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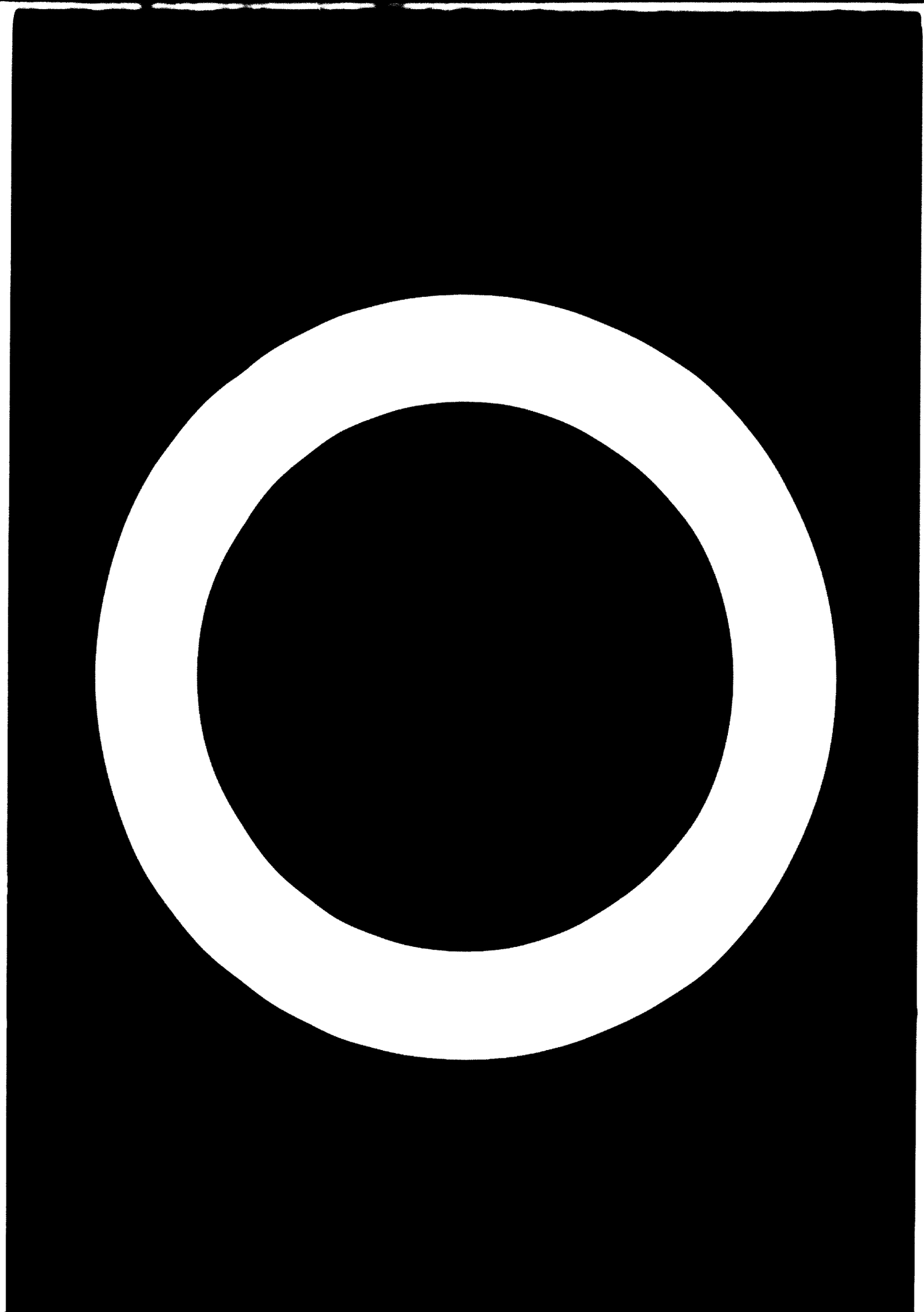
UNITED NATIONS INDUSTRIAL DEVELOPMENT ORGANIZATION
Vienna International Centre, P.O. Box 300, 1400 Vienna, Austria
Tel: (+43-1) 26026-0 · www.unido.org · unido@unido.org



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I. SUMMARY

A. PURPOSE AND SCOPE

The Government of Iran wishes to establish pharmaceutical industry sectors that will develop into viable enterprises and which will provide the type and quantity of pharmaceuticals needed to maintain a high standard of therapeutics. The United Nations Development Program (Special Fund), on the basis of a request from the Government of Iran, is carrying out a project entitled "Research Center for Industrial and Trade Development (UNDP/Special Fund Symbol IRA-107" The United Nations Industrial Development Organization (UNIDO) which is the executing agency for that project requested the assistance of Arthur D Little, Inc (ADL) in the preparation of a plan for the development of the pharmaceutical industry in Iran

The prime purpose of ADL's study is to undertake an exploratory study of those factors selected by UNIDO to describe the future direction the pharmaceutical industry in Iran should follow The basic objective of the study is to define and evaluate the current and anticipated pharmaceutical needs of Iran and to advise how best to service these needs

To answer this objective, we undertook the following tasks

(1) Assess realistically the therapeutic requirements of Iran (both human and veterinary) identifying specific types of pharmaceutical preparations needed to satisfy these requirements

(2) Suggest where appropriate a program of manufacturing as many as possible of the important pharmaceutical products considering economics of production scale, availability of raw materials and the utilization of multiproduct equipment

(3) Determine the feasibility of producing selected pharmaceutical products considering active ingredients as well as their formulation to finished products including required quality control procedures and good manufacturing practices

(4) Consider problems that might arise in Iran if domestic pharmaceutical production is to increase in importance

The ADL study was designed to provide a reference point in positioning the Government's planning so that only those studies considered essential for a ruling on the major points were undertaken The study was not designed to provide an in-depth analysis but to provide pertinent data to understand the

likely future pharmaceutical needs in Iran and to assess the opportunity for domestic pharmaceutical production to service those needs.

B. METHODS USED IN STUDY

To assess the major therapeutical requirements in Iran, we utilized the Government data, which provides a gross picture of the total demands. We also analyzed data in the United States for comparative purposes, but tempered our analysis to reflect local conditions in Iran.

We also obtained detailed specifications on the use of pharmaceuticals for the National Iranian Oil Company. This extensive description of pharmaceutical use for a selected population sample was very useful. We recognize that the oil company's data cannot be extrapolated for the total country, but did employ it to depict use of pharmaceuticals in Iran in what may be classified as an optimized environment. That is, the oil company provided the best health care for its personnel and its dependents free of charge. This information was very useful to project the demands in an optimized situation. It also gave us more definitive information on the incidence of disease and the pharmaceuticals used to treat the various conditions.

Through interviews with physicians, hospital administrators, pharmaceutical manufacturers, Government officials and practitioners in retail pharmacy, we developed sufficient information to structure an analysis of the Iranian pharmaceutical sales by therapeutic classification. This analysis represents manufacturers' sales of pharmaceutical products used in Iran. Although this classification does not reflect an exhaustive market survey, it represents the importance of various therapeutic classifications and as such proved a useful tool for our analysis.

We also recognized that not everybody in Iran receives health care and that even among those receiving health care, different groups will have different needs. This same situation exists throughout the world, however. Thus, we compared U. S. per capita expenditures for pharmaceuticals with those in Iran to get a better understanding of Iran's future needs. We also utilized the expenditures for the oil company personnel as a reference point in describing the current optimum situation in Iran. We analyzed the current use of pharmaceuticals and the therapeutic needs to develop our future forecast.

C. FINDINGS AND CONCLUSIONS

1. The volume of finished pharmaceuticals imported into Iran increased by about 50% from 1341* (1962) to 1345 (1966) but since that time has remained essentially constant at approximately 3000 million Rials* ($40 million) per year.

*See Appendix B for comparison of Iranian and Gregorian calendars and Iranian and U.S. currency.

2. In contrast to imported finished pharmaceuticals, local production of pharmaceuticals has climbed from 150 million Rials ($2 million) to 2200 million Rials ($29 million) during the period of 1341 (1962) to 1349 (1970).

3. Including additional pharmaceuticals imported by the National Iranian Oil Co., the Armed Forces, the Red Lion & Sun, and the Workers Social Insurance Organization the total 1349 (1970) consumption of pharmaceuticals is estimated to be 5370 million Rials ($71.1 million).

4. Continued population growth, increasing urbanization, rising national income, improving levels of education and literacy, and expanded medical services all indicate that the market for pharmaceuticals in Iran will continue to develop rapidly during the next 10 years.

5. The 1354 (1975) Iranian pharmaceutical market is estimated at between 8600 million Rials ($115 million) and 9500 million Rials ($125 million). The corresponding estimates for 1359 (1980) are between 13,900 million Rials ($185 million) and 16,700 million Rials ($220 million).

6. While increased requirements can be met by increasing levels of imports, it would be preferable to meet these increased requirements through domestic production. Domestic industry has the following advantages for Iran:

- Pharmaceutical formulation industries normally have a very high national benefit ratio in developing countries, with typical ratios of gross benefits to cost of from 2:1 to 6:1. In other words, the national resources employed in pharmaceutical formulation produce from 100% to 500% more national income than they formerly produced.

- Local production of pharmaceuticals saves foreign exchange.

- Local production gives rise to other industries and gives additional training and opportunity for Iranian manpower.

7. The current total investment in pharmaceutical production facilities is estimated to be approximately 2,000 million Rials ($26.5 million). At present this investment is producing over 2,000 million Rials of pharmaceuticals but ultimate production should reach 6,000 million Rials. The industry could thus supply 90% of the 1351 (1972) requirements of Iran, but only about 40% of the estimated 1359 (1980) requirements.

8. Additional investment of approximately 2,500 million Rials ($33 million) will be required for expansion of present plants and for additional new plants to satisfy 90% of 1359 (1980) pharmaceutical demand.

9. To satisfy the requirements through domestic production, action is needed by both government and industry.

10. To satisfy the 1359 (1980) pharmaceutical requirement, 57 products in 10 categories have been selected for possible formulation. Most of these products are at present being manufactured in Iran and the others could be manufactured in the type of equipment now installed in Iran.

11. Many active medicinal ingredients are required in small volume in Iran and basic manufacture of individual ingredients is not economically feasible.

12. Synthetic organic medicinal ingredients may be made in a multi-purpose plant that could make several medicinal ingredients.

13. An impediment to the establishment of a multi-purpose medicinal plant is the profit limit of 12% on capital because the same type of plant could be used to make other materials which are not under profit control.

14. If the government can offer encouragements to the industry, a multi-purpose plant to manufacture simple organic chemical medicinals warrants a detailed feasibility study. Preliminary suggestions for the plant layout and operation have been made.

15. A pharmaceutical formulation plant to combine existing governmental production units has been described.

D. RECOMMENDATIONS

On the basis of our study we make the following four major recommendations:

1. The Iranian government *should not* erect government plants to produce the large requirements of pharmaceuticals needed in the coming decade.

2. The government *should* encourage private industry to invest in the required plants and plant expansion needed to meet Iran's pharmaceutical needs.

3. A detailed feasibility analysis of the suggested multi-product medicinal ingredient plant should be made to select the products to be manufactured and to select the most suitable companies for its operation.

4. If the government desires to continue its small scale pharmaceutical manufacturing operations, they should be combined in a well-run plant employing good manufacturing practices and optimum quality control following procedures recommended by the World Health Organization (WHO).

In addition to the major recommendations, the following recommendations are suggested to help meet Iran's future pharmaceutical needs.

- Industry and government must cooperate to insure the production of pharmaceuticals that are equivalent to those previously imported.
- Good manufacturing practices and excellent quality control procedures must be established by industry and monitored by government.
- Industry and government should cooperate to counteract counterfeiting and smuggling.
- Government should streamline plant licensing procedures to avoid costly delays in putting plants into effective production.
- Government should continue to monitor prices, but should not be as deeply involved in setting prices for individual dosage forms.
- The government should establish an effective plant inspection group and improve the government pharmaceutical testing laboratory.
- Government should simplify import licensing and control procedures to speed up delivery of raw materials and thus reduce the required inventories.
- Government should decrease some of its present regulation of the production of pharmaceuticals, but increase control of certain aspects of the dispensing of pharmaceuticals to the public.
- Development programs should be initiated by industry to improve formulations, containers, packaging, labeling, and distribution methods to produce products better suited to the climate of the country and the needs of the people.

II. THE PHARMACEUTICAL INDUSTRY IN A DEVELOPING COUNTRY

A. GENERAL DESCRIPTION OF THE PHARMACEUTICAL INDUSTRY

For the purposes of this report it is not desirable to present an exhaustive description of the pharmaceutical industry, but the following brief description will serve to clarify terminology.

In talking about pharmaceuticals, we are emphasizing that activity which makes available a stable, useful dosage form of an active therapeutic substance. The main function of the pharmaceutical industry is to provide the delivery of the therapeutic substances. We emphasize this distinction to contrast the pharmaceutical industry with the chemical industry whose function is to synthesize various chemicals which may be useful in a variety of applications. It is true that the pharmaceutical industry may integrate vertically and become involved in the synthesis of active ingredients, but its major function is to prepare the tablets, injectables, ointments, capsules, etc. to provide what is needed, where it is needed, when it is needed.

The production and sale of pharmaceuticals may be outlined as a series of four steps:

1. *Research and Development:* New drugs are discovered and developed by research laboratories (principally those of the pharmaceutical industry itself but also those of government and educational institutions). After clinical trials and government approval the drugs are ready for general production and sale.

2. *Manufacture of Active Ingredients:* At this stage, the basic active drugs used in medicine are produced in bulk. These drugs can be categorized according to their principal ingredients as follows:

   (a) medicinal chemicals (such as aspirin and anthelmintics), inorganic chemicals (such as magnesium sulfate), fermentation products (such as penicillin and tetracycline), botanicals (such as quinine), and drugs from animal sources (such as insulin).
   (b) biological products, including vaccines (such as smallpox vaccine), toxoids (such as tetanus toxoid), serums (such as tetanus antitoxin), and products from the human blood (such as plasma).

3. *Formulation and Packaging:* The basic drugs which are manufactured in bulk are formulated into various dosage forms such as tablets,

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ointments, syrups, lotions, injectable solutions, etc. that can be taken by patients easily and in accurate amounts. The formulated products are packaged in appropriate containers.

4. *Pharmaceutical Marketing:* Pharmaceutical advertising and market promotion for a given product are aimed at physicians and pharmacists when the product is dispensed principally by medical doctors or by a pharmacy on a doctor's prescription. When the product is a home remedy that is usually purchased by the consumer without consulting the physician, advertising and promotion are also aimed at the general public.

The larger, established pharmaceutical companies engage in all four functions – research, manufacture, formulation, and marketing – although these may be carried out by separate divisions, often located many kilometers apart. Other companies, however, specialize in only one phase, such as manufacturing medicinal chemicals in bulk or formulating pharmaceutical products from purchased raw materials.

B. DEVELOPING COUNTRIES

1. Development of the Product Line

In any country desiring to produce its own products, the first pharmaceutical ventures usually involve the third and fourth steps listed in Section A: formulation and marketing. Manufacture of active ingredients is only added when a substantial market is assured. The formulation and marketing functions allow the greatest return on investment and greatest value added in the total four-step procedure. The research and development phase usually is undertaken only when the industry is well established because cost of research and development and risks of research failures can only be supported from an ongoing, profit-producing operation.

In the initial stages of industry establishment, steps one and two are normally supplied by licensors or joint venture partners.

In considering the type of products that can be most advantageously produced by a new venture it is readily apparent that tablet formulation is a practical initial phase. An embryonic pharmaceutical industry, especially in a developing country, typically begins by formulating tablets. Not only are tablets the most widely used method of administering medicines, but they can be produced by relatively simple processes. Tablets are made by compressing solid medicinal substances into shape. Sometimes the only substance in the tablet is

the active ingredient itself. In other tablets an inert substance such as lactose is added to the formula to bring the tablet up to a convenient size and weight. Other ingredients may be added to cause the tablet to disintegrate more rapidly when it is acted upon by the gastric juices. Some tablets are coated with sugar, gelatin, or a dispersible plastic to mask the unpleasant taste or odor of the medicine, to protect the ingredients against air and moisture, and/or to control the site of disintegration. Any of these processes can be adapted and used in a newly established venture.

Ointments and oral liquids such as cough syrups can be easily included in the product line if market conditions are favorable. Later, nasal solutions and ophthalmic solutions can be added, because they may be produced under "semi-sterile" conditions with antiseptic ingredients added to inhibit microbial growth.

Plants for sterile production of injectable pharmaceuticals are more costly, more complex, and difficult to run. These plants require much more extensive laboratory testing procedures including microbiological and animal test methods. Moreover, the market for sterile products may not be large enough to support many firms in the economical production of these pharmaceuticals. Consequently, such products are the last to be incorporated into a pharmaceutical product line.

2. Regulation of the Pharmaceutical Industry

The production and sale of pharmaceuticals have become increasingly regulated in recent years.

Regulation is both internal – by the company itself, and external – by trade associations, pharmacopoeia organizations, and government agencies. In the United States the principal interest of the government has been the safety and efficacy of the pharmaceuticals. Accordingly, only the very earliest research investigations may be done without involving participation of the Food and Drug Administration. From that stage through all other phases of research, development, active ingredient production, formulation, packaging of products and marketing, the government exercises strong controls.

In many countries, prices are determined by the manufacturers in a free market. In other countries varying degrees of price fixing by the government are employed.

In developing countries, regulations are usually imposed at a very early stage in the industry's development. Often, however, these regulations are overly restrictive and as a result they impede the development of the industry.

III. CONSUMPTION OF PHARMACEUTICALS IN IRAN

A. PRESENT CONSUMPTION OF PHARMACEUTICALS

1. Imported Pharmaceuticals

Several groups both inside and outside the Iranian government have attempted to gather exact data on imports of pharmaceuticals into Iran. Each group has had the same difficulty – the import figures include within individual import classifications not only finished pharmaceuticals in consumer packages but also active ingredient raw materials, inactive raw materials, and packaging materials that are destined for local production of the pharmaceuticals. The older import figures mainly represented finished pharmaceuticals, but in recent years the figures have reflected an increasing but unrecorded content of materials destined for local Iranian production. In one attempt to overcome this difficulty, the Plan Organization estimated the percentage of imported materials used by local manufacturers and, from the figures on local production, calculated a correction figure. This correction figure was subtracted from the import figures to give an estimate of finished pharmaceutical imports. The volume of locally produced pharmaceuticals was then added to obtain a total for pharmaceuticals available in Iran.

Additional import classification categories would permit the figures for finished pharmaceutical products to be obtained directly. Although this suggestion has been made, it has not been implemented. ADL therefore has also made estimates to correct the import figures and thus avoid double counting materials going into local production.

Interviews by ADL also disclosed that some organizations import pharmaceuticals into Iran under conditions that may result in no record of these imports in the usual import statistics. ADL believes that the following organizations import pharmaceuticals that have not been reported, or not completely reported, in import statistics: (1) Iranian Armed Forces, (2) National Iranian Oil Company (N.I.O.C.), (3) Red Lion and Sun, and (4) Workers Social Insurance Organization (W.S.I.O.).

While the armed forces obtain some of their pharmaceuticals through the Imperial Iranian Pharmaceutical Institute, the large majority apparently is imported directly without customs duties and without records being made by the customs services. ADL attempted to obtain the total value of pharmaceutical imports by the armed forces but was requested by them to estimate these figures. We have done this on the basis of the estimated number of men in the armed services plus an equal number of dependents and have assumed a per capita pharmaceuticals cost of 225 to 265 Rials ($3.00 to $3.50). *The Economist* of October 31, 1970, estimated the total manpower of the Iranian

Armed Forces at 166,500. With dependents, ADL estimates that medical coverage is extended to approximately 350,000 persons. At 225 Rials ($3.00) per capita the pharmaceutical purchases of the Armed Forces would be approximately 80,000,000 Rials ($1,050,000) and at 265 Rials ($3.50) the corresponding cost would be approximately 93,000,000 Rials ($1,220,000).

In 1969 the N.I.O.C. imported approximately 38,000,000 Rials ($500,000) of pharmaceuticals and the Red Lion and Sun imported approximately 58,000,000 Rials ($770,000) of pharmaceuticals. Neither of these organizations pays any import duties and the sums apparently are not recorded in the import statistics.

In 1969 the W.S.I.O. purchased 100,000,000 Rials ($1,320,000) of pharmaceuticals of which approximately 35,000,000 Rials ($465,000) were imported directly without duties. Again, this group of pharmaceuticals apparently may not be counted in imports.

Imports reported by the Ministry of Finance are shown in Table III-1.

TABLE III-1
PHARMACEUTICAL IMPORTS* INTO IRAN BY YEAR
(in thousands of Rials)

Year		Value
Persian	Gregorian	
1341	1962/3	1,967,930
1342	1963/4	2,100,364
1343	1964/5	2,401,918
1344	1965/6	2,919,080
1345	1966/7	3,177,645
1346	1967/8	3,322,590
1347	1968/9	3,361,445

*Does not include direct imports by Iranian Armed Services, N.I.O.C., Red Lion and Sun, and W.S.I.O.

Sources: Yearbooks, 1341 to 1347, Foreign Trade Statistics of Iran, Bureau of Statistics, Ministry of Finance.

2. Locally Produced Pharmaceuticals

At present the majority of the products on the pharmaceutical market in Iran are supplied by imports, but an increasing portion of the market is supplied by local production. Although there are a large number of small manufacturers, the major production is supplied by 16 larger pharmaceutical plants. Most of these 16 have been established in the past ten years and have strong technical and/or financial connections with international pharmaceutical companies.

Data on the individual large plants are listed in Table III-2. Iranian production by these plants was 751 million Rials ($10 million) in 1346 (1967/68) and 1269 million Rials ($16.8 million) in 1347 (1968/69). Taking into consideration the size of the new plants and start-up problems, ADL estimates that 1348 (1969/70) production and 1349 (1970/71) production will be approximately 1550 million Rials ($20.5 million) and 2000 million Rials ($26.5 million), respectively.

3. Total Present Consumption of Pharmaceuticals in Iran

As noted in Section A. 1, the finished pharmaceuticals imported by Iran may be estimated by subtracting the estimated raw material consumption of the local pharmaceutical manufacturers from the import figures. For this purpose we have assumed that the raw materials and packaging materials imported for local production of pharmaceuticals are equal to 30% of the total value of local production. Local production estimates for the years 1341 to 1345 (1962 to 1966) are from the Plan Organization and those for 1346 to 1349 (1967 to 1970) are by ADL. The latter figures are based on the production of the 16 large manufacturers and an estimate that these 16 are now making about 90% of the Iranian production in terms of monetary value.

