

Pharmaceuticals Manufacture in Sri Lanka

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In this paper Mrs. L. G. Jayawardana (D.T.M. & H.PhD) and Mr. H. M. N. Bandara (B.Sc. Dip. Food Sc.) maintain that Sri Lanka's dependence on companies of "Developed Countries" (for at least very essential items required for primary health care) could be reduced in the near future if the expanding programmes launched by both public and private enterprises of the local pharmaceutical industry are encouraged. They also show that there is a need and potential for the development of the pharmaceutical industry within the Third World countries, but this has to be done on a rational basis. The development of the industry should be linked with controls that prevent the exploitation of the country or its people.

The arrival of Western nations in the East, influenced the life of its people in many ways. From the time of their arrival, they played a dominant role due to their advanced industrial development and technological know-how. An area in which this development gap is most marked, is in the compact and sophisticated field of pharmaceutical manufacture. The knowledge of the use of Western pharmaceutical products spread to the East with the teaching of western medicine and has far outpaced the knowledge of its manufacture. Further, the treatment of diseases with western drugs has significantly replaced (if not extensively) the indigenous systems of medicine. In the Southeast Asian and Asian Pacific Regions, only two countries can boast of real technological knowledge in pharmaceutical manufacture. Sri Lanka along with many others has lagged far behind.

Historical Aspect

At the beginning of the second half of the 20th century, small manufacturing units were set up in Sri Lanka. These were mostly for repacking of finished pharmaceuticals imported in bulk. Later they were improved and modified for formulation as well.

Presently there are 18 registered pharmaceutical "manufacturing" units in Sri Lanka (of these only one is under State administration). Among 17 approved private sector units only 12 were actively engaged in 1977/1978.

1. M/s Pfizer Ltd.
2. M/s Glaxo (Ceylon) Ltd.

3. M/s. M. S. J. Industries (Ceylon) Ltd.
5. M/s. Warner-Hudnut (Lanka) Ltd.
6. M/s. Reckitt & Colman of Ceylon Ltd.
7. M/s. Maharajah Organisation Ltd.
8. M/s. Unical (Ceylon) Ltd.
9. M/s. Arfon Laboratories Ltd.
10. M/s. Associated Pharmaceuticals Ltd.
11. M/s. Metro Pharmaceuticals Ltd.
12. M/s. Mackwood Industries Ltd.

All these manufacturers are engaged in repacking and formulation of pharmaceutical preparations using imported raw materials. Only one of them makes injectables.

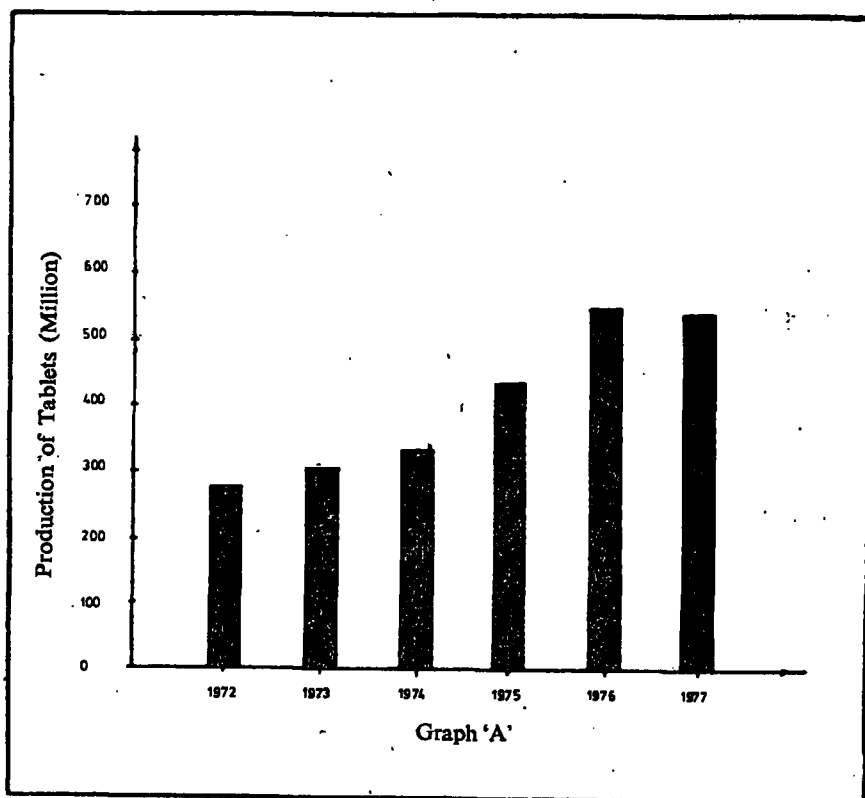
General Features of Local Manufacture of Pharmaceuticals

