the development of standard list of essential requirements, on the evolution of standard specifications for common items, and on the bulk procurement and distribution of those items at the lowest possible cost to the ultimate user. The WHO with its essential drug list and UNICEF, with its guide lists and standard specifications for basic health care items provide useful starting points for action by ACDIMA.
- 20. Economics of scale and the rationalization of purchasing and distribution could also be achieved by the standardization of requirements and of specifications for pharmaceutical packaging materials, such as glass ware, ampoules, etc.

21. Similarly the establishment by ACDIMA of numerous pharmaceutical formulation plants offers valuable opportunities for the adoption of standard items of equipment for the various formulation processes and for the necessary laboratory equipment. The standard-ization of such equipment will provide opportunities for procurement on the most favourable prices basis and to simplify the problems of maintenance, spare parts and after-sales servicing.

### RECOMMENDED

R.12) In addition to the working programme of the Procurement
Unit as in R.6 above ACDIMA to make all efforts within
its own organization and through its participation in technical
committees with other competent Arab authorities to reach
agreement on essential items of common need, to produce
standard specifications on these items, as the basis of common
procurement and distribution. These efforts to be directed to:

Pharmaceutical Raw Materials
Pharmaceutical Finished Products
Packaging Materials of all types

Medical Appliances, on a sector by sector basis

- R.13 In the efforts proposed in R.12 above, consideration to be given to the work that has all ready been done in the international field by WHO and by UNICEF on essential drugs and medical applicances, also to current studies by WHO and other international organizations concerning the purchase, distribution and prescription of drugs by their generic names.
- R.14) Special attention to be given to the standardization of pharmaceutical production machinery and laboratry equipment in the design, planning and ultimate contracts for new formulation plants to be established or financed by ACDIMA

### D. Distribution

22. The pharmaceutical industry in Egypt is co-ordinated and controlled by the Supreme Pharamaceutical council, headed by the Minister of Public Health. Aided by various secretariats, the Supreme Council is responsibel for strategic planning. Technical and operating functions are carried out by the individual enterprises.

The manufacture of pharmaceutical chemicals is carried out by the state-owned El-Nasr Company at Abu-Zaabal, 45 km from Cairo. Its fermentation facilities are presently not operating for the production of antibiotics, but its synthetic programme includes the production of Salicylic æid compounds, Sulfa compounds and Chloramphenical from intermediates. The El-Nasr plant also operates its own fromulation plant.

The formulation of pharamaceuticals is carried out by the E1- Nasr Company as indicated above and six other plants in the Government sector, i.e.

Alexandria Co. for Pharmaceutical and Chemical Industries, Alexandria.

Arab Drug Co. , (ADCO) Cairc

Kahira Pharmaceutical and Chemical Industries Cc. Shoubra, Cairo.

Memphis Chemical Company, Cairo

Nile Company for pharmaceuticals and chemical Industries, Cairc.

The government enterprise, El Goumhouria is responsible for the procurement and distribution of pharmaceutical raw materials and intermediates; laboratroy supplies and equipment; pharmaceutical production equipment and all medical appliances. It prepares the consolidated annual requirements, invites tenders, purchases, imports and handles the distribution to Government plants, Government institutions and the private sector through a network of port and central werehouses and depots in the twenty - five governorates. Its sister organization the Egyptian Pharmaceutical Trading Company (EPTCO) performs a simalar function with respect to finished pharmaceutical products; it prepares the country's annual estimated requirements and arranges for their purchase and importation. All imported drugs are distributed by the EPTCO through a country-wide network to its own pharmacies and to the private sector pharmaices.

No or little information is available regarding the distribution systems prevailing in the other ACDIMA member states. Further action is desirable to obtain comparitive data on the distribution systems existing in the other countries concerned and with respect to the price structures for pharmaceutical raw materials, packaging materials and medical appliances in Egypt and for these categories as well as for finished pharmaceutical products in the other ACDIMA member states.

- countries to illustrate the wide spreads between import costs and retail selling prices, also the spreads between the prices of generic drugs and brand name drugs and between different brands of the same generic product. Distribution cost spreads from factory to consumer may vary from 7% in the case of some socialist countries to as high as 300% or more in other instances. The general data provided on the Egyptian price structure should be amplified and similar data compiled on a comparitive basis for representative items in all ACDIMA countries.
- 24. A recommendation for compiling comparitive information on distribution costs is given in paras 32, 33 and Recommendation R.15 below.
- 25. From the description of the Egyptian drug distribution system, it will be noted that there are no less than eleven duplicating distribution channels for drugs, eight operated by Government concerns and three operated by Government/Private Sector joint enterprises.

  In Egypt, there is, conversely, one single large distribution system, for the distribution of such diverse and numerous items as pharmaceutical raw materials, pharmaceutical machinery, laboratory supplies and equipment and the entire range of medical appliances. ACDIMA must eventually determine the most effective channels for the distribution of the products of its own manufacturing units and of other supplies and equipment which it may import, distribute and possibly market. It is therefore

### RECOMMENDED:

R.15) ACDIMA to evaluate the existing channels of distribution in the member states on the basis of the studies recommended in paras. 32 and 33 below and determine the most suitable channels or to create new channels - avoiding duplication where possible but organizing separate networks for:

Pharmaceutical Raw Materials and Packaging Materials
Finished Pharmaceutical Products
Medical Appliances

Production Machinery and Laboratrcy Equipment

26. Good warehousing and stock-keeping is an essential part of good distribution; and proper inventory controls, ordering and issuing procedures have an important bearing on the cost of warehousing and distribution. Warehousing conditions in Egypt are admittedly less than ideal due to a variety of constraints including financial, trained manpower, and the general infrastructure. In this connection it is f

### RECOMMENDED:

R.16) In the course of senior ACDIMA staff visiting Europe, advantage to be taken to visit such establishments as the UNICEF central warehousing operations in Copenhagen or similar commercial facilities with a view to developing criteria and goals for the organization of suitable facilities in the ACDIMA member states.

### E. Data and statistics

- 27. The general policies of ADCIMA express inter alia "the Company's need to be in possession of all the information, data and statistics which would portray a true picture of the available potentialities and the needs of every Arab country"; further that "the Company has to seek to know the existing conditions in the areas of pharmaceutical production and consumption and the projects ready for implementation or planned in every Arab country, a knowledge in the light of which the Company will work its projects".
- 28. ACDIMA has made considerable efforts to compile basic data on the production and consumption of pharmaceuticals, a field in which the difficulties of assembling comparative data have already been noted. Also considerable technical data has been assembled and organized in ACDIMA's Technical Department. Otherwise major information gaps exist, i.e. with respect to importation and procurement statistics, data on medical appliances in general, and a proper inventroy of existing

production facilities for pharmaceiutcals, packaging materials and medical appliances. This was one of the major problems faced by the UNIDO/CESO team.

- 29. ACDIMA's data requirements may be broadly divided into three categories:
  - 29.1 Procurement sources of supplies, equipment and services:
  - 29.2 Technical including technologies, licenses, patents, etc.
  - 29.3 Economic including data on existing production facilities, production costs, import costs and selling prices for the Arab countries as a whole.
- 30. The organization of procurement data (29.1) would be carried out by the Procurement Unit (see Recommendations R.1 and R.4 above). The occlection of technical data (29.2) has already been initiated by the Technical Department. The outstanding need is for economic data and statistics (29.3). The organization of such information should be centralized within ACDIMA. It requires a system of collection, recording and retrieval. It requires linkages through the ACDIMA representatives to data sources in each member country; it should also have linkages to other data centres outside the Arab countries.
- out, in part, by ACDIMA's own staff and representatives, and in part by using the services and resources of existing Arab organizations, e.g., the Council for Arab Economic Unity, IDGAS, etc. The assembly of data by these methods would be more effective and considerably less expensive than by using foreign consultants or experts. Outside assistance might be required for organization of the system but the datagathering together with its compilation should be done by ACDIMA and indigenous resources.
- 32. Two information areas call for urgent attention: firstly an inventory of existing and planned production facilities for pharmaceuticals, paokaging materials and medical appliances. The data should be established in the form of industrial profiles indicating historical data, organization, capitalization, employees, machinery, production capacity, current production, present markets and distribution channels. Similar data should be obtained periodically, up-dated, from each ACDIMA member country relating to planned new production facilities. Secondly, data is required on present costs for

importation, production, distribution and selling prices, particularly for drugs and medical appliances, on a comparative basis for all ACDIMA member states. As previously recommended (para. 19), action should be initially centred on essential common items.