Estimates of the total value of finished pharmaceuticals, both imported and locally produced, are given in Table III-3. The 1349 (1970) total of 5200 million Rials ($68.9 million) does not include an estimated 166 million Rials ($2.2 million) imported by the Armed Forces, the N.I.O.C., the W.S.I.O., and the Red Lion and Sun. The 1349 total would therefore be approximately 5370 million Rials ($71.1 million).

From the figures in column (e) of Table III-3, it is apparent that the annual rate of growth of total pharmaceutical products from 1341 (1962) to 1349 (1970) was 12%. The rate for the last five years, 1344 (1965) to 1349 (1970), has been at a slightly lower but constant rate of 10.8%.

TABLE III-2
INVESTMENT AND SALES DATA ON LARGE PHARMACEUTICAL PLANTS IN IRAN
(in millions of Rials)

Name of Firm	Investment			Sales	
	Total	Equipment and Machinery	Year of Start-up	1346	1347
Bayer Pharma Iran	80		1340	60	68
Berlimed Iran	72		1340		
Cyanamid – KBC	167	24	1345	128	133
Darou-Pakhsh	768*	84	1342	223	274
Dan Baxter Iran	20			80	80
Deper	12				80
Iran Hoechst	75	26	1347		
Iran Merck	60	10	1340		
Iran Organon	80	17	1346	32	80
Lapetit Iran	76			70	76
Parke-Davis	60	23	1347		165
Pfizer Iran	45	24	1346		200
Sanofi-Pars	260*	16	1342	20	40
Squibb & Sons of Iran	60	12	1347		
Tehran Chimie	60	15	1340		
Tofidaru	100	105		100	100
Totals	2020			751	1200

*ADL believes these figures may include some non-pharmaceutical investments.

Source: Dr. Alavi, Research Centre for Industrial and Trade Development, Ministry of Economy.

TABLE III-3

PHARMACEUTICALS IMPORTED* AND LOCALLY PRODUCED IN IRAN
(in millions of Rials)

Year		(a) Imports of Pharmaceuticals and Raw Materials	(b) Local Production	(c) Raw Materials for Local Production (0.30b)	(d) Finished Pharmaceutical Imports (a-c)	(e) Total Pharmaceuticals (b+d)
Persian	Gregorian					
1341	1962/63	1988	150	45	1940	2090
1342	1963/64	2100	160	48	2050	2210
1343	1964/65	2482	210	63	2420	2640
1344	1965/66	2919	300	90	2830	3130
1345	1966/67	3178	600	180	3000	3600
1346	1967/68	3223	900	270	2970	3870
1347	1968/69	3901	1400	420	3480	4880
1348	1969/70	(3990)	1700	510	3480	4700
1349	1970/71	(3700)	2200	660	3040	5200

*Does not include direct imports of Iranian Armed Services, W.S.I.O., N.I.O.C., and Red Lion and Sun.

Sources: Imports from 1341 to 1347 from Yearbooks, Foreign Trade Statistics of Iran, Bureau of Statistics, Ministry of Finance. Years 1348 & 1349 – Arthur D. Little, Inc. estimates.

Local Production 1341 to 1345 from "Report on the Pharmaceutical Industry" by Tamara Jamiseddh of the Plan Organization and 1346 to 1349 are Arthur D. Little, Inc. estimates from UNIDO data collected by Dr. Atavi.

B. SUPPORT FOR FUTURE MARKET FOR PHARMACEUTICALS

In general, the demand for pharmaceuticals in Iran will increase because of increases in population, urbanization, income and levels of education, and because of improvements in health care delivery.

1. Population Trends

The determination of population trends in Iran has been complicated by the fact that only two censuses of population have been held: the first in 1335 (November 1956) and the second in 1345 (November 1966). The 1335 population was given as 18,954,704 and the 1345 population was listed at 25,781,090. If both of these figures are correct, the annual population increase was approximately 3.1%. However, there is general agreement that the first census understated the population of Iran because of the difficulty in counting many of the nomadic people and people in remote areas. It is felt that the second census is more nearly correct, but it also might be slightly low for the same reasons.

The uncertainty of the two census figures has led to considerable variances in the assumed populations for these two periods and corresponding differences in figures for annual population increase. The "Fourth National Development Plan" (published in 1968) quotes a figure of 2.6%, while more recently many of the government agencies have been using a figure of 2.82% per annum. The Iran Statistical Center in the Plan Organization has used a growth rate of 1.3% in projecting population figures to 1349 (1970). See Table III-4.

We have projected Iranian population at 2.82%, 3.0% and 1.3% (Figure III-1). In this report we use the projection based on 2.82%, which is the figure currently used by the Ministry of the Economy. It is our impression that this rate is conservative and the other population figures are used to give upper limits to figures based on per capita consumption of pharmaceuticals.

Despite the different growth rates, two facts stand out. First, the population is increasing substantially. Second, a high percentage of the 1345 population - 55% according to the Iran Statistical Center - was in the 0-14 year age group. Since the population is young, and since better health care has lowered the death rate, a high growth rate may be anticipated for several years to come before birth control programs have a significant effect.

2. Urbanization

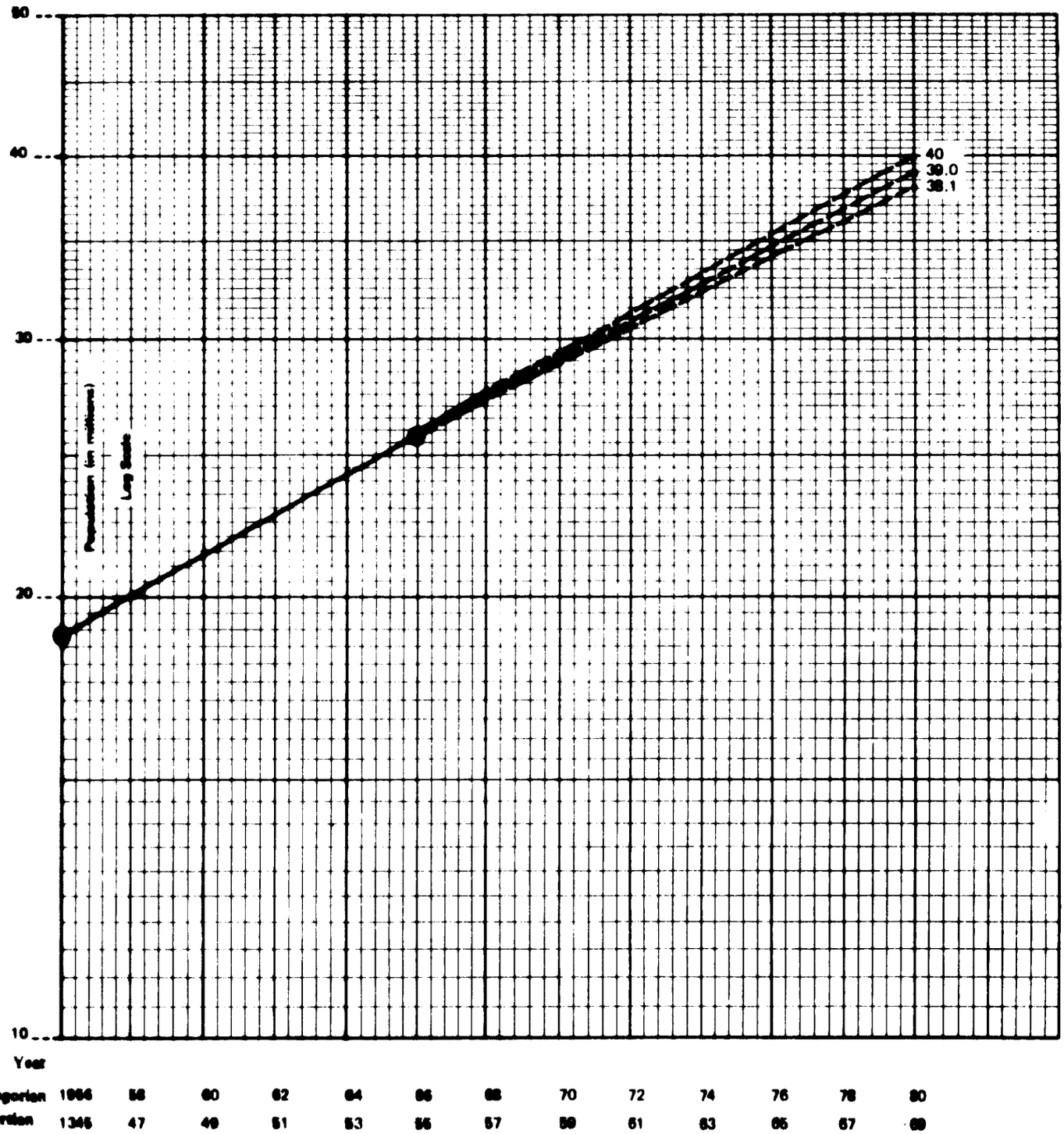
At the time of the 1335 (1956) census, the urban population made up only approximately 29% of the total population. In 1345 (1966) the urban

TABLE III-4

ESTIMATED POPULATION OF IRAQ FROM 1952 TO 1969 (1953 TO 1970)
(In thousands)

Year		Both Sexes	Male	Female
1952	1953	[illegible]	[illegible]	[illegible]
1953	1954	[illegible]	[illegible]	[illegible]
1954	1955	[illegible]	[illegible]	[illegible]
1955	1956	[illegible]	[illegible]	[illegible]
1956	1957	[illegible]	[illegible]	[illegible]
1957	1958	[illegible]	[illegible]	[illegible]
1958	1959	[illegible]	[illegible]	[illegible]
1959	1960	[illegible]	[illegible]	[illegible]
1960	1961	[illegible]	[illegible]	[illegible]
1961	1962	[illegible]	[illegible]	[illegible]
1962	1963	[illegible]	[illegible]	[illegible]
1963	1964	[illegible]	[illegible]	[illegible]
1964	1965	[illegible]	[illegible]	[illegible]
1965	1966	[illegible]	[illegible]	[illegible]
1966	1967	[illegible]	[illegible]	[illegible]
1967	1968	[illegible]	[illegible]	[illegible]
1968	1969	[illegible]	[illegible]	[illegible]
1969	1970	[illegible]	[illegible]	[illegible]

Source: Iraq Statistical Center



Source: Extrapolation by ADL. 1345 and 1355 population figures from Iran Statistical Center.

FIGURE III-1 IRANIAN POPULATION EXTRAPOLATED AT RATES OF 2.82%, 3.0%, AND 3.2%

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population had risen to 38% of the total. The Plan Organization has projected an urban percentage of 43% for 1351 (1972). We estimate that by 1359 (1980) 50% of the population will be settled in urban areas. City dwellers, of course, have greater access to and make greater use of medical services, both government and private, and are reached much more easily by the pharmaceutical distribution system.

3. National and Per Capita Income

In countries where a government provides very little in the way of medical care or pharmaceuticals to its population the level and distribution of individual income is a very important factor in drug purchases. In Iran, however, where many medical services are provided by the government, the national income provides one important index for the ability to purchase pharmaceuticals. Although many rural areas in Iran have a per capita income of less than 4,000 Rials per year, these people increasingly are cared for by the Health Corps and other health centers. Accordingly, they will consume more pharmaceuticals than would be indicated by their low income level. (Table III-5). Moreover, the national income (at constant price) is expected to increase at a rate of approximately 10% per year, a growth rate we believe to be realistic, especially in view of the fact that oil revenues are expected to increase during the coming year (Table III-6).

4. Educational Level and Literacy

His Imperial Majesty the Shahanshah Aryamehr has taken strong action to improve the educational level and literacy level of the entire country. Not only has the number of children going to regular schools increased, but a Literacy Corps has been formed to operate in rural areas which have been traditionally lacking in school systems and National Anti-Illiteracy Committees have been formed to operate in urban centers and selected rural areas.

In 1337 (1956) only 14.9% of the population was literate as contrasted to 28.1% in 1347 (1966). By the end of the Fourth Plan in 1351 (1972) more than 30% of the total population and more than 50% of the urban population are expected to be literate. As Table III-7 indicates, the number of pupils in the primary grades is expected to more than double in the ten-year period from 1341 to 1351, while the number of pupils in the secondary schools is expected to quadruple. Although numerical ratios relating educational level and consumption of pharmaceuticals have not been demonstrated, past experience indicates that as the educational level of the population rises, and literacy increases, more people will recognize the importance of modern medical treatment and the role of pharmaceuticals in good health programs.

TABLE III-5
PAST AND PROJECTED PER CAPITA INCOME
IN RIALS AND U.S. DOLLARS BY YEAR

Year		Per Capita Income	
Persian	Gregorian	Rials	U.S. Dollars
1340	1961	14,570	193
1341	1962	14,647	194
1342	1963	14,949	198
1343	1964	16,336	269
1344	1965	16,469	218
1345	1966	17,440	231
1346	1967	18,990	251
1347	1968	19,930	264
1349	1970 (Projected)	22,650	300
1354	1975 (Projected)	31,710	420
1359	1980 (Projected)	43,790	580

Source: Ministry of Economy for years 1340 to 1347
Projections for 1349 (1970), 1354 (1975) and 1359 (1980) by Arthur D. Little, Inc.

TABLE III-6

NATIONAL INCOME AT CONSTANT PRICE
(In Billions of Rials and U.S. Dollars)

Year			Income	
Persian	Gregorian		Rials (Billions)	Dollars (Billions)
1340	1961		322.6	4.27
1341	1962		332.9	4.41
1342	1963		350.6	4.64
1343	1964		370.2	4.90
1344	1965		408.8	5.41
1345	1966		445.3	5.89
1346	1967		460.3	6.01
1347	1968		549.5	7.28
1349	1970	Projected	670.8	8.87
1354	1975	Projected	1070.8	14.23
1359	1980	Projected	1730.8	22.83

Source: Ministry of Economy for years 1340 to 1347
Projections for 1349 (1970), 1354 (1975) and 1359 (1980) by Arthur D. Little, Inc.

TABLE III-7

PAST AND PROJECTED NUMBER AND DISTRIBUTION OF PUPILS IN IRAN
(in thousands)

Year						
Persian	Gregorian	Kindergarten	Primary	Secondary	Vocational	Higher Education
1341/42	1962/63	13	1710	336	9	25
1346/47	1967/68	16	2900	696	17	36
1351/52	1972/73	20	3720	1368	50	60

Source: Plan Organization

5. Health Care Systems

To determine the market for pharmaceuticals it has been necessary to study in depth the delivery system of health care in Iran and the plans for such systems. Only through a full understanding of to whom, how and where health care is delivered can such an assessment be made.

a. The Rural Population

More than 16 million Iranians live in a rural setting scattered through an area of over 1.5 million square kilometers. Only 250 of their 54,000 villages have populations ranging between 2500 and 5000. About 38,000 villages have populations of less than 250.

It has not been possible to provide health care at every one of these villages. The distances involved, the sparse population, difficulty of access, inadequate housing, low socio-economic levels and other considerations made it unattractive for physicians to settle there. Furthermore, even if a physician were stationed in a village the people in the outer areas of the district served by the village would still have difficulty reaching him. When clinics were established it was noted that patient visits are in inverse ratio to distances from the clinics. Patients living far from these clinics would visit them only when acutely ill. The solution was to make health-care services mobile.

b. The Semi-urban Industrialized Areas

Throughout Iran, industrial and other organizations employing large numbers of workers have established their own medical services. These services operate hospitals and clinics for the benefit of employees and dependents as a result of special arrangements between these industries and the Workers Social Insurance Organization. Typical examples of such organizations are: The National Iranian Oil Company, the Shapour Chemical Company, the National Gas Company, the Khuzestan Water and Power Company, and the Sugar Company. These services provide high-quality medical care for a "population" of possibly 300,000. Within each organization, the number of people served will tend to remain fairly constant. New industries, such as the steel mill now nearing completion in the vicinity of Esfahan, will require the establishment of new services.

Complete information has been obtained from the National Iranian Oil Company, the largest of these organizations, regarding their operations in Khuzestan and Teheran.* Their services are free, including the provision of

*See Acknowledgement Page

drugs. About 95% of the drugs they dispense in the Abadan area are imported from abroad free of duties. On the basis of the Company's figures the cost of pharmaceuticals per person amounts to 260 Rials per year or a total expenditure of approximately 80 million Rials per year for all such organizations.

c. The Urban Setting

Approximately 10,000,000 Iranians live in urban areas. The various medical services available to them can be divided into:

(1) Hospitals and clinics of the Workers Social Insurance Organization

(2) Hospitals and clinics of the Red Lion and Sun Society

(3) Clinics and hospitals of the Ministry of Health

(4) The Armed Forces hospitals and clinics

(5) Medical services in University-operated facilities

(6) Private facilities where patients can obtain care through direct payment or third-party insurance coverage.

Serving this population and the population in semi-urban and rural areas are several medical services. These are described briefly in the following sections.

d. The Health Corps

In January 1964, His Imperial Majesty, the Shahanshah, established the Health Corps by Imperial Decree.

This decree established "teams" of physicians, pharmacists, dentists, and university graduates in social sciences as well as secondary school graduates surplus to Army requirements. These teams are dispatched to remote areas where no medical care is available. They are based, for 18-month terms, in village clinics but also serve peripheral health units in other villages two or more days a week.

In 1964, more than 2000 professionals served in the Health Corps, giving 25% of the rural population access to "health care". By 1967, 45% of this rural population had access to health care through the Health Corps. Today, there are more than 400 Health Corps teams and the objective of the present 4th Development Plan (1968-1973) is to bring health care to 65% or even 70% of the rural population.

This extension of health services will increase the quantity of drugs dispensed by the Health Corps. Health Corps data indicates 8 visits per day per 1000 population or 2.9 visits per person per year at an average cost of 26 Rials of drugs per visit. On this basis, extension of health care services will increase Health Corps drug expenditures from 570 million Rials to 830 million Rials by March 1973. Over the longer term, the increase will be even greater since the annual expenditure per person covered per year will probably reach a minimum of 76 Rials. At present only about 20% of these drugs is imported directly or indirectly.

e. The Imperial Organization for Social Services

This charity organization was established by an Imperial Decree of the Shahanshah in April 1947. As part of its numerous charitable activities, the Imperial Organization for Social Services operates more than 250 dispensaries in isolated larger villages, providing outpatient care and in some cases limited in-patient treatment (see Figure III-2). Several modern hospitals in larger cities are also operated by the Organization. The dispensaries are generally comprised of three buildings: one for the care of patients, one for the residence of the physician, and one for housing the staff. Coordination between the Imperial Organization and the Ministry of Health through the Chief Public Health Officer in each Ostan (province) prevents duplication of services in villages. The dispensaries treat about 4,300,000 patients per year and the hospitals over 37,000 in-patients. Outpatients who can afford it pay 10 Rials per visit, which includes the cost of drugs prescribed.

The Organization plans to increase the number of clinics, add new programs such as Family Planning, and improve the quality of care provided. The implementation of these plans will increase the consumption of drugs. It is estimated that the drugs dispensed cost 30 Rials per clinic visit, or a total cost of 130 million Rials last year. These expenditures are expected to increase at least 15% per year. Only 15-20% are imported directly or indirectly. The cost of drugs for in-patient services is estimated to be 60 Rials per day per patient, or about 22 million Rials per year. This value will tend to remain constant unless new hospitals are built.

f. The Workers Social Insurance Organization

In Iran the Workers Social Insurance Organization provides direct and indirect medical care to nongovernment workers and dependents. Through a system of contributions from the employees, the employers, and the Government, the WSIO provides care at 56 hospitals and 143 outpatient clinics that they operate. In addition, through contract arrangements, care is provided to

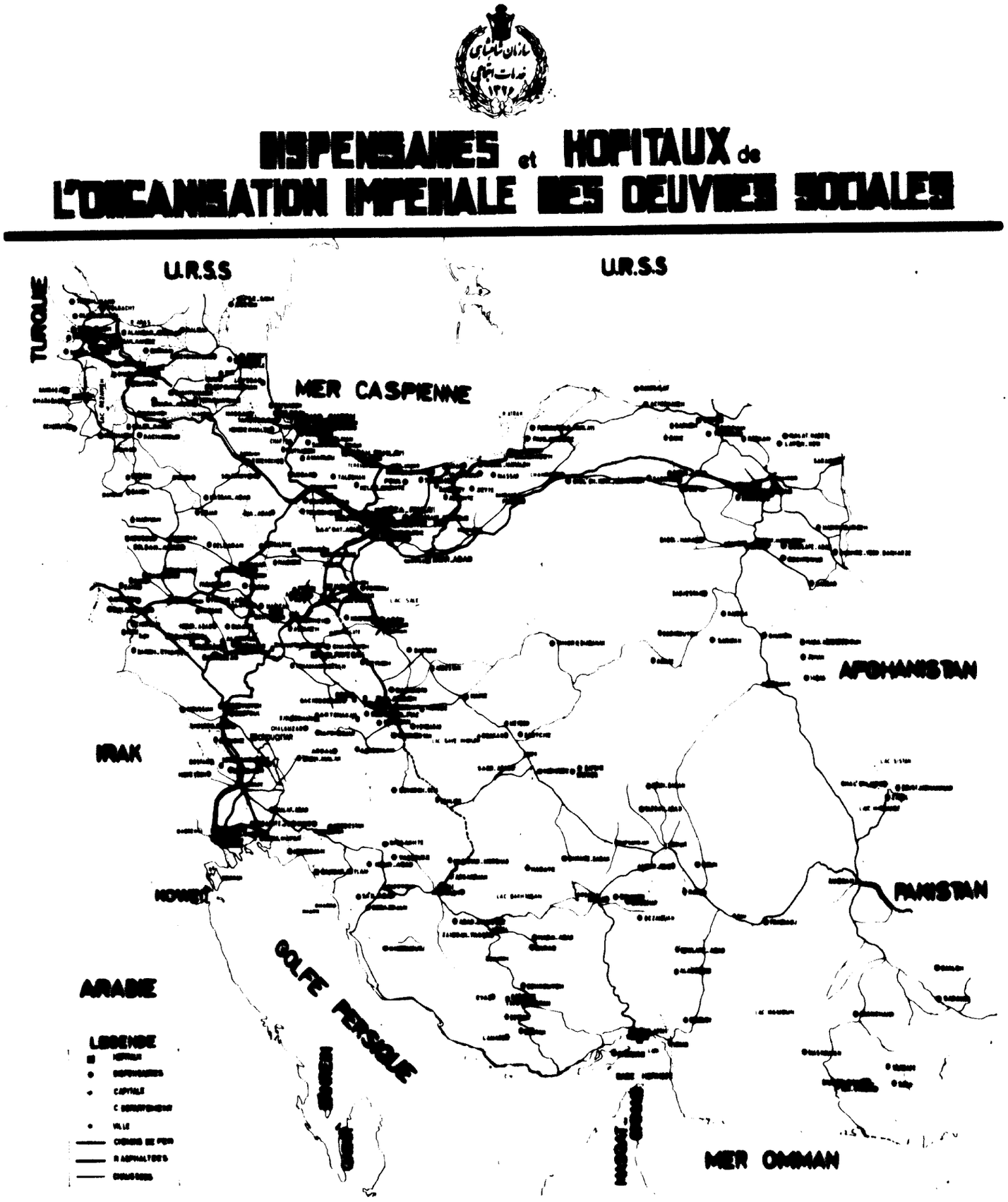


FIGURE III-2 DISPENSARIES AND HOSPITALS OF THE IMPERIAL ORGANIZATION FOR SOCIAL SERVICES

selected groups at private and Government hospitals in areas where it would not be economical for WSIO to have its own installations. Other arrangements are also made with very large employers, as described earlier.

