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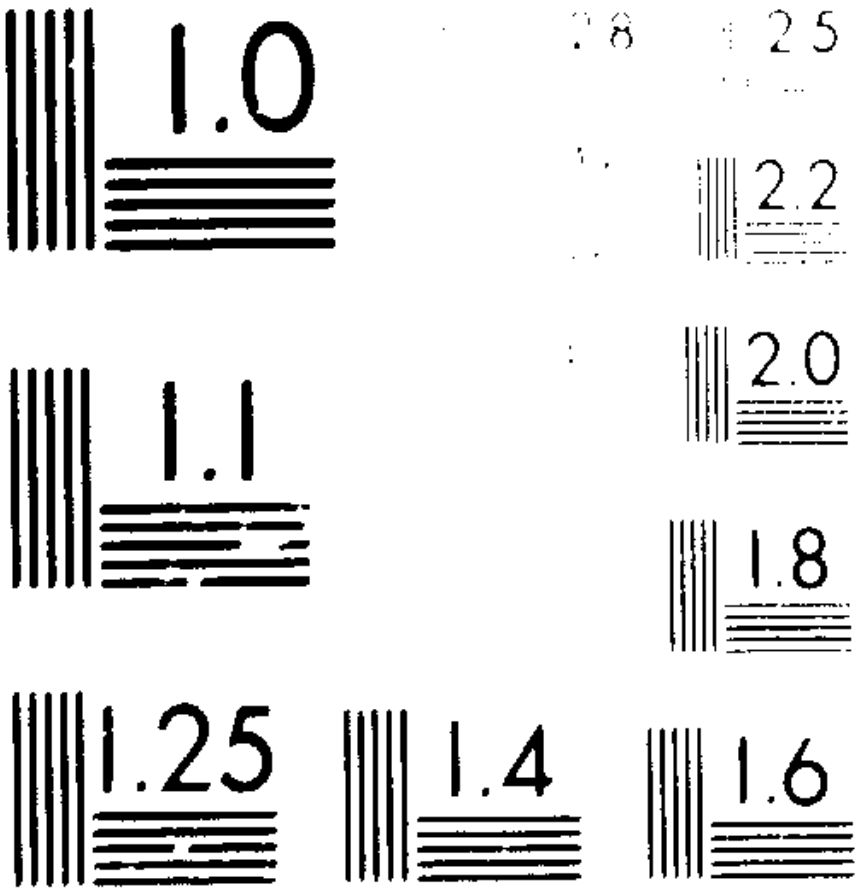
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PHARMACEUTICAL INDUSTRY IN ZAMBIA .

SI/ZAM/82/801

Technical Report

(January - November 1982)

Prepared for the Government of Zambia

by the United Nations Industrial Development Organization

Based on the work of Riaz Ahmed Khan,
expert in quality control

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I PURPOSE

1. The writer was asked by the United Nations Industrial Development Organisation (UNIDO) to undertake an assignment to provide the Government of Zambia with policy oriented technical and economical advice on long range strategy and short term plans for the development of pharmaceutical industry. A similar UNIDO assignment was undertaken in January 1973 (Report TCD/200)

2. The writer was assigned to the Ministry of Health as Director of Pharmaceutical Services to assist the Government of Zambia in the following:-

1) Determination of priority needs and survey of existing industrial activities.

2) Visit existing pharmaceutical factories and offer advice on technical, economic and managerial matters.

3) Prepare a survey on existing industrial manpower and technical skills, projecting future demands and determining the training required to meet the needs.

4) Work out the rationalisation of production activities of Medical Stores Limited including:

   a) Planning of a quality control laboratory

   b) Assessment of existing capacity of space, production equipment, personnel and their optimum utilisation.

   c) Rationalization plan for production of liquid forms, ointments and creams.

   d) Drawing up of plans for alterations in the existing premises and preparation of additional production equipment.

4) Evaluation of proposals received and formulation of new project proposals.

6) Identify Government inputs required for the implementation of the proposed projects on the development of a pharmaceutical industry and assistance to be provided.

7) Collect market data.

8) Prepare reports required on ad-hoc basis.

9) Dissemination and use of collected material

10) On the spot training of local personnel

11) Submission of a detailed report containing the findings and recommendations.

3. The assignment was taken up in January 1982 for six months and was subsequently extended for another three months. At the time of the arrival, the Government of the Republic of Zambia was facing an acute problem of pharmaceutical supplies. For this reason the writer's main task from the Government's point of view was the re-organisation of pharmaceutical services with the immediate pricrity of resolving the problem of drug supply. Existing arrangements with Medical Stores Limited, a parastatal company had run into difficulties and the Ministry of Health felt the necessity of setting up a Department of Medical Supplies while retaining the Medical Stores Limited as its agent for procurement, storage and distribution of drugs. A Drug Supply Committee was formed by the Hon. Minister of Health, on a directive from the Right Hon. Prime Minister.

4. For the present assignment, the tasks assigned to the writer in effect were as follows which also consitituted the Work Plan:-

1) Organisation of medical supplies listed in the Medical Stores catalogue through the establishment of Medical Supplies Department, which involved planning of supplies through estimates on a provincial and national basis, purchasing of all medical supplies and their storage and distribution both at the Centre as well as to the stations in the provinces.

2) Control and co-ordination of the activities of the three parastatal pharmaceutical manufacturing companies, National Drug Compnay (NDC), General Pharmaceuticals Limited (GPL), and Medical Stores Limited (MSL) in order that these companies can adequately supply the requirements of the Ministry of Health. Similar control to be exercised on pharmaceutical units in the private sector.

3) Preparation of drug legislation and enforcement of regulations for registration of pharmaceutical products manufactured in and imported into the country and controlling their quality, including prescribed procedures for registration and inspection.

II PROJECT AREA

1. General

1.1 The Republic of Zambia, having an area of about 752,612 sqaure kilometres, is a land-locked country with a population of about 5,700,000 (1981 census), the annual increase rate being 3.1%. The main population density is in the Copperblet Province and the City of Lusaka, the capital. The average life span is estimated as 45 years. The total number of persons employed is estimated as about 400,000 out of which about 20,000 are non-Zambians.

1.2 The Gross National Product at current prices in 1978 is recorded as kwacha 2,291* millions, giving a per capita income of K402.00. The manufacturing sector forms about 20% of the total Gross Domestic Product. Copper is the main source of foreign exchange earning, but the country has economic problems due to decline in copper prices in the world market. The balance of payments calculated on the basis of imports and exports and combined with services, transfers and official transactions stands unfavourably.

1.3 Zambia has associated itself more closely with neighbouring countries like Angola, Botswana, Lesotho, Malawi, Mozambique, Tanzania, Swaziland, Zimbabwe in an economic grouping formed in 1980 as Southern Africa Development Cooperation Conference (SADCC) with the main objective of developing resources and infra-structure to reduce dependence on South Africa. Internationally, Zambia participates in programmes of Economic Commission for Africa and regionally in plans for Preferential Trade Areas, besides being an active member of the United Nations, its Agencies and subsidiary organisations

2. Communications

2.1 Zambia being a landlocked country has only one direct point of entry i.e. by air. The Lusaka International Airport has enabled the country to be on a wide variety of jet air-routes connecting Zambia with Britain, Europe and a number of African countries. In addition to normal air cargoes, air charters also operate. However, the cost of air freight is high.

2.2 The sea-routes are through Tanzania's main seaport Dar-es-Salaam, Mozambique's Beira and Maputo, South Africa's Port Elizabeth and Durban and Angola's Luanda and Lobito. Dar-es-Salaam takes the majority of sea cargoes because of good rail and road links between Tanzania and Zambia. Angola's ports are at present rarely used.

2.3 The internal communications are well developed. A railway net-work operated within Zambia. The movement of goods to and from the Copperbelt and from Lusaka are mainly through the haulage companies, which operate internally and externally.

3. State Policy on Trade and Industry

3.1 The Government of Zambia provides a legislative base for investment, taxation, tariff, import and export, labour relations, price control and professional matters. Since independence, the Government, while encouraging private enterprise, has embarked on setting up industries in the parastatal sector, which are either wholly owned by the Government or in participation with private sector. However, the management and control of companies in the parastatal sector rests with Government nominees on the Board.

*1 Kwacha = US dollar 1.083

III HEALTH FACILITIES AND DRUG SUPPLY

1. Health Care

1.1 Broadly the Health Policy of the State is to provide a free Health Service to all people in Zambia so that health facilities are within 'easy reach' of the population. Zambia has 82 hospitals containing 14.000 beds, 676 Health Centres and Clinics with 5,600 beds and 16 leprosaria. The above figures are of 1978 and include mission and mining hospitals. In 1980, 2732 medical practitioners, 363 pharmacists and 43 pharmacy technicians were registered with the Medical Council of Zambia.

The pharmacists and pharmacy technicians are mostly employed in the Government, retail and wholesale trade, and production units.

1.2 The National Expenditure (recurrent) in 1977 was about K660,700,000 which rose to the budgetted figure for 1979 as K725,500,000, the Health Sector accounting for 7.7% while the capital expenditure was K160,000,000 and 124,000,000 respectively. The per capita budget for the Health Sector for 1978 was K10.2. The figures for the years 1981 and 1982 budgets are as follows:-

	1981	1982
National Budget (Recurrent)	K1070m	K1169.4m
National Budget (Capital)	K242m	K332m
Health Secretor (Recurrent)	K78.67m	K95m
Health Sector (Capital)	K8.6m	K11.8m
Health Sector of National Budget	6.65%	7.11%
Per capita Budget	K15.3	K18.7

1.3 Zambia suffers from diseases common to the whole Africa, the majority being associated with environmental and social conditions and malnutrition. The major diseases in terms of hospital attendance and admissions are resipiratory, abdominal ailments, injuries, infections (bacterial, viral and parasitical) and malaria, skin, eye and ear infections, anaemia, malnutrition, measles and tuberculosis.