The pharmaceutical industry in developing countries could be broadly classified into the following groups :

- (a) **Group I** : Countries which have no pharmaceutical industry who are totally dependent on imported pharmaceuticals in their finished form.
- (b) **Group II** : Countries which have started repacking of processed pharmaceuticals imported in bulk and also make simple formulations.
- (c) **Group III** : Countries that produce a wide range of formulations in various dosage forms and also manufacture simple bulk drugs from imported intermediates.
- (d) **Group IV** : Countries which manufacture a wide range of bulk drugs from imported intermediates and who also manufacture some intermediates from locally available raw materials.
- (e) **Group V** : Countries having facilities to manufacture most of the intermediates required for the pharmaceutical industry and also having the facilities to carryout local research in order to develop new products and manufacturing processes.

Sri Lanka falls into Group II of the above classification since the industry is mostly concerned in the formulation of simple drugs and the

Local Production of Tablets



repacking of processed pharmaceuticals imported in bulk. At present over 190 preparations are formulated locally and about 20 preparations are imported in bulk for repacking into consumer packs.

Table I
Percentages of the various groups of formulation processed locally in the year 1977

Groups	Percentage
Vitamins, cough remedies	36%
Antimicrobial, antiprotozoal, antiseptic	10%
Anthelmintic, antipyretic, antifungal	13%
Others	41%

Production of Tablets

The annual requirement of tablets in Sri Lanka is in the region of 1300-1400 millions of which about 600 millions is currently manufactured locally. Ten private sector manufacturers are engaged in this activity. It has been estimated that their capacity, based on the availability of machinery is about 800 millions per annum. Although 10 firms manufacture tablets, only 4 have adequate facilities for sugar coating. Others manufacture only plain tablets. At present about 70 types of tablets are manufactured for both private and public sector distribution. It is noted that tablets for "primary health care" only account for about 20% of production for private sector distribution.

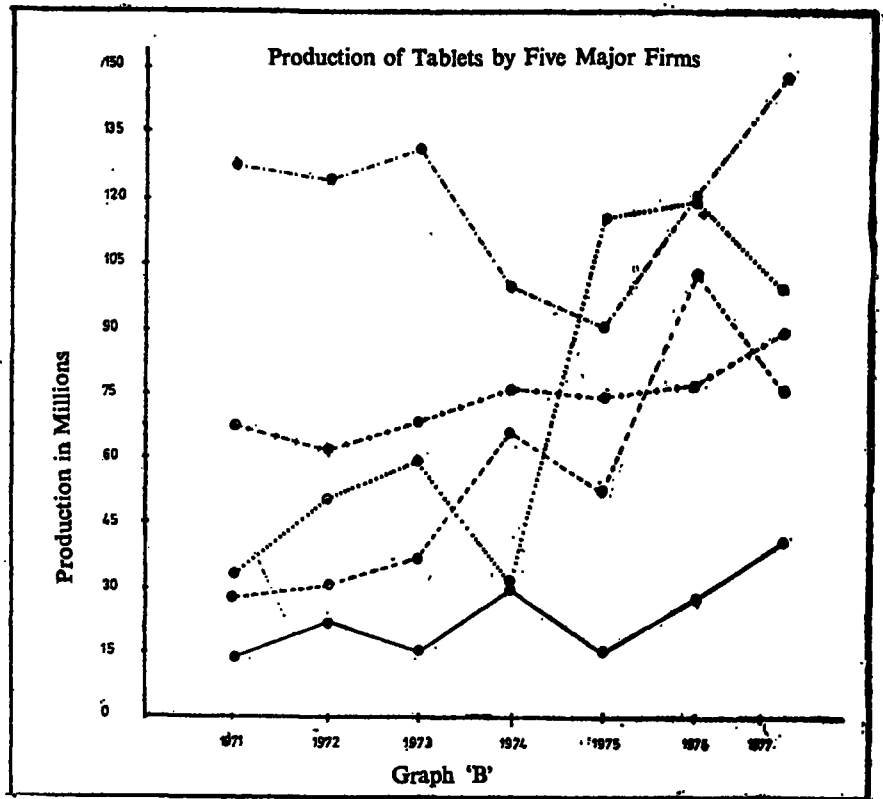
The figures for the production of tablets from 1972-1977 (Graph A), on page 26 that there is a considerable development from 290 millions to 544.2 millions in 1976 (an increase of 187%).