Although 1,700,000 persons throughout Iran are entitled to such care, only half of them were receiving this benefit as of 1969. This ratio is expected to be maintained until 1973, even though the number of eligible people will increase. (About 2,200,000 will be eligible by the end of 1971.) The cost of the drugs supplied at the outpatient clinic is, at present, 24 Rials per visit, or 82 million Rials per year. It also costs 70 Rials per in-patient day for drugs at WSIO hospitals, or an additional drug cost of 8.9 million Rials per year. About 35% of the drugs used by WSIO is imported.

The WSIO and the extension of its radius of action will tend to increase in years to come. With more and more new jobs being developed, more and more workers and family members will require coverage. Moreover, the increased expectations of those already covered will place pressures on the Organization for improved quality of care and increased provision of services.

g. The Red Lion and Sun Society

This is the equivalent to the Red Cross Organization and represents the International Red Cross in Iran. Heretofore, most of their medical care activities were related to major catastrophes or disasters, such as times of earthquakes. However, for a number of years they have been running small hospitals, mainly maternity ones, as well as charity clinics for outpatient care.

As of December 1969, the Government of Iran decided that all the general hospitals that were being operated by the Ministry of Health (240 with about 17,000 beds) should be handed over to the Red Lion and Sun Society. The only exception will be hospitals in cities such as Teheran, Shiraz, Esfahan, Meshad and Ahwaz, where medical schools exist. In these latter locations the Ministry of Health hospitals will be operated by the Universities as part of their medical schools' teaching activities.

The new role imposed upon the Red Lion and Sun not only means new directions in care but represents very significant hospital and outpatient activities throughout the country that will affect the pharmaceutical consumption substantially. The Red Lion and Sun presently imports practically all their drugs through a cooperative agreement with the International Red Cross in Geneva. This arrangement allows them to obtain quality drugs at low cost and free of all duties. Extending this practice to the 240 hospitals they will now operate will increase importations and reduce local manufacture, which was an important source of drug supply for the Ministry of Health.

The present operating costs of the Red Lion and Sun Society include 60 million Rials for pharmaceuticals. This value is expected to rise to 100 million by 1975.

h. Ministry of Health

As described above, the responsibility for the operation of Ministry of Health hospitals has been passed on to the Red Lion and Sun Society or to universities. The only exceptions are specialized hospitals, such as those for treatment of tuberculosis and leprosy or mental patients, totaling around 4500 beds. These will be part of the national framework of care rather than part of the local community health care programs.

The policy recently approved by the Government is to have the Ministry of Health concentrate its resources for the development of public health activities. It will now limit its activities to planning, development of standards, and supervision and evaluation of programs. This change, of course, will radically influence the total costs of pharmaceuticals purchased by the Ministry. However, a considerable amount of drugs will still be used by the Ministry, not only at those hospitals that will remain under their jurisdiction but also at their more than 150 outpatient clinics and through their preventive medicine programs, for example, the distribution of suppressive drugs against malaria, for large groups of population.

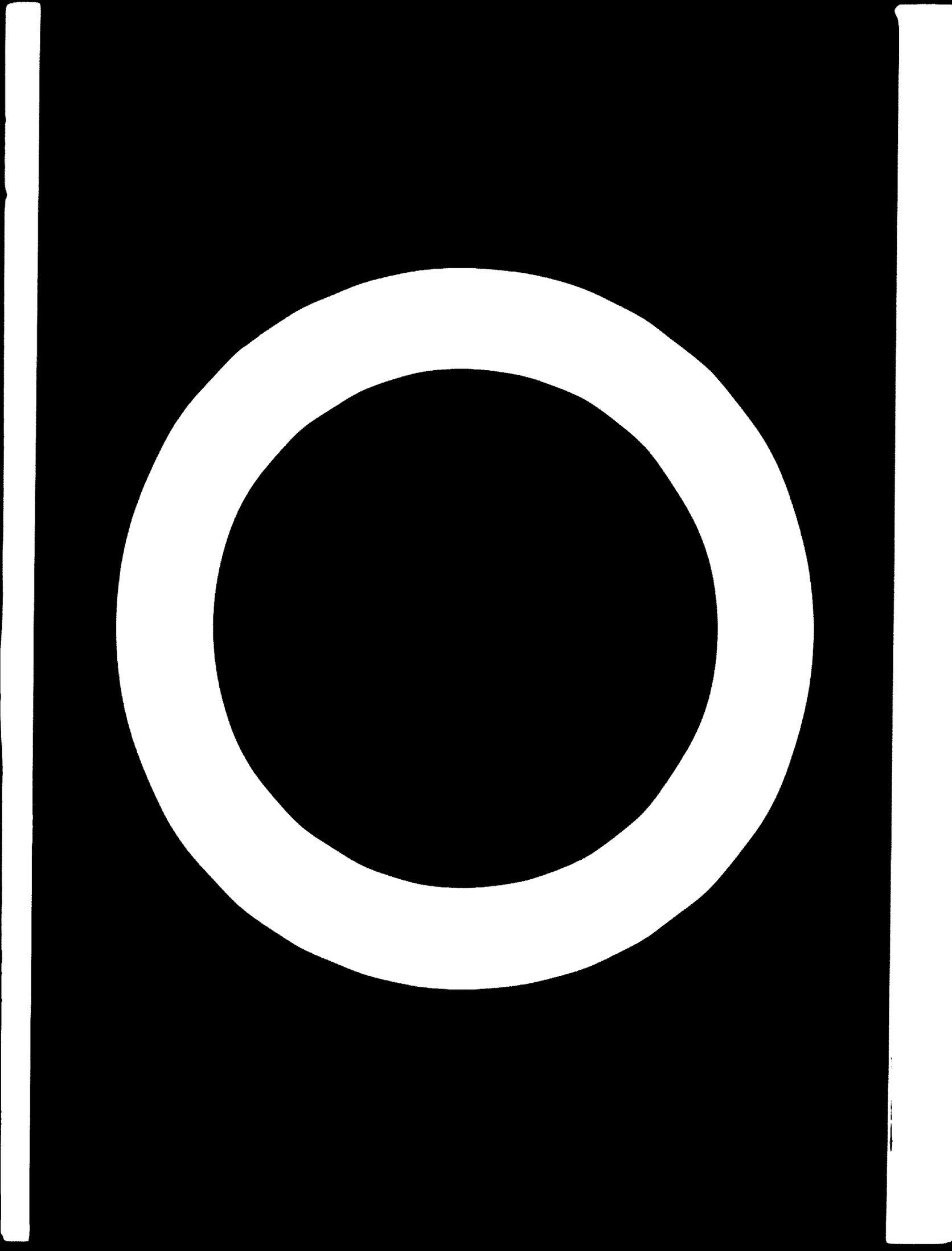
i. The Armed Forces Medical Services

As already reported, we were unable to obtain from the Armed Forces in Iran specific data about their medical services or their needs and procedures regarding pharmaceuticals. We therefore have assumed that these medical services and pharmaceutical requirements are comparable to those of the National Oil Company.

The Armed Forces do provide comprehensive health care to military personnel and certain dependent categories. The volume of such services will tend to remain steady unless there is a significant increase in the number of members of the Armed Forces which seems unlikely.

j. University-operated Medical Services

Several of the universities in Iran, through their medical schools, operate their own hospitals. These hospitals provide free or low-cost health care to a significant number of patients, particularly on a referral basis. The Government's decision to have universities operate the Ministry of Health hospitals in cities where medical schools are functioning will lead to greater use of pharmaceuticals



at these hospitals because of their newly acquired teaching and research functions, which tend to increase usage of drugs and particularly the more expensive ones. This increase, however, will level out since the number of beds is fixed and attendance at outpatient departments depends upon the number of clinics and physician time available.

k. Private Health-Care Institutions

In the larger cities of Iran – such as Shiraz, Esfahan and Abadan, and particularly in Teheran – private hospitals, generally operated for profit, provide medical care to patients who can afford private care through their own resources, through third-party insurance, or through contractual arrangements with their employers. The number of beds in these hospitals is about 1800. We estimate that at these hospitals the cost of pharmaceuticals consumed, is 180 rials per patient day or about 150 million Rials per year.

A recently adopted Government policy will tend to increase the number of private beds in Iran. Long-term loans will be granted for construction of hospitals, and the terms will be especially favorable when such hospitals are to be built in areas other than in large cities. Of the 4000 beds planned only 800 will be in Teheran. This policy will reduce the Government's role in the provision of direct patient care and will increase the consumption of locally manufactured or locally purchased drugs because private patients are the major purchasers of "over the counter drugs" in Iran. Furthermore, many patients – although entitled to coverage, including free medicines, through any of the systems described earlier – prefer to seek the help of private physicians. For example, Government employees and their dependents – some 400,000 persons in all – are covered by third-party insurance, but only about 175,000 use it. Finally, there are other large groups, such as the self-employed and domestic servants, that are not covered by "systems" of health care and therefore have to seek private health care or attend charity clinics.

C. PROJECTED CONSUMPTION OF PHARMACEUTICALS

In the United States, the increase in production of the pharmaceutical industry almost exactly parallels the increase in the gross national product. A study by the Organization for Economic Cooperation and Development yielded similar results for European pharmaceutical production. Information extracted from one of their reports is presented in Table III-8. From these data it is apparent that all European countries (with the possible exception of Italy in the last two reported years) had increases in the production of their pharmaceutical industries equal to, or exceeding the increases in their gross national product.

TABLE III-6
PHARMACEUTICAL INDUSTRY PRODUCTION (PIP) COMPARED TO
GROSS NATIONAL PRODUCT (GNP)

INDICES: [illegible]

Year	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Belgium GNP	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Belgium PIP			[illegible]	[illegible]	116	[illegible]
France GNP	[illegible]	[illegible]	[illegible]	111	[illegible]	[illegible]
France PIP	[illegible]	[illegible]	[illegible]	111	[illegible]	[illegible]
Germany GNP	[illegible]	[illegible]	[illegible]	[illegible]	117	[illegible]
Germany PIP	[illegible]	[illegible]	[illegible]	116	[illegible]	[illegible]
Italy GNP	[illegible]	[illegible]	[illegible]	114	[illegible]	[illegible]
Italy PIP	[illegible]	[illegible]	[illegible]	116	[illegible]	[illegible]
Netherlands GNP	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Netherlands PIP	[illegible]	[illegible]	[illegible]	[illegible]	110	[illegible]
Sweden GNP	[illegible]	[illegible]	[illegible]	[illegible]	110	[illegible]
Sweden PIP	[illegible]	[illegible]	[illegible]	113	127	[illegible]
United Kingdom GNP	[illegible]	[illegible]	[illegible]	[illegible]	114	
United Kingdom PIP	[illegible]	[illegible]	[illegible]	116	[illegible]	

Source: "Gaps in Technology - Pharmaceuticals", Organisation For Economic Cooperation and Development (Paris [illegible])

According to data obtained from the Ministry of Economy, the gross national product of Iran rose at an annual rate of 4.7% from 1340 (1961) to 1343 (1964) but from 1343 (1964) through 134[illegible] (1968) the rate was 11% per year. As indicated in Section B.1 the national income at constant price has been increasing at a rate of approximately 10% per year. By making the reasonable assumption that the demand for pharmaceuticals in Iran will closely parallel the rise in gross national product and national income, we estimate that demand for pharmaceuticals should increase at 10-11% per year. This growth rate agrees with the actual 10.8% growth rate for the last five years, as reported in Section A.3. Because other factors, such as urbanization and increased medical facilities will have an impact on pharmaceutical usage, we believe the growth in pharmaceutical usage may slightly exceed these figures. Therefore we have bracketed the expected growth rate for pharmaceutical products between 10 and 12% per year.

By extrapolating the present pharmaceutical requirements of 5370 million Rials ($71.1 million) at rates of 10 and 12% (Table III-9), we estimate a pharmaceutical market of 13,900 to 16,770 Rials ($185 to $220 million) in the year 1359 (1980). Although this projected requirement represents a sizable increase in the consumption of pharmaceuticals in Iran, the resulting per capita consumption of pharmaceuticals is less than one-third the 1970 per capita consumption in the United States and less than the 1970 average of 15 European countries. We believe that the 1980 estimates provide a reasonable guide for planning future requirements of the Iranian pharmaceutical industry in 1980.

TABLE III-9
PROJECTED IRANIAN PHARMACEUTICAL SALES
(In millions)

Year		Growth Rates			
		10%/yr		12%/yr	
Persian	Gregorian	Rials	U.S. Dollars	Rials	U.S. Dollars
1349	1970	5370	71.1	5370	71.1
1350	1971	5907	78.2	6014	79.7
1351	1972	6498	86.1	6738	89.2
1352	1973	7147	94.7	7544	99.9
1353	1974	7862	104.1	8449	111.9
1354	1975	8648	114.5	9463	125.3
1355	1976	9513	126.0	10599	140.4
1356	1977	10465	138.6	11871	157.2
1357	1978	11511	152.5	13295	176.1
1358	1979	12662	167.7	14890	197.2
1359	1980	13928	184.5	16677	220.9

Source: Arthur D. Little Inc. estimates

IV. SATISFYING PROJECTED CONSUMPTION OF PHARMACEUTICALS

In the previous section we have indicated 1980 pharmaceutical requirements for Iran which are approximately three times the present usage. This large increase in pharmaceutical requirements poses many difficult questions for the Iranian government. Decisions must be made to either encourage local production of these products or to increase their importation.

A. IMPORTANCE OF LOCAL PHARMACEUTICAL PRODUCTION IN IRAN

Several past reports on the Iranian pharmaceutical industry and interviews by ADL personnel in Iran indicate a general lack of appreciation for the pharmaceutical formulation industry. Comments are often made that it is merely an assembly operation and is not a basic industry or "mother industry". In our discussions, we emphasized the central importance of the formulation portion of the industry and we would like to re-emphasize it here.

While the manufacture of active medicinal ingredients should not be minimized, it should be pointed out that many of these ingredients are made by independent chemical companies that are not a part of the pharmaceutical industry or by the chemical division of large companies that have separate pharmaceutical divisions. In the manufacture of formulated products, the active ingredients are incorporated into dosage forms that the patient may easily and effectively take for the preservation of health or cure of disease. Extreme care must be taken in this formulation operation to ensure the production of wholesome products with the proper ingredients in the correct amounts.

It is not economically possible to manufacture all the active ingredients for pharmaceuticals in Iran and, because the largest proportion of added value occurs in the formulation and marketing steps, the manufacture of active ingredients is not of overwhelming importance to Iran. We feel that a comparison to the manufacture of Persian carpets may help illustrate our point. The raw materials ingredients of a Persian carpet are dyes and fibers such as cotton, wool or silk. Even if all these raw materials were imported by Iran, the value added and the care and skill required for Persian carpet manufacture would obviously remove the industry from classification as an "assembly" operation and the industry would remain an important contributor to the economy. For the same reasons, the formulation and marketing of pharmaceuticals should be considered a valuable contributor to the Iranian economy.

1. Comments on the National Benefits to Iran of Local Pharmaceutical Production

The value of a pharmaceutical production operation may be considered from three points of view: (1) commercial, (2) national income and (3)

effect on foreign exchange. The commercial viewpoint is of most interest to the investors because they expect the enterprise to be profitable. The Iranian government should be primarily concerned with a project's performance as a creator of national income and as a saver of foreign exchange. The three viewpoints should not be confused as it is possible to provide a protected climate for an industry to make it commercially profitable but which would not be in the best interest of the country from the point of view of national income or foreign exchange.

The national benefits and costs to Iran of local pharmaceutical manufacture must be calculated on a project by project basis, but certain generalizations can be made. From a national point of view the values created by pharmaceutical manufacturing operations would be the sums otherwise paid to foreigners for the same pharmaceutical products minus whatever amounts must be paid to foreigners to provide the raw materials, management, capital, etc. needed for the success of the enterprise. Fortunately the ratio of gross benefits to costs of pharmaceutical manufacture in developing countries is usually very favorable, typically amounting to ratios of from 2:1 to 6:1. In other words the national resources employed in the projects produce from 100% to 500% more national income than they formerly produced. This measurement of national benefits and costs does not depend in any way on the prices at which the items produced in the plant are sold. These prices affect the pattern by which the net benefits are distributed among the Government, drug retailers, private buyers, etc., but the total of the national net benefits remains unaltered.

Until such time as the pharmaceutical products produced in Iran are exported in large quantity, the principal saving of foreign exchange will be due to the smaller total amounts paid to foreigners for raw materials, management, capital, etc. in contrast to the larger sums paid for finished pharmaceutical products. Pharmaceutical plants can be run by Iranian personnel after short training periods, the plants are not capital-intensive, and the value added in manufacture is high; therefore, the sums paid out to foreigners can be much less than for finished imported pharmaceuticals, thus allowing substantial foreign exchange savings.

B. DISADVANTAGE OF IMPORTING PHARMACEUTICALS

By careful buying on bids, government agencies can often buy imported products at a lower price than the locally produced products, resulting in a saving for the budget of the agency. However, the cost to the nation may be considerably greater than for the local products because the net amount paid to foreigners may be higher than for the locally produced products. In general a government can purchase local pharmaceutical products at less than the regular trade prices so that the impact on agency budgets is reduced, while still retaining

the advantage of increased national income produced by the local manufacturers. Over a period of time the net cost to the government is further reduced by individual and corporate taxes of the manufacturing enterprise.

Local pharmaceutical production usually gives rise to other industries such as those that supply printing, packaging, bottles, tubes, etc. There are also diversification effects due to the development of commercial marketing skills, training of technical personnel, and increased outlets for the productive capabilities of Iranian manpower. All these benefits are lost when products are imported.

C. ABILITY OF LOCAL PRODUCTION TO MEET PHARMACEUTICAL REQUIREMENTS

As stated in Section III A. 2, the present investment of the 16 large pharmaceutical companies is approximately 2000 million Rials. Counting investments by other local companies and by the additional investments to be added this year, the total investment in pharmaceutical production facilities is estimated to be approximately 2,400 million Rials. At present this investment is producing over 2,000 million Rials of pharmaceuticals but it should be capable of producing approximately 6,000 million Rials of products. With diligent work by the companies and excellent cooperation by the Government, the 6,000 million level of production should be reached. This level of production could supply 90% of the 1351 (1972) requirements of Iran but only about 40% of the estimated 1359 (1980) requirements of about 16,000 million Rials ($210 million). To supply 90% of the 1359 (1980) requirements will necessitate the expenditure of approximately 2,500 million Rials for expansion of the present plants and the erection of perhaps two to four additional plants.

Private industry is better adapted than government to erect new plants or expand existing plants. The advantages of private industry over the Iranian Government in pharmaceutical manufacturing derive from the following factors:

- The modern pharmaceutical industry is heavily dependent on research and the major companies spend on research an amount equal to approximately 10% of their total sales.

- It is economically unjustified for a developing country to do large scale pharmaceutical research. For example, a single large American company spends approximately $60 million per year on pharmaceutical research; and, for comparison, the present total annual pharmaceutical consumption in Iran is approximately $71 million.

- It is very difficult for a government plant to obtain licenses to produce newly discovered pharmaceuticals and almost impossible to obtain permission to export these new products to other countries in competition with the company that developed the product.

- Iran has plants representing a good cross section of the world's pharmaceutical companies; thus pharmaceuticals that have been approved in the pharmaceutical manufacturer's home country can be advantageously accepted.

- Government can be a more effective and objective regulator of the pharmaceutical industry if it is not also a manufacturer.

V. INCREASING THE USE OF DOMESTIC PHARMACEUTICALS

Both the Government and the local pharmaceutical producers have a stake in the increased use of products in Iran. Some actions must be initiated by the industry, others by government, and still others by joint effort of government and industry.

A. ACTION REQUIRED OF BOTH INDUSTRY AND GOVERNMENT

One impediment to the acceptance of locally produced pharmaceuticals is the suspicion in the minds of many doctors and of the general public that the local products are somehow not as good as those that are imported. Partly this suspicion is the result of genuine past difficulties as the industry was just starting, but partly it is psychological. Poor packaging and printing have been responsible for some of the psychological reactions to the local products with the production of an uneasy feeling that the product inside might have been made as carelessly as the outer package. It will require the cooperation of both industry and government to inspire confidence in local products.

It is to the advantage of the industry to utilize good manufacturing practices and to employ excellent quality control procedures. The government must provide inspection personnel to monitor the practices of all the local producers.

Other problems that require the cooperation of both industry and government are counterfeiting and smuggling. Because pharmaceuticals are of high value, there is a great temptation to make imitation products that do not contain the proper ingredients or the full amounts of the proper ingredients. Likewise, authentic products that have passed the expiration date may be smuggled across the border and introduced into trade channels. The use of tracer compounds by the manufacturers and prosecution by the government can combine to discourage both counterfeiting and smuggling.