2. DRUG REQUIREMENTS

2.1 The total Government expenditure on medical supplies budgetted for 1982 is K16 million, out of which the drug requirements are estimated as K9 million. The requirements of mining hospitals and private wholesale and retail sector are taken as additional K5 millions, making the country's requirements of drugs as K14 millions. This estimate has been found as insufficient in the light of prevailing drug shortage in Zambia.

2.2 In terms of dosage form presentation, the present requirements are composed of the following:-

		Quantity	Price (K)
a)	Tablets	500,000,000	7,500,000
b)	Capsules	70,000,000	1,250,000
c)	Syrup/Liquids	500,000,000	3,000,000
d)	Ointments/Creams	100 tons	800,000
e)	Intravenous Fluids (units)	700,000	1,750,000
f)	Parenteral Products including dry filled vials and ampoules	8,000,000	4,000,000
g)	Suppositories	500,000	40,000
h)	Miscellaneous	100,000	500,000
	TOTAL		13,840,000

3. DRUG SUPPLY

3.1 The Ministry of Health (M.O.H.) is responsible for the supply of drugs to all Government and Government-aided Church Hospitals and Institutions. Approximately 70% of these supplies are provided by the Medical Stores Limited (MSL) a wholly owned parastatal company which is under the control of the Ministry of Health. The balance of 30% is provided either by direct imports or by local private wholesalers. Approximately 75% of the supplies are imported. The normal budget for medical supplies has been around K15 million.

3.2 The Medical Stores Limited receives requisitions from the Central, Provincial Hospitals and Mission and other health institutions including the medical centres. These institutions and stations are duly warranted by appropriate Central and Provincial Health Authorities. From these requisitions and on the basis of estimates prepared from past issues, the MSL orders the requisite quantities. The orders' procedure consists of preparation of enquiry documents by MSL for submission to the Central Supply and Tender Board (CSTB), which invites and receives quotations for commercial and technical adjudication by the MSL. On the formal approval by CSTB, MSL arranges for the requisite letters of credit and orders are placed.

3.3 A short history of Medical Stores Limited is relevant to understanding the drug and medical supply situation in Zambia. Until 1976, MSL was a Department of Ministry of Health. In 1976, in an effort to give the Government a bigger share in the supply of pharmaceuticals, MSL became a parastatal company under the Ministry of Mines and Industry. In 1977, the company was handed over to the National Import and Export Corporation (NIEC), which is owned by the super-parastatal company, Zambia Industrial and Mining Corporation (ZIMCO). In 1980, MSL came under the jurisdiction of the Ministry of Health, but retained its status as a parastatal company.

3.4 There has been a serious shortage of drugs for a considerable time. Government drug expenditure fell from K14.7 million in 1980 to K10.7 million in 1981. The budgetary allocation for 1982 is K16.4 million, but constraints of non-availability of cash and shortage of foreign exchange persist in the way of utilising the full allocation.

3.5 Attempts have been made to supplement the imports of drugs by obtaining supplies from local manufacturing units. This has not been successful due to inadequate production and abnormally high prices (in comparison with import prices) from both the public and private sectors (the private sector, incidentally lacks quality control facilities as well). The notable exception is the supply of intravenous fluids from General Pharmaceuticals Limited, a parastatal company set up with UNIDO/UNDP assistance, which supplies the entire requirements of the country.

3.6 The parastatal Mining Company, Zambia Consolidated Copper Mining Company Limited (ZCCM) runs its own hospitals and medical facilities. It obtains drugs and medical supplies through its subsidiary in United Kingdom, Zambia Engineering Services and its normal budget is K2,000,000 per year.

3.7 The procurement for the private sector is done by private wholesalers and the parastatal National Drug Company Limited (NDC), a subsidiary of NIEC. The NDC has its own chain of retail pharmacies, Holdsworth Chemists in the main cities and towns. In addition, smaller chains of privately owned pharmacies are run in various parts of the country.

4. PHARMACEUTICAL INDUSTRY

4.1 A survey was conducted of pharmaceutical manufacturing companies in Zambia. A list of companies either licensed or in the process of being licensed was obtained from the Ministry of Commerce and Industry. This list contains the names and addresses of 24 companies, to which have been added two companies, which, from personal knwledge. are manufacturing pharmaceuticals. However on making enquiries, it was learnt that only 11 companies are actually manufactuing or intend to undertake manufacture in

the near future, and only these companies were visited. The rest either exist on paper only or have very long-term plans, if any. Some companies not included in the list, import bulk pharmaceuticals for local packaging.

4.2 The parameters chosen for calculating capacities were on the basis of 250 effective working days in a year, 7 hours operative working hours per day.

4.3 There are three manufacturers in the public sector as follows:-

a) National Drug Company Limited (NDC), Lusaka

b) Medical Stores Limited (MSL), Lusaka

c) General Pharmaceuticals Limited (GPL), Kabwe

4.4 NATIONAL DRUG COMPANY

4.4.1 The production range of this company includes 65 products in tablets, 2 in capsules, 15 in ointments, 7 in creams, 4 as rubs, embrocation and pastes, 14 antiseptic solutions and 40 syrups, elixis, liquids, mixtures, linctus and tinctures. In addition, they have also a toileteries and cosmetics range which includes glycerines, creams, hair creams, dog shampoos, etc.

4.4.2 Tablets

The production department has the following equipment:-

a) Weighing: two balances, 250 kg and 20 kg capacity

b) Mixing: one Diona Mixer, 100 kg capacity, which is basically for wet mixing, capable of blending 500 tons of powder per year. There is no mixer for dry blending.

c) Granulation: one Manesty Granulator, 50 kg capacity

d) Drying: one Fluid Bed Dryer, capable of drying about 240 tons of granules; 2 cabinet dryers, capacity 40 tons per year, making a total capacity of about 280 tons of granules per year.

e) Compression: four tablets compression machines as follows:-

	Annual capacity
i) F2-single punch,	5,000,000 Tablets
ii) RBB (27-stations)	190,000,000 Tablets

iii)	B3H (16-Stations) Rotary	50,000,000 Tablets
iv)	Express (25-stations) Rotary	160,000,000 Tablets
	TOTAL	405,000,000 Tablets

f) Packing: one Counting Machine, maximum of about 100,000,000 Tablets per year. One small strip-packing machine of indeterminate low capacity.

4.4.3 Capsules

The basic equipment under "Tablets" is utilised in pre-weighing, mixing, granulation and drying. One semi-automatic capsule filling machine has a capacity of 8,000,000 capsules.

4.4.4 Syrups

This section has 4 mixing tanks, each of 250 litres capacity, two of the mixing tanks are steam jacketted. These tanks have a capacity of producing over 1,000,000 litres of liquids, and syrups per year. For filteration, 3 filter presses are used, which are adequate for the purpose. Four filling machines can fill up to 600,000 bottles of diverse sizes. However, the total production is just over 100,000litres, well below the installed capacity.

4.4.5 Ointments and Creams

The equipment for the production of ointments and creams consists of 3 mixing bowls of 100 litres capacity each and steam-jacketted, with a total production capacity of 45 tons annually. The capacity for filling and sealing is about 70 tons per year. The actual production, however, is about 70 tons annually leaving a large capacity un-utilised.

4.4.6 Quality Control

The Quality Control Laboratory is reasonably well equipped and staffed and is capable of testing all pharmaceutical production batches. It is headed by a qualified Quality Control Manager who has two assistants. The laboratory at present has the entire equipment located in one large room.

4.4.7 Management and Sales

National Drug Company is a parastatal company and operates as a subsidiary of National Import and Export Corporation (NIEC) which in turn is under the Zambia Industrial and Mining Company (ZIMCO). The management structure consists of a General Manager who has overall responsibility for three divisions of the company as follows:-

a) Retail Division

b) Wholesale Division

c) Factory Division

Each division is under a manager responsible for its operations. In addition, there is a Chief Accountant in charge of all accounts system including cost accounts. The divisional managers are assisted by managers of middle-management level. National Drug Company is planning to set up two additional divisions, one for marketing and the other for merchandise and supply. With a larger range of products, the most profitable activity of NDC is their Retail Division, which consists of their chain of pharmacies, Woldsworth. The manufacturing Division is consistently running at a loss.

4.5 MEDICAL STORES LIMITED

4.5.1 Medical Stores Limited is a parastatal company and is at present under the control of the Ministry of Health The functions of this company are mainly to act as agents of the Ministry of Health for procurements and storage of Medical Supplies and also arrange for the distribution of the same to the hospitals and other stations in Lusaka and the towns in the provinces. The Company is located in Lusaka and has large premises which include warehouses and stores, a manufacturing section and office accommodation.

4.5.2 At present Medical Stores Limited produces syrups, liquids, ointments and creams for hospital requirments in bulk packs. There is also a small quality control laboratory attahced to the production section but it is not yet fully operative. Most production processes are semi-automatic or manually operated.

4.5.3 Syrups and Liquids

This department has the following equipment:-

a) Pre-weighing: Two balances of 360 kg and 100 kg capacity

b) Mixing: Four mixing tanks with stirrers (capacity 1500, 800 (2) and 200 litres) and one of 400 litres, steam-jacketted.

The total capacity is 3,700 litres in all the five tanks. Calculated on the basis of the performance with these tanks plus the filter presses, this department has a capacity of producing 700,000 litres of syrups and liquids per annum. However, the actual production has not exceeded 300,000 litres annually. This is due to lack of damand from the hospitals and difficulties of importing raw materials.

The filling processes are semi-automatic and manual. A total filling of 500,000 litres in 5 litre and 1 litre polythene containers can be achieved with the existing equipment.

4.5.4 Ointments and Creams

The department uses the pre-weighing facilities of the syrups section. It has an Ointment Mill of 40 Kg. capacity for homogenisation and two mixers of 200 litres capacity each. The equipment gives a total theoretical annual capacity of about 80 tons.