Graph B shows the increase in production of tablets by five individual firms for the period 1972-1977.

Production of Capsules

Five manufacturers have facilities for capsulating. Four are at present engaged in production. It has been estimated that about 60 million capsules could be manufactured with the available capsulating machines.

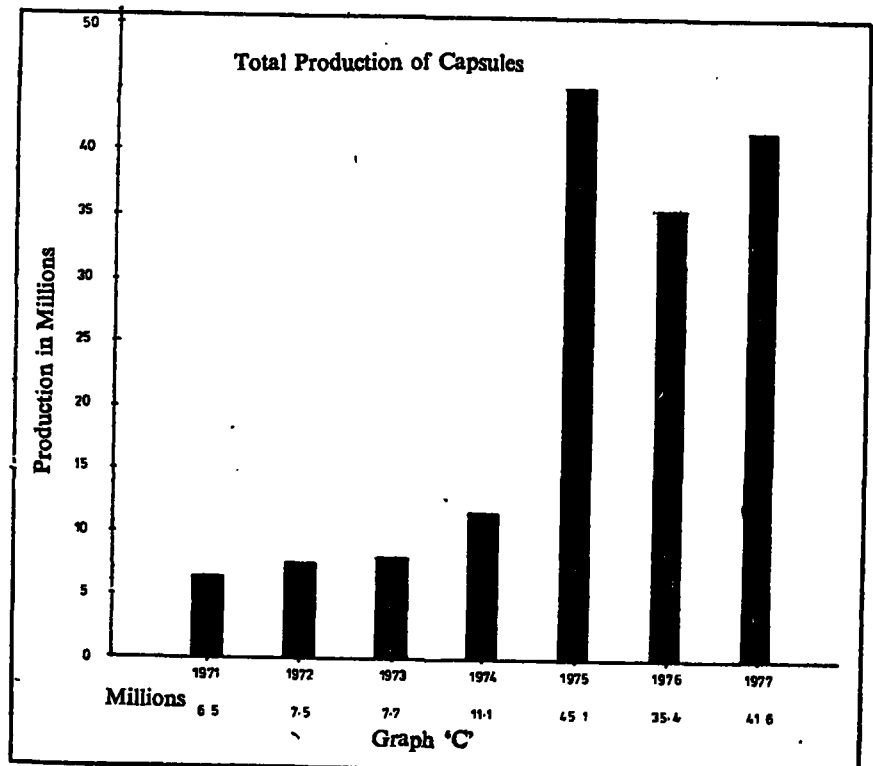
The local production of capsules was also underutilised. In 1972 the production was only 15% of the possible capacity until the SPC



commenced its contract manufacturing programme. In 1975 over 45 million capsules were manufactured locally. However, a drop in production was seen in 1976/77 due to technical problems faced by one

of the major capsule manufacturers (refer Graph C).