33. Basic data of the types described in para. 32 above is essential in proper planning; consequently it is:

### RECOMMENDED:

R.17) an Economic Research Unit be established to assemble and make available comparative data on all aspects of current production, planned production, distribution costs and selling prices for representative or basic pharmaceutical raw materials, drugs, packaging materials and medical appliances with reprect to all Arab countries.

### F. Marketing

- New manufacturing facilities will require a minimum of two to three years before production commences. Modifications to or the expansion of existing plants may be accomplished in somewhat shorter time. Meanwhile ACDIMA must consider establishing a presence and obtaining operating experience in the distribution and marketing of products. These latter objective should be accomplished by the importation and distribution of selected products of common use and need in the member states. A further recommendation is made with respect to medical appliances in para. 39, Recommendation R.20. In some cases the importation and marketing of products could be linked to eventual local manufacture of the articles; local production as it becomes available could replace the imported goods, utilizing the then established channles of distribution.
- Marketing arrangments in general could be concluded in a shorter period that the time required to bring new facilities into production.

  Marketing should not replace but should supplement plans for local manufacture. The negotiation and conclusion of marketing arrangments would depend on the development of consolidated requirements (para.12,R.9); on the results of price and distribution cost studies (para 33,R.17); and require decisions on the distribution channels to be used (para25,R.15).

#### Therefore it is

#### RECOMMENDED:

R.18) ACDIMA undertakes the importation and marketing under its own brand names of selected items of medical supplies and equipment of common use and need in the Arab countries as a complementary scheme to its own local production programme, the decision in terms of products to be taken in the course of its current production planning and based upon its own basic data gathering or upon separate feasibility studies.

### G. Medical appliances

- 36. This subject will be reported on in detail by the concerned experts. However, the following comments and recommendations are included in this report:
- It involves consumable and non-consumable goods; it comprises of non-mechanical, mechanical and electronic items and products made from all materials, i.e., wood glass, plastic and metal. Some basic items are required in high volume and lend themselves to mass production.

  Some articles are suitable for sub-contracting arrangments and assembly operations; others are highly sophisticated and purchased infrequently. The sophisticated items involve critical problems of maintenance.
- 38. One group amongst others medical and dental instruments is appropriate for cottage or small scale industry production. During the last twelve years, the Government of Pakistan has developed an important production of these commodities which are exported throughout the world. The industry is based on the importation of stainless steel, cottage or small workshop production by native craftsmen, and marketing and exportation through co-operatives or export houses. It is

#### RECOMMENDED:

R.19) ACDIMA to contact the Government of Pakistan to study the development of the medical and dental instruments industry in that country with a view to importing and distributing the products in the Arab countries and to determine the feasibility of establishing production as part of a small scale industries programme in one of the member countries.

39. The multiplicity of items comprised in medical appliances makes it difficult for ACDIMA to establish a presence or make an early impact in the distribution of these products based on new or expanded local production. The purchase and distribution of medical appliances also requires long established connections and expertise in the maintenance of stocks and prompt responses to demands. The trade in medical appliances is to a large extent controlled by large wholesaler/stockists headquarters in the USA, Europe and Japan. Considering the above facts it is

### RECOMMENDED:

R.20 ACDIMA examines the possibilities of acquiring a financial interest in an established overseas firm specialized in the stockage and distribution of medical appliances and develops arrangments for the importation and distribution of these products through this established overseas facility, marketing the products or a selected range of products in the Arab countries under ACDIMA brand names.

### H. ACDIMA organization and personnel

- of a Procurement Unit with Staff experienced in purchasing and contracting, and of an Economic Research Unit involving industrial economist and industrial information personnel. The successful operation of these proposed new units is dependent on the organization, staffing and functioning of the ACDIMA secretariat as a whole.

  Consequently the following conclusions and recommendations are offered with respect, first, to ACDIMA organization and staffing; and second, with respect to general policy.
- 41. ACDIMA has completed a first stage of activities with the development of its policies and its initial administrative organization. It is now about to enter the phase of industrialization, with the evaluation of proposals and their subsequent implementation in terms of plant construction and associated operational activities. These new developments, create new staff needs and implementation of the industrialization stage requires a strong multi-disciplinary approach. In addition to procurement specialists and economists, the need now centres on engineering skills: chemical, mechanical, industrial engineering,

production engineering. Although many of the eventual engineering services will be provided by outside contracting, the need still remains for competent ACDIMA counterpart staff to deal with contractor services. Furthermore, these skills are needed at the present time to deal with the evaluation of proposals and their implementation.

- 42. As an intergovernmental organization, ACDIMA must necessarily reflect its membership structure in the staffing pattern. To obtain the best qualified people on a regional geographical basis implies that ACDIMA remuneration scales should reflect the best prevailing rates in the Arab region.
- 43. ACDIMA will require from time to time expertise and high level consultancy to deal with specific problems as they arise, for which their own staff resources are not sufficient or require reinforcement.

  A means must be established whereby these needs can be promptly filled by qualified personnel.
- 44. Finally, the productive efforts and the results achieved by its present and augmented staff, as well as the participation of outside experts and consultants depends to a large degree on the adequacy, efficiency and motivation of the general administrative and supporting staff.
- 45. On the basis of the foregoing conclusions, it is

  RECOMMENDED:
- R.21) ACDIMA's present organization be augmented to deal with the new industrialization phase of activities, aimed at the creation of a strong multidisciplinary approach by the addition of the required skills in engineering, economics, statistics, financial, legal and procurement;
- R.22) to obtain the best qualified staff and achieve a fully geographical approach, ACDIMA to establish levels of remuneration equal to the best prevailing rates in the Arab countries.
- R.23) ACDIMA to make the necessary administrative and financial arrangements whereny it may obtain on short notice experts or consultants in the various specialized fields, i.e., pharmaceuticals, packaging, medical appliances, industrial information services and procurement; and the expertise to be sought through both the UNIDO roster and panels of experts

established by ACDIMA.

- R.24) Recognizing the importance of efficient supporting staff services, ACDIMA to ensure the adequacy of support necessary to obtain the maximim results possible from its own senior staff as well as outside experts and consultants; and to continue its supervision and motivation of the staff in such a manner as to obtain their fullest participation in the organization's goals.
- R.25) Considering the compatibility between the goals of ACDIMA and the resolutions of the United Nations with respect to the establishment of a new Internation Economic Order, ACDIMA should maintain its liaison with the UN Agencies and UNIDO in particular.
- R.26) ACDIMA to continue to seek technical co-operation on a bilateral basis through friendly governments, particularly those of other developing countries where pharmaceutical and medical appliance industries have been developed; in addition to continuing liaison with Hungary and India, contacts also to be made with such countries as Greece, Mexico, Spain, Turkey and Yugoslavia.
- R.27) ACDIMA to develop and diversify its commercial contacts in the search for technology, supplies and equipment contacts, where mutually beneficial, with the major transnational companies; with Japan; with medium or smaller established national firms as in Scandinavia; with Eastern Europe as important procedures of pharmaceutical raw materials; and with new, world suppliers of raw materials and appliances such as China, and with firms in the developing countries of Latin America, Southern Europe and Asia.
- R.28 ACDIMA to assist in improving the qualities of existing production in the Arab countries; to rationalize and make maximum use of existing facilities; to encourage inter-Arab production and distribution.

- R.29) ACDIMA to initiate discussions and agreements through the appropriate Arab bodies regarding the degree and form of of protection to be given to existing and newly-established pharmaceutical and medical appliances industries in the Arab countries, considering the alternative incentives of tariffs, import-duty concessions, tax benefits and government purchasing policy, i.e., preferential treatment for locally manufactured products; in addition to give support through the Arab Economic Unity Council for the harmonization of national tariffs with respect to raw materials. packaging materials, finished drugs and medical appliances.
- R.30) ACDIMA to enlist the support of both the responsible national Ministries of Health and the national Ministries of Industry to achieve an integrated development of the industries for the production of pharmaceuticals and medical appliances.