The filling of ointments and creams in jars is done manually and it is difficult to estimate the theoretical capacity for this purpose. There is a semi-automatic machine for filling in aluminium tubes and sealing them.

4.5.5 Quality Control

The laboratory has adequate space and benching and the requisite amenities. The equipment is on order and the laboratory is expected to operate when the equipment has been received and installed. At present there are three technicians whose work is supervised by the Production Manager.

4.6 GENERAL PHARMACEUTICALS LIMITED

4.6.1 General Pharmaceuticals Limited manufacture intravenous fluids under licence from VIFOR of Geneva. The factory was set up in 1978 and the production commensed in early 1979. A team of UNIDO experts was provided to assist the company in general management, production and quality control. The equipment comprises of water demineralising units, distilation stills, filling machines and autoclaves. Strict precautions are taken to perform the entire operations in a clean environment.

4.6.2 The total capacity of the plant is 1,000,000 PVC bags year. However, the present requirements of the country do not exceed 700,000 bags. The company, therefore, is meeting the entire needs of the Government Hospitals. Mining Hospitals and other public health institutions and is in a position to meet increased requirements over the next three years.

4.6.3 General Pharmaceuticals Limited have a well equipped quality control laboratory with bulk of equipment supplied by UNIDO. It is now capable of analysing all production and other samples at GPL in Kabwe. When the factory was initially set up all samples had to be sent to the licensors VIFOR of Geneva for testing and passing. Progressively, as the facilities and equipment and expertise improved under UNIDO assistance programme the samples sent to Geneva were reduced. Last year, the laboratory became entirely self sufficient and no samples are now being sent to Geneva for testing.

4.6.4 The management of the company consists of a General Manager, a Production/Commercial Manager, Quality Control Manager and a Chief Accountant. UNIDO had given training to four technically qualified Zambians in the laboratories of VIFOR in Geneva. Unfortunately all the four persons which included the Production and Quality Control Managers have left the company.

4.7 Private Sector

4.7.1 Out of a total of 25 companies listed in the private sector by the Ministry of Commerce and Industry, contact could be established with 9 firms and visits made to them. The rest were either not traced or the writer was advised that they do not undertake nor do they intend undertaking any manufacture in the near future.

4.7.2 INTERNATIONAL CHEMICALS LIMITED

This company has been in existence for ten years and was engaged purely in wholesaling. Three years ago, they set up a pharmaceutical factory and have been manufacturing syrups, toileteries etc. The manufacturing is carried out in a building which from its interior shows signs of unsatisfactory up-keep. The reason given for not improving the present premises is that they are going to vacate these premises in favour of a new factory which is at present at the stage of architect's drawings. They have acquired land adjacent to their present offices and warehouses. The new factory is expected to be ready in two years' time though construction has not yet started. The writer was advised that the factory is likely to be commissioned in 1984-85.

4.7.3 VINDAS DRUG HOUSE

This company shares premises with CAPS Limited a South African importer. The factory consists mostly of warehouses and some pharmaceutical equipment for production of syrups and tablets. However, the equipment is scattered in various places along with boxes and cartons of raw materials and finished products. At the time of the visit no production was being undertaken. It was stated that inactivity in the manufacturing operations was due to shortage of raw materials which can not be imported in the absence of requisite import licences.

The factory has a Manesty B2B Rotary machine and two cabinet dryers and a mixer of 25 kg capacity. With this equipment the capacity for manufacturing of tablets was assessed at 50,000,000. The capacity for the production of syrups was estimated at a maximum of 80,000 litres per year. There are no filling machines as the operations are conducted mannually. It appears that an extra unit for production of eye preparations may also be put to use.

There is no quality control laboratory or any arrangements for testing and analysis. It was stated that the production samples are sent to Zimbabwe for obtaining test reports which is an unsatisfactory procedure.

4.7.4 I.T.R. PHARMACEUTICALS LIMITED

This company is situated almost adjacent to Vindas Drug House. Their product range is mostly for over the counter sales and consists of cough-syrups, tonics, ear-drops, soaps ointments etc. There is no definite fixed prodcut line and the company produces whatever appears to be a good sales item at a particular time. Due to difficulties of obtaining raw materials and not receiving the import licences the company changed the formulations at will which is not in accordance with Good Manufacturing Practices.

The capacity calculated on the present equipment is 1,000,000 tablets and 50,000 litres of syrups. The actual production is very much lower. There is no quality control though there is space set aside for this purpose.

The factory also has some equipment for the production of ampoules which is lying unused though separate rooms have been ear-marked for the purpose. The equipment consists of an ampoule filling and sealing machine and other ancillary items. The company does not intend to go into this line of production.

4.7.5 LUSAKA PHARMACY LIMITED

Lusaka Pharmacy Limited is a chain of chemists in Lusaka. The proprietors are expanding their activities into manufacturing of drugs. For this purpose a new factory has been constructed in the Industrial Area where at present some syrups are manufactured.

The present capacity of the production of syrups is 80,000 litres per year. The basic production equipment for this purpose has been installed but there is no arrangment for filteration of syrups. The production at present is very low because of absence of import licences to produce raw materials. There is space for a quality control laboratory fitted with benches. It was stated that the equipment for analysis and testing has been ordered and the laboratory will be operating in the not too distant future.

4.7.5 CHEMOPHARM LIMITED

This company is very much like Lusaka Pharmacy as they have extended their chain of pharmacies to manufacturing operations as well. The present production consists solely of syrups and liquids whose capacity cannot be accurately determined at present. The proprietors have plans for a new factory under the name of Gamma Pharmaceuticals Limited.

4.7.6 GAMMA PHARMACEUTICALS LIMITED

This company was set up recently to manufacture a large range of pharmaceuticals including tablets, capsules, syrups, liquids, ointments and creams. The production of sterile pharmaceuticals is also included in their future programme. The factory building is located in the industrial area of Ndola, and is expected to be ready for commissioning in October, 1982.

The company has ordered two Rotary Compression Machines, a Granulator of 50 kg capacity and a Fluid Bed Dryer. With this equipment they intend to have an initial capacity of 100,000,000 tablets which can be increased four-fold if an extra mixer can also be ordered by them. For the production of capsules they have ordered an automatic machine with a capacity of producing 30,000,000 per year. For liquids they are procuring equipment which can produce 40,000 litres per annum. The production of ointments and creams is also planned. A Quality Control Laboratory is also part of the factory.

4.7.7 STERLING PRODUCTS (Z) LIMITED

This company is in Ndola and is a subsidiary of Sterling-Winthrop International of the U.S.A. The factory is small but has been planned well. It is equipped to produce tablets though other ranges of products are intended to be added. It is adequately staffed with qualified personnel and the production operations are conducted in a neat and clean manner. The Quality control laboratory is well equipped and is able to handle the small range of tablet products.

The company imports pre-mixed granules from their sister subsidiary in Malawi. These granules are mixed and compressed after slugging. Facilities also exist for the production of tablets right from the stage of granulating etc. The capacity for production of tablets was assessed at 200,000,000 tablets.

4.7.9 SPECIALITY FOODS LIMITED

This company is in Kitwe and is mainly engaged in the manufacture of food products but also has a pharmaceutical division. A new small factory has been completed adjacent to their main operations.

5. PHARMACEUTICAL CONTROL AND LEGISLATION

5.1 Drug Control in Zambia is vested in the Ministry of Health through a Chief Pharmacist. The following legislation is in operation for control of drugs and regulation of the Pharmaceutical Profession:-

a) Medical and Allied Professions Act

b) Pharmacy and Poisons Act

- Therapeutic Substances Act
- Dangerous Drugs Act
- Food and Drugs Act

5.2 The above legislation is selective in its objectives and is meant to meet specific needs. The matter of prescribing standards for the manufacture and sale of all types of drugs has not yet been provided for. No regulations exist for registration of drugs nor is there an inspection system. The present laboratory in the University Teaching Hospital to control food quality does not enjoy a legal status for control on drugs.

6. PHARMACEUTICAL EDUCATION

There is at present no degree education in Zambia. The pharmacists in the country have qualified from the United Kingdom and other countries. The number of pharmacists required do not appear to justify the setting up of a full-pledged school of pharmacy. However, the Evelyn Hone College in Lusaka has a two year course for Pharmacy Technicians started in 1972. The Pharmacy Technicians have been employed in hospitals, laboratories and manufacturing units and have provided service in these institutions in jobs where fully qualified pharmacists are not needed.

IV PROJECT ACTIVITIES AND OUTPUTS

1.1 Zambia was in the midst of a crisis on pharmaceutical supplies, when the writer took up the assignm The Right Hon. Prime Minister, in a meeting, direct he problem of drug shortage should be tackled as a top . The Hon. Minister of Health consitituted a Drug Su committee to study the problem of drug supply and suggest proposals to resolve the problem of grave shortage of drugs. Simultaneously, the Ministry of Health asked the writer to give proposals for the establishment of a Department of Medical Supplies, which will regulate and supervise the activities of pharmaceutical administration, purchase and distribution, pharmacy and drug legislation, and industrial development coordination and control. The writer assisted in the deliberations of the Drug Supply Committee which endorsed the establishment of the Department of Medical Supplies.

1.2 A proposal was therefore prepared for the establishment of a Department of Medical Supplies, which included details of personnel and their functions and office accommodation and equipment and costed for the expenditure to be incurred by the Government in the first year of its creation. The proposal is presented as Annex I. It has been submitted to the Cabinet for final approval and a decision is awaited.