B. ACTION REQUIRED OF GOVERNMENT

If the Iranian pharmaceutical industry is to meet the demands of the Iranian people in the coming decade, great cooperation and encouragement by the Iranian government will be required. We are not suggesting that all governmental controls on the industry be relaxed, but that procedures be simplified or streamlined to allow the rapid attainment of the production so vital to the country.

1. Plant Licensing Procedures

Initial approval for the construction of a pharmaceutical plant is given by the Ministry of Economy on the basis of the types of products expected to be manufactured and their sales forecasts. The products must also be considered essential by the Ministry of Health. After the plant is erected, it is inspected by the Ministry of Health to determine if the plant is suitable for the production of the contemplated products. After inspection and approval, the potential manufacturer must apply to the Ministry of Economy for approval of selling prices for each of the products. So much time is taken in these procedures that some plants have been ready for production for almost a year before actual production could be commenced. These delays are not only costly to the foreign and Iranian investors, but are costly to the nation as well. Inspections of the plant during the late stages of construction and approval of all prices at that time could allow production of products shortly after completion of construction.

2. Price Controls

Theoretically the selling prices for pharmaceuticals are set by the Ministry of Economy to allow a 12% return on invested capital, borrowed capital and interest actually paid. Since the prices are set before production has commenced and are in force for a period of three years, it has obviously been impossible to calculate costs with the required accuracy. In practice, prices have apparently been set by using the former import price as a base and cutting these prices by an average of approximately 20% for the entire product line. Because the price approval by the Ministry of Economy and the product approval by the Ministry of Health both expire at the end of three years, the producing company finds its entire line of products in jeopardy every three years. Such procedures are not designed to inspire investor confidence and it may be difficult to attract the additional capital required for further expansion of this important industry. The present system of price controls will gradually drive older, but still effective, products out of the company's product line and new products will be introduced in an attempt to maintain favorable profit margins.

Alternative methods that would remove government agencies from detailed involvement in price determination should be investigated. Prices could be monitored by a government agency to ensure that they were reasonably comparable to those in other countries but the companies could be allowed much greater latitude in setting prices for the various dosage forms to be sold. The government has the ability to redistribute the profits produced through use of its taxing policies.

3. Plant Inspection and Pharmaceutical Testing

To assure the Iranian public that everything is being done to insure the production of quality drugs in Iran, the Ministry of Health needs a well-trained staff of plant inspectors to visit all local pharmaceutical plants on a routine basis. These inspectors can be given on-the-job training by a qualified foreign expert or by an Iranian who has received training in plant inspection by the U.S. Food and Drug Administration. Their principal function is to ensure that the "Good Manufacturing Practices" of Iran are followed. These practices should be based on the procedures of the United Nations as published in "Quality Control of Drugs", Offprint from Official Records of the World Health Organization No. 176 (Geneva 1969). Another function of the inspectors is to investigate any complaints against specific lots of product to determine if the material was improperly made at the factory or mishandled in the field.

Quality is built into a pharmaceutical product through many steps from the time the raw materials are received until the finished pharmaceutical is distributed. It is not possible for a government laboratory to test a few samples of a given product and determine that the entire lot has been satisfactorily manufactured. However, if the company has a good quality control group and the government inspectors have also done their jobs properly, periodic tests by a central government laboratory of freshly produced products and those that have been on the retail shelves for some time will give usable information as to the quality of production. The existing government laboratory does not have the resources to do this monitoring job in a proper manner.

4. Import Licenses and Controls

Raw materials for pharmaceutical production are imported at low duty rates but some delays are apparently introduced because of the paper work involved. The uncertainty of delivery dates forces the producers to hold much larger inventories of raw materials than if they could be assured of speedy delivery.

5. Regulation of the Pharmaceutical Industry

While we believe there has been a tendency to over-regulate certain phases of the production of pharmaceuticals, the distribution of certain drugs has been under-regulated. Although doctors prescribe pharmaceuticals in Iran, it is not necessary to have a prescription in order to buy most pharmaceuticals with the exception of narcotics.

In the United States some products are usually used only in hospitals or clinics where the patients can be tested for possible adverse reactions, yet these

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Dr. A. Nagaraja Rao is Project Manager and Chief Advisor, UN Special Fund Project IRA 16, United Nations Industrial Development Organization (UNIDO) at Teheran, Iran. Dr. Rao was the chief local UNIDO representative in Teheran and arranged our initial contacts with the proper officials of the Iranian Government. During the course of the study he gave constructive guidance, and he and his staff made a critical review of the final draft report.

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Mr. Paul M. Terlizzi, Industry specialist, UNIDO, Vienna, Austria met with us and gave constructive suggestions at the final draft review.

Mr. D. Gardellin, UNIDO Technical Equipment Procurement and Contracting Office and Mr. M. A. Siddiqui, Chief, Section for Asia and the Far East Technical Cooperation Division UNIDO, participated in contract monitoring and draft review.

His Excellency Mr. J. Ashrafi, Deputy Minister of Economy and Managing Director of the Research Centre for Industrial and Trade Development and Mr. H. A. Mehran, Director General of the Research Centre for Industrial and Trade Development gave us guidance as to what their Ministry wished to obtain from the study.

His Excellency Dr. M. Shahqoli, Minister of Health and His Excellency Mr. M. Assar, Director General - Planning and Programming gave us an excellent presentation of the present status and future goals of their Ministry in the health service field. Dr. A. Naderi who oversees the quality control of imported and domestic pharmaceuticals presented a clear explanation of his department's pricing and control functions.

products may be purchased in Iran without a prescription. While it is not desirable to place all pharmaceuticals under prescription requirements, some additional safeguards should be built into the system to protect the general public.

C. ACTION REQUIRED OF INDUSTRY

In addition to the joint actions to be taken with government, industry can help increase the use of domestic pharmaceuticals. Development programs can be initiated that will improve formulations, containers, packaging, labeling and distribution methods so that products better suited to the climate of the country and the needs of the people may be produced.

VI. PRODUCTS SUGGESTED FOR PRODUCTION IN IRAN

A. BASIS FOR SELECTION

Although an exhaustive study of the drugs used to treat all diseases was not within the scope of our work, we did analyze some of the data to determine what type of pharmaceuticals would be needed in Iran.

Life expectancy in Iran, for example, is only 46 years and infant mortality rates are about 160 per thousand. One-half of the infant mortality cases reported were caused by diseases of the digestive tract, respiratory system, or other infections and parasitic disease (Table VI-1).* These data indicate a strong need for anti-infective agents such as antibiotics.

We also reviewed the medical records of the National Iranian Oil Company and identified the causes of the 326 deaths reported in 1969 (Table VI-2). These data confirm the widespread incidence of infection, but they also indicate a significant incidence of cardiac ailments and other chronic conditions that affect the type of drugs required.

Table VI-2 also confirms the susceptibility of infants and young children, and people over 50 to infectious diseases. These two categories accounted for more than 75% of the deaths in the group studied.

We have listed the major diseases reported for this selected group (Table VI-3). Again, the data demonstrate the importance of anti-infective agents to treat these diseases.

Finally – from interviews with pharmaceutical manufacturers, government officials, and various retailers in Iran – we have listed the sales of pharmaceutical products in Iran (Table VI-4). This listing clearly indicates the importance of antibiotics (about 21% of the total) and of vitamins and nutrients (14%).

The relative importance of these two categories of drugs is also obvious from a comparison of pharmaceuticals use in Iran and the United States (Table VI-5), and from the 50 products most often prescribed in the United States and in Iran (Tables VI-6 and VI-7, respectively).

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*The analysis, of course, is subject to possible errors in reporting. For example, causes of death in remote regions may not be investigated thoroughly.

TABLE VI-1
MORTALITY RATE IN IRAN
CAUSE OF DEATH/THOUSAND CASES OF MORTALITY

Disease of infants	152
Disease of digestive system	142
Disease of respiratory system	121
Infectious parasite disease	86

Source: Fourth National Plan - Plan Organization

TABLE VI-2
ANALYSIS OF DEATHS IN A SELECTED POPULATION GROUP

Study of 328 deaths in a treated population of 136,000

Cause of Deaths		Percent
1.	Respiratory	16.5
2.	Neoplasm and Blood Dyscrasia	13
3.	Cardiac Infarction and Failure	10
4.	Cardiovascular and Lymphatic	9
5.	GI (Colitis, Dysentery, Diarrhea)	8.5
6.	Burns	3.5
7.	Poisoning	1
8.	Accidents	4
9.	Senility	4
10.	Infections	7
11.	Miscellaneous	23.5

Age at Death

Years	Percent
0-5	36
6-10	3.5
11-20	4
21-60	16.5
Over 60	40

Source: Arthur D. Little, Inc. estimate of National Iranian Oil Company data.

TABLE VI-3
MAJOR INFECTIOUS AND PARASITIC DISEASES IN SELECTED COMMUNITY OF 135,000

Streptococcal Infection	953
Measles	579
Infectious Hepatitis	491
Influenza	383
Dysentery Bacillary	219
Mumps	216
Chicken Pox	184
Malaria	128
Typhoid Fever	108
Rheumatic Fever	68
Food Poisoning	53
Scarlet Fever	33
TB Pulmonary	29
Leishmaniasis	27
Whooping Cough	26
Meningitis	24
Paratyphoid Fever	19
TB Non-Pulmonary	13
Poliomyelitis	9
Dysentery Amoebic	8
Cholera	5
Erysipelas	5
Measles German	4
Scabies	3
Gonorrhea	2
Total	3064

Source: Arthur D. Little, Inc. estimate of National Iranian Oil Company data.

TABLE VI-4
ANALYSIS OF USE OF PHARMACEUTICALS IN IRAN
SALES BY MAJOR THERAPEUTIC CATEGORIES, 1980
(Thousands $)

Anabolics	100	Dermatological Preps	2,100
Analgesics	3,500	Diabetic Therapy	800
Anesthetics	300	Diagnostic Agents	200
Antacids	1,600	Diuretics	600
Anthelmintics	700	Enzymes	800
Anti-arthritic Agents	2,310	Gynecological Preps	475
Antiseptic (Urinary)	500	Hematinics	2,000
Antibiotics	14,000	Hemorrhoidal Preps	200
Anticoagulants	100	Hemostatics	400
Anticonvulsants	200	Hormones	3,000
Antidiarrheals	1,200	Laxatives	600
Antihistamines	700	Muscle Relaxants	200
Antimalarials	100	Ophthalmological Preps	1,400
Antinauseants	200	Psychostimulants	800
Antispasmodics	2,200	Sedatives	1,000
Biologicals	1,200	Sulfonamides	300
Bronchial Dilators	600	Tranquilizers	1,800
Cardiovasculars	2,110	Tubercular Drugs	200
Cholesterol Reducers	700	Vitamins & Nutrients	9,000
Cough & Cold Preps	4,200	Others	4,000
		Total	70,000

Source: Arthur D. Little, Inc., estimate.

TABLE VI-[illegible]
DRUGS - THERAPEUTIC CATEGORIES
[illegible]

	United States		Iran	
Therapeutic Category	($M)	% of Total	($M)	% of Total
Analgesics	[illegible]	[illegible]	[illegible]	[illegible]
Antacids	70	1.0	[illegible]	[illegible]
Antiarthritics (nonhormonal)	70	2.0	[illegible]	3.3
Antibacterials	70	1.0	[illegible]	[illegible]
Antibiotics	[illegible]	14.1	[illegible]	[illegible]
Antihistamines	[illegible]	1.0	0.70	1.0
Antispasmodics	[illegible]	[illegible]	[illegible]	3.3
Cardiovasculars	[illegible]	[illegible]	2.11	[illegible]
Cough and Cold Preparations	[illegible]	[illegible]	[illegible]	6.1
Diabetic Therapy	110	[illegible]	[illegible]	[illegible]
Diuretics	[illegible]	3.1	[illegible]	[illegible]
Hematinics	[illegible]	1.0	[illegible]	3.1
Hormones	[illegible]	[illegible]	[illegible]	[illegible]
Muscle Relaxants	[illegible]	[illegible]	[illegible]	[illegible]
Psychostimulants	[illegible]	1.0	[illegible]	[illegible]
Sedatives	70	1.0	[illegible]	1.0
Sulfonamides	[illegible]	1.2	[illegible]	[illegible]
Tranquilizers	[illegible]	[illegible]	[illegible]	[illegible]
Vitamins & Nutrients	[illegible]	6.1	[illegible]	[illegible]
Others	[illegible]	[illegible]	17.14	[illegible]
Total Ethical	[illegible]	100.0	[illegible]	100.0

Source: Arthur D. Little, Inc., estimate.

[redacted]

[redacted]

[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	tranquilizer	85.0
[redacted]	[redacted]	tranquilizer	78.0
[redacted]	[redacted]	analgesic	65.0
[redacted]	[redacted]	antibiotic	46.0
[redacted]	[redacted]	diabetic agent	42.0
[redacted]	[redacted]	hormone	38.0
[redacted]	[redacted]	antiarthritic	35.0
[redacted]	[redacted]	antibiotic	35.0
[redacted]	[redacted]	antibiotic	32.0
[redacted]	[redacted]	antibiotic	31.0
[redacted]	[redacted]	antibiotic	25.0
[redacted]	[redacted]	tranquilizer	24.0
[redacted]	[redacted]	tranquilizer	24.0
[redacted]	[redacted]	antibiotic	22.0
[redacted]	[redacted]	tranquilizer	20.0
[redacted]	[redacted]	tranquilizer	20.0
[redacted]	[redacted]	hormone	20.0
[redacted]	[redacted]	cardiovascular	20.0
[redacted]	[redacted]	antibiotic	18.0
[redacted]	[redacted]	diuretic	18.0
[redacted]	[redacted]	antibiotic	18.0
[redacted]	[redacted]	tranquilizer	18.0
[redacted]	[redacted]	diuretic	18.0
[redacted]	[redacted]	anesthetic	18.0
[redacted]	[redacted]	hormone	18.0
[redacted]	[redacted]	psychostimulant	18.0
[redacted]	[redacted]	diuretic	18.0
[redacted]	[redacted]	antibiotic	18.0
[redacted]	[redacted]	analgesic	18.0
[redacted]	[redacted]	antibiotic	18.0
[redacted]	[redacted]	antibiotic	14.0
[redacted]	[redacted]	antibiotic	14.0
[redacted]	[redacted]	antibiotic	14.0
[redacted]	[redacted]	antispasmodic	14.0
[redacted]	[redacted]	antispasmodic	14.0

TABLE VI-6 (cont)

TOP FIFTY PHARMACEUTICALS SOLD IN THE UNITED STATES, 1988

Brand Name	Manufacturer	Therapeutic Category	Sales ($MM)
Vibramycin	Pfizer	antibiotic	14.0
Talwin	Winthrop	analgesic	13.0
Ornade	Smith Kline & French	cough and cold	13.0
Meprobamate	several	tranquilizer	12.0
Combid	Smith Kline & French	antispasmodic	12.0
Gantrisin	Roche	sulfonamide	12.0
Pavabid	Marlen	cardiovascular	12.0
Bar-Ap-Es	Ciba	cardiovascular	12.0
Chloromycetin	Parke, Davis	antibiotic	12.0
Macrodantin	Eaton	antibacterial	12.0
Diabinese	Pfizer	diabetic agent	12.0
Terramycin	Pfizer	antibiotic	12.0
Mysteclin F	Squibb	antibiotic	12.0
Dimetapp	Schering	cough and cold	11.0
Lomotil	Searle	antidiarrheal	11.0

Note: Top 50 account for 25% of total ethical sales.

Source: Arthur D. Little, Inc., estimates.

TABLE VI-7
TOP FIFTY PHARMACEUTICALS SOLD IN IRAN, 1969

Product	Manufacturer	Therapeutic Category	Sales MRIs
Tetracycline	several	antibiotic	3.5
Ampicillin	several	antibiotic	2.7
Phenethicillin	several	antibiotic	1.5
Streptomycin	several	antibiotic	1.2
Penicillin	several	antibiotic	1.0
Ascorbic Acid	several	vitamin	0.8
Promethazine	several	antihistamine	0.7
Chloromycetin	Parke, Davis	antibiotic	0.7
Librium	Roche	tranquilizer	0.6
Oxytetracycline	several	antibiotic	0.5
Abdec	Parke, Davis	vitamin	0.5
Valium	Roche	tranquilizer	0.5
Cericidin	Schering	cough and cold	0.4
Chloxacillin	several	antibiotic	0.3
Pro-Banthine	Searle	antispasmodic	0.3
Codeine Compound	several	analgesic	0.3
Hydrocortisone	several	hormone	0.3
Amitriptyline	Merck Sharpe & Dohme	tranquilizer	0.3
Rastinon	Hoechst	diabetic drug	0.3
Benadryl	Parke,Davis	cough and cold	0.3
Optalidon	Sandoz	sedative	0.3
Seriden	Roche	sedative	0.3
Halothane	Hoechst	anesthetic	0.3
Iron Dextran	several	hematinic	0.3
Chlorpromazine	several	tranquilizer	0.3
Aneurine	several	vitamin	0.25
phisohex	Sterling	antiseptic	0.25
Bellergal	Sandoz	antispasmodic	0.20
Chlorhexidine	several	antiseptic	0.15
Chloroxylenol	several	antiseptic	0.15
Clinitest	Ames	diagnostic	0.15
Robaxin	Robins	muscle relaxant	0.15
Aldomet	Merck Sharpe & Dohme	cardiovascular	0.15
Flagyl	Searle	amebicide	0.15
Nitrofurantoin	several	antiseptic	0.15

TABLE VI-7 (cont)

TOP FIFTY PHARMACEUTICALS SOLD IN IRAN, 1989

Product	Manufacturer	Therapeutic Category	Sales ($M)
Butazolidin	Geigy	antiarthritic	0.15
Betamethasone	Schering	hormone	0.12
Delviran	Bayer	sedative	0.12
Stelazine	Smith Kline & French	tranquilizer	0.12
Garverin	Roche	sulfonamide	0.10
Hydrochlorothiazide	several	diuretic	0.10
Atromid-S	ICI	cholesterol reducer	0.10
Melleril	Sandoz	tranquilizer	0.10
Dilantin	Parke, Davis	anticonvulsant	0.10
Synalar	Syntex	hormone	0.07
Lasix	Hoechst	diuretic	0.07
Tofranil	Geigy	psychostimulant	0.07
Indocid	Merck Sharpe & Dohme	antiarthritic	0.07
Insulin	several	diabetic agent	0.07
Inderal	ICI	cardiovascular	0.07

Note: Top 50 account for 31% of total ethical sales.

Source: Arthur D. Little, Inc., estimates.

Dr. Masoud Rouhani, Director, Health Department, National Iranian Oil Company (N.I.O.C.) made available his entire staff in Abadan and Teheran to cooperate in this study. He also released to us through Dr. Partow and Mr. A. Akbar Sadeghi of the Abadan region a complete computer printout of pharmaceutical usage by the N.I.O.C. and detailed reports on hospital admissions, disease rates, etc.

The World Health Organization supplied other data on disease incidence (which were compared to the N.I.O.C. data) as well as publications on quality control and good manufacturing practices in the pharmaceutical industry.

Finally we should like to recognize the assistance of Mr. Jamshid Garajedaghi, Managing Director, Industrial Management Institute, who put the facilities of the institute at our disposal. Mr. Syamak Partovi of his Economic and Marketing Committee was assigned to the project and was invaluable because of his knowledge of the Iranian Government and the pharmaceutical industry.

In addition to the people named above, others contributed valuable information to the study and most of these are listed in Appendix A.

B. VETERINARY USES

Pharmaceutical products are also used to treat animals, not only to cure disease but also to increase their weight and thus enhance their value. The major portion is accounted for by the same categories as those for human use: antibiotics and vitamins and nutrients. As shown in Table VI-8, these two categories account for nearly one-half the pharmaceuticals used in the U. S. veterinary market. We believe the same type of distribution is prevalent in Iran.

However, veterinary pharmaceuticals are only a small percentage of the total pharmaceutical market. On the basis of other countries' experiences and our interviews with companies that provide pharmaceutical products in Iran, we estimate the total market for veterinary pharmaceuticals at $1 million (75 million Rials) per year.

C. PRODUCTS THAT MIGHT BE PRODUCED IN IRAN

Table VI-9 lists the top 15 therapeutic categories and their projected sales for 1359 (1980). These categories will represent 75% of pharmaceutical sales by then.

From our evaluations, we believe a number of products in each category could be produced in Iran. Table VI-10 lists some of the more promising and many of these are being formulated at present in Iran.

Notice, however, that we are not suggesting manufacture of the basic pharmaceuticals but rather their importation and formulation into dosage forms. It would be difficult, for example, to justify the establishment of a manufacturing operation to synthesize ascorbic acid or similar active ingredients. But formulating the multi-vitamins or specific vitamin forms (for example, an effervescent ascorbic acid in a 1-gram tablet) represents a realistic opportunity.

Similarly, the various normal derivatives could be formulated into effective pharmaceutical products in Iran. The products used to treat respiratory ailments, such as the cough and cold products, are a combination of active ingredients which could also be formulated very effectively in an Iranian pharmaceutical plant.

Some active ingredients, such as analgesics or antihistamines, might be synthesized in a multi-functional plant, if the syntheses involved do not require specialized equipment.

