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ASSISTANCE TO THE PHARMACEUTICAL UNIT

RP/UGA/76/002

UGANDA

Mission report

Based on the work of W. Sobieszewski, senior pharmaceutical adviser

id.77-3165

Explanatory notes

A full stop. is used to indicate decimals.

A comma (,) is used to distinguish thousands and millions.

References to dollars (\$) are to United States dollars, unless otherwise stated.

The monetary unit in Uganda is the shilling (USh). During the period covered by the report, the value of the USh in relation to the United States dollar was \$US 1 = USh 8.33.

UPL is the Uganda Pharmaceuticals Ltd.

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## ABSTRACT

The project entitled "Assistance to the Pharmaceutical Unit" (RP/UGA/76/002) forms part of a larger project which originated in a request submitted in January 1975 to the United Nations Development Programme (UNDP) for an exploratory mission to evaluate the feasibility of undertaking a programme to strengthen and expand the pharmaceutical industry in Uganda. The request was approved by UNDP in June 1975, with the United Nations Industrial Development Organization (UNIDO) designated as executing agency and the Uganda Ministry of Health as government counterpart.

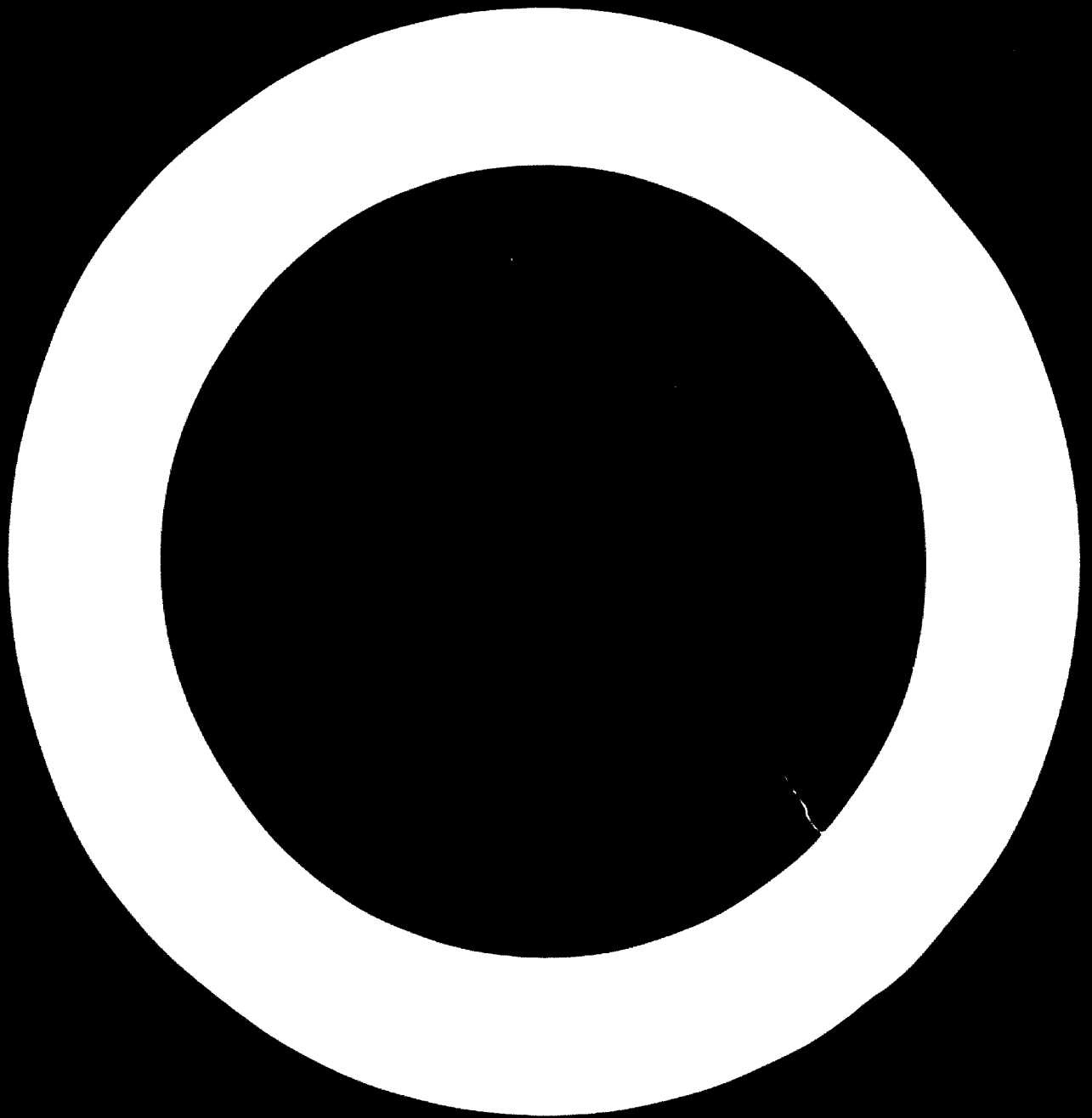
On the basis of the exploratory mission, it was considered feasible to undertake a programme in two phases, the first devoted to the strengthening of pharmaceutical production and distribution, and the second to the expansion and establishment of new units. This report covers a mission carried out as part of the first phase of the programme. The mission began in December 1976, and ended prematurely in March 1977, when the Government of Uganda cancelled the project without explanation.