1.3 One of the recommendations of the Drug Supply Committee related to the status of Medical Stores Limited, which acts as an agent of the Ministry of Health for procurement, storage and distribution of 3000 items of medical supplies for the Government. The procedures and methods of MSL were studied which included the starting stage of receiving requisitions from hospitals etc. to the placing of orders, receiving supplies and their distribution to about 200 stations. This also involved the study of stock control and financial procedures as well. The main problem encountered was the absence of any system to forecast demands and consumption, which could form the base of formulating a reliable programme for drug supplies. In this confused situation, delivery times tended to be inordinately long. This was further complicated by intricate invoicing and payment procedures existing between the Ministry of Health and Medical Stores Limited and the reconciling of bills and their payments was not achieved on a regular basis. Again the cash shortage during this year in the Government, compounded with the outstanding bills, produced a situation, whereby the Ministry of Health owed the Medical Stores Limited about K12,000,000. This disparity in payments now stands at K9,000,000. The Government is taking energetic measures to obtain sufficient cash to wipe out this deficit, in order that the drug supply system can be given a fresh start without any liabilities.

1.4 In order to put the supply system in a working order on a long-term basis, it is essential that the stock control should be organised to yield meaningful information output, which can be utilised in establishing a reliable estimates and forecasting machinary. The purchases can then be harnessed to estimates in a scientific manner. Also there is a necessity of strict financial and budgetary control on the expenditure of drugs in the Ministry of Health, the Medical Stores Limited and the hospitals and stations. The Government was advised to seek assistance of Electronic Data Processing (EDP) to develop a reliable information system and quotations were obtained for micro-processors and programming. The introduction of EDP was, however, kept in abeyance, till other means have been investigated as described in the following paragraphs.

1.5 A suggestion was received from the Zambia Consolidated Copper Mines Limited (ZCCM) that the drugs and medical supplies required by the Ministry of Health, can be ordered by Medical Stores Limited through the ZCCM subsidiary in the United Kingdom, Zambia Engineering Services Limited (ZES). It appears that ZES already purchases medical supplies for ZCCM and are in a position to undertake similar work for the Ministry without any commission or mark-up. The main advantage will be a speedy flow of goods as ZCCM/ZES are better placed in terms of allocation of foreign exchange. Negotiations have been held recently and a Government decision is awaited.

1.6 The Government has been trying other avenues of bilateral aid in drug supply, particularly for Primary Health Care through Scandinavian groups like Swedish (SIDA) and Danish (DANIDA) agencies and assistance is expected from these sources, which could alleviate the difficult supply situation.

2. PHARMACEUTICAL INDUSTRY

2.1 A survey of pharmaceutical industry in Zambia, with special reference to present and potential capacities in the public and private sectors has been described in para 4 of Chapter III. Based on this study, an effort has been made .. to co-relate the capacities in the parastatal companies with the actual requirements in the public sector. Also consideration is given to the present capacities in the private sector, added to the above and related to total requirements of the country which is presented in the Table below:-

Product Forms	CAPACITY			REQUIREMENTS
	Public	Private	Total	Total
Tablets (millions)	400	250	625	650
Capsules (millions)	8	-	8	100
Syrups/Liquids (million litres)	1.7	0.3	2.0	1.0
Ointments/Creams (tons)	170	30	200	100
Intravenous Fluids PVC bags	1,000,000	-	1,000,000	700,000

2.2 The above shows that there is abundant capacity for the production of syrups/liquids, ointments/creams and intravenous fluids, but a minor short-fall in the production of tablets and large deficit in the production of capsules. In order to have a safety margin in the supply of tablets and capsules, additional capacity is needed to be provided in the public sector.

3. NATIONAL DRUG COMPANY (NDC)

3.1 National Drug Company is the largest parastatal drug producer. Unfortunately, according to the present production, less than 20% of the capacity is utilised. The Manufacturing Division, therefore, is running at a loss for several years, as there is large idle time on equipment and personnel. There are several reasons for the non-utilisatio of capacity, the main ones being high cost of production and low sales turnover due to high prices

charged by the company. The writer had the opportunity to attend the meetings of the NDC Board, where the Chairman requested assistance in the following:-

a) A study of the constraints in the way of effective and optinum utilisation of production capacity.

b) A study of inventory and stock control methods including procedures of procurement of raw and packing materials.

c) A study of sales pattern of NDC pharmaceutical products, particularly to large customers such as Medical Stores Limited and Government hospitals.

Out of the above studies, two were completed i.e. (a) and (c) in the sub-para above, (b) was not attempted due to insufficient time available to the writer.

3.2 The constraints for study were identified as equipment, personnel and raw materials supply. It appears that NDC have adequate equipment and personnel to reach the production target. The only deficiency is in respect to packing operations where it was considered advisable that NDC should invest in at least one high speed strip-packing machine for tablets. The coating section was considered surplus to the requirements as coated tablets do not appear to be part of the production programme.

3.3 The inadequacy of raw materials supply was found to be a real constraint. This can be made up by an efficient policy of procurement, storage and stock control of raw materials. The problem of insufficient raw materials is due to difficulties of obtaining import licences and foreign exchange allocation where Government assistance is required.

3.4 In addition to sales to the NDC retail outlets, it is essential that the negotiations being conducted, on the initiative of the writer, with Medical Stores Limited for long-term contracts for purchases of the following products with quantities should be brought to a successful conclusion:-

1.	Aspirin Tablets	80,000,000
2.	Codeine Compound Tablets	70,000,000
3.	Paracetamol Tablets	50,000,000
4.	Chloroquine Tablets	70,000,000
5.	Theophylline Co. Tablets	20,000,000
6.	Sulphadimidine Tablets	10,000,000
	TOTAL	300,000,000

The above off-take will guarantee NDC with 75% utilisation of its present capacity.

3.5 The Quality Control Manager at present reports to the Factory Manager. In order to maintain the independence of the Quality Control Function, it is advisable that the Quality Control Manager should report directly to the General Manager. The Guide to Good Manufacturing Practices (GMP) prepared on the basis of a draft prepared by the writer should be adopted by the MDC management and enforced.

4. Medical Stores Limited (MSL)

4.1 The production process for syrups is at present unsatisfactory, as there is no supply of demineralised water. A suitable Demineraliser (output about 400 litres per hour) is urgently needed and should be procured without delay. The number of storage tanks needs to be increased by two stainless steel tanks of 1,000 litres capacity each.

4.2 The production in MSL is on a custom-built basis, i.e. it is planned on the basis of order or orders received and deliveries made accordingly. There is need for accurate estimates to be made so that adequate quantities can be procured in advance of ready stocks maintained for quick deliveries.

4.3 A UNIDO Feasibility Study on Local Manufacture of Drugs in Zambia (DP/ZAM/78/008) was prepared by a team of Czechoslovak consultants in 1980. The Government approved the Study and accorded it a high priority for implementation, which was planned on a tri-lateral basis. The Government was responsible for all expenditure in local currency i.e. construction of a new building in extension of the present premises of Medical Stores Limited and cost of personnel and local needs. Assistance was sought from the Government of Czechoslovakia for purchase of equipment and training of technicains. UNIDO was requested to provide expertise and fellowships for managerial level personnel. The project passed through various vicissitudes and has so far been unable to obtain the requisite financing.

4.4 The Rt. Hon. Prime Minister took a special interest in the project and directed that urgent action should be taken to implement the project. In order to achieve quick results, the project was recast in the light of practical realities in the country. A revised project proposal was prepared incorporating the modalities of implementation in two phases as follows:-

a) Phase I - which will commence immediately with the rearrangement of present production areas in Medical Stores Limited to allow manufacture of essential and large consumption of Tablets, maximising the output of Syrups and setting up a Quality Control Laboratory.

b) Phase II - which will involve the construction of building extension in which the production of tablets will be expanded and production of capsules commenced.

/...

The Work Plan envisaged the start of production in Phase I in July 1983.

4.5 The project costs for Phase I were estimated as follows:

a)	Building Alterations	K20,000
b)	Equipment	K350,000
c)	Raw Materials (first year)	K1,000,000
d)	Local Personnel (annual	K100,000
e)	Sundries	K30,000
	TOTAL	K1,500,000 = US $1,650,000

Quotations have been obtained for building alterations based on 300 m^2 available space in MSL. The list of equipment and approximate cost on raw materials and personnel is detailed in Annex II.

4.6 The Government has agreed to provide the cost in local currency in the State Budget for 1983. The Czechoslovaks were requested to provide the cost of equipment on a soft loan basis, which has not materialised. The Government is trying to obtain financing from other sources.

4.7 UNIDO was requested to provide expertise and training for Phase I and the costs were projected as follows:-

a)	Expertise 12 m/m	US $88,300
b)	Fellowships 18 m/m	27,500
c)	Equipment	10,000
d)	Sundries	3,500
	TOTAL	US $129,300

The request is still under consideration of UNIDO and no decision has been arrived at. The above cost is in addition to that presented in sub-para 4.5, giving a grand total for PHASE I of the project as approximately US dollars 1,800,000.

5. GENERAL PHARMACEUTICALS LIMITED

This company was assisted by UNDP/UNIDO which resulted in its being established and managed in a competent manner whereby the entire requirements of intravenous fluids in Zambia are met. However, there is need for consistent vigilance by the Zambian personnel, so that this critical item of medical supply is produced in accordnace with international standards and is available in adequate quantities.

6. ORAL REHYDRATION SALTS

6.1 As part of diversification plans for General Pharmaceuticals Limited (GPL) a project for production of oral rehydration salts was prepared in 1980 by the UNIDO experts. This project has been considered from time to time by various Government agencies. WHO and UNICEF also showed interest without any hint of financial support. A formal project proposal was submitted to UNIDO for assistance in expertise and equipment. A decision is still awaited.

6.2 The GPL and their holding company, INDECO, while expressing their commitment to the project, have not taken concrete and tangible action to bring about its implementation. Their costing has been unrealistic as they wish to offer it to the Ministry of Health at 50 ngwee (app. 50 US cents per sachet (WHO formula), while similar product imported from UNICEF costs no more than 10 ngwee per sachet. At one time Medical Stores Limited were preparing it on a manual basis, and had also collected enough data to be able to embark on this project in their present premises. The Government may well be advised to shift the project to Medical Stores Limited for its early implementation.