A salient feature in the production of capsules is that the major share is occupied by items that are required

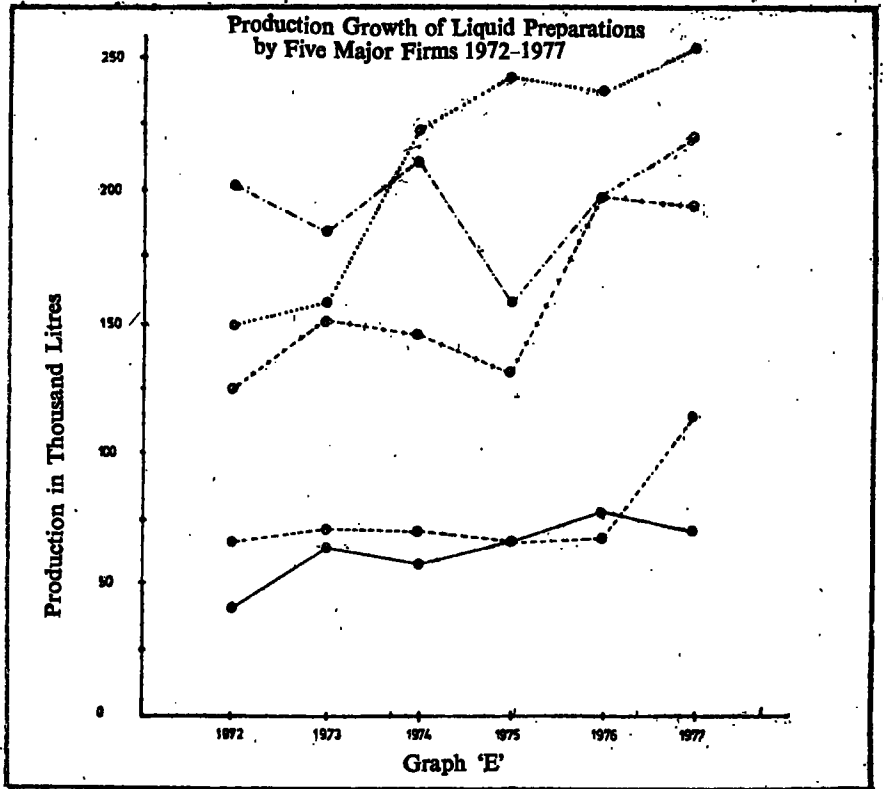
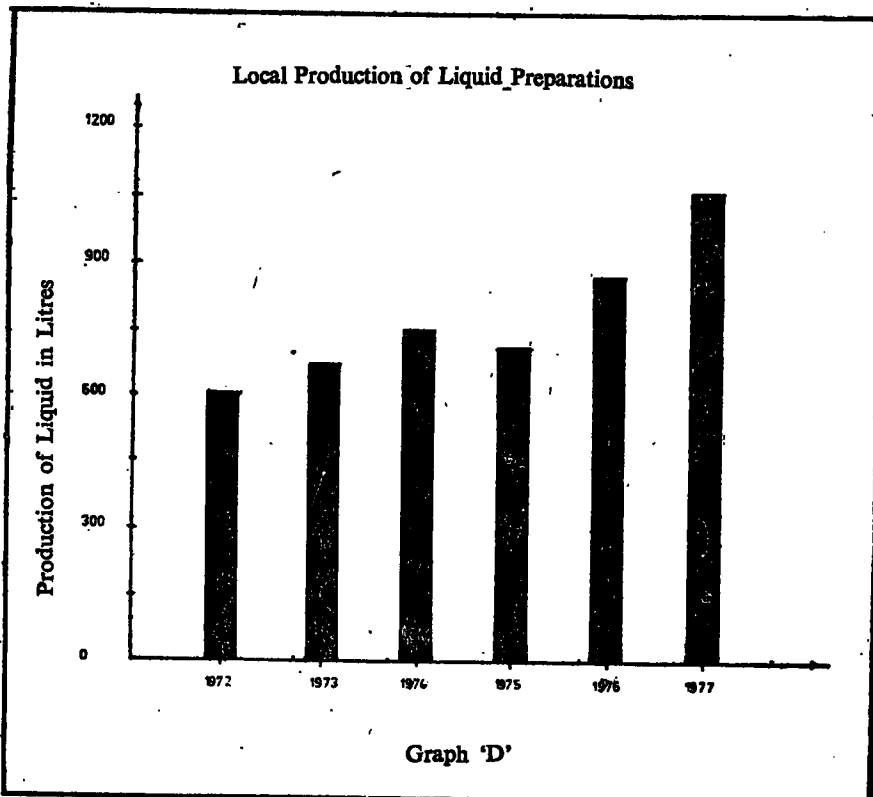


for primary health care due to the manufacturing programme of the SPC.