The following conclusions are noteworthy:

(a) A sound pharmaceutical imports policy for Uganda requires co-ordination in the selection of import sources, full indexes of pharmaceutical imports, and reliable forecasts (a year in advance) of future needs;

(b) A suitable control system, including a Quality Control Laboratory and inspection of existing production units, should be organized in Uganda, and special legislation introduced to ensure fair prices for medicines, to control stocks and the distribution of supplies, and to make the most economical use of foreign exchange.

The report recommends that Uganda Pharmaceuticals Ltd should be assisted in its efforts to strengthen its staff with a sufficient number of pharmacists, dispensers, and data-recording and data-analysis personnel.



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## INTRODUCTION

Uganda is spending increasing amounts of foreign exchange for imports of drugs, medical supplies and related products, which altogether amounted to about US\$ 140 million in 1974. This figure is expected to rise to an unacceptable level with the increase in population, the expansion of medical services, the rise in import prices and the increase in the number and variety of drugs and allied products. In view of this situation, the Government of Uganda submitted in January 1975 an official request to the United Nations Industrial Development Organization (UNIDO) to carry out an exploratory mission for evaluation of the existing pharmaceutical industry and to draft a programme for development and expansion of the industry to become self-sufficient. The request was approved by UNDP in June 1975, with UNIDO designated as the executing agency and the Uganda Ministry of Health as government counterpart.

On the basis of the exploratory mission it was considered feasible to carry out a phased programme of assistance to the pharmaceutical sector in Uganda. The first phase would be devoted to strengthening pharmaceutical production and distribution, and the second to the expansion and establishment of new units.

This report covers a project entitled "Assistance to the Pharmaceutical Unit" (RP/UGA/76/002), which was undertaken as part of the first phase of the above-mentioned programme. The budget for the mission dealt with in this report called for a UNDP contribution of \$US 16,000. The expert, in co-operation with the government authorities, was expected to perform the following duties:

- (a) Assist in the formulation of the restoration and consolidation plan of the pharmaceutical sector;
- (b) Co-operate with medical and pharmaceutical bodies in the specification of the most important items to be imported, and eventually manufactured;
- (c) Assist in the elaboration of stocks, distribution and price control policies and systems;
- (d) Assist in policies and systems for the rationalization and control of importation;
- (e) Assist in setting up criteria for evaluation and measures for appraisal of suitable local manufacturing units, and the best utilization of their facilities;
- (f) Assist in the establishment of data recording and analysis systems in the public and private importation, distribution and production enterprises;

(g) Assist in the selection and recruitment of personnel for specific functions, and in training programming (according to the needs of development and availability of suitable personnel);

(h) Technically elaborate an industrial project and quality control which would assist the country to achieve self-dependence.



## I. PROJECT ACTIVITIES AND FINDINGS

The mission involved a series of visits, meetings and discussions in which representatives of UNDP and WHO, the Chief Pharmacist and Medical Services Departments of the Ministry of Health, and Uganda Pharmaceuticals Ltd (UPL) participated.

The programme of activities included, in particular, field visits to the following local manufacturing units: Universal Pharmacy Factory (Kampala), Universal Pharmaceutical Industry (Kampala) and the OPA Pharmacy Factory (Jinja).

### A. Plan of action

For the organization and control of pharmaceutical and related consumption and for the mobilization of the pharmaceutical sector, the practical plan of action outlined below was drawn up for 1977.