7. DRUG LEGISLATION

In order to institute control on all drugs imported, manufactured and sold in Zambia, it is essential to enact legislation for this purpose. The present laws, Foods and Drugs Act, Therapeutic Substances Act and Pharmacy and Poisons Act are selective in their respective fields and do not make possible an efficient system of total drug control which will include registration, inspection and laboratory analysis. For this purpose, the 1973 report of a WHO Consultant on this subject was studied and a draft legislation proposed which is presented in Annex III. The draft is under consideration of the Ministry of Health.

V CONCLUSIONS AND RECOMMENDATIONS

1. The tasks entrusted to the writer have been attempted and accomplished within the limitations of time and period allocated to this assignment. Proposals have been made for the organisation of drug supply and placing pharmaceutical industry in Zambia on a sound base. However, from the Government point of view, proposals alone do not by themselves resolve the problems faced in Zambia on drug supply and pharmaceutical production. A number of projects have been proposed eg. establishment of a Medical Supplies Department, coordination of the production activities of the parastatal manufacturing units, setting up of a local production unit for manufacture of tablets and capsules and production of oral rehydration salts, and some progress achieved in their implementation. The Government's desire and objective that these projects should be fully implemented and brought into operation has not been realised. This would have taken another year or so. It is expected that the Government will proceed on its own or with other assistance to realise its objectives.

2. The following recommendations are made:

2.1 A Department of Medical Supplies be established in the Ministry of Health with the functions and structure detailed in Annex I.

2.2 An Information System based on Electronic Data Processing may be located in the Medical Stores Limited and the Medical Supplies Department to determine in a scientific manner the actual needs and requirements of the Government hospitals and institutions for the purpose of arriving at estimates for regulation of purchases and reliable forecasting for budgetary and other purposes.

2.3 The negotiations started with ZCCM/ZES for undertaking purchases of medical supplies on behalf of the Ministry of Health, on orders placed by Medical Stores Limited, be pursued to a successful conclusion in order to obtain supplies expeditiously.

2.4 The Government should provide adequate import licences and foreign exchange to the 3 parastatal manufacturing companies, Medical Stores Limited, National Drug Company and General Pharmaceuticals Limited to enable them utilise fully their existing production capacities.

2.5 An integrated management structure for the three parastatal companies (NDC, MSL, GPL,) should be created to bring about effective coordination in their management and production activities with the objective of ensuring a steady supply of drugs for the Ministry of Health. A new parastatal company should, therefore be formed for this purpose under the Ministry of Health.

2.6 An effective liaison be established between the Ministry of Health and the Ministry of Commerce and Industry for the healthy promotion of a pharmaceutical industry.

2.7 The production activites of MSL, NDC, and GPL should be strengthened, rationalised and co-ordinated for better production and supply planning.

2.8 The Medical Stores Limited as a parastatal company under the Ministry of Health be given a formal status with the constitution of a regular Board of Directors under the chairmanship of the Permanent Secretary of the Ministry of Health.

2.9 Medical Stores Limited and the other parastatal companies, NDC, and GPL should mutually negotiate about production of specific items and their prices keeping in view the terms of preferential contract purchases of large output items.

2.10 The project at Medical Stores Limited for local manufacture of drugs should be implemented on a priority basis in accordance with the Work Plan, so that production of tablets under Phase I of the project can commence in July 1983.

2.11 The National Drug Company (NDC), should operate exclusively as a pharmaceutical company, producing, wholesaling and retailing drugs and divest themselves of cosmetcs and toileteries range. The latter can be handled by the holding company, NIEC which already have numerous wholesaling and retail outlets for consumer items.

2.12 General Pharmaceuticals Limited (GPL), should implement their expansion and diversification projects, particularly in relation to production of Oral Rehydration Salts. If GPL are unable to do so within a fixed time-limit, the project should be transferred to Medical Stores Limited.

2.13 The pharmaceutical industrial units in the private sector should be carefully controlled in their operations and expansion plans, in order not to waste valuable foreign exchange, These units should be compelled to have adequate quality control facilites without which their operations should be drastically curtailed.

2.14 Stringent quality control on all imported and manufactured pharmaceutical products should be instituted. Good Manufacturing Practices as recommended by WHO should be enforced for all pharmaceutical manufacturing units.

2.15 The draft Drug Legislation as proposed in Annex III should be enacted as speedily as possible to ensure quality and safety of drugs imported and manufactured and sold in Zambia.

VI ACKNOWLEDGEMENT

1. The assistance, encouragement and support from Dr. J. M. Kasonde, Permanent Secretary and Director of Medical Services, Ministry of Health is gratefully acknowledged. The cooperation extended by Mr. P. G. Moore, Chief Pharmacist, the staff of the Ministry of Health and the staff of the parastatal pharmaceutical companies is deeply appreciated.

2. The assistance and cooperation given by the UNDP Resident Representative, Lusaka and his staff is duly acknowledged. Special thanks and appreciation are due to Mr. Keshap C. Sen, UNIDO SIDFA for his constant help and guidance.

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ANNEX 1

ORGANISATION STRUCTURE FOR DEPARTMENT OF MEDICAL SUPPLIES

I GENERAL

1. The Department headed by a Director of Pharmaceutical Services will be divided into two sub-departments as follows:-

1.1 Administration, headed by an Assistant Director of Pharmaceutical Services which will include Drug Control.

1.2 Supply, headed by an Assistant Director of Pharmaceutical Services.

2. The office accommodation for the Department will be provided in the present Ministry of Health Stores premises at Tuletaka Road by requisite extensions.

3. Medical Stores Limited will be responsible for purchase and distribution and will also act as Stores for the Department.

4. The details for the above are described in the following paragraphs of this Note, and presented in Appendices I, II, III, and IV.

5. The establishment for the department is shown in Appendix II.

II PERSONNEL

1. Director of Pharmaceutical Services

The Director of Pharmaceutical Services will hold the overall administrative, technical and professional responsibilities of the Department.

2. Sub-Department I - Administration

2.1 The functions of this sub-department are already being exercised by the Chief Pharmacist who is located at the Ministry of Health Headquarters whose designation will now be A/D.P.S. The functions are summarised below:-

2.1.1 Professional Control of pharmacies and pharmacists in hospitals and other state and private institutions, including mining hospitals and mission hospitals and dispensaries, and administrative control and supervision of provincial pharmacies and pharmacists.

2.1.2 Secretary of the Zambia National Formulary Committee and also of its Editorial Committee.

2.1.3 Administration and enforcement of professional matters relevant to the practice of pharmacy included in the Medical and Allied Professions Act.

2.1.4 Administration and enforcement of Pharmacy and Poisons Act including inspection under this Act.

2.1.5 All other functions at present being exercised by the Chief Pharmacist.

2.1.6 Draft legislation for drug control comprising of a Drugs Act (separate from the Food and Drugs Act) and Drugs Rules made under the Act, to regulate import manufacture, sale and export of pharmaceuticals and to harmonise with the existing legislation e.g. Pharmacy and Poisons Act.

2.1.7 Prescribe and enforce registration procedures for all drugs imported, manufactured and sold in Zambia.

2.1.8 Conduct inspection of premises and factories dealing in pharmaceutical storage, sale and/or manufacture.

2.1.9 Prepare and execute a Plan for the co-ordination of the manufacturing activities of the pharmaceutical parastatal organisations with a view to bringing about rationalisation and economy in their operations.

2.1.20 Co-ordinate the production in the pharmaceutical units in the private.

2.1.11 Assist the pharmaceutical units in resolving the problems faced by pharmaceutical industry.

2.1.12 Prepare long-term plan for the development of pharmaceutical industry particularly in referennce to United Nations feasibility studies.

2.2 It is suggested that this sub-department may be kept with its functions in paragraph 2.1 in its present location for the time being. Its integration with the Department of Medical Supplies in respect of its location and staff requirements may be considered in the light of the availability of new and expanded premises for the Department.

3. Sub-Department II - Supply

3.1 This sub-department will be controlled by A/D.P.S. and divided into two sections estimates.

3.2 Section I - Estimates

3.2.1 This section will:-

3.2.1.1 Receive orders from stations, check them for accuracy and commit orders to expenditure, after a price check.

3.2.1.2 send orders to Medical Stores Limited and other suppliers where relevant and receive copies of delivery notes checking them for accuracy and prepare them for the computer for record purposes.

3.2.1.3 prepare estimates from computer consumption figures and submit them to Medical Stores Limited.

3.2.14 monitor stocks and consumption of drugs and medical supplies.

3.3 Section II - Accounts

3.3.1 This section will operate a separate account for drugs and medical supplies and:-

3.3.1.1 check accounts for accuracy and commit purchases to expenditure.

3.3.1.2 advise stations of expenditures and exercise financial control.

3.3.1.3 submit vouchers to computer and arrange payments to Medical Stores Limited and other suppliers.

3.3.1.4 prepare annual budget estimates for all votes under the control of the Director of Pharmaceutical Services.

3.3.1.5 prepare monthly cash-flow schedules for submission to the Ministry of Finance (FO Ministry of Health).

3.3.1.6 maintain all internal and external accounts and computer records.

3.4 GENERAL

3.4.1 Medical Stores Limited will be responsible for the purchase of all medical supplies and for the receipt, including Customs Clearance and claims of all consignments of Medical Supplies either acquired or donated to the Ministry of Health.

Also they will store such consignments and distribute them on instructions issued by the Ministry of Health.

3.4.2 Details of working procedures between the Department of Medical Supplies and the Medical Stores Limited will be worked out and agreed upon on matters as follows:-

a) Systems and Documentation

b) Charges to be made by Medical Stores Limited for acting as agents for the Ministry of Health.

c) Accounting System including procedures for payment to Medical Stores Limited.

d) Laison and co-ordination

3.4.3 The present Ministry of Health Stores at Teuletaka Road will be disbanded and the personnel absorbed in the other sections and sub-department of the Department of Medical Supplies.

III OFFICE ACCOMMODATION

1. The office accommodation for the Department, its two Sub-Departments and their Sections as proposed is presented in Appendix IV.

