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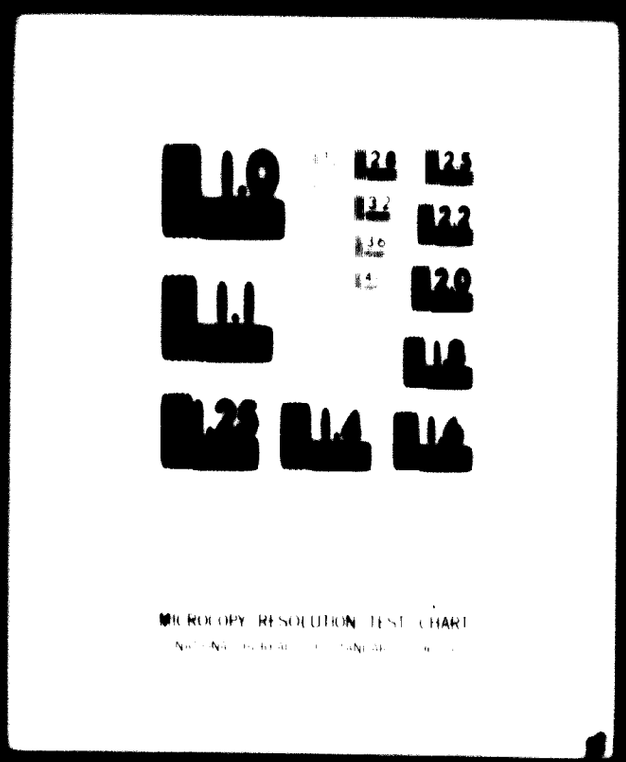

united nations industrial development organization

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establishment of a pharmaceutical industry sector in the east african community

interim report
part I : the production units

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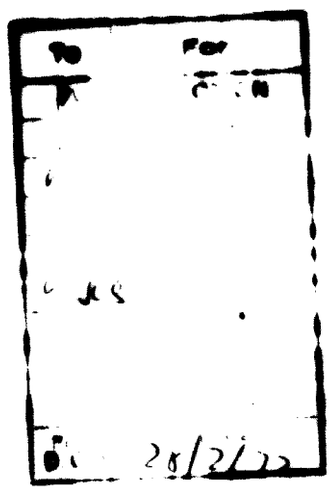
UNITED NATIONS INDUSTRIAL DEVELOPMENT ORGANIZATION

ESTABLISHMENT OF A PHARMACEUTICAL INDUSTRY SECTOR IN THE EAST AFRICAN COMMUNITY



INTERIM REPORT
PART I : THE PRODUCTION UNITS

UNIDO CONTRACT N° 71/44
Project n° SIS 70/784 AFR 10
Phase II

ESKA (SERVA INTERNATIONAL)
Division "Marketing et Développement Industriel"
P A R I S

C. 32 448

February 1972

SUMMARY

VETERINARY PRODUCTS

PHARMACEUTICAL PRODUCTS FOR VETERINARY USE

EXECUTIVE SUMMARY.

The animal industry development is very different with regard to the three States.

Kenyan industry is the most highly developped : beside traditional breeding, there are many ranches that perform the newest elaborated operations. The Kenya Meat Commission administrates two slaughter houses that ensure an important flow of meat expert amounting to million shillings in 1970.

TANZANIA holds a certain number of ranches but most of its production comes from traditional breeding. It owns a slaughter house in DAR ES SALAM that ensures a fairly important expert flow.

UGANDA only owns one traditional breeding and few ranches, and does not expert tinned-meat. A steady arrival of Kenyan herds in the Uganda slaughter houses shows that the Uganda cattle is not sufficient to meet with local needs.

Of course it is in KENYA that the most important and modernized organisation has been set up, and the yields are high enough to prevent the Government from giving care subsidies : they are taken over by the stock-breeders themselves.

Most of the used pharmaceutical products are vaccines and antibiotics. The antibiotics used by veterinaries are fairly close to those used in human medecine, we thus will not talk about them in this chapter.

As far as vaccines are concerned, there are three organisations in KENYA that produce them :

- the KABETE Laboratory (Kenya Veterinary Services),
- EAVRO's (E.A. Veterinary Research Organisation), and
- BURROUGHS-WELLCOME Foundation's,

the three of them are able to supply most of the veterinary vaccines required in EAST AFRICA.

The KENYA animal industry deals in most cases with these organisations, but UGANDA and TANZANIA have their vaccines coming from elsewhere; so far we have not been able to figure out the reasons of it beside the fact that the KABETE laboratory is practising a very shy commercial policy.

Considering the perfect Kenyan organisation, we think it unnecessary to advise the setting up of another vaccine producing firm.

On the other hand, we think it is highly desirable that the KABETE Laboratory should adopt an efficient commercial policy and come to an agreement with commercial firms that should accept commercializing their products. They actually appear willing to do so.

[illegible]

We are giving in the supplement a list of all [illegible] diseases in EAST AFRICA.