- (a) Preparation of the full index of medicaments imported by UPL in 1976, with import sources, quantities and prices;
- (b) Selection of import sources and comparison with those of the Ministry of Health;
- (c) Testing of machines at the existing production units;
- (d) Taking the necessary steps to establish special legislation and to control stocks and the distribution of supplies, including the establishment of the necessary records and inventory controls;
- (e) Collection of tenders from pharmaceutical companies (import sources) for the supply of raw materials and finished products, and selection of those offering good products at the most favourable prices;
- (f) Planning the import of medicaments for UPL and the private sector, taking into account overall demand and the rise in the cost of medical services and prices;
- (g) Preparation of a single comprehensive list of medicament requirements a year in advance, in order to ensure regular, stable and economic import supplies;
- (h) Arranging for bulk imports (on a small scale) of aspirin and chloroquine for tableting (this would involve the testing of machinery and the training of personnel);
- (i) First steps toward the establishment of practical control of stores, shops and hospitals;
- (j) First steps toward the organization of a Quality Control Laboratory (personnel, equipment, premises);
- (k) Arranging for a three-month fellowship for the Quality Control Laboratory biologist or pharmacist connected with the biological investigations of antibiotics;

(l) First steps toward the quality control of some medicaments according to the requirements of the Pharmacopoeia;

(m) Tableting of the aspirin and chloroquine, and, if possible, the gradual elimination during the coming year of the import of these medicaments in tablet form.

#### B. Imports and distribution

The products used in the Ministry of Health are based on the selection of medicines needed for hospitals and are suitably controlled, both in number of items and prices, by the Ministry of Health's Medical Stores Advisory Committee, composed of consultants and specialists in various medical disciplines.

The Medical Stores receive foreign exchange allocations from the Foreign Exchange Cabinet Committee, within the approved budget, for importing drugs under tenders approved by the Uganda Tender Board, and the supplies are distributed to hospitals, district medical officers and other health services. The full list of the medicaments needed for the Ministry of Health is prepared twice a year and is checked and examined quarterly by the above-mentioned Advisory Committee.

Uganda Pharmaceuticals Ltd (UPL) is a government-owned company responsible for importing medicaments and other related supplies, within its foreign exchange allocations, for both the private and public sectors. The 28 private importers, who are retailers and wholesalers to mission hospitals and pharmacies, submit their import applications to UPL. This company shares out the foreign exchange allocations between the private importers and itself. When the medicaments and related products arrive, they are immediately received by their importers, which pay UPL for their supplies in local currency.

In 1975, 1976 and during the first 3 months of 1977, the foreign exchange allocations shown in table 1 below were made.

Table 1 shows that UPL is playing a key role in the import of pharmaceuticals and should be assessed in strengthening its staff with a sufficient number of pharmacists, dispensers, and data-recording and data-analysis personnel.

Table 1. Recent foreign exchange allocations for pharmaceutical imports

Allocation date	Amount (millions of US\$)	Amount received (%)	
		UPL	Others
<b>1975</b>			
March	4	82.5	17.5
April	2.5	68.0	32.0
October	2	60.0	40.0
November	0.5	50.0	50.0
<b>1976</b>			
February	1	84.0	16.0
May	2	48.5	51.5
October	2.5	66.0	34.0
<b>1977</b>			
January	2	100.0	
February	5	60.0	40.0
March	1	95.0	5.0

C. Selection of import sources

UPL imports for the private sector require price-control measures in order to reduce the quantity of ineffective or overpriced imports, and the tendency to use expensive antibiotics and similar items should be subject to control, taking into account the quality of medicaments and the sources of imports.

A full index of medicaments and related products imported by UPL in 1976 has been prepared. The index includes the sources of imports, the quantities and prices of the items, and data concerning their distribution to UPL and other recipients.

On the basis of the above-mentioned index and other materials, the following additional indexes were established:

(a) Index of 28 companies approved by the Uganda Advisory Board of Trade to import pharmaceuticals into Uganda through UPL, in accordance with Decree No. 9 of 1974;

(b) Index of the suppliers of UPL and the private (direct) importers of pharmaceuticals and related products (see annex).

Selection of the import sources could be easily done at present by UPL with the assistance of a UNIDO expert. A comparison of the import sources of medicaments imported for UPL with those of the Ministry of Health confirmed that in many cases the same products were imported from different sources. Examples are given in the annex, table 2. The expert therefore considers that selection of the import sources should be made by UPL with the assistance of pharmacists and official representatives of the Ministry of Health, in order to influence private importers in future and to ensure that imported medicaments shall be from among those selected and confirmed by the appropriate authorities, taking into account the quality of the items and the best use of foreign exchange. This problem was discussed with the Chief Pharmacist of the Ministry of Health.