### I. Assistance by UNIDO

Implementation of ACDIMA's plans for the development of integrated 47. pharmaceutical and medical appliances industries to serve the Arab member states would be an important step forward in fulfilling the Lima Deolaration and Plan of Action on Industrial Development and Co-operation and the establishment of a New Economic Order as called for in UN General Assembly resolutions. ACDIMA's mandate represents an effort in regional co-operation involving presently 13 member governments and a population of approximately 160,000,000 people. ACDIMA's plans foresee the utilization and processing of indigenous natural resources, i.e., petroleum to petro-chemicals, to pharmaceutical raw materials, and of medicinal plants and animal by-products. The accomplishment of these plans depends upon the transfer of technologies from and investment by the industrialized countries in a developing area of great economic and political importance. The planned development would create vital and strategio consumer goods industries directly related to socio-economic development. The process of developing the pharmaceutical and medical appliances sector will involve maximizing the use of existing plant and equipment and the establishment of new large and small scale Industries.

The goals and policies of ACDIMA are therefore in full alignment with important objectives of the United Nations and of UNIDO. Moreever the necessary funds for ACDIMA's activities already exist in terms of an initial capatalization of fifty million Kuwaiti Dinars (approx. US \$ 175,000,000).

ACDIMA needs and will continue to need for the attainment of its objectives technical assistance in the form of expertise and information and in the sectors of chemical industries (pharmaceuticals); engineering (medical appliances); industrial planning; infrastructural support (standardization, quality control, industrial information); access to expert roster data; and in procurement and contracting.

Additionally, information may be required on factory establishment and management, in training and in investment promotion. Assistance in these various fields will be required over a period of a decade or more.

### Appendix

### MAJOR IMPORTED PHARMACEUTICAL RAW MATERIALS, EGYPT

```
10
             Chloramphenical Powder BP 63
     tons
                               11
 2
     **
                    11
                                    micronizes
 7
     .
             Oxytetracycline hydrochloride BP 63
3.5 m. dose Penicillin G Benzethene, G.Sod. procaine plus .5 g. streptomycin
1.1 m. "
                        G. Proc
             Streptomycin Sulphate
35
     tons
38
     11
             Tetracycline Base
 3.6 "
                          micronized
 q
     **
             Tetracycline HC1
55
             Acetone, 5 kg
242
             Acid Acetyl Salicylic 25 kg.
     *
                11 11
210
                                    50 kg.
             Acid Boric Pdr. 50 kg
88
             Acid Citric Anhydrous 1 kg
10
                         11
250
                                    50 kg
 8
             Acid, Lactic, 10 kg
10.5 "
             Acid Salicylic 50 kg
                            "uncrompressed"
15.5
                 10
             Acid Tartaric, 100 kg
122
158
  5
             Alcohol, Absolute 2.5 kg
  2
             *
                      **
                                5 kg
             **
                                drums
  4
  7
      **
             **
                      Cetostraryl, 25 kg
500
      **
             **
                      Ethyl
             ••
 18
                      Isopropyl
             Alum. Potash Pdr. 1 kg
 10
                 " " 50 kg
 20
                   Hydroxide 10 kg
 22
  9
             Aminopyrine 50 kg
  5
             Amino phylline 1 kg
             Amm. Carbonate
 30
  5
             Amm. Chloride 1 kg
 15
             Amm. Chloride 5 kg
215
             Analgin (Soviet P.VII Dipyron 5 kg
      **
                                           50 kg
 50
 20
      Ħ
             Barium Sulphate 50 kg
 20
             Borax Powder
 11
             Caffeine 50 kg
             Calamine 50 kg
 11
 60
             Calc. Benzamide Salicylate 5 kg
             Calc. Bromide Lactobromate
 10
120
             Calc. Carbonate, prec. 50 kg
                               prep. 1kg
140
             **
                   **
      *
 10
                   Cluconate
                               50 kg forinj.
             **
 12
                               oral 50 kg
             *
 15
      **
                   Glycerophosphate 50 kg
      Ħ
             **
                   Lactage 50 kg
 16
      **
             **
 70
                    Phosphate 50 kg
      11
             **
                              tri-basic 50 kg
 13
 90
                   Sulphate 10 kg
```

```
16
     tons
             Chloroform 1 kg
             Chloroquine Phosphate 25 kg
22
     ••
     **
12
             Cresylic Creosote 100 gm
102
     ..
             Dextrose anhydrous, 50 kg
     11
192
             Dextrose monohydrate 25 kg
      **
35
      **
             Di-iodohydroxyquinoline 50 kg
32
             Enzyme mixture A (Wander)
      **
 10
 1.6 "
                    **
                             В
             Ephedrine Hydrochloride 5 kg
68
      11
      11
             Ether Anaesthetic 1 kg
 14
      **
             Ethyl Chloride
160
      11
             Ferric Amm. Citrate 5 kg
 33
 25
      11
             Ferrous Sulphate Exs. 1 kg
             Festal Mixture of Ferments, Hoechst
      11
 18
      **
              Formosulphathiazole 5 kg
 10
      11
              Hexamine 5 kg
 20
              Hydrogen Peroxide Sol.Str.25 kg
      11
 20
              Iodo-Chlorhydroxyquinoline 25 kg
 10
      11
                                with sapamine, pre-granulated
      **
 25
                                ready for tabletting 25 kg.
 16
      11
              Isoniazide 50 kg
190
      11
              Lactose 50 kg
              Methylated Spirit 5 kg
 18
      11
              Naphthalene Purified Scales 25 kg
 20
              Paracetamol 5 kg
 20
              Phenyl Butazone 25 kg
 11
      11
              Pthalysulphathiazole 50 kg
 10
              Piperazine Citrate 50 kg
 34
              Polyethylene Glycol 400 50 kg
      11
 18
                                   4000 50 kg
                            "
      11
 28
                                   6000
 10
      11
              Polysorbate 80 (Tween 80) 25 kg
 15
              Polyvinyl Pyrolidone 25 kg
 19
 60
              Pot. Citrate 25 kg
              Pot. Hydroxide 5 kg
  10
              Procaine Hydrochloride 5 kg
 13
              Propylene Glycol 50 kg
 115
              Sod.Amino Salicylate Granules 25 kg
  50
              Sod. Benzoate 5 kg
 28
       **
       11
              Sod. Bicarbonate 50 kg
 675
              Sod. Chloride for inj. 50 k.
 345
       19
  60
              Sod. Citrate 50 kg
  25
       11
              Sod. Salicylate 1 kg
       11
              Sod.Sulph. Anh. Exs.
  10
       91
              Sorbitol Sol. 100 kg
 125
       11
              Starch Maize 5 kg
 346
       **
               Starch Wheat 50 kg
  12
               Sulphacetamide Sod. 25 kg
  13
               Sulphadiazine 50 kg
  40
       11
               Sulphadimidine 50 kg
  16
                               Sod. 25 kg
  12
```

```
41
     tons
             Sulphaguanidine 50 kg
10
     *
             Sulphamerazine 50 kg
20
     **
             Sulpha ?
     **
             Sulphasomadine 50 kg
13
27
      11
             Terpineol 50 kg
      **
             Tit. Dioxide 5 kg
52
      11
             Tolbutamide 50 kg
19
      **
             Yeast, dried, 25 kg
57
      11
30
             Zinc Oxide 25 kg
210
      **
             Acetic Anhydride
             Aluminium Sulphate
50
             L.Amine (Levo Nitrobase)
             Ammonium Sulphate
300
             Benzyl Chloride
 10
             Calc. Chloride Anhyd. Pdr.
22
             Salicylic acid, tech.
350
 18
             Sod. Hydroxide pearls
 65
      ••
             Sulphanilamide
      **
             P-Toluene sulphonamide
 30
 12
      11
             Urea, Tech.
  2
             Mercury Metal
      11
  2
             Zerolit
 35
             Amm. Chloride
200
      **
             Glycerol
             Dimethyl Thionthrene (misulphan)
 10
150
             Talc Powder
 25
             Acid Ascorbic 50 kg
             Choline Bitartrate 1 kg
 12
      **
             Sod. D. Pantethenate ?
 25
             Nicotinamide 25 kg
 37
      **
             Arachid Oil 50 kg
 12
             Castor Oil 25 kg
112
             Cod Liver Oil 25 kg
 70
             Paraffin Liquid
140
             Paraffin White Soft BP 63
530
             Seasame Oil BP 63 10 kg
 32
 40
             Wool Fat Anh. BP 63 50 kg
```