The critical point in identifying products which might be made in Iran is that almost all pharmaceutical products which will be used in the next decade

TABLE VI-6
ANNUAL VOLUME OF PHARMACEUTICALS FOR
VETERINARY USE IN THE UNITED STATES
1978

Antibiotics	28%
Vitamins and Nutrients	16%
Anthelmintics	15%
Parasiticides – external	8%
Sulfonamides	7%
Antiseptics	3%
Intravenous solutions	1%
Hematinics	1%
Tranquilizers	1%
Others	19%

Source: Arthur D. Little, Inc. estimate of published U.S. Government Data (Department of Commerce, Bureau of the Census Current Industrial Report – March 3, 1978)

TABLE VI-9

PROJECTED SALES OF SELECTED MAJOR THERAPEUTIC CATEGORIES, 1988
(million $)

Antibiotics	40.0
Vitamin Products	35.0
Hormones	12.0
Cough and Cold Preps	12.0
Analgesics	10.0
Cardiovascular	7.5
Hypnotics	7.5
Dermatology Products	7.0
Antiarthritics	7.0
Antiseptics	7.0
Tranquilizers	6.2
Antacids	5.0
Biologicals	4.0
Ophthalmologicals	4.0
Antidiarrheals	4.0
Sulfonamides	3.0
Total	169.2

Source: Arthur D. Little, Inc., estimate

TABLE VI-10
SELECTED PHARMACEUTICAL PRODUCTS FOR POSSIBLE MANUFACTURE IN IRAN

Antibiotics	
Tetracycline	capsules and injectables
Ampicillin	capsules and injectables
Streptomycin	capsules and injectables
Erythromycin	tablets
Phenethicillin	capsules
Penicillin	tablets and injectables
Vitamins	
Ascorbic acid	tablets and injectables
Multi vitamin	capsules and tablets
Multi vitamin with Fluoride	tablets
B Complex	capsules
Hormones	
Hydrocortisone	tablets, lotion
Meticorten	tablets
Betamethasone	tablets
Combination of progestogen and estrogen	tablets
Various estrogens	capsules and injectables
Androgen	tablets and injectables
Triamcinalone	tablets and injectables
Conjugated estrogens	tablets
Cough and Cold Preparations	
Aspirin, Phenacetin, Caffeine Combination	tablets
Antihistamine with Salicylamide	capsules
Antihistamine, expectorant and cough supressant	capsules and syrup
Analgesics	
Propoxyphene	capsules
Propoxyphene A.P.C.	capsules
Aspirin	tablets
Codeine compound	tablets
Aspirin and barbiturates	capsules and tablets
Talwin (pentazocine)	tablets
Meperidine	tablets and injectables

TABLE VI-10 (cont)
SELECTED PHARMACEUTICAL PRODUCTS FOR POSSIBLE
MANUFACTURE IN IRAN

Cardiovascular	
Pentrate (pentaerythritol tetranitrate)	tablets
Methyl dopa	tablets
Methyl dopa with hydrochlorothiazide	tablets
Papaverine	tablets and capsules
Nicotinyl alcohol	capsules
Isosorbide	capsules
Reserpine	tablets
Hematinics	
Ferrous sulfate	tablets
Iron dextran	tablets
Cyanocobalamin	tablets
Ferrous fumarate	tablets
Ferrous gluconate	tablets
Ferrous sulfate with ascorbic acid	tablets
Dermatological Products	
Fluocinolone	lotion-cream-ointment
Fluocinolone with Neomycin	lotion-cream-ointment
Gentamycin	lotion-cream-ointment
Hydrocortisone	lotion-cream-ointment
Anti-Arthritic Products	
Phenylbutazolidin	tablets
Phenylbutazolidin with alkalines	tablets
Indomethacin	capsules
Buffered aspirin	tablets
Xyloprim	tablets
Colchicine	tablets
Sulfonamides	
Sulfasuxazole	tablets, liquid
Sulfathiazole	tablets, liquid
Sulfamerazine	tablets, liquid
Sulfadiazine	tablets, liquid
Sulfamethazine	tablets, liquid
Triple sulfas	tablets, liquid

could be formulated in a pharmaceutical plant in Iran. Many of the products which will be in demand – such as the vitamin products, the cough and cold preparations, the dermatological products, antispasmodics, hematinics, ophthalmological products, antidiarrheals, and antacids – represent the skillful selection and combination of active agents to treat a particular condition. Even those agents which tend to be single entities, such as antibiotics or hormones, represent attractive opportunities for a pharmaceutical operation in Iran. We emphasize, however, that the opportunity lies not in the synthesis of the active ingredient, but in the preparation of the active material in a useful pharmaceutical form. In this activity the greatest value is added to the pharmaceutical preparation and for that reason this area should be stressed. Pharmaceutical plants to accomplish this goal should have the equipment required for the tabletting and encapsulating activities as well as for the preparation of sterile injectable products for the preparation and packaging of suitable lotions, syrups, etc. The following Chapters deal with the equipment or techniques required for manufacturing the various products likely to be used in the future.

VII. REQUIREMENTS TO MANUFACTURE SUGGESTED PRODUCTS

A. PHARMACEUTICAL FORMULATIONS

The pharmaceutical plants already in Iran are capable of manufacturing almost any type of pharmaceutical product that is made today or is likely to be made in the near future. The 16 large plants mentioned in Section III-A have facilities for producing plain and coated tablets, hard capsules, soft capsules, suppositories, powders, sterile and nonsterile liquids, injectables, ointments, etc. The Razi Institute and the Pasteur Institute are well equipped for the production of biologicals.

Even though the productive capacity of the Iranian plants is not being utilized fully, they will produce more than 40% of Iran's pharmaceutical needs this year. However, pharmaceutical usage is expected to grow 10 to 12% per year and with some government encouragement to allow local production of up to 90% of the nation's requirements, excess capacity will vanish. Consequently, additional plants or plant expansion will be necessary.

Because of the rapid advances being made in pharmaceutical research, most of the plant expansion should be undertaken by the large international drug companies so that new pharmaceuticals may be introduced quickly into Iran and produced locally. We understand that the Iranian government does not wish to expand its activities in areas which can be handled by private enterprise. Nevertheless, some pharmaceutical production operations are currently being conducted by the government; for example, the W.S.I.O., the Imperial Pharmaceutical Institute and Teheran University. Thus, there is a precedent for a government pharmaceutical plant.

We would not recommend setting up a very large government pharmaceutical plant, but it may be desirable to consolidate the existing manufacturing operations. The present manufacturing facilities are producing principally rather simple tablets, ointments, syrups, and powders. There is a general need for products of this type in the government-financed health services of the nation and such operations would not take large amounts of business away from the private pharmaceutical companies and would permit them to concentrate on their specialty products.

At least three advantages could accrue from the establishment of a well-run government-sponsored pharmaceutical plant:

(1) Consolidation of the manufacture of the simple products now being made would allow good quality control practices to be established. (The present fairly extensive manufacturing operation of Teheran

University runs without benefit of a control laboratory because they have not received approval for approximately 375,000 Rials ($5,000) needed for laboratory equipment.)

(2) The plant could be used to train chemists, engineers, and pharmacists in drug production and control methods under practical operating conditions.

(3) The plant could be used to manufacture certain pharmaceutical products on an emergency basis during times of crisis such as strikes, war, or natural disasters.

While the plant should be designed and started by experienced pharmaceutical personnel, we do not believe it should have any permanent relationship with international pharmaceutical companies. Its scope of operations would not require a close and continuing relationship with a foreign company. Therefore, it would not be similar to the present operation of the plant owned by the Pahlavi Foundation, Darou-Pakhsh, whose production operations are run by Allen and Hanbury of England.

Details of a suggested pharmaceutical plant are presented in Chapter VIII.

B. ACTIVE MEDICINAL INGREDIENTS

The first priority for Iran is to establish adequate pharmaceutical formulation, packaging, and marketing operations to meet the present and projected needs of the country. As these facilities become well established there will be opportunity for the production of certain active ingredients for incorporation into the formulated products.

Basic active ingredients are made by the Razi Institute and the Pasteur Institute for incorporation into biologicals which are now manufactured in Iran. Because many active biological ingredients do not ship or store well, their local production has been a necessity. On the other hand, most other active ingredients for pharmaceuticals – for example, synthetic organic chemicals and antibiotics – may be shipped and stored for long periods. Consequently, these active ingredients have been manufactured in foreign countries and imported into Iran by the developing pharmaceutical industry.

The small size of the Iranian market initially made the local production of active ingredients financially unattractive. This situation is still true of many active ingredients but there now appears to be enough usage of a variety of synthetic organic chemicals to justify erection of a multi-product organic synthesis plant. The major obstacle to the establishment of such a plant is the

price and profit control system imposed by the government on pharmaceutical operations. These controls apparently restrict return on investment to 12%. Since the same general purpose plant could produce dye and pigment intermediates, rubber chemicals, plastics and additives, etc., whose production is not under profit controls, there has been little incentive to manufacture medicinal chemicals. In Chapter IX we have suggested several possible government measures to avoid this difficulty.

The type of synthetic organic chemical plant we envision would not be capable of manufacturing chemicals such as ascorbic acid, which requires many complicated chemical steps as well as a fermentation step in its synthesis. However, many sulfonamides, analgesics and anti-tubercular drugs can be made with one-, two-, or three-step processes and could be produced by an experienced chemical-pharmaceutical manufacturer. Most products of this type are no longer covered by patents, so the principal criterion in selecting the owner-operator of the plant would be experience and know-how in manufacturing the products.

Sulfonamides make up the category of synthetic drugs that are used in the largest quantity in Iran. Local usage is estimated at almost 100,000 kilograms per year and there may be possibilities for export to neighboring countries. With sulfonamides as a base, other products such as analgesics could take up the 225,000-Kg capacity for a medicinal chemical plant as suggested in Chapter VIII. Preliminary feasibility analyses are promising enough to warrant a detailed study that will determine the exact products to be manufactured and the best type of operating company.

We have also considered the possibility of establishing fermentation plants for the production of antibiotics and vitamins. Iran's 1349 (1970) consumption figures for tetracycline – less than 10,000 Kg, with a sales value of less than 26,400,000 Rials ($350,000) – do not indicate sufficient income to support a plant that would require an investment of at least 11,300,000 Rials ($1.5 million). The sales volumes and plant costs for penicillin, streptomycin and vitamin production also appear uneconomic. A very detailed study might indicate the feasibility of a fermentation plant that could produce all three antibiotics but it might still be necessary to insure some exports to justify the production volume needed. We are not optimistic about the national benefits of a fermentation industry and believe the detailed study can be postponed for a year or two. We would especially like to point out that there are too many examples of uneconomic plants being foisted on a developing nation. An excellent example is the penicillin plant installed in Egypt with such small fermentors (9500 liters) that penicillin cannot be made economically.

VIII. PROPOSED PHARMACEUTICAL PLANT PROJECT

A. ORGANIZATIONAL FRAMEWORK

As indicated in Section VII, the major responsibility for meeting the pharmaceutical requirements of Iran should be assigned to the private sector. The plant described in this section is not intended to replace any private sector operations but is designed to consolidate some of the present production operations of the Iranian government and allied agencies. At the government's discretion it could be made a portion of the operations of the Imperial Pharmaceutical Institute, Teheran University or other government institutions. None of the products would be sold directly to the public but they would be distributed through the various national health programs. The plant would not require any extensive marketing staff because the products would be supplied on order to the various government agencies. The remainder of the organization would be very similar to that of any commercial operation and good quality control and good manufacturing practices would be observed. Standard accounting procedures should be followed to allow the repayment of capital and to allow proper maintenance and plant improvements.

B. PLANT LAYOUT AND PROCESS

The proposed plant is designed to produce a variety of uncoated or coated tablets. Provision has also been made for a small liquid-production line as well as for future expansion into other products such as eye drops, topical ointments, and capsule filling operations.

If it is to supply a significant portion of the Iranian Government requirements at reasonable costs, the plant must be capable of producing at least 150,000,000 tablets per year. The proposed plant has a theoretical capacity of more than 375,000,000 tablets per year if three compression machines are run eight hours per day for 250 days per year. Because of changeovers from one product to another, machine cleanup, etc., the practical capacity is about 200,000,000 tablets per year on a one-shift basis. With a two-shift operation, capacity could be approximately doubled. Up to one-third of the tablets can be produced with a sugar, gelatin, or plastic film coating if required.

Although the tablets could be packed in bottles of 1,000 tablets, we suggest they be packed in film strips rather than in bottles. The film packs would assure hygienic dispensing, would reduce the time required to distribute medicines, and, because of clear labeling in Farsi (or Farsi and English), would help to avoid mix-ups in the hospital wards as well as by the outpatients.

The size and layout of the factory would also be determined by Government requirements. For purposes of illustration we have suggested a well-insulated, air-conditioned plant consisting of a 700-square-meter warehouse section and a manufacturing, laboratory, and office section of approximately

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625 square meters. The general plan of the proposed plant is shown in Figure VIII-1 and the layout of the manufacturing, laboratory, and office building is presented in Figure VIII-2.

If the plant is not erected in an existing area, land requirements would be about 7000 square meters to allow for the necessary roads, parking, and future expansion.

To minimize cross-contamination and mix-ups, small plants customarily run products on a "campaign" basis so that only one product is processed in the plant at a given time. As may be seen from Figure VIII-2, operations in the proposed plant are segregated so one type of tablet could safely be coated while another type was being compressed.

A simplified flow sheet is presented in Figure VIII-3 to indicate the various steps entailed in producing various types of tablets. No flow sheet has been drawn up or detailed cost estimates made for production of liquid or ointment preparations.

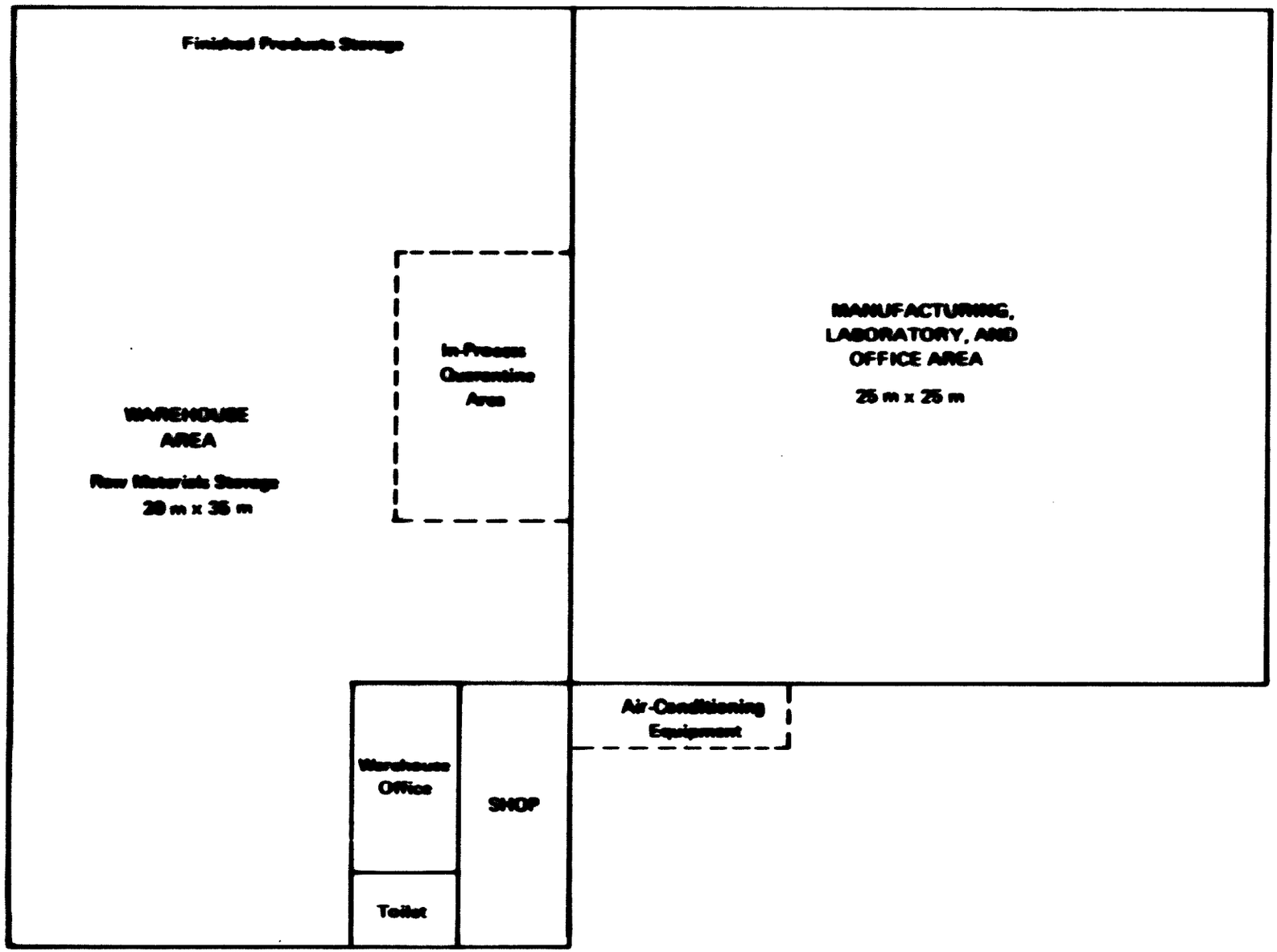
Three identical air conditioner compressor units are suggested to facilitate cross-connection or substitution of a different unit should the key unit fail. One unit would normally serve a system that supplies air conditioning to the front row of offices and locker rooms as well as the lunch room, supervisor's office, laboratory, and tablet-polishing room. Provision would be made in the latter two rooms for 100% makeup air to remove organic solvents and toxic fumes. The remainder of the production area and the shop and office in the warehouse could be handled by the second unit, again with 100% makeup to some areas. The third unit would supply the warehouse area.

C. INVESTMENT

The fixed capital requirements of the proposed project are estimated to be 47,000,000 Rials ($625,000) as shown in Table VIII-1. The investment (and the time required to start operation) could be reduced considerably if the operation were to be set up in an existing general purpose building. The total working capital required (Table VIII-2) is a function of the time that the raw materials and finished goods are held in storage and is estimated to be approximately 17,000,000 Rials ($230,000).

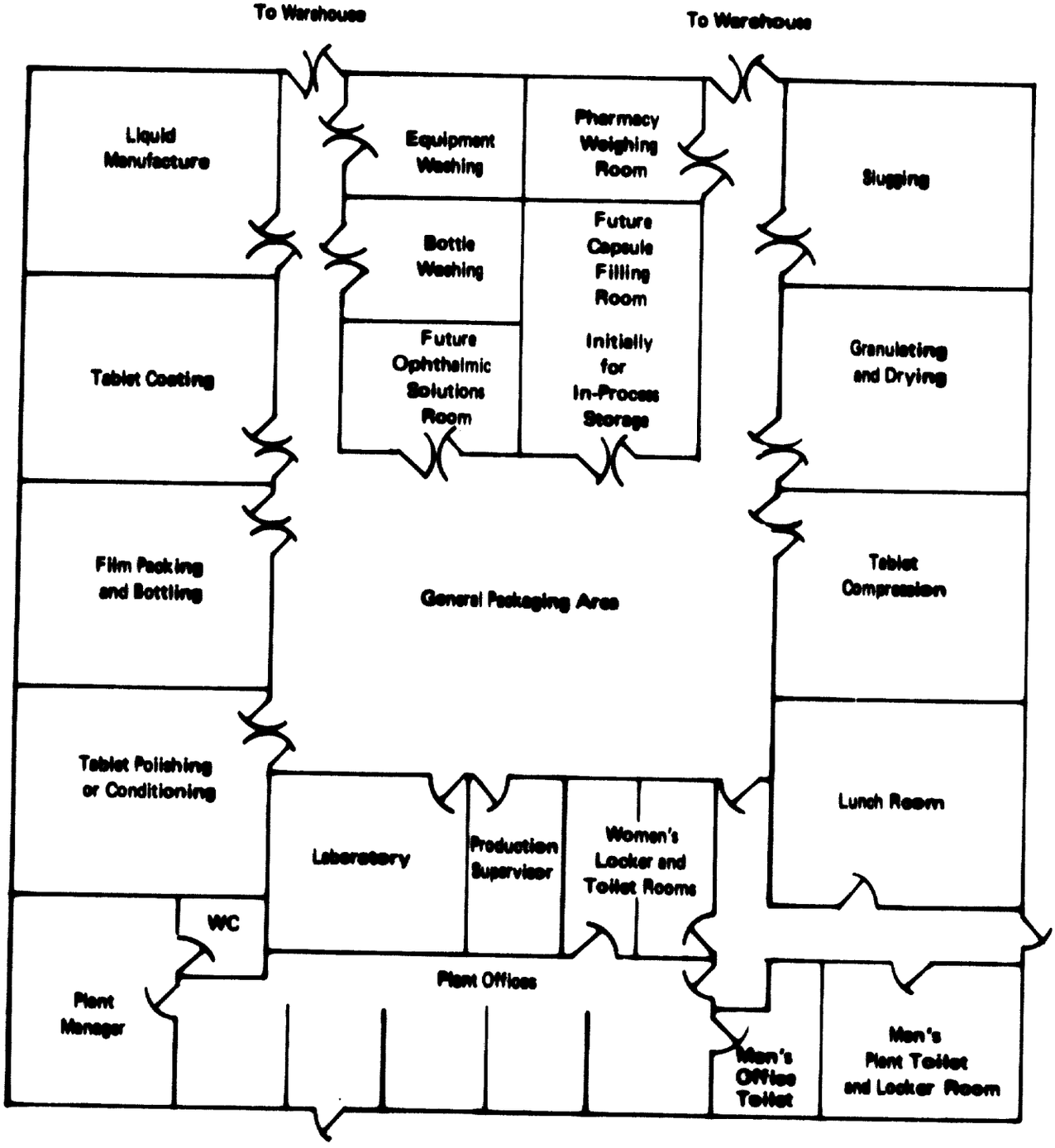
D. PERSONNEL REQUIREMENTS

The labor manning and expenses are shown in Table VIII-3. A total of 20 hourly operators are required for the one-shift operation.



Source: Arthur D. Little, Inc.