#### D. Import planning

It was agreed with the Chief Pharmacist and the General Manager of UPL that an effective imports programme requires that all items needed for private hospitals, dispensaries or shops should be determined once or twice a year in advance of the expected delivery date. If UPL had, at the end of each year, the full list of medicaments needed for itself and the private sector, it would be able to prepare joint import applications for larger amounts of the same items and send them to selected import sources, thus ensuring the most economical operations over the long run. Import planning, taking into account the rising cost of medical services, would be facilitated, and import sources would be stable and economic. It was agreed that in order to introduce import planning special legislation would be needed.

Under the plan of action for 1977, the applications to listed import sources (pharmaceutical companies) should be made by UPL, and all offers (tenders), with approximate prices, of raw materials and finished products from these companies should be collected and a selection made of the suppliers offering good products at the best prices. Such a selection should be made systematically, year by year, and for this purpose a special index should be established.

E. Inventory and distribution control

In order to ensure equitable prices for medicines, to maintain control over stocks and their distribution both in the public and private sectors, and to make the most economical use of foreign exchange, it was agreed that a suitable control system should be organized, for which purpose special personnel (inspectors) and legislation will be required. A programme was worked out comprising the following elements:

- (a) All items imported by UPL (especially for the private sector) should be registered by UPL in order to have precise records of the stocks and items sold by private dealers;
- (b) All doctor's prescriptions should be collected and registered at UPL and private sector shops, dispensaries or hospitals in order to ensure financial control of distribution;
- (c) Records of all indexes and bills of private shops or stores should be kept so as to be able to identify the channels of distribution;
- (d) UPL should maintain a large store for all the imported medicaments and related items ordered for itself and the private sector;
- (e) All medicaments and related items should be indexed and regularly distributed by UPL to private importers, for example on a quarterly basis. This would facilitate distribution and price control.

F. Local production units

Three pharmaceutical production units used by UPL were visited and inspected in order to determine what would be required to put them back into working condition.

OPA Pharmacy Factory (Jinja)

The expert, accompanied by the General Manager and a pharmacist of UPL and a Ministry of Health pharmacist, visited the OPA Pharmacy Factory at Jinja. The factory and premises were inspected and the following machines tested: filling and sealing machine for ampoules, washing machine for ampoules, water distillation machine, aerosol filling machine, liquid filling machine, strip-packing machine, ointment filling machine, two driers for tablets, two mixers, granulator, de-duster, three tableting machines, rotary granulator and pan-coating machine.

On-the-spot tests revealed that the following machines were in working conditions: one single punch machine which can produce 5,000 tablets per hour, one granulator, two mixers, two driers, one pan-coating machine and one ointment filling machine. The rest of the machines tested were found to be

out of order for reasons which could not be established during the visit. It was therefore agreed that the UPL mechanical engineer and production pharmacist should be sent to test each of the machines in detail, to determine what repairs are necessary.

It was considered that production of tablets (for example, aspirin and chloroquine) would be able to start in several months with the already working machinery. This would have to be done carefully, so as to establish by experience what is required to restore the factory to full production capacity. If all the tableting machines in the factory were restored to full production by the end of the current year, they would be capable of producing 60,000 to 70,000 tablets per hour (480,000 - 560,000 per day).

The skeleton staff required to start manufacturing at the factory in several months was proposed. It was considered that the following items would have to be imported in order to facilitate the start of production: talcum powder, magnesium stearate, screens (sieves) in sizes 8, 10, 12, 16, 24, 32, 40, 60, 80 and 100, 10 kg and 50 kg scales, two chemical electric balances, de-humidifier, one electric water still with a capacity of 4.5 litres per hour, two stainless steel reservoirs with capacities of 10 kg and 20 kg, two trolleys, plastic containers with screw caps for packing tablets (capacity of 1,000 tablets). The production pharmacist should work out the bulk requirements for the rest of the packing and raw materials.

Due to the stringent requirements for the preparation of injections, it was considered that this phase should be taken up at a later stage. At that time the following machines would be required: ampoule filling machine, autoclave, dry heat oven, labelling machine and electric distillation plant.

The land behind the present premises was also inspected, and it was considered adequate for the future construction and additional building for an injection department.