### V. EDUCATION AND TRAINING OF PERSONNEL

### A. Summary of recommendations

- (a) That an in-depth study be undertaken of the curricula of Faculties of Pharmacy in the Arab countries in comparison with the curricula of faculties in other countries with a view to remove imbalances in the courses.
- (b) That an immediate upgrading of facilities and equipment in Faculties of Pharmacy be commenced.
- (c) That special attention be given to courses on Industrial Pharmacy in the curricula, in close co-operation with the Pharmaceutical Industry.
- (d) That the governments institute a careful study of manpower in Pharmacy and establish a five year forecast.
- (e) That university enrolment in the future be governed by the figures in the forecast.
- (f) That in the establishment of new pharmaceutical industries a sound system of management be introduced.
- (g) That in new and existing pharmaceutical industries serious consideration be given to achieving proper proportion of university graduates who could each contribute their own particular expertise to the company.
- (h) That specialized training facilities be provided for the training of technicians for the pharmaceutical industry.
- (i) That personnel from the pharmaceutical industry play an' important part in the training programs for these technicians.
- (j) That high priority be given in the Arab countries to the training of sufficient skilled trades - people to meet the growing demands of the society.
- (k) That pharmaceutical industries employ as much mechanization and automation as possible in order to increase production and efficiency.

### B. Faculties of pharmacy in the Arab countries

The information available on the Egyptian Faculties of Pharmacy indicates that the supply of pharmacists should equal the demand. However, a deficiency in training must result from overcrowding in the large faculties. This problem may be solved after 1982-83, if fewer students are accepted from now on. In any event, it would seem that more modern equipment is needed in the undergraduate laboratories. The general laboratory facilities were far from adequate for good training of students. Graduates with better training are required by the Pharmaceutical Industry to assist in providing a more efficient operation of any Company. It would seem that the training of M.Sc. and Ph.D. graduates is adequate, but the industry in general feels that their training has an excess of the theoretical aspects and a deficiency in the applied. Graduates from the B. Pharm. program who take further study towards a Diploma in Drug Analysis, Industrial Pharmacy, etc. would presumably be better qualified to work in the Pharmaceutical Industry.

It would appear that B. Pharm. graduates from Baghdad University receive better training than those from Egypt, since there is no overcrowding and no lack of good equipment. The number of graduates from Baghdad seems to be sufficient to meet the needs of Iraq. Perhaps a critical review of the curricula in Arab Pharmaoy Faculties in comparison with similar curricula in Europe and North America would be of great value.

Graduates in various branches of engineering are also vital to the pharmaceutical industry, particularly the graduates in chemical, mechanical and electrical engineering. It would seem reasonable to assume that the relatively few graduates required for an expanding pharmaceutical industry would be available.

## C. Manpower in the pharmaceutical industries in Egypt and Iraq

A study of the number of employees in each category employed by four pharmaceutical companies in Egypt and Iraq is shown in appendix I and reveals interesting differences in the manpower components of the concerned companies. A breakdown showing the percentage of pharmacists, other university graduates and technicians is given in appendix II. The percentage of pharmacists varies from 5.8% to 40.2%, of other graduates from 6.0% to 36.1% and of technicians from 40.4% to 61.4%.

### The Structure and Organization of Pharmaceutical Companies

It is essential for the successful operation of any pharmaceutical company that there be an adequate representation of each of the following groups:-

- (a) Management
- (b) Professional
- (c) Technical
- (d) Tradesmen
- (e) Workers

### (a) Management

There should be experts in business administration, accounting, finance, sales, planning, personnel etc. Adequate secretarial assistance and modern business methods and equipment should be used.

### (b) Professional

There should be an adequate "mix" of graduates from several disciplines - pharmacy, science, the appropriate branches of engineering, and perhaps agriculture, to conduct the technical aspects of the operation. An active research program should also be in progress.

### (c) Technical

The contribution of trained technicians is vital to the operation of a company. There should be expert technicians in all departments of the plant who can, with a minimum of direct supervision, carry out routine work in the areas of chemical and microbiological analysis, in instrumentation, biochemistry, toxicology, pharmacology and in other departments where they exist. Adequate training facilities for technicians should be provided in appropriate locations in the Arab countries. Smaller countries could send their people for training to the larger countries. The existing technical schools could provide special training for the pharmaceutical industry, but the curricula should have the input of experts from the industry, and ideally, experts from the industry would participate in the technical schools as part-time instructors.

In Egypt there are several technical institutes (after secondary schools) with 18 month courses in chemical analysis, technological course, etc. Another three year course can be taken (after primary school) in a technical secondary school. There is also an apprenticeship training program - 5 years from primary school for trades—people particularly. El Nasr, for example, participates in the program and many of the apprentices then stay on with the company.

The establishment of new technical schools for the training of technicians for the pharmaceutical industry should be considered.

These could be operated by the industry alone or could be joint operations with the governments. The training of technicians should be adequate to require only a minimum of on-the-job training.

### (d) Tradesmen

It is essential that there be an adequate number of skilled tradespeople employed in the pharmaceutical industry - mechanics, plumbers, welders, machinists, electricians, painters, carpenters, etc., to provide prompt and efficient maintenance of the buildings and the machines and the various systems in the plant. Maximum production can only be achieved with a minimum of break-downs.

It is understood that at CDI there was a lack of tradespeople in all industries and that high priority should be given to increasing the training facilities in these areas. Such an increase would benefit all industries.

### (e) Workers

Workers fall into three groups - unskilled, semi-skilled and skilled, and most companies employ large numbers of workers. While this practice provides jobs, plant production suffers. Consideration should be given to the use of modern machines available for doing many of the time consuming jobs in a plant - filling, labelling, and packaging are areas that should be automated as much as possible. The employees released could be transferred to other essential industries and make a greater contribution there. Concurrently, automation would provide a substantial increase in production at an eventual lower cost.

### (f) Discussion

In many of the existing pharmaceutical plants, there appear to be serious gaps in the structure just outlined. The unavailability of skilled tradesmen is serious everywhere. More technicians should be used instead of having University graduates carrying out technical functions. In some plants there are too many pharmacists and not enough graduates from the various branches of engineering and of science.

Developing countries should endeavour to upgrade all aspects of their economy and especially those areas that affect the health of the population. Although emphasis should be placed on preventative measures, it is recognized that diseases, disorders and abnormal physical states will always exist and must be treated by health professionals, and durgs in large quantities will always be needed. It is the responsibility of governments to assure that good drugs are produced in adequate quantities for the country. Proper therapeutics mean shorter illnesses and therefore more production.

An expanded pharmaceutical industry in the Arab countries will mean that more drugs and medicines will be available, fewer will have to be imported and new jobs will be created which will partially offset the jobs that will be lost by automation. The net results will be an upgrading of the health of the nation, and an increase in the gross national product.

In the light of above, it is recommended that:-

- (i) In the establishment of new pharmaceutical industries a sound system of management be introduced. Delegation of authority to the different levels of management is essential and the personnel involved would assume more responsibility (as well as accountability) in decision making.
- (ii) That special attention be paid to having a proper "mix" of university graduates who could each contribute their own particular expertise to the company.

- (iii) That new technical institutions be established and/or existing institutions be expanded for specialized training for the pharmaceutical industry. For this training there must be substantial input from the industry.
- (iv) That high priority be given in the Arab countries to the training of sufficient skilled tradespeople to meet the growing demands of the society.
- (v) That pharmaceutical industries employ as much mechanization and automation as possible; fewer workers would be required and greater production and efficiency would result.

### D. General

One serious problem in the pharmaceutical industry is the turn over of professionals. These people can receive up to ten times the salaries in Egypt in countries such as Saudi Arabia, U.K., and U.S.A. More attractive salaries would prevent this "brain-drain" from Egypt.