Production statistics for 1977 shows that five types of antibiotics and four types of vitamin capsules are manufactured in Sri Lanka. The increase in production between 1972-1977 was due to the restriction imposed on imports of pharmaceuticals which were being manufactured locally.

Production of Liquid Preparations

Currently over 65 types of liquid preparations are formulated locally by eleven pharmaceutical manufacturers. However, the major share of production is being handled by three manufacturers. It is noted that in the year 1976 the total production of liquid preparation was around 873,000 litres of which over 400,000 litres are vitamin/cough remedies or similar products. Graph D shows the growth pattern of liquid production from 1972-1977. The slight drop in 1975 is mainly due to the increase in prices of raw material presumably as a result of the oil crisis (Graph D). The increase in production of liquid preparations by five major firms for the period 1972-1977 is shown in the Graph E.



Production of Injectables

M/s. Pfizer (Ceylon) Ltd., is the only local manufacturer having facilities for the production of injectables. The following types of pre-

parations are currently being manufactured by this firm: Vitamin B1, Oxytetracycline, Cyanocobalamin and Vitamin B Compound.

In 1977 the production of injectables was in the region of 140,000 units.

Categories of Local Production

Locally processed pharmaceuticals can be grouped according to the following :

- (a) Pharmaceutical preparations manufactured by the private sector for their own distribution.
- (b) Pharmaceutical preparations manufactured by the private sector for the State on contract.
- (c) Pharmaceutical preparations manufactured by the private sector for the State on tenders.
- (d) Pharmaceutical preparations manufactured by State institutions.

Pharmaceutical Preparations Manufactured by the private sector for their own distribution

Over 85% of the total local production for the private sector distribution is met by eleven pharmaceutical manufacturers. They utilise

raw materials and packing materials imported or purchased locally by them.

Number of items manufactured for the private sector distribution (1977)

Tablets	57
Capsules	5
Liquids	65
Injectables	4
Powders	8
External Applications	22
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In 1977 these manufacturers were engaged in the production of 161 preparations. Over 40% of their production was composed of Vitamin preparations, soluble Aspirin, cough remedies, counter irritants and similar preparations.

Pharmaceutical preparations manufactured by the private sector for the State on contract (to be distributed by the State Pharmaceuticals Corporation and the State Medical Stores)

A study made during 1972 on the local pharmaceutical industry revealed that the available capacities were not fully utilised by the local manufacturers.

Available annual capacities of manufacturing firms (working one 8 hrs. shift)

	Available annual capacities of manufacturing firms (working one 8 hrs. shift)	Utilised capacity
Tablets (in millions)	750	300 (40%)
Capsules (in millions)	40	6 (15%)

The annual requirements of tablets and capsules during that time was in the region of 1000 millions and 120 millions respectively and it was estimated that if all manufacturers worked one shift, 75% of the Island's requirements could be met. In order to make better use of the

underutilised capacities of the private sector, during 1973, the State Pharmaceuticals Corporation launched a special manufacturing programme called the "34-Drug Programme". Under this scheme the raw materials supplied by the Corporation were converted into finished products and sent back to the Corporation for distribution. A manufacturing fee was paid to the manufacturers for the items manufactured under this programme.

Problems encountered in carrying out "34-Drug Programme"

The expected benefits of the 34-Drug Programme have not been achieved due to several reasons of which the major ones are given below :

1. Delays in Delivery

There are delays in the supply of the items due to delays in issue of Drug Quality Control Laboratory certificates. Some manufacturers who also manufacture branded products for their own distribution do not give sufficient priority to the manufacture of SPC products.

2. Excess Stocks of Raw Materials

After the liberalisation of imports, sales of certain products manufactured under this programme suffered severely due to imports of branded products. This resulted in excess stocks of finished goods and raw materials.

3. Quality Problems

The manufacture of some items were suspended due to quality problems.