#### Universal Pharmacy Factory (Kampala)

The expert visited and inspected the Universal Pharmacy Factory in Kampala. The factory manufactures ointments, liquids, mixtures, powders, creams and cosmetics using the following machines: column for filtering water, tank (capacity of 1,000 l) with mechanical stirrer, tank (capacity of 1,000 l) without stirrer (both tanks made of stainless steel), four stainless steel tanks (each with a capacity of 100 l), filter press, one tank (capacity of 200 l), homogenizer, small homogenizer for laboratory use, five

plastic containers (capacity of 90 l), steam boiler (capacity of approximately 70 l), semi-automatic bottle-washing machine, gas boiler for ointment with cooler, electric boiler, labelling machine, dating machine, filling machine for creams and tube-sealing machine.

The above machines were operated by a staff of 13 people. Their average output of mixtures was 160 gallons, or 800 l per day. The present limitation in their productivity was due to the shortage of tanks of different capacities.

The current premises have two working offices and a laboratory, but the laboratory would need to be furnished with special equipment for control of the products from the factory.

#### Universal Pharmaceutical Industries (Kampala)

The factory of the Universal Pharmaceutical Industries, Kampala, has the following machinery: tablet strip-packing machine, pan-coating machine, tableting machine, bottle-filling machine, stainless steel mixer (capacity approximately 500 l) with stirrer and balances. All these machines should be tested by a mechanical engineer and eventually transferred to the OPA Pharmacy at Jinja.

#### G. Quality control

The organization of the Quality Control Laboratory was discussed with Uganda's Chief Pharmacist and the Director of Medical Services. During the discussions the importance of this problem was stressed.

The following scheme of such a laboratory, with personnel and special equipment, was worked out.

#### Quality Control Laboratory

<u>Post or unit</u>	<u>Personnel</u>
Head of Laboratory	Pharmacist
Analytical Chemistry	Chemist (1) Technical assistants (2)
Biological Investigations	Biologist (or pharmacist) (1) Technical assistants (2)
<u>Special equipment</u>	
pH meter	
Spectrophotometer	
Chemical balances (2)	

Automatic analytical balance (1)  
Autoclave (for sterilization of pipettes and plates  
for biological investigations) (1)  
Autoclave (for killing of the bacterial strains) (1)  
Thermostat (1)  
Electric dry heat oven  
Tablet hardness tester  
Tablet disintegrator tester  
Special equipment for biological assay of antibiotics  
Special bacterial strains for testing of antibiotics from the National  
Collection of Type Cultures (NCTC), Central Public Health Laboratory,  
Colindale, London  
Normal laboratory glassware  
Refrigerators (2)  
Chemicals

It emerged from discussions with the Chief Pharmacist that the organization of such a laboratory would be possible. Consideration was given to the possibility of selecting and training personnel for specific functions, and of providing a fellowship for the biologist (or pharmacist) connected with the biological investigations of antibiotics. The proposed programme for the laboratory involved the completion of organizational arrangements during the second half of 1977, the above-mentioned three months of fellowship training during the same period, and the start of operations (on a small scale) at the end of the year.

#### H. End of the mission

At the end of February the plan of action was discussed with the UNDP Senior Industrial Development Field Adviser from Nairobi, Kenya, but the expert was unfortunately not able to carry out all the duties assigned to him, as in mid-March, with the mission only half completed, the project was cancelled by the Government of Uganda without explanation.



## II. SUMMARY OF MAIN CONCLUSIONS AND RECOMMENDATIONS

### A. Conclusions

1. UPL imports for the private sector and the use of expensive antibiotics and similar items require price-control measures and close supervision.
2. A sound pharmaceutical imports policy for Uganda requires co-ordination in the selection of import sources, full indexes of pharmaceutical imports, and reliable forecasts (a year in advance) of future needs.
3. A suitable control system, including a Quality Control Laboratory and inspection of existing production units, should be organized in Uganda, and special legislation introduced to ensure fair prices for medicines, to control stocks and the distribution of supplies, and to make the most economical use of foreign exchange.

### B. Recommendation

1. UPL should be assisted in its efforts to strengthen its staff with a sufficient number of pharmacists, dispensers, and data-recording and data-analysis personnel.