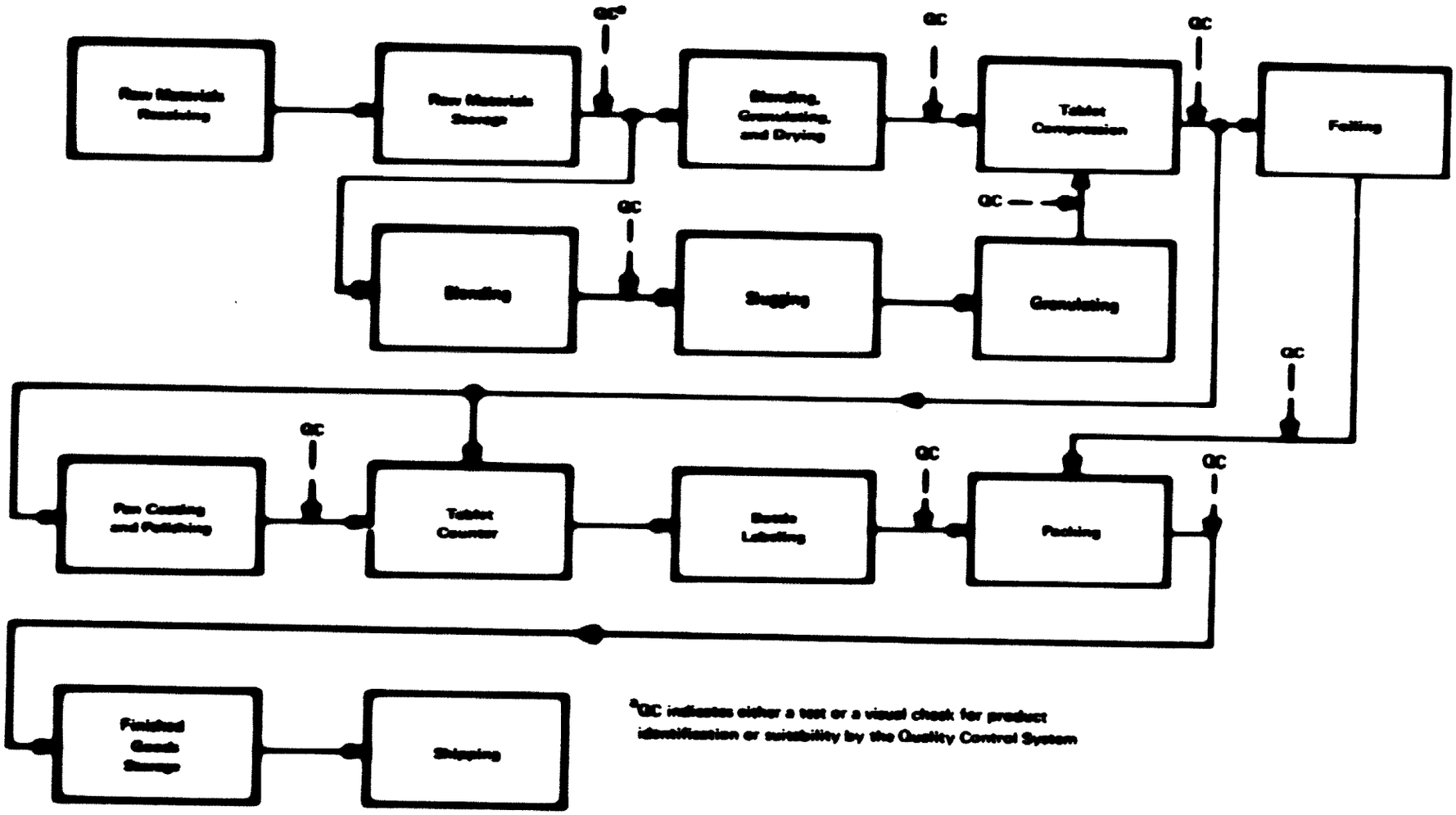
FIGURE VIII–1 POSSIBLE GENERAL LAYOUT OF PROPOSED PHARMACEUTICAL PLANT



Source: Arthur D. Little, Inc.

25 m x 25 m

FIGURE VIII-2 POSSIBLE LAYOUT OF MANUFACTURING, LABORATORY, AND OFFICE BUILDINGS



[a]QC indicates either a test or a visual check for product identification or suitability by the Quality Control System

Source: Arthur D. Little, Inc.

FIGURE VIII-3 SCHEMATIC FLOW SHEET

TABLE VIII-1
FIXED INVESTMENT

Process Equipment	Quantity	Purchase Price U.S. Dollars	Rials
Mixers, stainless steel	2	7,000	868,700
Granulators	2	4,300	334,000
Drying Ovens, Electric	2	4,000	338,700
Fitzmill	1	2,700	203,000
Twin Cone Blender	1	1,000	113,200
Slugging Presses	2	11,000	830,500
Tablet Presses	3	15,000	1,132,500
Dust Collectors	6	2,000	151,000
Punches & Dies	6 sets per machine	10,000	755,000
Coating Pans, 36"	4	7,000	528,500
Heated Air & Exhaust System		3,000	226,500
Polishing Pan with 2 extra pans	1	1,900	143,400
Tablet Counter	1	3,200	241,600
Mixing Tanks, s/s 300 gallon	2	3,000	226,000
Agitators, Electric	2	1,500	113,200
Colloid Mill, s/s	1	6,000	453,000
Filter Press, s/s	1	2,000	151,000
Bottle Washer	1	2,300	168,700
Liquid Fillers, hand operated	2	700	52,800
Foil Packer	2	12,000	900,000
Packaging Tables		2,300	168,700
Shop Equipment		5,000	377,500
Warehouse Equipment		7,000	528,200
Laboratory Benches, Hoods, etc.		7,500	565,000
Laboratory Equipment (spectro-photometers, balance, pH meters, etc.)		10,000	755,000
Small Pan Scales	6	75	5,600
Torsion Balances	3	900	67,800
Refer Smith Balances	1	300	22,600
Scale, 0-100 Kg	1	175	13,210
Scale, 0-500 Kg Flush with Floor	1	2,300	168,700
Deionized water equipment, water still and storage		3,000	226,000
Initial laboratory glassware and chemicals		2,300	168,700
Office Equipment		5,000	377,500
Total Process Equipment Cost (PEC)		107,000	11,107,010

TABLE VIII-1 (cont)

FIXED INVESTMENT

	U.S. Dollars	Rials
Process Equipment Cost (PEC)	147,000	11,147,000
Shipping Cost	11,000	000,000
Installation	35,000	2,642,000
Piping	18,000	1,350,000
Air conditioning & heating	60,000	4,550,000
Total Installed Equipment Cost (IEP)	371,000	28,000,000
Buildings and Supporting Facilities		
Site Preparation	10,000	755,000
Utility Connections	25,000	1,887,000
Warehouse (700 square meters) @ 2700 Rls/m^2	25,000	1,000,000
Manufacturing Building, Office, and Laboratories (655 square meters) @ 4300 Rls/m^2	38,000	2,887,000
Total Building and Supporting Facilities	00,000	7,000,000
Total Physical Plant Cost (PPC)	000,000	37,700,000
Engineering and Construction		
Design and Engineering (10% of PPC)	00,000	4,100,000
Purchasing, accounting, supervision during construction	70,000	5,300,000
Interest during construction	00,000	4,000,000
Contingency (20% of PPC)	73,000	5,512,000
Total Engineering and Construction	000,000	10,000,000
TOTAL FIXED INVESTMENT	000,000	47,000,000

Source: Arthur D. Little, Inc.

[redacted]

	U.S. Dollars	Rials
Raw Material and Finished Goods Inventories	[redacted]	16,100,000
Spare Parts @ 10% IPC	[redacted]	[redacted]
Total Working Capital	[redacted]	17,500,000

Source: Arthur D. Little, Inc.

[redacted]

[redacted]	No.	Annual Salary	Annual Cost
Skilled	7	110,000	770,000
Semi-skilled	5	65,000	325,000
Unskilled	6	40,000	240,000
[redacted]			
Skilled	2	110,000	220,000
Total Wages			1,555,000
Payroll Expenses, Wages @ 21%			327,000
Total Wage Expenses			1,882,000
			(894,000)

Source: Arthur D. Little, Inc.

The salaried personnel organization is set up on the assumption that the operation will be run in a manner very similar to that of a private interprise pharmaceutical company. Provisions are made for general management, plant management, and good technical and quality control support (Table VIII-4).

TABLE VIII-4
SALARIED PERSONNEL EXPENSES
(In Rials)

	Annual Cost
Plant Manager	700,000
Pharmacist	500,000
Chemist	400,000
Accountant/Bookkeeper	400,000
Production Supervisor	400,000
Q.C. Technicians 2 @ 250,000	500,000
Warehouse Clerk	200,000
Office Clerks 2 @ 150,000	300,000
Secretaries 2 @ 200,000	400,000
Total Salaries	3,800,000
Payroll Expenses-fringes @ 15%	570,000
Total Salary Expenses	4,370,000
	(667,889)

Source: Arthur D. Little, Inc.

E. OPERATING COSTS

Table VIII-5 summarizes the individual items in the total conversion cost of approximately 17,700,000 Rials ($235,000).

F. CONVERSION COST PER THOUSAND TABLETS

There is a difference in cost between coated and uncoated tablets. Therefore, we will assume a coated tablet production of 50 million tablets per year and an uncoated tablet production of 150 million tablets per year. Coated tablets cost about 50% more to make than uncoated tablets; therefore, it would cost as much to make 50 million coated tablets as it would to make 75 million uncoated tablets. At a yearly production rate of 200 million tablets, the yearly conversion cost would be divided according to the following formula:

$$150/(150+75) = \frac{150}{225}$$

which equals 66.67% for the uncoated tablets and 33.33% for the coated tablets. Therefore, 150 million uncoated tablets would have a yearly total conversion cost of 0.6667 x 17,746,000 Rials = 11,831,000 Rials or approximately 79 Rials ($1.05) per thousand tablets. The coated tablets would have a conversion cost of approximately 118 Rials ($1.56) per thousand.

G. TOTAL COST PER THOUSAND TABLETS

Additional cost for packaging material is approximately 8 Rials ($0.10) per thousand tablets if the material is packed in bottles of 1000 and approximately 25 Rials ($0.33) per thousand if packed in foil strips which are further packed in boxes of 1000 tablets each.

While the conversion cost per thousand tablets is quite constant for any of the tablets manufactured, the raw material ingredient cost will vary widely from product to product depending on the quantity of active ingredient per tablet and its unit cost per kilogram. Raw material costs may range from as low as 30 Rials ($0.40) for isonicotinic hydrazide to 600 or 700 Rials ($8.00 or $9.00) for the tetracycline antibiotics.

The total cost per thousand tablets can be calculated by adding the conversion cost for either coated or uncoated tablets to the packaging costs and raw materials costs.

TABLE VIII-6
CONVERSION COSTS*
(Plate)

BASIS: 1 Shift per day, 260 days per year

CAPITAL INVESTMENT:

Equipment Cost	–	36,667,000
Buildings, site	–	13,813,000
Total Fixed Investment	–	47,300,000
Working Capital	–	17,355,000

	Annual Cost	% of Total Cost
Raw Materials, delivered	–	–
Hourly Labor (from Table VIII-3)	1,552,000	10.6
Maintenance @ 2% IEC	400,000	2.3
Maintenance Supplies @ 2% IEC	400,000	2.3
Utilities and Laundry	1,600,000	10.7
Miscellaneous Production Supplies	160,000	0.9
Depreciation		
Equipment @ 10%	3,300,000	19.0
Buildings @ 3%	400,000	2.3
Interest @ 12% on Working Capital	2,004,000	11.7
Local Taxes and Insurance @ 3% of Fixed Investment	1,419,000	8.0
Salaried Personnel Expenses (from Table VIII-4)	4,370,000	24.6
Office Overhead: supplies, communications, etc. @ 25% of salaries	870,000	4.9
Freight Out	500,000	2.8
Total Conversion Cost	17,700,000	
	(rounded)	

*Includes all yearly operating costs except raw materials and packaging materials.

Source: Arthur D. Little, Inc.

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IX. FINE CHEMICAL MANUFACTURE

A. BACKGROUND

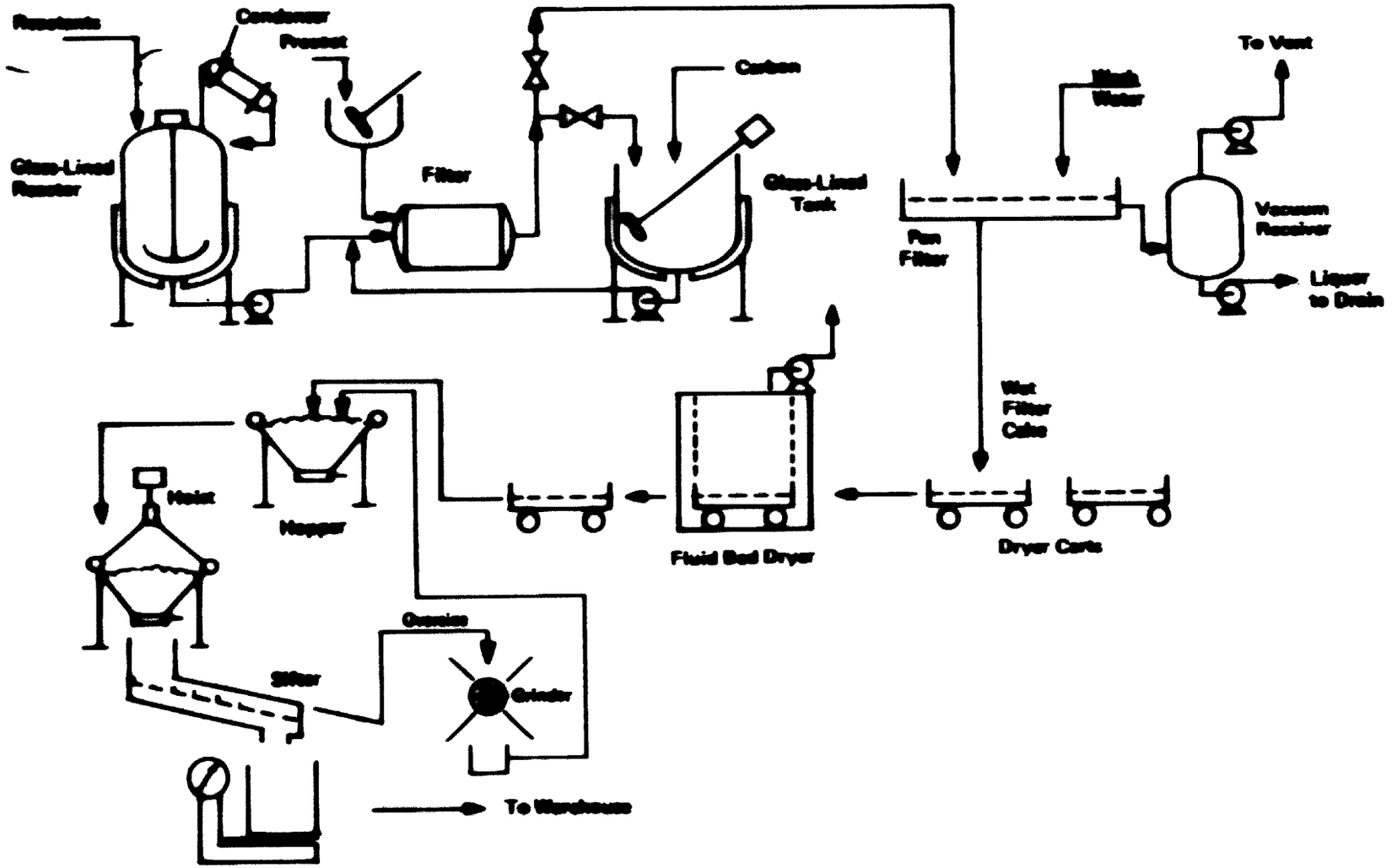
A general purpose process for fine chemical manufacture is described in this Chapter. The products from this plant, shipped in 25- or 50-kilo fiber drums, are to be converted into tablets or solution in subsequent steps. We have not specified the identity of the products but they could be medicinal chemicals such as sulfa drugs, analgesics, sedatives, etc. The process described here is carried out in general-process equipment and is typical of commercial processes for fine chemicals. The plant would be suitable for the manufacture of dye and pigment intermediates, some rubber chemicals, plastics additives, and other organic chemicals, as well as bulk pharmaceuticals. Starting materials would be standard products which could be imported on a competitive basis from many producing countries. For example, manufacture of sulfonamides could be based on imported acetyl sulfanilyl chloride (ASC) and it would not be necessary to synthesize laboriously this material from local petroleum sources. However, as an Iranian organic chemical industry develops, more compounds may become available locally.

Our calculations suggest the magnitude of the investment and the allocation of other resources necessary to produce fine chemicals on a reasonable commercial scale. The plant is sized to manufacture about 230,000 Kg of product per year in a 2-shift, 250-day operation. If the product has a sales price of 330 Rials per kilo, the annual sales value of the product is 75 million Rials per year.

B. PROCESS

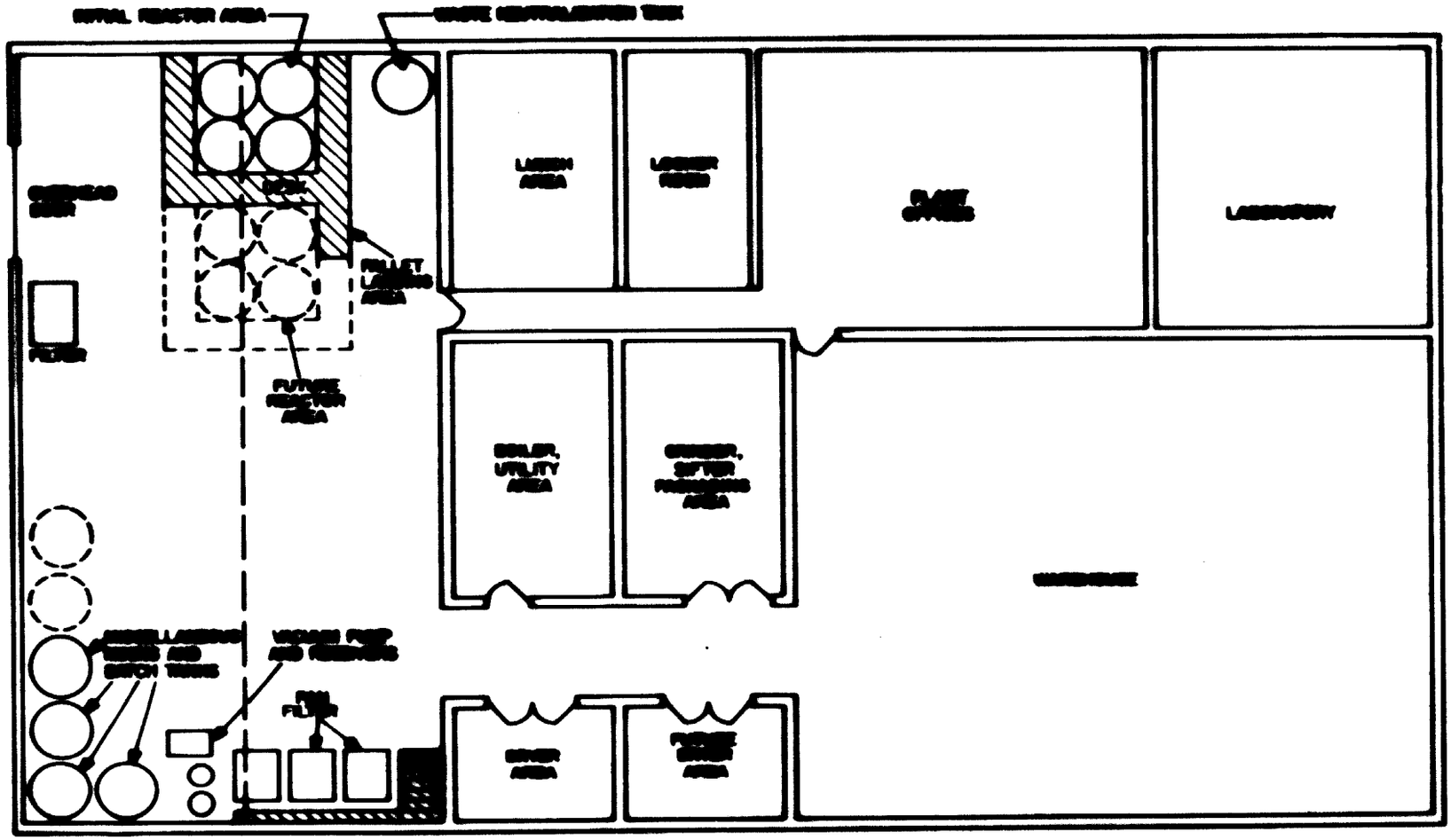
The process flowsheet is shown in Figure IX-1. Raw materials are charged from drums or bags or pumped into a 7500-liter (2000-gallon) glass-lined reactor. The reactor is equipped with an agitator, jacket, condenser, and receiver. At the completion of the reaction, the batch is pumped to a stirred hold tank. Carbon or other absorbent is added to remove color bodies or impurities, and the batch is recycled through a pressure filter until clear. It is then cooled to crystallize the product. The solid product is filtered on a vacuum tilting-pan filter. This type of filter is more versatile and less prone to maintenance problems than centrifuges or continuous filters. The wet filter cake is transferred to carts, and the product is dried on the carts in a batch fluid bed dryer. The dried solid is screened and packaged into weighed containers. Any oversize solid is ground and recycled to the sifter.

A yield of about 450 Kg per batch is assumed. The complete processing cycle for each batch should be about 16 hours. With two reactor systems in phased operation, the plant should produce two batches per day in two-shift operation.



Source: Arthur D. Little, Inc.

FIGURE IX-1 GENERALIZED FLOWSHEET



Source: Arthur D. Little, Inc.

FIGURE IX-2 POSSIBLE PLANT LAYOUT

C. PHYSICAL FACILITIES

Figure IX-2 shows a possible plant layout. The total plant area, not including general offices, is about 750 square meters, divided roughly into thirds for the reaction area, grinding and warehouse, and personnel facilities. A suggested layout for the reaction area is shown on the figure. The reactors are grouped in the center of the floor to provide early access for raw materials, convenient operation by one or two men, and inexpensive hookup of steam, water, and electricals. The in-process storage tanks can be located in any available floor area, because there is no requirement for operator access to them. However, it is essential to provide adequate floor space around the pan filters to permit efficient unloading of the filters and movement of wet cake carts. The reactor area provided will allow for some future expansion.

The dryer area and the grinder-packaging area are partitioned and ventilated separately to control dusting and prevent cross-contamination. If the majority of the production is packaged in 50-Kg drums, the warehouse space requirements will be moderate. A month's production is about 190 drums, which would require an area of about 55 square meters (including aisle space) if stacked on pallets two high. About 150 square meters of warehouse space are provided in the plant layout. Part of the additional space will be required if the product is put into a variety of package sizes or if there are a number of different products.

D. INVESTMENT

The fixed investment for the process is summarized in Table IX-1. The Installed Equipment Cost is about 27 million Rials, and Buildings and Supporting Facilities are estimated at 12 million Rials. The Total Fixed Investment, including Engineering and Construction, is 65 million Rials. The fixed investment estimate assumes starting from bare ground. The investment (and the time required to start operation) could be reduced considerably if the operation were to be set up in an existing general purpose building.