Appendix I

NUMBER OF EMPLOYEES BY CATEGORY IN FOUR
PHARMACEUTICAL MANUFACTURING COMPANIES

CATEGORY			COMPANY	
	EL NASR	C.I.D.	*ALEXANDRIA	SAMARA DEUG
			DRUG CO.	INDUSTRY-IRAQ
B. Pharm.	20	218	27	45
M.Sc.	5	3		5
Ph.D.	7	8	1	0
B.Sc.	70	0	4	15
Ag. Eng.	15	0		0
Chem. Eng.	9	3		9
Civil Eng.	1	0	2	1
Elec. Eng.	8	0		0
Mech. Eng.	8	7	1	5
Eng. (other)	1	0		4
Post Grad. Dip.	0	14	5	0
Technicians	200	290	<b>7</b> 0	57
Workers	1456	2457	230	1059
Total	1800	3000	670	1200

<sup>\*</sup> Data incomplete

Appendix II

# PERCENTAGE OF EMPLOYEES BY GROUPS IN FOUR PHARMACEUTICAL MANUFACTURING COMPANIES

GROUP		COMPANY		
	EL NASR	$\underline{\mathbf{c.i.b.}}$ .	ALEX.	<u>s.D.I</u> .
B. Pharm.	5.8	40.2	23.7	31.9
Other Graduates	36.1	6.0	14.9	27.7
Technicians	58.1	53.4	61.4	40.4

### VI. REQUIREMENTS OF ANTIBIOTICS AND SYNTHETIC DRUGS

### A. Summary

Based on statistics and data on production, imports, exports and consumption of antibiotics and synthetic drugs in five Arab countries, the requirements of the same were computed. These countries are Egypt, Iraq, Libyan Arab Jamahiriya, Sudan and Syrian Arab Republic. From these figures, a forecast of consumption in 1979 and 1985 is made which can be used as a base for production plans. A forecast has also been made by ACDIMA for 1980.

The weighted average of the increase in population in all Arab Countries from 1980 - 85 is 14.5%. According to ACDIMA estimates, per capita consumption will increase by 70% in the same period; this figure reflects the growing use of a greater number of drugs beyond the assortment already available in 1975. Consumption forecasts for 1985 have been made taking this aspect into account. Drugs consumed in quantities below one metric ton have not been included for economical reasons.

### B. Sources of data

- (1) Report on "Arab Pharmaceutical Consumption and Industries" furnished by ACDIMA.
- (2) UNIDO report on "Production plan for the Arab Pharmaceutical Industry in selected Arab countries to supply jointly the total Arab market. VC/INT/76/077 revision 4, 11 July, 1977.
- (3) Annual tenders for the procurement of drugs as invited by the Egypt, Iraq, Libyan Arab Jamahiriya and the Syrian Arab Republic.
- (4) Periodical chemical statistics, furnished by the data processing centre, El Goumhouria, Cairo representing the supply planning calculations for the requirements of the Public Sector and private sector plants and institutions in Egypt.

- (5) Production programmes of the plants of El Nasr P.C.Co., Egypt and S.D.I., Iraq.
- (6) Procurement plan of KIMADIA, Iraq.
- (7) Procurement plan of Directorate General of Medical Supplies and Medical Store, Baghdad, Iraq.

### C. Requirements of antibiotics

# Statement showing the estimated requirements of antibiotics in some Arab countries (kg)

s No.	ANTIBIOTIC	EGYPT	IRAQ	LIBYAN ARAB JAMA- HIRIJA	SUDAN	SYRIAN ARAB REPUBLIC	TOTAL
		1977		1975	1977-78	1975	
1.	PENICILLINS	16,700	20,067	4,030	19,588	3,866	64,251
2.	AMPICILLIN	1,900	11,000	10,000	2,355	5, 172	30,427
3.	TETRACYCLINE	53, 200	11,217	5,000	4,020	5, 458	78,895
	STREPTOMYCINE SULPHATE	51,200	10,287	800	8,000	2,720	73,007
5.	OXYTETRACYLINE	13,600	-	-	<b>61</b> 3	<b>48</b> 9	14,702
6.	ERYTHROMYCINE	400	4,500	2,000	50	951	7,901
7.	OTHER ANTI- BIOTICS	N.A.	5,899	1,162	N.A.	1,792	8,853

### Statement showing the estimated requirements of antibiotics in Arab countries (kg)

S NO.	<u>antibiotic</u>	IRAQ.	LIBYAN ARAB JAMA- HIRIJA	SYRIAN ARAB REPUBLIC
	and the second s		1975	1975
1.	PENICILLINS	20,067	4,030	3,866
2.	AMPICILLIN	11,000	10,000	5, 172
3.	OTHER SEMI- SYNTHETIC PENICILLINS	626	600	263
4.	TETRACYCLINE (HYDROCHLORIDE)	11,217	5,000	5,458
5.	STREPTOMYCINE	10,287	800	2,720
6.	ERYTHROMYCINE	4,500	2,000	951
7.	CHLORAMPHENICOL	6,000	N.A.	N.A.
8.	CEPHALORID INES	1,407	N.A.	365
9.	OTHER ANTIBIOTICS	3,866	562	1,164

### Statement showing the estimated requirements of

### antibiotics in Egypt and Sudan

(kg)

s no.	ANTIBIOTIC	EGYPT 1977 Tender	SUDAN 1977-78 Tender
		19// Tender	1711-10 1011001
1.	PENICILLINS	16,700-+	19,588
2.	AMPICILLIN	1,900	2,355
3.	OTHER SEMI-SYNTHETIC PENICILLINS	N.A.	N.A.
	TETRACYCLINE	53, 200	4,020
5.	ST REPTOMYCINE SULPHATE	51,200	8,000
6.	ERYTHROMYCINE	400	50
7.	OXYTETRACYCLINE	13,600	613

<sup>+</sup> PENICILLIN: 11,148 BOU + 1,125 kg Pen V + 9 t production of El Nasr.

D. Requirements of synthetic drugs

							LIBYAN			
		ŭ ŭ	EGVPF		El Nasr	IRAO	ARAB JAM.	SUDAN	FORECAST	AST
	1975	1975	1976	1977		1976/77	1976/77	1977/78	1979	1985
	1	5	3	4	5	9	7	8	6	10
SULFOWAMIDES AND OTHER										
ANTIINFECTIOUS AGENTS										
SULFANILAMIDE					9				50	25
SULFACETAMIDE / SODIUM-SULFAC.	11.9	20.5	8		6	4.5			100	135
SULFAGUANIDINE	41.1	43.1	8		100			37.7	100	150
SULFADIAZINE	39.7	28.6	100		250		1.5	68.8	250	300
SULFAMERAZINE	10.6	17.0	8		6			13	4	20
SULFAD EXIDINE	16.1	30.9	8		901		က	52.5	100	135
SULF AD IMETHOX INE							4	2.5	10	10 -
SULFAMETHOXAZOLE			4	5	8		0.8	0.5	25	65
PHTHALYLSULFATHIAZOLE	9.6	5.7		10			0.5	37.5	100	130
SUCCINYLSULFATHIAZOLE	3.9	3.4							25	40
SULFISOMIDINE	18.8	12.5							25	40
SUL <b>FATHIAZOLE</b>	2.9	1.9		N				18.5	0	
SULFISOXAZOLE	3.9	1.2	4						15	25
SULFAMETHIZOLE				<b>~</b>					8	30

		EGYPT	Į E		El Nasr	IRAQ	LIBYAN ARAB JAM.	SUDAN	FORECAST	AST
	1975 197	1975	1976 1977	1977		1976/77		1976/77 1977/78	1979	1935
	-	2	3	4	5	9	7	8	6	10
TRINETHOPRIM			0.1	0.1	4		0.02	0.1	5	15
CHLORAYPHENICOL			35			2.1	0.2	1.2	6	09
MALDIXIC ACD	3.1	1	4	3.1		0.01		0.01	10	50