4. Frequent requests for increases in manufacturing fees.

5. Stoppage of production without due notice.

6. Threatened litigation and claims by some firms.

Pharmaceutical preparations manufactured by the Private Sector for the State Pharmaceuticals Corporation on Tenders (to be distributed by the State Pharmaceuticals Corporation and/or State Medical Stores)

Most of the pharmaceutical preparations and raw materials required by the State Pharmaceuticals Corporation and State Medical Stores are obtained by calling world wide tenders. Local manufacturers too quote for such tenders. Special consideration was given to the saving in foreign exchange before November 1977.

When a tender is awarded to a local manufacturer the required raw materials are also obtained by the manufacturer unlike in the contract manufacture programme.

Production of pharmaceuticals on tenders from 1974-1978 is shown below :

Production	1974	1975	1976
Tablets (in millions)	43	80	89
Capsules (in millions)	2	--	--
Liquid preparations (in '000 litres)	8	15	66

Pharmaceutical preparations manufactured by the State Institutions

At present there is only one State Institution, the Medical Research Institute (M.R.I.) engaged in the production of Pharmaceuticals.

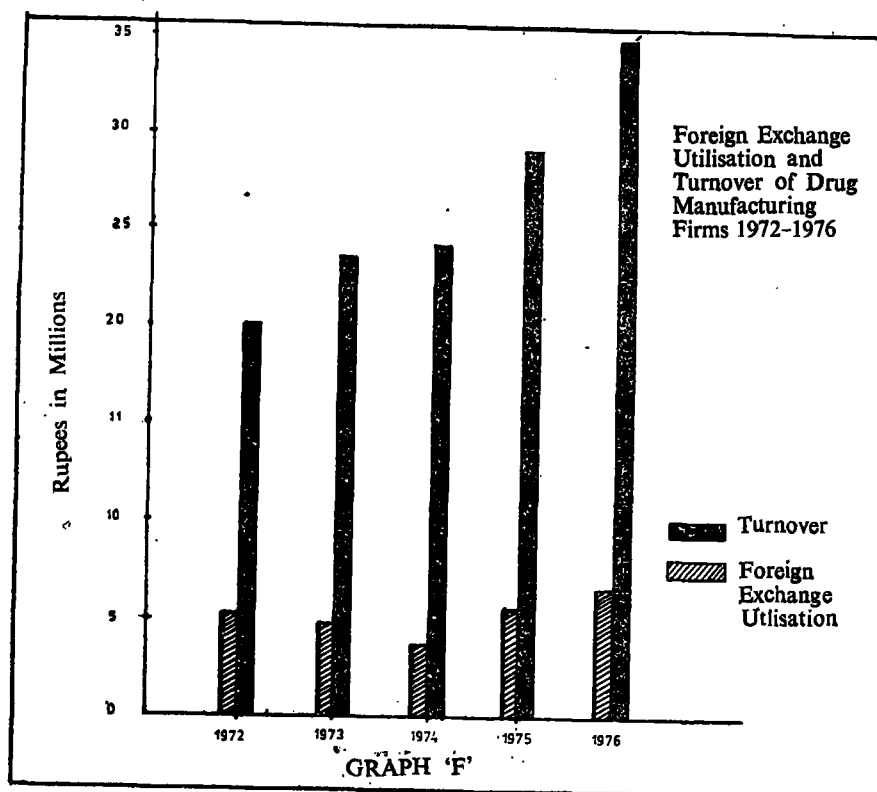
This Institution manufactures Anti-Rabies, Anti-Cholera, Anti-Typhoid and Small Pox Vaccine (Freeze dried) to meet the total public sector requirement.

Raw Materials in Local Manufacture

As mentioned earlier most of the raw material requirements for the pharmaceutical industry are obtained from foreign markets. However, a few items like Kaolin, Castor, Eucalyptus and Pine Oils are manufactured locally in small quantities. It is advisable that small units be set up for the extraction of some basic raw materials from locally available natural products. The Ceylon Institute of Science and Industrial Research has done considerable study on some of these items.

The Table shows Quantities manufactured under the "34-Drug Programme" during the period 1975-1978 together with the Ex-factory cost and approximate Foreign Exchange Savings for each year.