2. It is presumed that the office of the A/D.P.S. in charge of Administration and his staff will continue to stay at the Ministry of Health Headquarters. The rest of the department will be located in the extended premises at Tuleteka Road.

3. The cost as calculated by the Ministry's architect is estimated at K105,000. If the drawing in Appendix IV is accepted, the Ministry's architect may be asked to draw up detailed blue-prints etc.

IV EQUIPMENT AND ACCESSORIES

1. Furniture

1.1 The furniture required by the office in the proposed plan will consist of desks, chairs, filing cabinets, book cases, metal cupboards, correspondence trays etc. The cost is estimated at K50,000 which may be higher or lower in accordance with prevailing market prices.

1.2 In addition, electric fans and heaters will also be needed and the cost is estimated as K5,000.

2. Equipment

The following office equipment is required:-

1)	Telex Machine Installation etc	K3000	Annual Rent K600
2)	Duplicator	1,	Cost K5,000
3)	Photocopier	1 Ministry of Health Stores.	Already in the
4)	Typewriters	6	Cost K6,000
5)	Computer equipment, to be supplied by the Ministry of Finance Data Centre, estimated capital costs K25,000. plus annual running accessories K3,000.		
6)	Calculators with printers	4	Cost K2,2700

3. Total Cost

3.1 The total cost is as follows:

3.1.1 Capital

1) Furniture	K55,000
2) Equipment	K42,000
TOTAL	K97,000

3.1.2 Recurring annual expenditure

1) On equipment	K4,000
2) Miscellaneous	K6,000
TOTAL	K10,000

V CONCLUSION

1. Capital Expenditure

1) Building Alterations	K105,000
2) Equipment and Furniture	K97,000
TOTAL	K202,000

2. Recurring Expenditure (Annual)

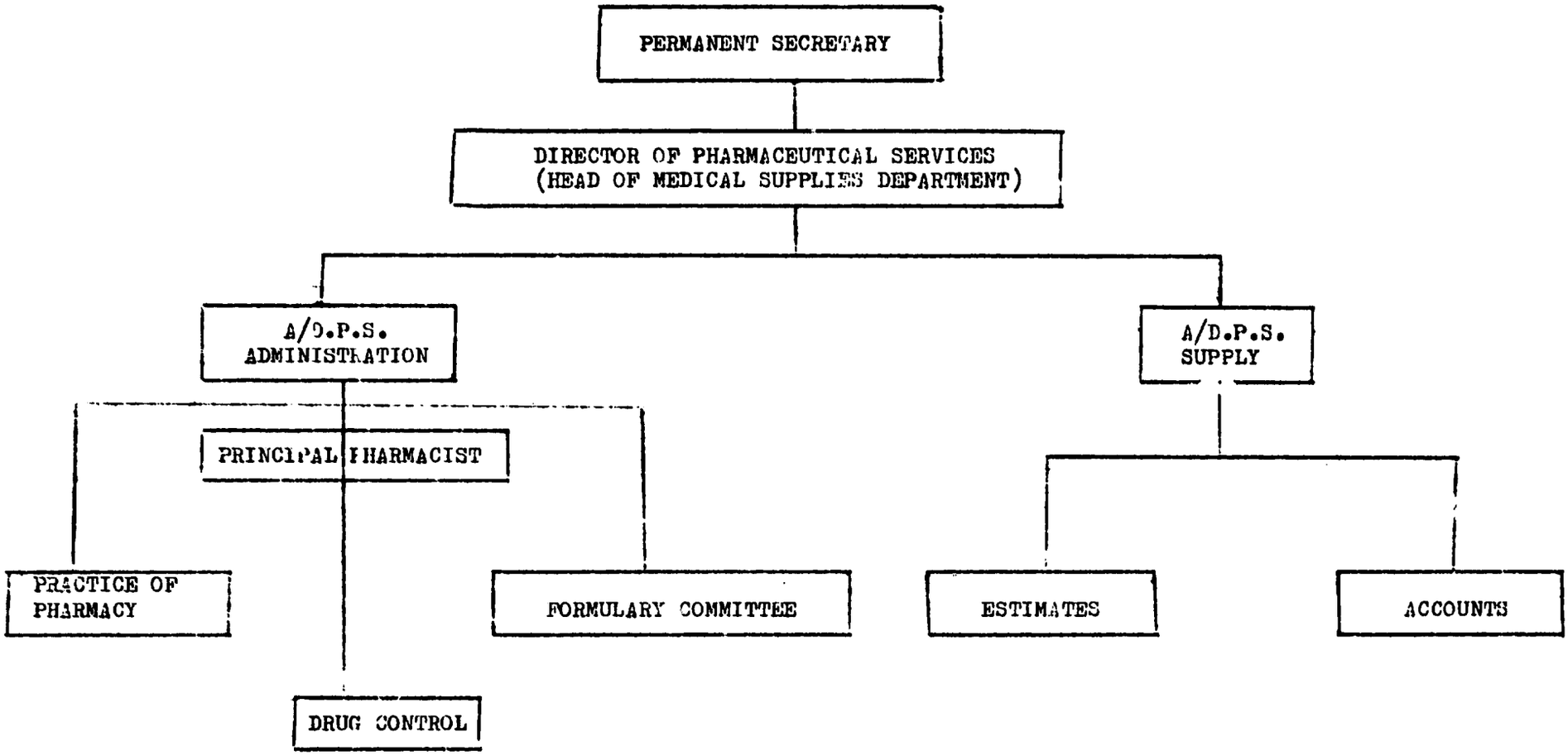
1) Establishment	K150,000
2) On Equipment	K10,000
TOTAL	160,000

3. Grand Total for the first year

1) Capital Expenditure	K202,000
2) Recurring Expenditure	K160,000
GRNAD TOTAL	K362,000

Appendix I

ORGANISATION CHART



PERSONNEL

1. Director of Pharmaceutical Services

1 x Director of Pharmaceutical Services	MS/3	1x12,576	= K12,576
1 x Stenographer	SS/5	1x4,164	= K4,164
1 x Clerical Officer	S/15	1x2,700	= K2,700
1 x Telephone Operator/Receptionist	S/15	1x2,700	= K2,700
1 x Systems Officer	S/11	1x5,400	= K5,400
1 x Machine Operator/Typist	SS/7	1x3,432	= K3,432
2 x Security guards (unclassified)		2x984	= K1,968
3 x Unclassified		3x984	= K2,952
	TOTAL		K36,876

2. Sub-Department I - Administration

1 x A/D.P.S.	GPS/5	1x10152	= K10,152
1 x Principal Pharmacist	GPS/6	1x9,876	= K9,876
1 x Pharmacist	GPS/9	1x7,860	= K7,860
1 x Pharmacist (inspection)	GPS/9	1x7,860	= K7,860
1 x Stenographer	SS/5	1x4,164	= K4,164
2 x Clerical Officer	S/15	2x2,700	= K5,400
1 x Typist	SS/7	1x3,432	= K3,432
	TOTAL		K48,744

3. Sub-Department II - Supply

3.1	1 x A/DPS	GPS/5	1x10,152	= K10,152
	1 x Stenographer	SS/5	1x4,164	= K4,164
	TOTAL			K14,316
3.2	1 x Senior Pharmacist	GPS/7	1x8,880	= K8,880
	1 x Senior Pharmacy Tech	MS/14	1x6,408	= K6,408
	2 x Clerical Officers	S/15	2x2,700	= K5,400
	1 x Typist	SS/7	1x3,432	= K3,432
	TOTAL			K24,120

3.3	1x Accountant	S/10	1x5,940	=K5,940
	1x Assistant Accountant	S/12	1x4,644	=K4,644
	1x Accounts Assistants	S/14	2x3,132	=K6,264
	2x Clerical Officers	S/15	2x2,700	=K5,400
	1x Typist	SS/7	1x3,432	=K3,432
		TOTAL		K 25,680