The main diseases are :

BOVINES

- Foot and Mouth Disease (FMD)
- Rinderpest
- Contagious Bovine Pleuro Pneumonia (CBPP)
- Trypanosomiasis
- Lumpy skin Disease
- Tuberculosis
- East Coast Fever and Tick Borne Diseases (TBD) such as
  - . Anaplasmosis and Red Water
- Anthrax
- Black Quarter
- Heart Water
- Rift Valley Fever
- Salmonellosis

SHEEP

- Bluetongue
- Nairobi Sheep Disease
- Sheep Scap

GOATS Contagious Caprine Pleuro Pneumonia

POULTRY

- Newcastle Disease
- Fowl Typhoid
- Fowl Pox
- Respiratory Fowl Cholera
- Coccidiosis

The most common ones are [illegible], Newcastle Disease, Sheep, Fowl Typhoid, Blue Tongue and a hard fight is being carried through against Anthrax, Blackquarter, Rift Valley Fever, Newcastle Disease, Fowl Typhoid, Foot Pox by way of vaccinations.

Against TBD dipping only is efficient. The KEMRI/A laboratory has worked out a vaccine against E.C.F. (East Coast Fever), but so far it has remained on experimentation grounds.

VACCINE PRODUCING ORGANISATIONS

There are three of them in KENYA.

The most important one, the KABETE laboratory depends on Veterinary-Services.
The K.A. Veterinary Research Organisation in MUGUGA.
The BURROUGHS-WELLCOME foundation laboratory in KIBAKASI.

THE KABETE LABORATORY

This laboratory was founded in 1970 and is now managed by Dr. J.M. TRUMLETT. It produces 18 vaccines in varying quantity (from half a million down to 300 doses). This figure might be raised up to 22.

A joined list of those vaccines as well as the issued quantities during the last few years will be found in the supplement.

This laboratory is entirely equipped for producing, stocking, controlling, commercializing and dispatching vaccines. The control operations also include "an after sale service" : after treatment the laboratory proceeds to the taking of serum and checking of antibodies.

The laboratory is far from working at its fullest, and it is likely that with a slight increase in staff, it could supply all EAST AFRICA with vaccines.

Let us point out that the laboratory already exports vaccines to UGANDA and SUDAN.

There still remains a field where its ability is limited : the issue of anti-rabies vaccines.

VETERINARY STAFF TRAINING

There are institutions that deal with the training of veterinary personnel.

THE FACULTY OF VETERINARY [illegible]

It takes the faculty five years to form veterinary graduates. The school was formed in [illegible] and forms [illegible] veterinary graduates a year.

THE [illegible] VETERINARY SCHOOL AT [illegible]

The school forms graduates in the following disciplines :

- Animal products
- Dairy
- Agricultural engineering
- Range Management
- General Agriculture
- Home economics
- etc.

There are three year courses.

THE VETERINARY TRAINING INSTITUTE AT [illegible]

The school forms certified students (certificate level - two certificates are awarded)

- Animal Health
- Ranch Management.

There are two year courses.

[illegible] schools have the same entrance examination : the best go to [illegible] and the others to [illegible].

The training institute can welcome 250 students it forms 100 graduates.

Besides the two courses destined for certification, the school also gives "in service courses" to the staff or students willing to acquire special qualification.

For instance the school gives course in :

- [illegible]
- Microscopy
- Artificial insemination.

This school is patronized by the EGYPTIAN Government, FAO and WHO and receives other subsidies as well. It welcomes students from [illegible], [illegible], and LEBANON as well as refugees from other countries.

THE NUMBER OF VETERINARIES

Now there are about 200 veterinaries in KENYA : 90 of them work for the government ; their functions are :

- Prophylaxy
- Supervision of Quarantine
- Control of Livestock Movement
- Artificial insemination
- Inspection of Meat
- Research

90 of them work at the University,
30 are in MUGUGA,
and another thirty work as "private practitioners".

The government is wishing that the number of private practitioners should increase so that the government veterinaries will be able to devote themselves to their control task and will no be free from all practice (treatment, artificial insemination, etc.).

IMPORTATION OF VETERINARY PRODUCTS

The main ones are :

- COOPERS, Mc DOUGALL, ROBERTSON AA Ltd (NAIROBI)
- TWIGA CHEMICALS
- E.T. MBAS
- PFIZER
- BURROUGHS-WELLCOME
- HOECHST
- HOWLE, Mc GREGOR

THE EAST AFRICAN PHARMACEUTIC COUNCIL

DUTIES OF THE EAST AFRICAN PHARMACEUTIC COUNCIL (E.A.P.C.)

The E.A.P.C would be the general centre for reflexion about pharmaceutical matters in East Africa; it should provide the three East African countries with reliable information on the pharmaceutical products available in the region and promote legislation conducive to the harmonious development of this sector for the benefit of the three Partner-States.