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		EGYPT			El Nasr	IRAQ	LIBYAN ARAB JAM.	SUDAN	FORECAST	SAST	1 1
	1975	1975	1976	1977		1976/77	1976/77	1977/78	1979	1985	1
	-	2	3	4	۶	9	7	8	6	10	1
AMALGESIC, ANTIPYRETIC, ANTI-											
INFLAMMATORY AGENTS											
SALICYLIC ACID/SODIUM SALI-											
CYLATE	731.4	344.8		3263)		46.8	0.5	2.6	30	45	
SALICYLAMIDE	2.2	6.0	8	စ္က	501)	9.6			150	180	
ACETHYLSALICYCLIC ACID	210.6	139.81)	300	452	700	43.8	8.0	33.7	700	1000	
FARACETAMOL	25.8	10.3	20	112)	100	24.2	5.5	25.1	100	150	,
AHALGIN-DIPYRONE	316.3	174.2	250	265	200	2.5	10.0	0.5	0	0	<b>- 1</b> 3′
PROPYPHEN <b>AZONE</b>									200	750	7 -
A: INOPHENA ZONE				10.1			4	5.5	0	0	
CCDEINE-PHOSPHATE				1.4		0.2			5	7	
PHENYLBUTAZONE	12.7	15.2		11			0.3		20	09	
INDOMETHAZINE						0.02	0.1		ო	Ŋ	
IBUPROFENE	1.2	0.7		1.2			0.3		ო	'n	
OXYPHENBU <b>TAZONE</b>	3.2	1.8				0.8			10	15	
1) pregranulated only	2) micr	micronized o	only	σ,	) used a	3) used as raw material	erial				

		E CANDE	<b>F</b> -		El Nasr	IRAO	LIBTAN ARAB JAM.	SUDAN	FOX	FORECAST	1
	1975	1975	376	1977		1976/77 1976/77	1976/77	1977/78	1979	1985	ı
	1 1	2		4	5	9	7	æ	6	10	ı
DRUGS ACTING ON THE											
HERVOUS SYSTEM										ı	
GLUTETHIMID	0.9	0.3		1.0			0.0		က	'n	
CHLORBITTOL	2.7	4.0		2.8					10	15	
PUFNORABITONE	5.2	7.0	5.5	5.5				1.1	20	52	
RITTORARBITTONE (BUTALBITAL)	,			2.0				0.04	<b>~</b>	7	
21.1.OBARBITONE	1.0	0.7		0.				0.7	ന	'n	
CHIORPROMAZINE	0.7	9.0				0.1	0.05	9.0	C)	'n	_
DIAZEPAN	0.09	0.07	0.09	0.09			9.0		\$	0	138
MEDROBAMAT	16.0	9.7		16.0		0.7			20	25	
anicinas								m	'n	7	
MINISTER			4					20	3	35	
BENZOCAIN				10.3					15	50	

							LIBYAN				
		EG.	EGYPT		El Nasr	IRAQ	ARAB JAM.	SUDAN	FORECAST	AST	
	1975	1975	1976	1977		1976/77	1976/77	1977/78	1979	1985	
	-	2	က	4	5	9	7	8	6	10	1
CIRCULATORY AND VASCULAR DRUGS									,	!	
EPHEDRINE		4.3		(89)				0.15	9	15	
HEPTAMINOL	1.0	4.0		9.0					ဂ	4	
Agod Tyhten	4.1	1.9		14.3		1.0	0.7	0.5	50	30	
PRENYLAMINE LACTATE	0.5	0.2		0.5					α	ന	
THEOPHYLLINE	8.5	5.5		8.5					25	30	
AMINOPHYLLINE	5.5	5.8		5.0		8.0	0.1	0.12	50		- 13
DIPHYLLINE	6.0	2.7							15		39 -
NIKETHAMIDE	3.4	2.9		3.5				0.16	10	15	
CARDIAC DRUGS									•	•	
PHENYTOIN (SODIUM)				1.5		<b>8</b> .0		0.2	4	ς.	
LIDOCAIN	1.2	0.5							N	က	
PROCAINAMIDE				13		0.02			50	25	
PENTAERYTHRITÄYLTETRANITRATE	0.3	0.01							<b>-</b>	1.5	
PROPRANOLOL	0.3	0.1		0.2		0.02		0.005	~	1.5	

							LIBYAN				
			1	į,	Takk (a	TRAO	ARAB Jak.	SUDAN	FORE	FORECAST	
		IAX SS		1		1076/77	1076/77 1976/77	1977/78	1979	1985	
	1975	1975	1976	13//		17/0/6		α	σ	10	
	-	2	3	4	2		,	,			
OPTION TO DELIGS										;	
FILIDIABOLES COM	t c	•	0	19	8				8	8	
TOLBUTAMIDE	100		3			ď	6.0	0.2	10	12	
CHLORPROPANIDE	3.4	2.3		3.5			3		•	er)	
						0.005	5.0		•	)	
GLIBENCLAMIDE				(			7.5		0	0	
netformin	4.6	2.5		0							
S dinto mountain											
DIURETICS, AIFOLENSIVES	1	•				0.2	0.1	0.3	5	7	
FUROSEMIDE	0.7	•					•	6	67	<b>~</b>	
	8.0	0.7				0.2	•	3	•	-	
ACETAZODARIUB		•					0.01		က	140 'N	4:40
HYDROCHLOROTHIAZIDE	0	?							N	n –	٠
HYDRALAZINE	4.0	0.2									

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		: : : :	l.				LIBYAN			
		EGYPT	Ę.		El Nasr	IRAQ	JAK.	SUDAN	FOR	FORECAST
	1975	1975	1975 1976	1977		1976/77	1976/77 1976/77	1977/78 1979	1979	1985
	-	2	3	4	5	9	7	8	6	10
ATTIHISTAMINIC AGENTS										
DI PHENHYDRAMINE	1.7	4.		1.8		0.2	0.0		<b>1</b>	7
ANTAZOLINE	1.6	1.5		1.5					<b>1</b>	7
PHENYLTOLOXAMINE	0.3	0.3							-	1.5
CHLORPHENIRAMINE MALEATE	0.5	0.5				0.03	0.02	0.12	01	ന
NEPYRAMIN	4.0	0.2					0.1	0.05	N	m
MECLOZIN	0.9	0.3							ന	<b>ب</b>
DRUGS ACTING ON THE										- 14
PESPIRATORY TRACT GHATACOL GLYCERYL ETHER	1.2	1.1		0					9	1 -
CODEINE	1.6	0.3							4	ń

					:		LIBYAN			
		EGY	EGYPT		El Nasr	IRAQ	JAM.	SUDAN	FORECAST	AST
	1975	1975	1976	1977		1976/77	1976/77	1977/78	1979	1985
	1	C1	3	4	5	9	7	8	6	10
ANTITUBERCULOSIS AND										
ANTILEPROTIC DRUGS										
p. AMINOSALICYLIC ACID			8	43.7			3.0	19.0	80	100
ISONIACID	15.8	6.7	16		ß		0.1	0.15	100	100
ETHALBUTOL	1.3	0	က			1.5	4.0	0.3	10	12
THIACETAZONE	6.1	0		6.5		0.07		0.02	20	25
PYRAZINAMIDE				0		1.0		0.05	က	5
BENZOYL-PAS, Ca-Salt			8	9	200				200	142
DAPSONE	0.45	0.25		4.0		9.0	0.1	0.3	5	7
ANTIVALARIALS										
CHLOROQUINE PHOSPHATE	21.6	20.8	22				0.05	56.2	9	100
ANCDIAQUINE	0.3	4.0		0.3					<b>~</b>	7

		EGYPT	i k		El Nast	IRAQ	LIBYAH ARAB JAM.	SUDAN	FOR	FORECAST	
	1975	1975	1976	1977		1976/77	1976/77 1976/77	1977/78	1979	1985	ı
	-	2	3	4	5	9	7	8	6	10	1
ANTIDYSENTERIC, ANTIPROTOZOAL											
AND RELATED DRUGS											
DI-IODOHYDROXYQUINOLINE	31.7	20.3	8	×	8	4.5	<b>1.8</b>	15.0	(150)	(175)	
IODOCHLOROHYDROXYQUINOLINE	25.7	0.0	10	35	200				(200)	(250)	
METRONIDAZOLE	1.2	1.4		1.2		0.2	90.0	1.45	~	9	
FURAZOLIDONE				6.7					9	12	
BUTYL-5-CHLORO-SALICYLANID	9.0	0.2							e	<b>ا</b>	
ANTHELMINTICS											- 143
PIPERAZINE AND SALTS	18.7	17.2	22.9	19.1				1.0	9	150	3 -
NIRIDAZOLE								0.5	8	5	
NICLOSAMIDE								0.2	Ø	5	