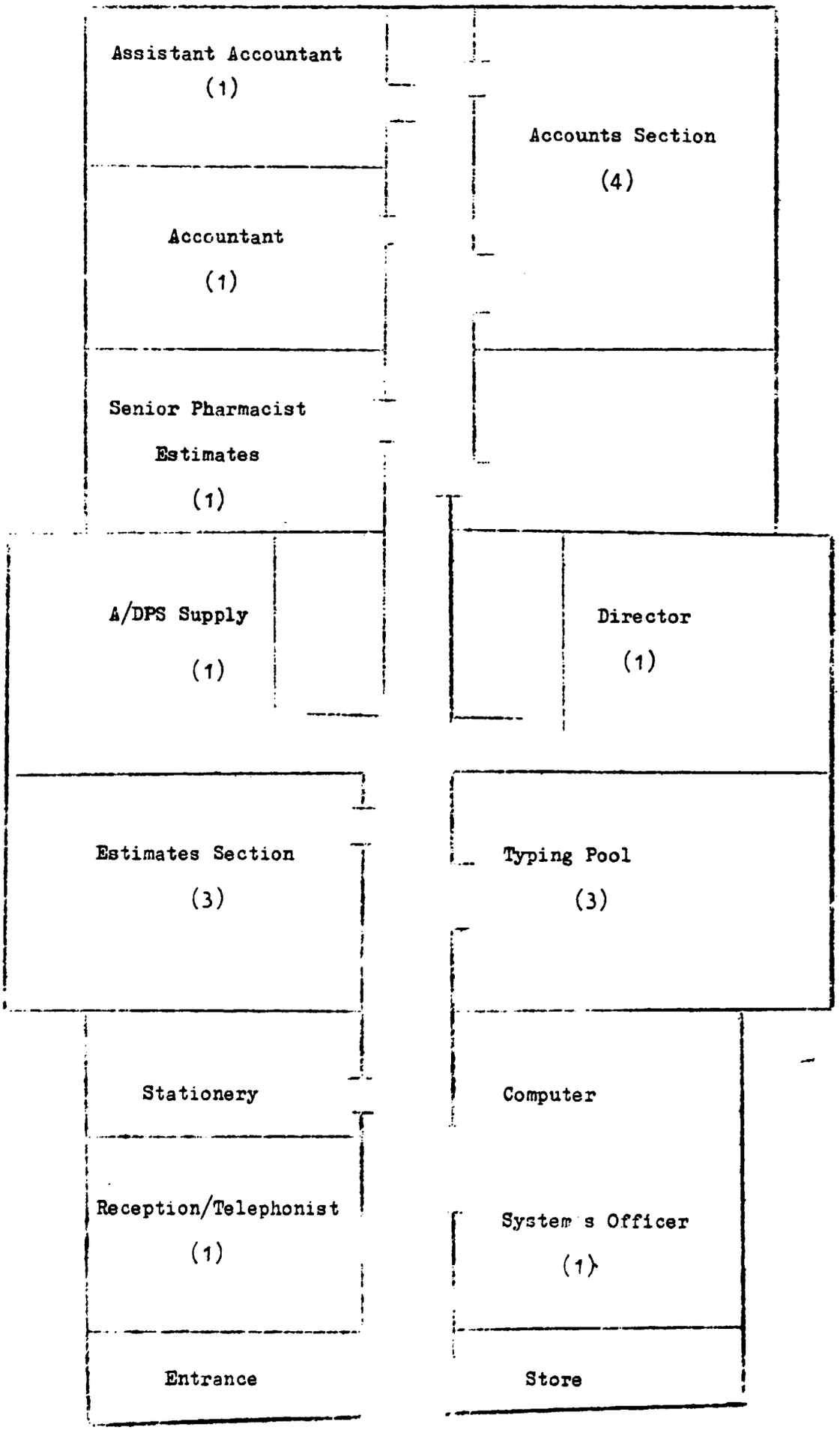
Appendix III

DEPARTMENT OF MEDICAL SUPPLIES

ESTABLISHMENT - POSTS

S. NO.	Posts	Grade	Admin	Supply	Total Posts	Salaries	Total Salaries	Remarks
1.	Director of Pharma. Service	MS/3	1	-	1	1x12,576	12,576	
2.	Assist. Director	GPS/5	1	1	2	2x10,152	20,304	
3.	Principal Pharmacist	GPS/6	1	-	1	1x9,876	9,876	
4.	Senior Pharmacist	GPS/7	-	1	1	1x8,880	8,880	
5.	Pharmacists	GPS/9	2	-	2	2x7,860	15,720	
6.	Senior Pharmacy Tech	MS/14	-	1	1	1x6,408	6,408	
7.	Accountant	S/10	-	1	1	1x5,940	5,940	
8.	Systems Officer	S/11	1	-	1	1x5,400	5,400	
9.	Assis. Accountant	S/12	-	1	1	1x4,644	4,644	
10.	Stenographers	SS/5	2	1	3	3x4,164	12,492	
11.	Typists	SS/7	1	2	3	3x3,432	10,296	
12.	Telephonist	S/15	1	-	1	1x2,700	2,700	
13.	Machine Operator	SS/7	1	-	1	1x3,452	3,452	
14.	Accounts Assistants	S/14	-	2	2	2x3,132	6,264	
15.	Clerical Officers	S/15	3	4	7	7x2,700	18,900	
16.	Daily Paid	--	6	-	6	6x984	5,905	

GRAND TOTAL K149,736



Numbers indicate number of personnel per office

ANNEX II/a

PERSONNEL FOR TABLETS PRODUCTION, MEDICAL STORES LIMITED

				K
1.	Production Manager	1		8,700
2.	Quality Control Manager	1		7,050
3.	Plant Engineer	1		7,050
4.	Production Pharmacist	1		7,050
5.	Section Supervisers	3	3 x 3600	10,800
6.	Lab Technician	1		3,600
7.	Engg. Technician	1		3,600
8.	Assistant Lab Technician	1		2,514
9.	Lab. Attendant	1		2,182
10.	Store Keeper	1		2,182
11.	Operators	6	6 x 1606	9,636
12.	Senior Hanymen	2	2 x 1188	2,376
13.	Handymen	4	4 x 912	3,648
14.	Secretary	1		3,100
15.	Clerk	1		1,606
	Total			K75,094
	+ miscellaneous personnel expenses			K25,000
	Grand Total (approx.)			K100,000

ANNEX II/b

LIST OF EQUIPMENT FOR TABLETS PRODUCTION, MEDICAL STORES LIMITED

NO.	ITEM	CAPACITY	QUANTITY	PRICE (f.o.b.)
1.	POWDER SIFTING MACHINE, WITH SIEVES	250 kg	1	US $5,500
2.	POWDER WEIGHING SCALE, DIGITAL OR DIALOMATIC SENSITIVITY 1 gm	100 kg	1	2,000
3.	MIXING MACHINE FOR WET GRANULATION	100 kg	1	22,000
4.	MIXING MACHINE FOR DRY GRANULES	200 kg	1	22,000
5.	GRANULATOR	50 kg	1	8,500
6.	FLUID BED DRIER	200 kg		35,500
7.	TRUCK TYPE ELECTRICAL DRYING OVEN WITH SS TRAYS	150 kg	1	16,500
8.	COMPRESSION MACHINE SINGLE PUNCH		1	12,000
9.	COMPRESSION MACHINE 16 STATIONS, ROTARY		1	17,000
10.	COMPRESSION MACHINE 27 STATIONS, ROTARY		1	21,000
11.	DUST EXTRACTORS		2	4,000
12.	PUNCH POLISHER (COMPLETE UNIT)		1	4,000
13.	TABLET HARDNESS TESTER		2	500
14.	TABLETS DISINTEGRATION TESTER		2	5,000
15.	TABLET COUNTER AUTOMATIC		2	30,000
16.	STRIP PACKING MACHINE FOR TABLETS AND CAPSULES		1	35,000

Total (f.o.b.)	US $	240,500
+ accessories and spare parts 10%		24,050
+	US $	264,550
+ CIF 20%		92,910
Total (CIF)	US $	317,460
Misc, to Warehouse, 10%		31,746
GRAND TOTAL	US $	349,206
Approximately	US $	350,000

ANNEX II/c

QUANITY (KG)	ITEM	COST (CIF Lusaka)
20,250	ACETYL SALICYLIC ACID BP/USP	US $ 54,000
26,250	PARACETAMOL BP/USP	130,000
12,500	CHLOROQUINE DISPHOSPHATE BP/USP	386,000
800	TRIMETHOPRIM BP	40,000
4,000	SULPHAMETHOXAZOLE BP/USP	91,000
1,000	VITAMIN C BP/USP	10,000
280	CODEINE PHOSPHATE BP/USP	90,000
375	NICOTINAMIDE BP/USP	3,000
25	VITAMIN B1 MONONITRATE BP	1,000
25	VITAMIN B2/USP	1,000
2,500	MAG TRICILICATE	30,000
1,200	DRIED ALU HYDROXIDE GEL. USP	3,000
2,600	THEOPHYLLIN BP/USP	22,000
480	EPHEDRINE HCL	7,000
160	PHENOBARBITONE	2,000
100 (Litres)	PEPPERMINTOL	1,000
300	TALC	1,000
1,250	DICALIC PHOSPHATE BP	12,000
1,250	MAG STEARATE BP/USP	4,000
70	STEARIC ACID BP	1,000
28,800	LACTROSE BP/USP	26,000
9,090	STARCH BP	5,000
5,000	SULPHADIMIDINE BP/USP	46,000
	TOTAL	US $974,000
	APPROXIMATELY	US $1,000,000

ANNEX III

DRAFT OF A DRUGS ACT FOR THE REPUBLIC OF ZAMBIA.

PREAMBLE

CHAPTER 1 - GENERAL

01 Definitions

(a) "Generic name", with reference to a drug means the general or chemical name in English by which the drug is commonly know; it also includes international non-proprietary names, as described in the latest WHO publications.

(b) "Expiry date" means any date after which a drug is not recommended for use.

(c) "Medical Practitioner" means a person authorized by the Medical Council of Zambia to treat patients with any drug.

(d) "Prescription" means a document given by a medical practitioner directing that a stated amount of any drug or mixture of drugs specified therein be dispensed to the patient named in the document.

(e) "Parenteral use" means administration of a drug by means of hypodermic syringe, needle or other instrument through or into the skin or mucous membrane.

(f) "Internal use" means ingestion by mouth or application for systemic effect to any part of the body in which the drug comes into contact with mucous membrane.

(g) "Distributor" means any person who engages in the sale of a product other than a retail pharmacy or a medical practitioner in the course of his professional practice.

CHAPTER 2 - REGISTRATION OF DRUG MANUFACTURERS, IMPORTERS AND DISTRIBUTORS

01 Every person upon first engaging in the manufacture, import, preparation, propagation, compounding, processing, sale or distribution of a drug or drugs in any establishment which he owns or operates in the Republic of Zambia shall immediately register with the Ministry of Health his name, address and place of business, and such establishment.

02 Every person duly registered in accordance with the foregoing section shall immediately register with the Ministry of Health any additional establishment which he owns or operates in the Republic of Zambia and in which he begins the manufacture, import preparation, propagation, compounding, or processing of a drug or drugs.

03 The Ministry of Health shall assign a registration number to any person or establishment registered in accordance with this section. Such registration shall be renewed every two years from the date of registration.

04 The foregoing sections shall not apply to:

(1) Medical practitioners authorized by the Laws of Zambia to prescribe or administer drugs and who prepare, or compound, drugs solely for use in the course of their professional practice;

(2) Persons who manufacture, prepare, propagate, compound or process drugs solely for use in research, teaching, or chemical analysis and not for sale;

CHAPTER 3 - REGISTRATION OF DRUG DOSAGE FORMS

01 For the purpose of this chapter, drug means a drug in dosage form.

02 Any manufacturer/distributor of a drug shall furnish to the Ministry of Health a notification signed by him or by a person authorized on his behalf, containing the following information:

(a) The name and address of every person, firm, partnership or corporation appearing on the label used in conjuction with the drug.