Year	Quantities manufactured in millions of tablets	Quantities manufactured in millions of capsules	Cost of raw materials including duty and clearing charges Rs. m.	Approximate manufacturing fees paid to local manufacturers Rs. m.	Total ex-factory cost Rs. m.	Approximate foreign exchange savings Rs. m.
1975	99	38	7.7	1.5	9.2	3.0
1976	210	27	8.0	2.5	10.5	2.8
1977	250	34	10.0	3.0	13.0	3.9
1978	335	25	13.2	3.85	17.05	8.0



Prior to the implementation of the Open General Licence scheme, approved pharmaceutical manufacturers were allowed to import their raw material requirements (without payment of Foreign Exchange Entitlement Certificate schemes) on the approval of the late Pharmaceuticals Corporation and the Ministry of Industries and Scientific Affairs. After the Government "liberalized" imports in November 1977, local manufacturers are able to import their raw material requirements without sanctions. It is expected that this release would have a favourable impact on the development of the pharmaceutical industry.

Fine Chemicals

The fine chemicals required for pharmaceutical industries are presently not manufactured in Sri Lanka. The poor demand, lack of machines and technical know-how are the main reasons for this situation. The WHO and UNIDO have suggested that the possibility of manufacturing fine chemicals on a regional basis be studied.

One country could undertake the manufacture of an item to meet the requirements of neighbouring countries as well. As an example,

Chloramphenicol, Ampicillin Trihydrate and Paracetamol could be manufactured in Sri Lanka out of late intermediates. In the case of Chloramphenicol we could set up plant having an annual output of 25 metric tons. The requirements of the country is only 5 metric tons per annum. The balance 20 metric tons could be sold to other countries in the region.

Examples of some bulk imports in Sri Lanka are given below for the year 1978

Aspirin	100 metric tons
Magnesium Sulphate	60 metric tons
Paracetamol	35 metric tons

Quality Assurance of Locally Processed Pharmaceuticals

The local authorities responsible for maintaining the quality assurance of locally formulated and packed pharmaceuticals are :

(a) The National Formulary Committee

This Committee deals with matters relating to therapeutics and was set up by the Government in 1959 as the Hospital Formulary Committee. This committee is working under the Ministry of Health and the major activities with regard to the local drug industry is the inspection of local pharmaceutical factories; to advise the government with regard to applications

made by local manufacturers for the formulation of new preparations, and to advise the government on applications for setting up of new pharmaceutical industries and other relevant matters. Their recommendations are implemented through the Ministry of Health and Ministry of Industries & Scientific Affairs.

(b) The Drug Quality Control Laboratory

The Drug Quality Control Laboratory was established in 1971 under the Colombo Plan Aid from Japan, and functions under the Ministry of Health. The major activity of the Drug Quality Control Laboratory is as follows :

- i. The testing of locally repacked and formulated drugs supplied to State Medical Stores and State Pharmaceuticals Corporation.
- ii. Conducting bio-availability studies and
- iii. Investigate complaints on drugs by the Medical profession and public.

This laboratory is the best equipped quality testing laboratory in Sri Lanka, and deals mainly with chemical analysis of drugs.

(c) Medical Research Institute

This is a research laboratory working under the Ministry of Health and carries out examinations on the biological activity of drugs.

(d) The Ceylon Institute of Scientific and Industrial Research

The Ceylon Institute of Scientific and Industrial Research is under the Ministry of Industries and Scientific Affairs and performs quality testing of drugs as and when required.

(e) Laboratories of Local Manufacturers

It is generally accepted that the manufacturer is responsible for maintaining rigid inspection of all stages of production, and that he has sufficient analytical facilities in respect of qualified staff, equipment and related services. It is also expected that he maintains proper records during all stages of production and of analytical tests performed.

Among the local manufacturers 6 have satisfactory Quality Control/Quality Testing laboratories. Others depend entirely on outside laboratories (local and foreign). However, all locally processed drugs released through the State Pharmaceuticals Corporation are tested and approved by the Drugs Quality Control Laboratory or other accepted Quality Control Laboratories.

Sales and Distribution

Sales and distribution of locally processed pharmaceuticals could be broadly classified into :

- (a) Private sector distribution by local manufacturers and their agents.
- (b) Public sector distribution by the State Pharmaceuticals Corporation and State Medical Stores.

Private Sector Distribution

Over 160 preparations manufactured locally are directly distributed by the private sector. Almost all local manufacturers have their own distribution systems which is generally by wholesale, under their trade names.