TABLE IX-1
FIXED INVESTMENT

Process Equipment	Purchase Price U.S. Dollars	Purchase Price Rials
2000-gallon Glass-Lined Reactors - 3 (includes one spare)	[illegible]	[illegible]
Pressure tank filter, stainless steel	[illegible]	[illegible]
Condenser, glass	[illegible]	[illegible]
5' x 5' stainless steel filter pans - 3	[illegible]	[illegible]
Vacuum pumps, tank, and controls for filters	[illegible]	[illegible]
Miscellaneous slurry tanks, receivers	[illegible]	[illegible]

[illegible] III-1 (cont)
[illegible] INVESTMENT

Process Equipment (cont)	Purchase Price U.S. Dollars	Plate
Liquid raw material storage tanks, glass reinforced polyester, 10,000 gallons - 4	[illegible]	[illegible]
Transfer pumps, centrifugal, stainless steel - 6	[illegible]	[illegible]
Portable mixers - 3	[illegible]	[illegible]
Filter cake transfer cars - 10	[illegible]	[illegible]
Fluid bed dryer	[illegible]	[illegible]
Dry solid transfer hoppers - 10	[illegible]	[illegible]
Mixer	[illegible]	[illegible]
Sifter	[illegible]	[illegible]
Grinder	[illegible]	[illegible]
Scale with recording device	[illegible]	[illegible]
Instruments, controlling - 4	[illegible]	[illegible]
Instruments, indicating - 10	[illegible]	[illegible]
Total Process Equipment Cost (PEC)	[illegible]	[illegible]
Process Equipment Cost (PEC)	[illegible]	[illegible]
Transportation to plant site @ 8% PEC	[illegible]	[illegible]
Equipment foundations, spotting on site, rigging @8% PEC	[illegible]	[illegible]
Steel decking, stairs, etc.	[illegible]	[illegible]
Process piping, steam and water connections to process equipment - materials and labor	[illegible]	[illegible]
Electricals: starters, panels, in-plant distribution - materials and labor	[illegible]	[illegible]
Instrumentation - installation, calibration - materials and labor	[illegible]	[illegible]
Instrument air compressor, installed	[illegible]	[illegible]
Painting and insulation	[illegible]	[illegible]
Lift truck	[illegible]	[illegible]
Total Installed Equipment Cost (IEC)	[illegible]	[illegible]
Buildings and Supporting Facilities		
Site preparation - grading, filling, roads parking area, fencing	[illegible]	[illegible]

TABLE IX-1 (cont)
FIXED INVESTMENT

	Purchase Price	
	U.S. Dollars	Rials
Buildings and Supporting Facilities (cont)		
Water system: well, pump, storage tank, cooling tower, lines to and from plant area	[illegible]	[illegible]
Boiler - 300 HP, packaged steam tube, with controls, distribution lines, fuel tank	[illegible]	[illegible]
Electrical distribution - transformer, lines	[illegible]	[illegible]
Chemical drains, settling pond	[illegible]	[illegible]
Process Building 280 m^2 (3000 ft^2) @ 3700 R./m^2	[illegible]	[illegible]
Warehouse and grinding building 280 m^2 (3000 ft^2) @ 2700 R./m^2	[illegible]	[illegible]
Laboratory, office, personnel area 180 m^2 (2000 ft^2) @ 4300 R./m^2	[illegible]	[illegible]
Total Buildings and Supporting Facilities	[illegible]	[illegible]
Total Physical Plant Cost (PPC)	[illegible]	[illegible]
Engineering and Construction		
Design (15% of PPC)	[illegible]	[illegible]
Purchasing, accounting, supervision during construction	[illegible]	[illegible]
Interest during construction: 12% of 75% of total investment for 1 1/2 years	[illegible]	[illegible]
Contingency	[illegible]	[illegible]
Total Engineering and Construction	[illegible]	[illegible]
TOTAL FIXED INVESTMENT	[illegible]	[illegible]

Source: Arthur D. Little, Inc.

The Net Working Capital (Table IX-2) is about 28 million Rials. More than half of this total is in receivables, assuming about 75 days for payment.

E. PERSONNEL REQUIREMENTS

The labor manning and expenses are shown in Table IX-3. A total of 24 hourly operators are required for the two-shift operation. The manning table has been set up on the assumption that a pool of skilled chemical operators is not available. Although the number of operators per shift is somewhat higher than for a comparable U.S. operation located in an area in which trained chemical operators are available, the total annual hourly labor cost is similar.

The salaried personnel organization (Figure IX-3) is set up on the assumption that the operation will be completely self-contained, with the exception of the original product and process development work. Provisions are made for general management, plant management, and technical support (Table IX-4). It is assumed that sales will be made to a small number of converters and regional distributors; therefore, the sales effort for the operation will be principally in scheduling and coordination.

F. OPERATING COSTS

Table IX-5 summarizes the operating costs for the assumed operation. The total conversion costs are estimated at about 130 Rials per Kg. The largest single conversion cost item is 50 Rials for salaried personnel expenses. Note that for most operations of this type raw materials (not included in our estimate) account for 50-70% of the total manufacturing cost, and all other expenses (as shown in Table IX-5) account for only 30-50% of the total.

G. FACTORS AFFECTING THE MANUFACTURE OF BULK MEDICINAL INGREDIENTS IN IRAN BY PRIVATE INDUSTRY

The bulk medicinal ingredient manufacturing operation outlined here would require a fixed investment of 65 million Rials ($869,000) and a working capital of 28 million Rials ($445,000). If the product were sold at 330 Rials ($4.40) per Kg, the operation would have annual sales of 75 million Rials ($1,000,000). Presumably, these sales would supplant present imports of approximately the same value. Assuming one-third of the value of the bulk pharmaceuticals would be imported as raw materials for the operation, the direct saving in foreign exchange would be 50 million Rials ($665,000) per year. In addition, the operation would have an annual payroll of about 13.5 million Rials ($180,000) and would add roughly another 16 million Rials ($210,000) to the economy in the form of payments for other services and materials.

TABLE IX-2
WORKING CAPITAL

Assume product is sold at 200 Rials ($4.40) per Kg
Annual sales are 75,000,000 Rials ($1,000,000)

	U.S. Dollars	Rials
Raw material inventory @ 1 month usage	[illegible]	[illegible]
Finished product inventory @ 1 1/2 month sales	[illegible]	[illegible]
Receivables @ 20% annual sales	[illegible]	[illegible]
Spare parts @ 20% installed equipment cost	[illegible]	[illegible]
Gross	[illegible]	[illegible]
Less Payables @ 1 1/2 months usage	[illegible]	[illegible]
Net Working Capital	[illegible]	[illegible]

Source: Arthur D. Little, Inc.

[redacted]

[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]:				
[redacted]	2	4	[redacted]	[redacted]
[redacted]	1	2	[redacted]	[redacted]
[redacted]:				
[redacted]	2	4	[redacted]	[redacted]
[redacted]	1	2	[redacted]	[redacted]
[redacted]	2	4	[redacted]	[redacted]
[redacted]				
[redacted]	2	4	[redacted]	[redacted]
[redacted]	2	4	[redacted]	[redacted]
[redacted]				[redacted]
[redacted]				[redacted]
[redacted]				[redacted]
[redacted]				[redacted]

Source: Arthur D. Little, Inc.

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TABLE III-4
SALARIED PERSONNEL EXPENSES

	Rials/Year
President and General Manager	[illegible]
Sales Coordinator	300,000
Plant Manager	700,000
Comptroller and Office Manager	[illegible]
Executive Secretaries (4) @ [illegible]	[illegible]
Purchasing Agent	300,000
Clerks, Bookkeepers ([illegible]) @ 100,000	700,000
Process Control Supervisor	300,000
Inventory Clerk	300,000
Production Supervisor	300,000
Shift Foremen, Production ([illegible]) @ [illegible]	[illegible]
Chief Plant Engineer	[illegible]
Engineer	300,000
Draftsmen, Engineering Clerk ([illegible]) @ [illegible]	400,000
Maintenance Shift Foremen ([illegible]) @ [illegible]	[illegible]
Chief Chemist	[illegible]
Chemist	300,000
Q.C. Technicians ([illegible]) @ [illegible]	700,000
Process Technicians ([illegible]) @ [illegible]	[illegible]
Secretary	100,000
Total Salaries	9,700,000
Payroll expenses, fringe @ 15%	1,400,000
Total Salary Expenses	11,210,000
	([illegible])

Source: Arthur D. Little, Inc.

TABLE IX-6
OPERATING COSTS *
(Rials)

BASIS: 1 batch (450 Kg) per shift, 2 shifts per day, 250 days per year

ANNUAL PRODUCTION: 227,000 Kg

CAPITAL INVESTMENT:

Equipment Cost	— 26,535,000
Buildings, site	— 38,620,000
Total Fixed Investment	— 65,155,000
Working Capital	— 28,370,000

	Annual Cost	Cost per Kg
Raw Materials, delivered	....	....
Hourly Labor (Operating and Maintenance from Table IX-3)	2,335,000	10.29
Containers and Labels	950,000	4.18
Maintenance materials @ 5% IEC	1,330,000	5.86
Utilities	1,000,000	4.41
Miscellaneous Production Supplies	750,000	3.30
Depreciation:		
Equipment @ 10%	2,654,000	11.69
Buildings @ 3%	1,160,000	5.11
Interest @ 12% on Working Capital	3,400,000	14.98
Local Taxes & Insurance @ 3% Fixed Investment	1,900,000	8.38
Salaried Personnel Expenses (from Table IX-4)	11,210,000	49.38
Office Overhead: supplies, communications, travel, contributions, etc. @ 20% salaries	2,200,000	9.91
Freight out @ 4.40 R./Kg	1,000,000	4.41
Total Conversion Cost	30,000,000	132.16
	(8388,889)	(91.79)

* Includes all yearly operating costs except raw materials.

Source: Arthur D. Little, Inc.

As fine-chemical manufacture is not capital-intensive, the minimum economic plant size is not large. A plant of the size described here could compete economically with virtually any plant in the world making similar products, assuming that it were not at a disadvantage with regard to raw material position, access to the market, or Government-controlled factors (e.g., taxes, tariff position, incentives, etc.). In a highly-diversified economy, a plant of this type would be built by a company with a large captive market, or by a company seeking to supply a position of a large free (i.e., noncaptive) market. In a less diversified economy, a plant of this type would more likely be built specifically to supply the present and projected requirements of existing end-product marketers. Although the plant design lends itself to manufacture of a wide variety of chemicals, in a less-diversified economy there would be restricted opportunity to convert the plant to other products if the markets for the initial products did not materialize as expected. Therefore, the prospective manufacturer of bulk pharmaceuticals must be confident that he will achieve his projected sales levels in the specific products he is planning to manufacture. It may be concluded that existing users of the bulk chemicals (i.e., existing marketers of pharmaceutical preparations) would be the most likely candidates for manufacture of these products in Iran.

Many bulk pharmaceuticals are no longer protected by patents throughout most of the world. However, over many years the manufacturers of these products have developed very strong commercial positions through diligent market development work, promotion of proprietary formulations and trade names, and development of consistently high-quality products. As a result, most existing manufacturers have built a strong competitive position and are enjoying the result of this effort in the form of a relatively high return on investment. All other factors being equal, it would require an equally good or better return on investment to induce one of these companies to manufacture in Iran rather than supply bulk pharmaceuticals to the Iranian market from existing plants outside of Iran.

In the United States a new investment in fine chemicals would be expected to return more than 30% (before taxes) on total capital employed. Obviously, many other factors must be considered in an investment decision, but if the projected return were much less than 30%, the project would not be considered economically attractive. We understand that present Iranian law limits the return on investment for pharmaceutical operations. Because of the vast body of technical expertise built up in pharmaceutical manufacture, it is likely that outside investment or assistance will be required to establish pharmaceutical manufacture in Iran. It is also likely in the light of the present profit restrictions that Government incentive in some form will be required to induce outside firms to participate in a venture of this type in Iran.

The investment incentives which could be offered to a new venture are well known to Government. Some characteristics of this particular potential project which should be considered in reviewing possible incentives are as follows:

(1) Because of the constantly-changing technology and markets for pharmaceutical products and the consequent risk of technological obsolescence, pharmaceutical manufacturers strive for the earliest possible payout on initial investment. Incentives that assist early recovery of invested capital should be more attractive than incentives which improve overall project profitability over a long period.

(2) This project may be considered technology-intensive rather than capital intensive. The major problem in establishing the project lies in acquiring or developing the technology, and assembling and training and skilled management and labor team. Once this "center of excellence" has been established, the investor is naturally anxious to apply it over as broad a base as possible. Incentives that would encourage this possibility would be particularly attractive. For example, some assurance could be provided that the venture would be in a favorable competitive position for a number of years to supply the Iranian market with specified classes of bulk pharmaceuticals. Particularly important would be any assistance the Government could provide to enable the Iranian venture to supply the same bulk pharmaceuticals to other markets; for example, Turkey, Iraq, and Pakistan.

(3) Incentives that relieve the venture of most of the costs of training management and hourly employees would be useful. Establishment of related educational programs at universities and trade schools would be beneficial.

Because the project would not be a major user of fuel, power, water, rail transportation, and other infrastructure elements, incentives relating to these factors would not be decisive.

In general, preliminary analysis indicates that manufacture of bulk pharmaceuticals in Iran could be attractive to private investors and to the economy as a whole. More detailed analysis could be made when specific proposed projects are identified.

APPENDICES

APPENDIX A

PERSONNEL CONTACTED IN IRAN FOR ADL-UNIDO PHARMACEUTICAL STUDY

UNIDO Office

Dr. A. N. Rao, Project Manager
Mr. F. G. Lamont, Chemical Engineer
Mr. F. Bazargani, Chemical Engineer
Dr. Alavi, Pharmacist
Dr. Abu El-Haj, Economist

Ministry of Economy

H. E. Mr. J. Ashrafi,	Deputy Minister of Economy and Managing Director of the Research Centre for Industrial and Trade Development
Mr. H. A. Mehran,	Director General of Research and Deputy Managing Director of the Research Centre for Industrial and Trade Development
Dr. Tari,	Price Control
Mr. Maghbeli,	Bureau of Statistics

Pharmaceutical Companies

1. Triton S.A.
   Dr. F. Mossanen
2. Berlimed Iran AG
   Mr. Wolfgang Bernhardi
3. Tolidaru
   Mr. Mohammad Robati, Plant Manager
4. Cyanamid-KBC
   Dr. A. Nouri
5. Darou-Pakhsh
   Dr. R. Samii
6. Sterling Products International, Inc.
   Mr. Georg Eidenschink
7. Pfizer Iran
   Mr. R. H. Honol

APPENDIX A (cont)

Central Bank of Iran

Mr. B. Homayoon, Chief, Economic Statistic Department

United States Embassy

Mr. Charles A. Mast, Vice Consul

Association of Pharmaceutical Manufacturers in Iran

Dr. Nabavi, Secretary

Plan Organization

Mr. M. Baquer Namazi
Dr. Amini
Dr. Tarmara Jamilzadeh

Ministry of Health

H. E. Dr. M. Shahqoli, Minister
H. E. Mr. M. Assar, Director General – Planning & Programming
Dr. M. Dadgar, Director General and Chief Health Corps
Dr. A. Naderi, Director, Drug Control
Dr. Ghane, Director of Health Corps at Isfahan
Dr. Tavana, Director General of Health, Isfahan
Dr. Mehdi Loghmani, Dep. Director of Health, Isfahan
Dr. Amiri, Doctor at Health Corps Unit at Mourtche-Khort

Iran Statistical Center, Census Bureau, Plan Organization

Dr. Sotoudeh
Mr. Farrokh
Miss Tamerzian

Imperial Iranian Pharmaceutical Institute

Dr. Jalal Badakhshan, Executive Director

Workers Social Insurance Organization

Dr. Fakhra'i

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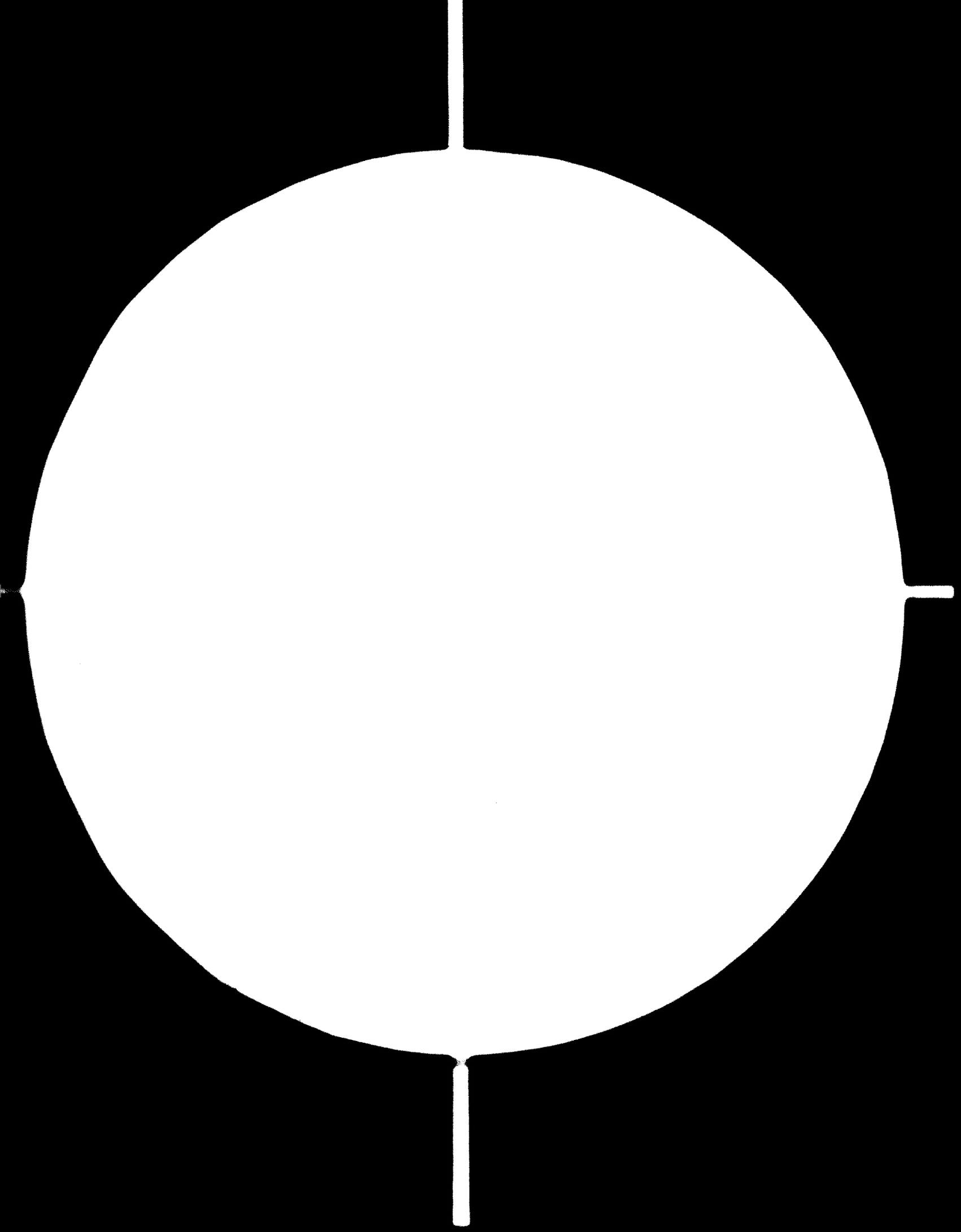

III. PRICES AND PROFITS IN THE PHARMACEUTICAL INDUSTRY

With a few exceptions the pharmaceuticals provided by the pharmaceutical industry until the 1930's were not curative but merely palliative. Consequently the pharmaceutical companies were rather small businesses that were regarded as helpful assistants to the doctors who were at the forefront of the fight against disease.

Introduction of the sulfonamides began to change both the practice of medicine as well as the character of the pharmaceutical industry. The companies started to invest heavily in research for new sulfonamides and set up clinical testing programs to evaluate them on patients. The industry's rate of change was stepped up by the successful production of penicillin during World War II. The profits from the sale of penicillin in the immediate post-war years financed much of the research that led to newer antibiotics, hormones, central nervous system drugs, etc. that spilled out of the laboratories in the next twenty years. Sales and profits climbed rapidly as a few fortunate companies (especially those in the antibiotic market) grew as much as fiftyfold in the post-war period.

By 1960 the U.S. pharmaceutical industry was "big business" and came under attack in the famous Kefauver drug price hearings in the U.S. Senate. Subsequently the international pharmaceutical industry was investigated in dozens of countries around the world.

Other industries (such as the automobile industry after World War I) had gone through periods of rapid growth in sales and profits without incurring the public wrath accorded the pharmaceutical industry. Why was the latter different? The difference is at least fivefold: 1) pharmaceutical products can be of life and death importance; 2) many pharmaceuticals are paid for by governments as part of increasingly expensive health care systems; 3) it is an innovative industry based on heavy research expenditures and it uses the patent system to protect its heavy research investments; 4) unlike many other research-based industries (such as space and aircraft firms), its research is not appreciably financed by governments and the research and development costs must be borne by its commercially successful products; 5) also unlike the traditional economic model of companies competing by price competition, the pharmaceutical companies compete mainly by product substitution.

The above differences were not generally recognized by economists, politicians, the lay public and even by the executives of many pharmaceutical companies. Many pharmaceutical executives forgot that they were in a business that concerned the life and death of human beings and concentrated on maximizing product introductions, sales and profits. Although the Kefauver investigations were patently unfair to the industry, they did force the industry to review its social as well as business role.

On the other hand, people who, without complaint, paid $3.50 for a carton of cigarettes or $7.00 for a bottle of whiskey objected to paying a like amount for "a few little pills" even if they were life-saving. Many critics stated that the pharmaceutical companies were making "excessive" profits and countless meetings were held throughout the world to determine what a "reasonable" profit for the companies should be. Likewise attacks were made on the limited monopoly granted under the patent systems. Some groups took the position that the pharmaceutical industry should make a profit no greater than the average of all manufacturing industry; others thought that the industry should be taken over by the government and run as a non-profit government enterprise.

Despite the fact that to this day there is no agreement as to what constitutes a fair rate of profit for pharmaceutical companies, the decision was made by many governments of the world that pharmaceutical prices were "too high". Therefore, a variety of price control schemes were introduced. Some of these schemes involved only hard bargaining on the part of government purchasing agents but others involved disregard of patent rights, refusal to list certain drugs as compensable in the country's health plans, fixing of wholesale or retail prices, etc.