(b) The name under which the drug is sold.

(c) The use and purpose for which the drug is recommended.

(d) A quantitative list of the medicinal ingredients contained in the drug and preservatives by their generic names.

(e) The recommended dosage of the drug.

(f) A copy of the inner and outer labels used in conjunction with the drug or a fascimile of the labels, a copy of the package insert, if any, and copy of any further prescribing information mentioned thereon as available upon request.

03 Every manufacturer, importer or distributor of a drug who is required to give notification to the Ministry of Health pursuant to section 02 in this chapter in respect of that drug shall:

(a) where he withdraws the drug from the market or discountinues the sale of the drug, inform the Ministry of Health within 30 days of the withdrawal or discontinuation of the drug the reasons thereof;

(b) where he changes the formulation of the drug, its recommended dosage or use or the name under which the drug, is manufactured or sold, notify the Ministry of Health 30 days prior to such change;

(c) if the Ministry of Health does not disapprove the sale of the drug under the changed formula within 30 days of such notification, the changes may be implemented.

04 No person shall import a drug into Zambia for sale unless that person has furnished to the Ministry of Health the notifications required by sections 02 and 03 under this chapter in respect of that drug.

CHAPTER 4 - LABELLING OF DRUGS

01 No person shall sell a drug that is not labelled as required by the regulations.

02 No person shall sell, advertise, display or orally represent any drug to the general public as a treatment, preventatives or cure for any of the diseases, disorders or abnormal states mentioned in the Third Schedule to these regulations.

02 Where it is necessary to provide adequate directions for the safe use of a parenteral drug or a drug requiring a prescription that is used in the treatment or prevention of any disease, disorders or abnormal physical state mentioned in the Third Schedule to the Act such diseases, disorders or abnormal physical states may be mentioned on the labels and inserts accompanying the drug.

04 (1) The main panel of both the inner and outer labels of the container or containers of a drug for which a standard is contained in any publication mentioned in the First Schedule of the Act shall show the proper or common name of the drug and indicate the standard that the drug professes to meet.

(a) where a standard contained in any publication mentioned in that schedule is used, by showing the name of the publication or the abbreviation thereof provided in that Schedule; or

(b) where a manufacturer's standard is used, by setting forth such fact.

(2) Where there is a proprietary or brand name for a drug referred to in subsection (1) the generic name of the drug shall immediately proceed or follow the proprietary or brand name shown on the main panel of both the inner and outer labels of the drug in type no less conspicuous than the proprietary or brand name.

(3) Where a standard for a drug is not described in any publication mentioned in the First Schedule of the Act, the main panel of both the inner and outer labels of the drug shall show

(a) the name and address of the manufacturer of the distributor of the drug;

(b) the batch number of the drug;

(c) adequate directions for use of the drug;

(d) a quantitative list of medicinal ingredients of the drug by their proper or common name, but such a list need not be shown on:-

(i) shipping cases or wrapping material;

(ii) drugs dispensed pursuant to a prescription.

(e) The expiry date on drugs identified by the Ministry of Health in the Third Schedule

(4) The net amount of the drug in the container in terms of weight, measure or number.

(5) Where the drug is intended for parenteral use, a quartitative amount of any preservative or preservatives present therein by their generic names.

05 Where a package of a drug has only one label, that label shall contain all the information required by these regulations to be shown on both the inner and outer labels.

06 A drug packed in a container too small or otherwise unable to accommodate a label with sufficient space to bear the information required by these regulations shall be exempt provided that:

(1) the label bears:

(i) The proprietary name of the drug.

(ii) The generic name of the drug.

(iii) An identifying batch, lot or control number.

(iv) The name and address of the manufacurer, packer or distributor of the drug.

(v) The expiry date of the drug, if required under the Second Schedule.

(2) all information required to appear on the label by the Act and regulations appears on the carton or other outer container or wrapper if such carton, outer container or wrapper has sufficient space to bear such information, or such complete label information appears on a leaflet with the package.

07 All information required by this part to be carried on a label shall be

(a) clearly and prominetly displayed thereon, and

(b) readily discernible to the purchaser or consumer under customary conditions of purchase and use.

08 No reference, direct or indirect, to the Act or these regulations shall be made upon any label of or in any advertisement for a drug unless reference is a special requirement of the Act or these regulations.

09 Where a drug is sold in bulk form for further manufacturing, reprocessing or repackaging, the labelling provisions of this chapter shall not apply provided that the label of the bulk drug contains the following information:

(i) The proprietary name of the drug.

(ii) The proper or common name of the drug.

(iii) A statement of net contents

(iv) An identifying lot or control number:

(v) The expiry date of the drug, if any and the statement, "CAUTION : BULK DRUGS FOR MANUFACTURING PURPOSE ONLY".

CHAPTER 5 - STANDARD FOR DRUGS

01 Any drug for which a standard exists in a publication listed in the First Schedule of this Act must conform to all conditions noted in the monograph therein.

02 Any drug for which no standard exists in any publication listed in the First Schedule of this Act must meet such standards that are

(a) generally recognized as being suitable for that drug to ensure its safety and efficacy for its purported use;

(b) approved for the drug and its purported use in the country or origin;

03 Where a manufacturer's standard is used for a drug which is not not identified in a publication lised in the First Schedule of this Act, the manufacturer shall make available to the Ministry of Health, upon request, details of that standard and of a method of analysis for the drug acceptable to the Ministry of Health.

04 Good Manufacturing Practices which shall include as a minimum the practices and procedures required to guarantee total quality control shall be set forth in regulations to be made for this purpose under the Act and such regulations will be enforced through inspection and control measures on manufactures, processors packers holders of drugs.

CHAPTER 6 - NEW DRUGS

01 For the purposes of the Act and this chapter "new drug" means

(a) a drug that contains or consists of a substance, whether as an active or inactive ingredient, carrier, coating, excipient, or other component, that has not been sold as a drug in the Republic of Zambia and in sufficient quantity to establish in the Republic of Zambia the safety and effectiveness of that substance for use as a drug;

(b) a drug that is a combination of two or more drugs, with or without other ingredients, and that has not been sold in that combination or in the proportion in which those drugs are combined in that drug, for sufficient time and in sufficient quantity to establish in the Republic of Zambia the safety and effectiveness of that combination proportion for use as a drug; or

(c) a drug, with respect to which the manufacturer prescribes, recommends, proposes or claims a use as a drug, or a condition of use as a drug: including dosage, route of administration, or duration of action and that has not been sold for that use or condition of use in the Republic of Zambia, for sufficient time and insufficient quantity to establish in Zambia the safety and effectiveness of that use or condition of use of that drug;

02 No person shall import, manufacture, sell or advertise for sale a new drug unless he has complied with the regulations made for this purpose under this Act.

CHAPTER 7 - IMPORTED DRUGS

In addition to all other requirements of the Act and the regulations made thereunder,

No person shall import a drug into the Republic of Zambia for sale unless each specific lot of drugs is accompanied by a certificate of analysis provided by the exporter or importer in accordance with regulations made for this purpose under the Act.

CHAPTER 8 - DRUGS TECHNICAL ADVISORY BOARD

01 The Government shall constitute a Drugs Technical Advisory Board to advise the Minister of Health on all technical matters relating to the administration of the Drugs Act and the Regulations made thereunder.

02 The composition of the Board shall be determined by the Minister of Health. The Board shall meet as often as required, but not less than once every three months.

CHAPTER 9 - INSPECTION

The Minister of Health shall establish an Inspectorate of Drugs and appoint such persons to it as he deems fit to carry out inspection of premises where drugs are sold, manufactured, imported and/or stored and carry out such functions as are prescribed in the Regulations to be made under the Drugs Act for this purpose.

CHAPTER 10 - DRUG CONTROL LABORATORY

01 The Minister of Health shall establish a Central Drugs Laboratory to perform tests as prescribed in documents in the First Schedule or such other tests as he deems necessary to ensure quality control on drugs imported, manufactured and/or sold in Zambia.

02 The Central Drugs Laboratory shall perform such other functions as are entrusted to it under Regulations framed under this Act.

CHAPTER 11 - POWERS TO MAKE REGULATIONS

The Minister of Health shall have powers to make regulations under the various sections and sub-sections of the Act in order to operate and enforce the provisions of the Act.

CHAPTER 12 - PENALTIES AND LEGAL PROCEDURES

CHAPTER 13 - INDEMNITIES

FIRST SCHEDULE

British Pharmacopeia latest edition

United States Pharmacopeia and
National Farmulary, latest edition

International Pharmacopeia (WHO),
latest edition

British Pharmacopeia Codex, latest edition

Any other Pharmacopeia, approved by the Ministry of Health under Chapter 8 of the Act.

SECOND SCHEDULE

Antibiotics, their salts and derivatives, and preparations thereof

Insulin

Vitamins, single or combinations thereof

Hormones, single or combinations thereof

Corticosteroids, and preparations thereof, their esters and derivatives and salts of esters of such derivatives

All preparations for parenteral use.

THIRD SCHEDULE

Alcoholism
Alopecia
Anxiety State
Appendicitis
Arteriosclerosis
Bladder disease
Cancer
Convulsions
Depression
Diabetes
Disease of the prostate
Disorder of menstrual flow
Dysentery
Edematous state
Epilepsy
Gall bladder disease
Gangrene
Glaucoma
Gout
Heart disease
Hernia
Hypertension
Hypotension
Impetigo
Influenza
Kidney disease
Leukemia
Liver disease
Nausea and vomiting of pregnancy
Obesity
Pneumonia
Pleurisy
Poliomyelitis
Rheumatoid arthritis
Scabies
Septicemia
Sexual impotence
Tetanus
Thyroid disease
Tuberculosis
Tumor
Ulcer of the gastro-intestinal tract
Vaginitis
Venereal disease
Rheumatic fever