Public Sector Distribution

The State Pharmaceuticals Corporation sells drugs directly to chemists, doctors and authorised institutions. Several area distributors have also been approved recently in order to provide a better distribution of drugs throughout the island. The Corporation also retails pharmaceuticals through 3 retail shops (Osus Salas) in Colombo.

State Medical Stores

This stores looks after the distribution of drugs to government hospitals/institutions. Requirements for the State Medical Stores are obtained through the State Pharmaceuticals Corporation and delivered direct to the State Medical Stores.

From the State Medical Stores, drugs are sent out to the divisional drug stores. Each divisional store is responsible for the distribution of drugs to the government medical institutions in their respective areas.

Brand and Generic Names

Drugs manufactured locally for the State Pharmaceuticals Corporation are labelled and marketed by their official (generic) names. Drugs manufactured for private sector distribution are permitted to be labelled by both official (generic) and brand names. However, manufacturers are requested to label drugs by their official (generic) names in bold type and brand names (given beneath) in half size.

General Discussion

In the field of pharmaceutical industry, Sri Lanka is still at an early stage of development. The necessity for expanding the technical know-how of pharmaceutical

manufacture becomes more important due to the large sum of foreign exchange spent in importing processed pharmaceuticals (ref. Graph F). In the year 1978 this figure was approximately Rs. 134 millions and for 1979 this may even exceed Rs. 143 millions. This trend will be more marked due to the increase in price of petroleum products and the consequent effect on inflation. Since our labour costs are low, dependence on pharmaceutical manufacturing companies of "Developed Countries" could be eased to a large extent by expanding local manufacture by both private and public sectors. From past experience it is noted that private enterprise concentrates mainly on products that could yield high profits irrespective of their necessity for primary health care. It is therefore, necessary that the state should take steps to manufacture items that are essential for the health needs of our country. In doing so, in addition to providing employment, a substantial saving of foreign exchange can be effected. Drugs could be produced locally at a cheaper price with confidence and security of the service provided by the State to the country. One of the most important features will be the increase of technical know-how which will reduce the present dependence on foreign countries.

Under the present liberalisation policy of the Government, manufacturers have been permitted to import raw materials, packing materials and machinery without control. This has given an elastic atmosphere to the industry which should result in increased production. The Government is also planning to manufacture some of the essential drugs for primary health care locally. It is expected that a sum of Rs. 20 million could be saved annually in foreign exchange by the setting up of such a project. The government has already called for tenders for setting up a local plant to manufacture infusions. This will reduce the need to import and store these finished pharmaceuticals as is done at present.

Sri Lanka's dependence on companies of "Developed Countries"

(for at least very essential items required for primary health care) could be reduced in the near future if the expanding programmes launched by both public and private enterprises of the local pharmaceutical industry are encouraged. If we achieve this we could move on to the next phase in pharmaceutical production, namely the manufacture of intermediates and basic chemicals.

Conclusion

It is an established fact that in all its aspects, in the pharmaceutical industry, the greatest progress has been made by the developed countries. It is also well known that the consumption of the manufactured production is also highest in these countries. In fact, it is said that "life has been reduced to diseases to be cured by the sales propagation techniques of the Pharmaceutical Industry". The per capita consumption of drugs per annum per person (1976) is less than 1 U.S. \$ in developing countries; it is as high as 50 U.S. \$ in the developed world.

It is estimated that the developed world accounts for about 88% of the global (pharmaceutical) production and about 85% of the consumption (Ref. Publication UNIDO's role in the development of the pharmaceutical industry in developing countries, 1978). It is known that the teeming millions of the world are in developing countries; that they are ridden by ill-health and poverty and that there is a great need and potential for the development of the pharmaceutical industry.

In a country such as Sri Lanka, the estimated per capita consumption per annum is U.S. \$ 0.60 (Ref. WHO's report on drug policies and management seminar 1978). It needs little comment that there is a vast potential for the development of this industry here. Graph F shows the finance of manufacturing companies in Sri Lanka between 1972-1976 and needs little explanation. The development of the industry should, however, be linked with controls that prevent the exploitation of the country or its people.