Annex

IMPORTS OF PHARMACEUTICALS AND RELATED PRODUCTS

Suppliers to UPL and private (direct) importers  
of pharmaceuticals and related products

Alembic Chemical Works (India)  
Armour Pharmaceutical Co. Ltd (United Kingdom)  
Bayer AG (Germany, Federal Republic of)  
Beecham Research Laboratories (United Kingdom/Singapore)  
Boehringer Sohn C.H. (Ingelheim, Germany, Federal Republic of)  
Boots Co. Ltd (United Kingdom)  
Bristol Laboratories (Bristol Myers) (United Kingdom)  
Cadila Laboratories (India)  
Chropi SA (Greece)  
Ciba-Geigy (Switzerland)  
Ciech Polfa (Poland)  
Dumex (Denmark)  
E.R. Squibb (United Kingdom)  
Fisons Ltd (United Kingdom)  
G.D. Searle & Co. Ltd (United Kingdom)  
Glaxo-Allenburys (United Kingdom)  
Gruppo Lepetit S.p.A. (Italy)  
Gujarat Pharmaceutical Works (India)  
Hoechst Ag (Germany, Federal Republic of)  
Imperial Chemical Industries (ICI) (United Kingdom)  
Kalindi Ltd (India)  
Lederle Laboratories (United States)  
May & Baker Ltd (United Kingdom/Kenya)  
Merck Sharp & Dohme (United Kingdom/Holland)  
Nicholas Overseas Ltd (Kenya)  
Parke-Davis (United Kingdom)  
Pfizer Corporation (United Kingdom/Belgium)  
Roche Products Ltd (United Kingdom)  
Roussel Laboratories (United Kingdom)  
Sandoz Ltd (Switzerland)  
Scanpharm (Denmark)  
Schering AG (Germany, Federal Republic of)

Shering Corporation (United States)

Smith Kline & French Laboratories (United Kingdom)

Smith & Nephew (United Kingdom/Pakistan)

Sterling Winthrop (Kenya)

Upjohn (United States)

Wellcome Foundation (United Kingdom/Kenya)

Table 2. Selected imports and suppliers

Imports <sup>a/</sup>	Import sources	
	For the Ministry of Health	For UPL
Sulphadimidine (T)	Uganda Pharmaccs	Scanpharm (Denmark)
Sulphametoxypyridazine (T)	Welcome of Roche	Scanpharm (Denmark)
Sulphaguanidine (T)	Welcome of Roche	Scanpharm (Denmark)
Sulphadiazine (T)	Welders (Norway)	Scanpharm (Denmark)
Sulphapyridine (T)	Welders (Norway)	May & Baker (United Kingdom)
Phenylbutazon (T)	Paris Chemicals	Evans Medical Ltd
Chlorpromazine (T)	May & Baker (United Kingdom)	Halewood Chemicals Ltd
Phenobarbiton (T)	Paris Chemicals	Medimpex (Budapest)
Ephedrine (T)	Uganda Pharmacos	Halewood Chemicals Ltd
	Medimpex (Budapest)	Eupharma Labs (India)
	Pharbita (Holland)	
Chloroquine (T)	J.C.J. (United Kingdom)	May & Baker (Kenya)
Chloroquine (I)	Astra (Sweden)	Eupharma Labs (India)
	Paris Chemicals	Karlo Helm (Germany, Federal Republic of)
Benzylpenicillin (I)	Glaxo (United Kingdom)	
Procaine Penicillin fortified (I)	Galenika (Yugoslavia)	Alembic Chemicals (India)
		Alembic Chemicals (India)
		China National Chemicals
Streptomycin (I)	Galenika (Yugoslavia)	China National Chemicals
		Krka Pharm (Yugoslavia)
Syrup Chloramphenicol	Lepetit (Italy)	Medimpex (Budapest)
Powder Chloramphenicol	Lepetit (Italy)	Lepetit (Italy)
Chloramphenicol	Medimpex (Budapest)	Parke Davis (United Kingdom)
Eye Drops Chloramphenicol	Paris Chemicals	Scanpharm (Denmark)
Eye Ointment Chloramphenicol	Sarabhai (India)	Krka Pharm (Yugoslavia)
		Buchman (Germany, Federal Republic of)
Inj. Tetracycline	Sarabhai (India)	Lepetit (Italy)
Syrup Tetracycline	Pieter (Italy)	Karlo Helm (Germany, Federal Republic of)
Tabl. Tetracycline	Channel (Ireland)	Karlo Helm (Germany, Federal Republic of)

<sup>a/</sup> T or I following the name of a medicament indicates that it comes in tablet form or must be administered by injection.

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