							LIBYAN				ı
		į			TACK LE	TRAO	ARAB JAM.	SUDAN	FORECAST	AST	1
	250	1075	1976	1977	100 TO	1976/77	1976/77	1977/78	1979	1985	
	19/2	6	2/2	77	2	9	7	တ	6	10	1
	-	J	À								
VITAMINS									ç	Ş	
AXERCHIHOL AND ESTERS	9.3	4.7							2	} ;	
TAMINE	23.4	21.2	24			9.0	0.1	4.0	20	65	
	3.4	1.7				0.1		0.3	10	13	
ZIBOF LAVIN			11		8	0.8	9.0	1.5	100	130	
NICOTIN <b>AMIDE</b>	c • 95		5			Ċ	1,0	0.7	25	35	
PYRIDOXINE	7.9	6.3				•	; ;			Ç	•
ASCORBIC ACID			8			8.6	1.3		500	9	- 14
CATCIFERENCE	0.1	0.08							N	က	4 –
CALCAS ENOB	7	,							15	50	
D, LTOCOFEROL ACETAIN	*	ř							5	7	
PANTHOTHENOL	1.3	3.2						•	, ,	. <b>v</b>	
PANTHOTHENIC ACID (Ca-Salt)	4.3	2.6				<b>0.</b>		0.0	2	2	
ROBORANTS						`	•		Ę	150	
FERROUS GLUCONATE	48.2	52.4				e S	· -		3 1		
CALCTIM GLUCONATE				22					2	3	
	14.2	3.1		12					20	75	
Ca-GLYCEXOPHOS PRAIS		•				7.0			50	75	
Ca-LACTATE						2.			<b>`</b>		

							LIBYAN			
		EGY	GYPT		El Nasr	IRAQ	ARAB Jam.	SUDAN	FORECAST	AST
	1975	197	1976	1977		1976/77	1976/77 1976/77	1977/78	1979	1985
	-	1	3	4	5	9	7	3	6	10
WATER THREE THREE TONS										
									(V	ო
AMINOCAPROIC ACID									•	c
MARCUMAR (PHENPROCOUM)									-	<b>u</b>
STAGET SOLD						0.7	0.1		'n	10
	<b>4</b>	4.5							20	9
CHOLIN BITAKIKAIE		•							-	N
BENZYL NICOTINATE	•	0.003 0.008	·n							Ċ
COLAMINE				-					22	ç
CINCICLIBRATE A 1111 AS ASSESSMENTS A SE				20					30	4
DIMETRICIAL										-
										1

							TIBLYN				
		EGY	EGYPT		El Nasr	IRAQ	JAK,	SUDAN	FORE	FORECAST	ł
	1975	1975	1976	1977		1976/77	1976/77 1976/77	1977/78 1979	1979	1985	ł
	-	2	င	4	5	9	7	80	6	9	1
DISIMFECTANTS											
CHLORHEXIDINE	5.6	5.6				0.5			9	80	
DICHLOROPHEN	<b>6.</b> 0	2.6							15	ဗ္ဂ	
CETRIMONIUM BROMIDE (CETRIMID)	5.4	5.0		5.5					<b>52</b>	€.	
WETHYL PARABEN	4.3	2.3		4.5					10	<b>52</b>	
P-CHLORO-m-XYLENOL				3.0					10	15	
nitrofur <b>azone</b>				1.0					N	Ŋ	
CHEMICALS											- 1
TARTARIC ACID	147.5	84.2		280					450	700	46 -
CITRIC ACID				260	2000				2000	2000	-
GLUCOSE			850			8			1000	1500	
LEVULOSE				8					8	8	

# Appendix

#### ESTIMATED CONSUMPTION OF ESSENTIAL DRUGS IN ARAB COUNTRIES BY 1980 (Forecast by ACDIMA)

Particulars	Quantity (TONS)
Bensyl Penicillin and Semi- synthotic Penicillin (ampicillin)	100
Streptomycin	50
Tetracyclines	<b>5</b> 0
New Antibiotics	10
Citric acid anhydrous and citric acid monohydrate	2000
Ascorbio acid	1000
Paracetamol	100
Analgin	500
Acetyl Salicylic acid	700
Calcium Benzamide Salicylate	100
Sulphaguanidine	100
Sulphadimidine and Sodium	100
Sulphacitamide Sodium	100
Sulphadiazine	<b>25</b> 0
Sulphamerazine	40
Sulfamethoxasole	20
Isoniasid	100
Nicotinamide	100
Seniasid	50
Di-iodohydroxy Quinoline	150
Iodo hydroxy Quinoline	200
Glucose B.P. for injection	1000
Sodium Chloride for injection	1000
Ephidrine Hydrochloride	200

VII. SURPLUS FACILITIES AVAILABLE AT EL NASR P.C. CO., EGYPT AND S.D.I., IRAQ

#### A. Summary

According to a survey of the facilities available for the production of antibiotics at El Nasr P.C.Co., Egypt and S.D.I., Iraq, surplus facilities are available. These include a number of equipments suitable for the production of antibiotics and synthetic drugs and spare capacities of utilities. The surpluses are the result of partial utilization of fermentation facilities at both the plants. The equipments are in reasonably good condition and in the case of utilities, they are being used by rotation and form part of regular maintenance programme.

# B. Surplus equipment available at El Nasr P.C. Co.

s No.	PARTICULARS	QUANT ITY
1	Reactor for corn steep liq.	
	steel cap. 70 m <sup>3</sup>	1
2	Reactor for hydrol steel cap. 70 m <sup>3</sup>	1
3	Receiver steel cap. 500 lit.	1
4	Measuring tank 50 Lit. Steel	1
5	Reactor 250 Lit. steel	1
6	Measuring tank 300 Lit. st.	1
7	Measuring tank 500 Lit. St.	1
8	Measuring tank 300 Lit. steel	
9	Reactor 300 Lit. steel	1
10	Measuring tank 200 Lit. steel	1
11	Measuring tank 200 Lit. stainless steel	1
12.	Reactor 500 Lit. steel	1
13	Column for sterilization	1
14	Cooker 500 Lit. steel	2
15	Horizontal tank 12,000 Lit. Steel	1
16	Reactor 3000 litre stainless steel	6
17	Carbon filter Ø 350 steel	6
18	Carbon filter Ø 175 steel	2
19	Centrifugal pump 11 m <sup>3</sup> /h, 17 m C.I	2

<u>s 110.</u>	PARTICULARS	QUANT ITY
20	Rotary vacuum filter 2 m2 stainless steel	1
21	Receptacle 1500 Lit. steel	1
22	Receiver 10.000 Lit. steel	1
23	Plate and frame filter 84 m2 C.I.	1
24	Plate and frame press	1
25	Plate and frame press 84 m2, C.I.	1
26	Cooler, 20 m2 stainless steel	1
27	Cooler 3 m2, steel	1
28	Reactor 750 litre, steel	1
29	Filter Ø 300 steel	1
30	Centrifugal seperator 1500 L/h,	9
	stainless steel	
31	Receiver 1000 litre stainless steel	1
32	Centrifugal pump 0.3 m3/h, H=10 m steel	2
33	Centrifugal seperator 1500 L/h	3
	stainless steel	
34	Centrifugal pump 1 m3/h, H=30 m	2
35	Receiver 500 litre steel	1
36	Table 2000 x 1000, wood lined with	2
	iron	
37	Receiver 1000 litre, stainless steel	1
38	Centrifugal pump 5 m3/h, H=8 m	1
	stainless steel	
39	Holding tank 300 litre, steel enamel	1

S NO.	PARTICULARS	QUANTITY
40	Holding tank 300 litre, stainless steel	1
41	Holding tank 300 litre, stainless steel	1
42	Funnel receiver 200 litre, stainless steel	1
43	Holding tank 300 litre, stainless steel	1
44	Centrifugal pump 300 L/h H=10 m steel	2
45	Reactor 750 litre, stainless steel	1
46	Reactor 750 litre, stainless steel	1
47	Reactor 50 litre, stainless steel	1
48	Measuring tank 750 litre, steel	4
49	Receiver 750 litre, steel	1
50	Four steam jet ejector 5 kg/h, C.I.	3
51	Reactor 50 litre, st.st.	1
52	Reactor 100 litre, st.st.	1
53	Freon vapour - compression refrigeration machine 10,00 Kcal/hr,	1
54	Evaporator A = 35 m2	1
55	Centrifugal pump 9 m3/h, H=12 m C.I.	2
56	Ion exchange filter Ø 500, steel rubber lined	6
57	Resin ion exchange filter # 300 steel rubber lined	2
58	Film evaporator 1 m2, st.st.	1