A complete discussion of prices and profits in the pharmaceutical industry is outside the scope of this report as the subject is so broad that several books have been written on the subject. For a good background on the industry as seen by the U.S. Health, Education and Welfare Department (HEW) we would recommend "The Drug Makers and the Drug Distributors" and "Current American and Foreign Programs" both authored by the Task Force on Prescription Drugs of the HEW. Another book which gives the outlook of many academic and industrial professionals is "The Economics of Drug Innovation" subtitled "The Proceedings of the First Seminar on Economics of Pharmaceutical Innovation, April 27-29, 1969", edited by Joseph D. Cooper, The American University, Center for the Study of Private Enterprise, School of Business Administration (1970).

The latter book contains a wide ranging discussion of the pharmaceutical industry and includes comments on the Task Force reports listed above.

Two British authors have produced very readable books that give valuable insight into the pharmaceutical industry. Dr. Wyndham Davies had been in the pharmaceutical industry in Britain and then spent from 1964 to 1966 as a Member of Parliament before writing "The Pharmaceutical Industry", Pergamon Press (1967). Professor Michael Cooper authored the first analysis of the pharmaceutical industry by an economist. ["Prices and Profits in the Pharmaceutical Industry", Pergamon Press (1966).] While some of the data are now over five years old, the basic analysis is still valuable.

The HEW Task Force determined that the 1968 pre-tax profits were 19% for the pharmaceutical industry and 13% for all manufacturing groups. The corresponding after-tax profits would be approximately 9.5% and 6.5% respectively. Table 2 gives the net sales and net earnings after taxes of the U.S. companies listed in Table 1. The net income after taxes is also calculated as a per cent of net sales for each company. These companies have been very profitable in the past and appear to have a good potential for the next few years. The pharmaceutical industry as a whole has been quite profitable but there is some concern that the profitability

may drop in the future because important pharmaceutical research breakthroughs apparently have slowed down in recent years.

The effect of changes in the industry's profit margin on U.S. prescription costs were stated by Dr. Simon N. Whitney, Professor of Economics, New York University to be as follows:(1)

> ...How much, by the way, would be saved if the Task Force were to get profits down to the average for all industries? Not having located the Task Force's estimate, I'll offer the following: To reduce the 1968 manufacturer's profit from 19 to 13 percent (the all manufacturing average) would have lowered the after-tax margin on sales from 9.5 to 6.5 percent. On a four-dollar prescription--if we use the standard estimate where half the retail price goes back to the manufacturer--the consumer would be saved exactly six cents. The savings might be upped to twelve cents if we allow for the tax loss from which the consumer benefits until he or someone else makes it good. This is the little mouse which the mountain of effort will bring forth and for which thousands of consumer letters are clamoring. I think that at least we economists should try to keep calm heads and exert our function as educators. Educate me, if that is the problem, and if I turn out to be wrong. But, if I am right, educate the public.

(1) "The Economics of Drug Innovation", p. 158.

TABLE 2

SELECTED U.S. PHARMACEUTICAL COMPANIES' SALES AND INCOME, 1969

Company	Net Sales (U.S. $ Millions)	Net Income After Taxes (U.S. $ Millions)	Net Income After Taxes as Percent of Net Sales
Abbott	404	32	7.9
American Home Products	1,192	123	10.3
Baxter	160	13	8.1
Bristol-Myers	928	68	7.3
Cutter	59	2.3	3.9
Lilly	537	83	15.5
Merck	647	101	15.6
Pfizer	806	72	8.9
Schering	214	27	12.6
Searle	164	28	17.1
Smith, Kline & French	315	40	12.7
Sterling	547	52	9.5
Upjohn	371	37	10.0

Source: Arthur D. Little, Inc. calculations based on data from "Standard Corporation Descriptions", Standard and Poor's Corporation.

IV. PRICE CONTROLS

Any price control method based on restriction of company profits must consider the effect that such restriction will have on investments the company is able and willing to make in future plant expansion and research. Some very bad mistakes have been made in price controls, as for example, Brasil's freezing of pharmaceutical prices in February 1965 while prices of all ampules, vials, printing, cardboard, tubes, etc. rose about 40% in the period to September 1965 due to the general inflation problems that have plagued the country for years.

Because of higher than average profits, the pharmaceutical companies have been willing to reinvest their retained earnings in hope of receiving additional profits. Without the profit incentive very few plants in developing countries would have been built. How much restriction on profits can be imposed without decreasing the flow of new investments is a very difficult question and is beyond the scope of our present broad study of the pharmaceutical industry in Iran.

We have stated in the main report that "Alternate methods that would remove government agencies from detailed involvement in price determination should be investigated" and that "Prices could be monitored by a government agency to ensure that they were reasonably comparable to those in other countries but the companies could be allowed much greater latitude in setting prices for the various dosage forms to be sold." Because the world prices of pharmaceuticals have stabilized in recent years we see no great danger for Iran in such an approach. However, the price control problem is a serious one, beset with many economic and political difficulties, and without an extensive study we cannot give a solution that will simultaneously insure low pharmaceutical prices and a healthy flow of capital into the Iranian industry.

V. BASIC MANUFACTURE OF MEDICINAL INGREDIENTS

We stated in the main UNIDO report that "The small size of the Iranian market initially made the local production of active ingredients financially unattractive. This situation is still true of many active ingredients but there now appears to be enough usage of a variety of synthetic organic chemicals to justify erection of a multi-product organic synthesis plant."

In our discussions in Teheran last month, we elaborated on the problems of developing basic medicinal ingredient manufacture in Iran and our reasons for indicating that only limited opportunity existed for integrating manufacture of active ingredients with the existing Iranian pharmaceutical formulation industry.

A. SMALLEST ECONOMIC UNIT FOR MEDICINAL INGREDIENT MANUFACTURE

The smallest unit that could compete economically in world trade would require a fixed investment of $750,000 to $1,000,000 for a simple (one to three step) organic synthesis plant and 6 to 10 million dollars for an antibiotic fermentation plant. To be economically feasible these plants should manufacture products whose annual value would be equal to the fixed investment or greater than $750,000 to $1,000,000 for the organic plant and greater than 6 to 10 million dollars for the fermentation plant.

B. EVALUATION OF POSSIBLE ANTIBIOTIC FERMENTATION PLANT

The five largest selling pharmaceuticals in Iran in 1969/70 were all antibiotic products as shown in Table 3. The value of the formulated product and estimates of the value at world market prices of the active ingredient are given. The estimated ingredient value for tetracycline is not sufficient to support a fermentation plant.

Even adding the estimated values for streptomycin and penicillin would not produce sufficient ingredient sales volume. Assuming that 1980 sales for tetracycline, streptomycin and penicillin are three times present volumes, the active ingredient values would be $1,000,000 to $1,500,000, $400,000 and $300,000 respectively, but still insufficient to support a truly economical fermentation unit. Ampicillin and phenethicillin are still under patent restrictions and also require additional investment in synthetic chemical equipment.

As shown in Table 3 the present requirement for tetracycline is approximately 10,000 to 15,000 kilograms per year. A fermentation plant with 2,500 gallon (9,000 l.) fermentors, delivering 6,000 l. per day would produce approximately 25,000 kg. of tetracycline per year. These are uneconomic-sized fermentors; production costs fall rapidly as fermentor size is increased but costs flatten out above 30,000 gallon (110,000 l.) fermentors so that 100,000 gallon fermentors are only slightly more efficient.

TABLE 3

LARGEST SELLING PHARMACEUTICALS IN IRAN 1969/70

	Sales Formulated Product (US$)	Estimated Ingredient Content (Kg)	Estimated Value of Ingredient (US$)
Tetracycline	$3,500,000	10-15,000	$350,000-$500,000
Ampicillin	2,700,000	(Semi-Synthetics)	-
Phenethicillin	1,500,000	(Semi-Synthetics)	-
Streptomycin	1,200,000	-	$120,000
Penicillin	1,000,000	-	$100,000

Source: Arthur D. Little, Inc.

We do not believe that a fermentation plant would be economic nor have positive national benefits at present. The 1980 antibiotic requirements may not be sufficient to support a fermentation plant that can compete on a cost basis with world antibiotic prices. However, the 1980 market might support a plant that could have positive national benefits. Due to changing conditions, we do not believe that a feesibility study on a fermentation plant is justified at this early dete. Major present emphasis should be placed on expanding the phermaceutical formuletion industry which will be critically short of cepacity in 10 years.

C. EVALUATION OF SYNTHETIC ORGANIC CHEMICAL PHARMACEUTICAL INGREDIENT PLANTS

The next five lergest selling phermaceutical preparations contain ascorbic acid, promethezine, chloramphenicol, chlordiazepoxide (Librium) and oxytetracycline with sales values of the formulated products of $800,000, $200,000, $700,000, $600,000 and $500,000 rsspectively.

Ascorbic acid requires a very lerge and compliceted plant and there are many steps in the synthesis. An economic plant would be much too large for the Iranian market. The next three ingredients are specialty products made in small volume and with expensive steps. Synthesis might be possibls for the company holding the patent if it also operated the general product plant we suggest, but volume is not sufficient for production as the sole product of a plant. Oxytetrecycline is e fermentation product and all succeeding formulated products individually sell for less than $500,000 per year.

We are therefore faced with the necessity of finding general categories of products that have a reletively large sale and whose ingredients might be manufactured in a single plant. Analgesics have a combined Iranian sales volume of $3,500,000 et present and sulfonamides sell at e present rate of $350,000. We estimate thet the present consumption of the active ingredient sulfonamides is approximately 35,000 Kg. per year worth about $250,000. With local production, an Iranian market for about 100,000 Kg. should be easily attainable by 1975. The production of several sulfonamides and one or more analgesics should give sufficient sales to support an organic synthesis plant of the type suggested in our UNIDO report.

APPENDIX

BREAKDOWN OF 1969 ANNUAL SALES OF SELECTED U.S. PHARMACEUTICAL COMPANIES BY SALES CATEGORY

	% of Sales
Abbott	
Professional Pharmaceuticals	18.4
Hospital Products, Diagnostics, Laboratory Medicinals	22.8
Pediatric Products	17.5
Consumer, Animal Health, Agricultural and Chemical Products	13
Overseas Sales	28.3
American Home Products	
Ethical Drugs	36
Packaged Drugs	17
Housewares	11
Foods	14
Household Products	12
Candy	10
Baxter	
Parenteral Solutions and Blood Containers	31
Disposable Sets for Above	10
Medical Specialties	43
Enzymes and Specialty Chemicals	8
Instrumentation	8
Bristol-Myers	
Toiletries and Cosmetics	35.1
Prescription Medicines	21.5
Proprietary Medicines	16.2
Nutritional Products	13.4
Household Products	12.9
Other Products	0.9
Cutter	
Hospital Products	68
Other Human Health Products	11
Veterinary	15
Plastic Products	6

APPENDIX (Cont'd.)

	% of Sales
Merck	
Merck Sharp & Dohme Division	37.7
Merck Sharp & Dohme International	33.5
Merck Chemical	14.8
Calgon Corporation	14.0
Pfizer	
Pharmaceuticals	46
Chemicals	24
Consumer Products	18
Agricultural Products	12
Schering	
Corticoids	22
Cold Products	19
Anti-infectives	16
Antihistamines	10
Psycho-pharmaceuticals	9
Other Products	24
Upjohn	
Antibiotics	23
Steroids	19
Antidiabetics	15
Other Pharmacologicals	14
Agricultural Products	15
Chemicals	13
Clinical Laboratory Services	1

Source: "Corporation Descriptions", Standard and Poors' Corporation.

Imperial Social Service Organization

H. E. Senator Dr. Sheibani
H. E. Dr. Kasemi
Dr. Mortazavi, Doctor at Dispensary at Dortche

Red Lion and Sun Society

Dr. Arbabzadeh
Dr. Zekri, Head of Hospital at Khorramshahr

National Iranian Oil Company

Dr. Massoud Rouhani, Director – Health Department
Dr. A. Kehnemi, Deputy Director – Health Department
Dr. Partow, Medical Director in Abadan Region
Mr. A. Akbar Sadeghi, Chief Administrator for Medical Division in Abadan Region
Plus many pharmacists and doctors in their hospitals and clinics in Abadan and Teheran.

Pars Clinic, Teheran

Dr. Shirazi, Pediatrician and Part Owner of Clinic

Razi Institute, Karaj

Dr. Morteza Kaveh, Director General
Dr. Mir Shamsi, Deputy Director

Teheran University

Dr. Hadi, Drug Section

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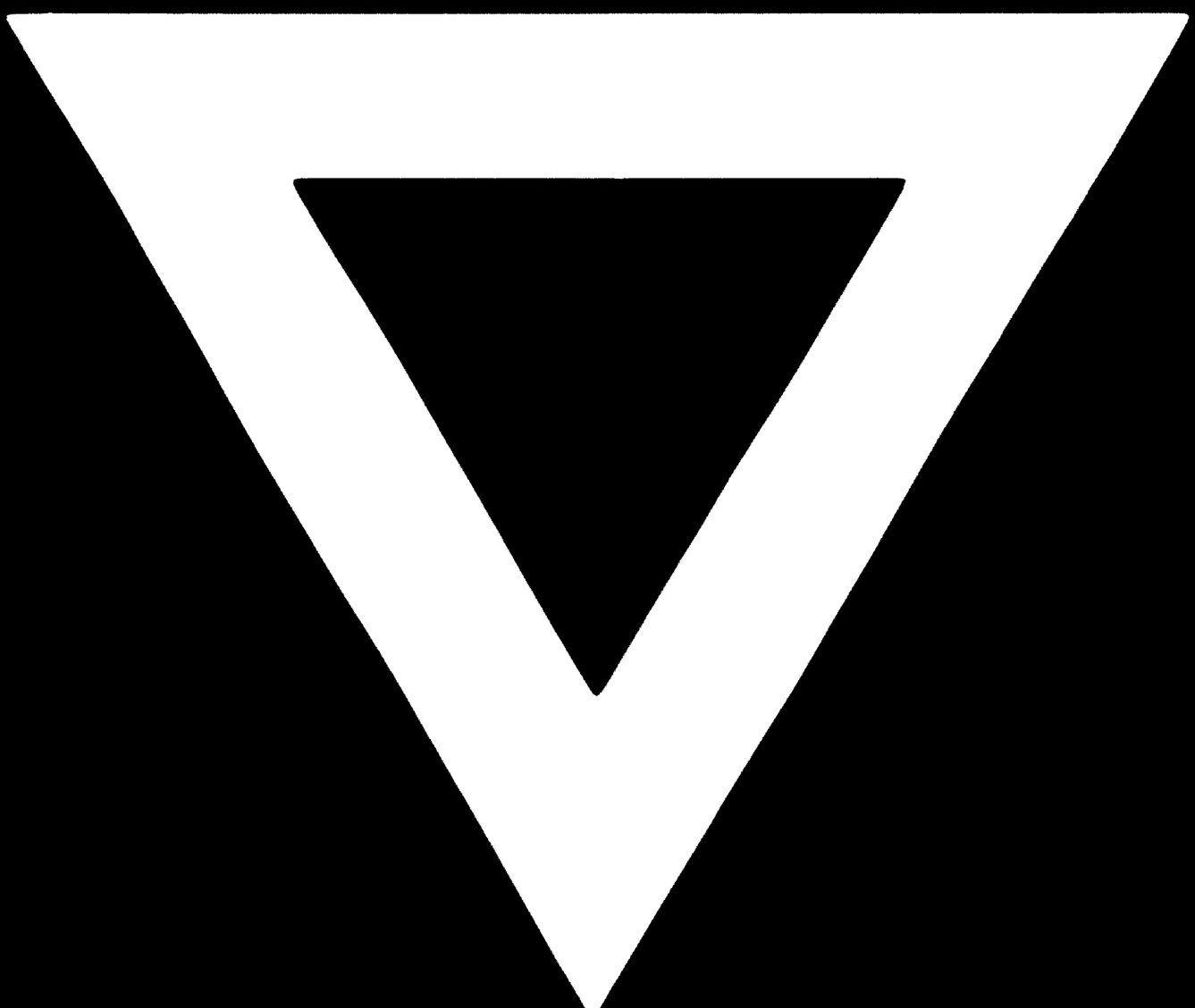

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APPENDIX B

IRANIAN CALENDAR AND IRANIAN CURRENCY

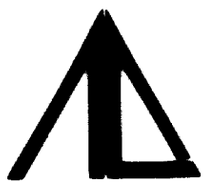
CALENDARS

The Iranian Calendar year ends on March 20 of the Gregorian calendar. Both dating systems are used in this report. When the year 1969 or 1969/70 is stated in reference to Iranian statistics, the period covered is from March 21, 1969 to March 20, 1970 and corresponds to the Iranian year 1348. The following table gives the correspondence of recent dates and future projections.

Year		Year	
Persian	Gregorian	Persian	Gregorian
1341	1962/63	1351	1972/73
1342	1963/64	1352	1973/74
1343	1964/65	1353	1974/75
1344	1965/66	1354	1975/76
1345	1966/67	1355	1976/77
1346	1967/68	1356	1977/78
1347	1968/69	1357	1978/79
1348	1969/70	1358	1979/80
1349	1970/71	1359	1980/81
1350	1971/72		

CURRENCY

Monetary value is usually stated in both Iranian Rials and U.S. Dollars. The conversion rate in recent years has been approximately 75 to 76 Rials per U.S. Dollar. For conversion purpose we have used a ratio of 75.5 Rials.



CAMBRIDGE,
MASSACHUSETTS

CHICAGO
NEW YORK
SAN FRANCISCO
WASHINGTON
ATHENS
BRUSSELS
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PARIS
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TORONTO
ZURICH

01923
(2 of 2)

SUPPLEMENTAL REPORT
ON THE IRANIAN PHARMACEUTICAL INDUSTRY

Report to

UNIDO

C-72842

May 1971

Arthur D Little Inc

I. INTRODUCTION

A representative of Arthur D. Little, Inc. (ADL) was asked to meet with UNIDO personnel and members of the staff of the Iranian Ministry of Economy in Teheran on April 5-8, 1971. The purpose of the meetings was to discuss ADL's report to UNIDO on the Iranian pharmaceutical industry and to give additional background on some of the information presented.

The principal concern of the participants in the meetings was in regard to the reasons for the small number of present opportunities for integrating basic ingredient manufacture into the existing Iranian pharmaceutical operations. The group also wanted additional information on our reasons for using a ratio of three dollars of annual sales per dollar inveated in pharmaceutical plants.

In addition the group wanted a broader background of information on the pharmaceutical industry and the problems of price controls and pharmaceutical profits.

In the following sections, we diacuss these subjects and give referencea for extendad reading on the general economics of the industry.

II. COMPARISON OF NET PROPERTY INVESTMENT AND NET SALES OF PHARMACEUTICAL COMPANIES

Comparison of the ratio of yearly net sales to net property investment is confined to U.S. corporations because the sketchy financial reports required of European corporations do not show these details.

The investment and sales figures given in the comparisons in this section were all taken from "Standard Corporation Descriptions" published by Standard and Poor's Corporation and cover 1969 annual reports because not all 1970 reports were available.

A difficulty in determining ratios of sales to investment in pharmaceutical manufacture is that all of the U.S. pharmaceutical companies have diversified so that the pharmaceutical portion of their business may produce a major share of their income or may be less than 25%. In Table 1 we have grouped representative companies into two categories based on the portion of sales derived from pharmaceuticals and one category based on specialization in a certain type of product. (Companies showing less than one-third of their income from pharmaceuticals were not included. The breakdowns of sales in different categories for these companies is given in the Appendix.)

The companies listed in the first section of Table 1 produce a large proportion of "ethical" drugs not advertised to the public and mostly sold on prescription in the U.S., whereas those in the mid-section (with the exception of Pfizer) produce a higher proportion of "proprietary" drugs usually advertised to the consumer and sold "over-the-counter". The required investment tends to be higher in relation to sales for the first grouping of companies because they usually manufacture a higher percentage of their medical ingredients (again with the exception of Pfizer) and basic chemical or antibiotic manufacture requires a larger investment per unit of sales.

These differences are reflected in the ratio of net annual sales to net investments, being about 6 to 1 for companies with high proportions of proprietary preparations and about 3 to 1 for the ethical pharmaceutical producers.

Also as indicated in Table 1, producers having a high proportion of intravenous solutions in the product line tend to have lower sales to property ratios.

The overall average weighted ratio of net annual sales to net property investment for all the companies listed in Table 1 is 3.7. In addition to data of this type, we know from past calculations of sales to investment ratios for plants in developing countries that the ratios can be influenced markedly by local conditions. A typical pharmaceutical plant in a developing country should have a higher ratio of sales to investment than the company's

plants in its home country because no expensive basic synthesis or fermentation plants are normally required. On the other hand plant sales may be restricted due to difficulties in obtaining supplies, monetary or import restriction, etc. so that sales ratios are lowered. In our main report we used a ratio of net annual sales to net investment of 3. In the Iranian economy a sales to investment ratio of 3 should be a reasonable average for the pharmaceutical industry as a whole. However, the ratios for individual companies may turn out to be from 2 to 6. The threefold ratio was used for making a reasonable estimate of the investment required to meet Iran's 1980 pharmaceutical demand and obviously should not be used to reward or penalise companies who do not match the expected ratio.

TABLE 1

NET PROPERTY INVESTMENTS AND NET SALES OF SELECTED U.S. PHARMACEUTICAL COMPANIES, 1969

	Net Property Investment (Land, Buildings, Equipment) (U.S. $ Millions)	Net Annual Sales (U.S. $ Millions)	Sales/Property Ratio
Companies With Over 2/3 of Income From Diversified Pharmaceuticals			
Searle	41	164	4.0
Merck	180	647	3.6
Upjohn	157	371	2.4
Lilly	225	537	2.4
Smith, Kline & French	77	315	4.1
Schering	47	214	4.6
Total	727	2,248	3.1
Companies With Between 1/3 and 2/3 of Income From Diversified Pharmaceuticals			
Am. Home Products	187	1,193	6.4
Bristol Myers	165	928	5.6
Pfizer	259	806	3.1
Sterling	90	547	6.1
Total	701	3,474	5.0
Companies Heavily in Production of Intravenous Solutions			
Abbott	183	404	2.2
Cutter	16	59	3.7
Baxter	81	160	2.0
Total	280	623	2.2
TOTAL	1,708	6,345	3.7

Source: Arthur D. Little, Inc. calculations based on data from "Standard Corporation Descriptions," Standard and Poors' Corporation.