S NO.	PARTICULARS	QUANT TI'Y
59	Five stage steam jet ejector kg of dry air/h. C.I.	2
60	Entrainment seperator Ø 150 st.st.	1
61	Measuring tank 200 litre st.st.	1
<b>6</b> 2	Measuring tank 200 litre st.st.	1
63	Resin ion exchange filter Ø 500 steel rubber lined	2
64	Resin ion exchange filter Ø 300 steel rubber lined	2
65	Receiver 500 litre st.st.	1
66	Receiver 250 litre st.st.	1
67	Measuring tank 500 litre st.st.	1
68	Receiver 200 litre st.st.	1
69	Condenser A=10 m2, st.st.	1
<b>7</b> 0	Receiver 250 litre st.st.	. 1
71	Measuring tank 200 litre st.st.	1
72•	Measuring tank 200 litre, st.st.	1
73	Resin ion exchange filter \$\overline{9}\$ 500 steel rubber lined	1
74	Receiver 250 litre st.st.	1
75	Receiver 250 litre st.st.	1
76	Reactor 300 litre, C.I. enamel	1
77	Measuring tank 60 steel enamel	1
78	Dissolving tank 25 lit. st.st.	1
79	Centrifuge Ø 600, steel rubber lined	1
80	Receiver 250 litre stainless steel	1

S NO.	PARTICULARS	QUANTITY
81	Receiver 50 litre st.st.	1
82	Pressure filter Ø 700 st.st.	1
83	Receiver 250 litre st.st.	2
84	Hood 1500 x 750 x 2000 st.st.	1
85	Reactor 50 litre stainless steel	1
86	Strainer 0.4 m2, st.st.	1
87	Measuring tank 50 litre st.st.	1
88	Reactor 250 litre st.st.	1
89	Measuring tank 200 stainless steel	1
90	Resin ion exchange filter	1
91	Receiver 250 litre st.st.	1
92	Receiver 500 litre st.st.	1
93	Receiver 4000 litre steel	1
94	Cation exchange filter Ø 1000 steel rubber lined	1
95	Amion exchange filter step 1 \$\varphi\$ 1000 steel rubber lined	1
96	Cation exchange step 11, Ø 1000 steel rubber lined	1
97	Anion exchange filter, step 77  ### 1000 steel rubber lined	1
98	Anion exchange filter # 1000 steel rubber lined	1
99	Filter # 1000 steel rubber lined	1
100	Receiver 4000 litre st.st.	e
101	Centrifugal pump 12 m3/h, H=16.8 m	2

S NO.	PARTICULARS	QUANTITY
102	Receiver 2000 litre, steel enamel	1
103	Measuring tank 100 litre steel	1
	ename 1	
104	Receiver 1000 litre, steel enamel	1
105	Receiver 2000 litre, steel enamel	1
106	Receiver 2000 litre, steel enamel	1
107	Receiver 2000 litre, steel enamel	1
108	Centrifugal pump 5 m3/h., H=30 m	1
	graphi te	
109	Receiver 1000 litre, steel enamel	1
110	Receiver 1000 litre, st.st.	1
111	Centrifugal pump 6 m3/h, H=18 m	1
	st.st.	
112	Reactor 1000 litre steel	1
113	Measuring tank 200 litre st.st.	1
114	Fermentor 10 L, st.st.	6
115	Reactor 100 litre st.st.	4
116	Reactor 500 litre st.st.	4
117	Carbon filter Ø 175 steel	4
118	Reactor 600 litre C.I. enamel	1
119	Plate and frame filter press, 56 m2	1
	C.I.	
120	Condenser 1 m2, stainless steel	2
121	Reactor 600 litre C.I. enamel	1
122	Centrifugal seperator 1500 L/h. st.st.	1

S NO.	PARTICULARS	QUANT ITY
123	Receiver 100 litre st.st.	1
124	Receiver 350 litre, st.st.	1
125	Receiver 300 litre enamel	1
126	Receiver 500 litre steel	1
127	Reactor 300 litre, st.st.	1
128	Reactor 50 litre, st.st.	• 1
129	Measuring tank 100 L, enamel	1
130	Ion exchange column Ø 100 glass	8
131	Measuring tank 150 litre st.st.	2
132	Measuring tank 50 litre st.st.	1
133	Vacuum evaporator 1 m2 st.st.	1
134	Holding tank 250 st.st.	7
135	Receiver 50 litre steel	2
136	4-stage steam jet ejector	1
	5 kg/of dry air/h, C.I.	
137	Hot well, 500 L, steel	1
138	Vacuum dryer A=26 m2, st.st.	1
139	Mixer for water and steam # 120 mm stainless steel.	1

# C. Surplus capacities of utilities available at El Masr P.C. Co., Revot

# UTILITY

Steam at 10.5 kg/cm<sup>2</sup>

Brine at 4°C

Compressed air at 1.6 kg/qm<sup>2</sup>

Industrial water in recyclic system (8 - 18°C)

Drinking water at 5 kg/cm<sup>2</sup>

Power

# SURPLUS CAPACITY AVAILABLE

5.5 tons/hr

50,000 k.oal/hr.

1,800 m<sup>3</sup>/hr.

20,000 k.oal/hr.

40,000 m<sup>3</sup>/month

6,000,000 K.W.H.

# D. Surplus facilities available at S.D.I., Samara, Iraq

#### 1. Permentation Equipment

Fermentors stainless steel 10N<sup>3</sup>

Capacity 7

Seed fermentors stainless steel 3M<sup>3</sup> capacity 7

Seed fermentors stainless steel 500 litre capacity 7

#### 2. Utilities

Steam at 9 kg/om<sup>2</sup>

10 tons/hr.

Refrigeration

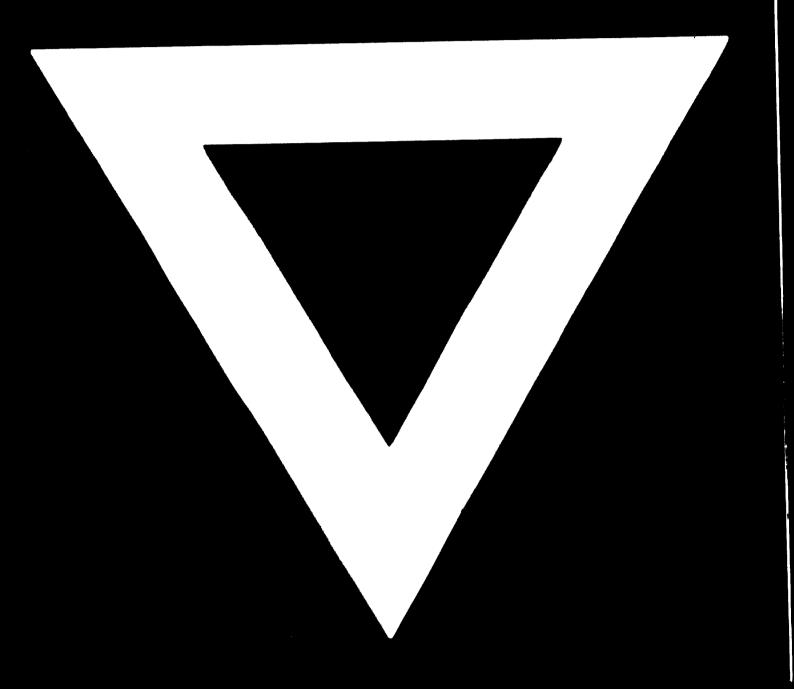
1,432,300,000 k.cals/year

Compressed air at 2 kg/cm<sup>2</sup>

5,027,500 m<sup>3</sup>/year

Drinking water

11,000 m<sup>3</sup>/day (now sold to Samara town) C-628



81.10.23