To this end, it should :

- collect full and exhaustive documentation on drugs existing or due to be introduced in E.A.; in particular, and as first priority, no drug or preparation should be allowed to be introduced until the manufacturer's dossier of tests and controls has first been seen and examined. The E.A.P.C. should also keep itself aware of results, including mishaps (1) recorded after the drug is made available to the public;

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(1) Chloramphenical is used in the treatment of typhoid and typhus, successfully in the vast majority of cases. But in one case out of 150,000 it destroys not only the microbe of these diseases but also the bone-marrow cells which produce red globules. It is reckoned that more than five million typhoid and typhus cases had to be treated with chloramphenical before the medical profession realised that the drug was responsible for the unexpected outcome. A further example that may be cited is that of tranyleypromine, used as an anti-depressant, which in some cases produces dangerous hypertension when the patient eats certain kinds of cheese containing tyramine : This effect was not discovered until long after the drug had been put on sale.

- In a second stage, the E.A.P.C. should publish and keep up to date a list of the preparations available in the country, and check the appropriateness of introducing a particular drug on the basis of test and supervision dossiers ; on the strength of this information, the E.A.P.C. could recommend the banning of particular drugs as being out of date or dangerous;

- So far as possible, the E.A.P.C. should collect all the statistics needed for a better knowledge of the sector; in particular, it should gather basic material for a cost-benefit analysis of the effect of certain drugs on the major endemic diseases ;

- It should endeavour to assemble the fullest possible information on the pharmaceutical industry in E.A. and in the world;

- Similarly, in close liaison with the W.H.O., it should draft and propose to the Governments of the Community legislation adapted to their needs and resources concerning quality control, manufacturing standards, rules for distribution, and the registration of new drugs. It should also make recommendations about training personnel;

- Relying at first on manufacturers' test dossiers, and then increasingly on the results of tests carried out locally as the range of testing by the Drug Quality Control Laboratory (D.Q.C.L.) is progressively extended and consolidated, the E.A.P.C. should publish at regular intervals a Drug Selection Guide (D.S.G.) to assist those responsible for purchasing or prescribing drugs.

This in our view is one of the major functions of the E.A.P.C. and is sufficient in itself to justify economically the cost of the establishment;

- Lastly, the E.A.P.C. should preside over the establishment of the Drug Quality Control Laboratory responsible for inspecting, or initially, supervising the inspection of the Safety and Efficacy of Drugs. Both drugs and production processes will be subject to control. On each of these there is a general text of the W.H.O.(A 24/4/4 of 5.4.1921 ; Safety and Efficacy of Drugs - Principles for Drug Control, and Annex 12 to Doc. A/22/P and B/12 of 6.6.1969 ; Quality Control of Drugs -Good Practices in the Manufacture and Quality Control of Drugs) ; these papers deal fully with the two subjects ; quotations from them are appended to this Report.

Drug control will be carried out by the D.Q.C.L. The control of manufacturing processes at the place of production will be the responsibility of a corps of Inspectors under the E.A.P.C.

Drug control might cover :

- Products sent by Medical Stores for inspection at their request,
- drugs already on sale to the public, whether imported or locally produced,
- imported raw materials, either submitted for inspection by the manufacturer, or specimens taken by the E.A.P.C.,
- drugs submitted to the D.Q.C.L. by importers for approval.

ATTRIBUTION POWERS OF THE E.A.P.C.

Apart from its function in the field of information and preparing legislation, the authority of the E.A.P.C. will largely depend on how far the Partner-States, more precisely their Health departments, are prepared to hand over some of the responsibilities of the Drug Inspectors and Advisory Committees whose duties and powers overlap with those of the E.A.P.C.

At one extreme, it is possible to visualise the E.A.P.C., simply advising the Department concerned, each of which would retain its present structure: clearly, this would greatly reduce the impact of the E.A.P.C.
At the other extreme, the Health department would delegate full powers to the E.A.P.C. in regard to pharmaceutical information and control : this would give the E.A.P.C. a high degree of effectiveness. Needless to say, in the second case, the three Ministers or their representatives would be ex-officio members of the Board of Governors of the E.A.P.C.

Similar structures already exist in the Community : each of the three countries has its own Ministry of Transport and yet ports, railways, and air transport are Community matters.

OTHER FUNCTIONS OF THE E.A.P.C.

The E.A.P.C. should :

- Supply the three Partner-States with basic material for health policy,
- Organise and finance medical research in East Africa,
- approve the production of new drugs in East Africa.

THE DRUG QUALITY CONTROL LABORATORY

DRUG QUALITY CONTROL

"In the pharmaceutical industry, overall control is essential to ensure that the individual consumer receives drugs of high quality. Haphazard operation cannot be permitted in the manufacture of substances that may be necessary to save life or to restore or preserve health" (1).

Reading the introduction of that WHO document and then visiting the majority of the production units of available pharmaceutical products (except the Medical Research laboratory, NAIROBI) is enough to realize that pharmaceutical industry in East Africa is far from having this goal and that the consumer is wholly within the hand of the producing firms. (beside a few obvious cases of bad manufacturing).

A few products or vaccines, either imported or locally manufactured are known to be of dubious quality by the medical profession, but nc control has yet been done, neither there nor abroad.

The producing process is far from being completed according to the required strictness. To quote but one detail, the WHO suggests in the document mentionned above (see the supplement) :

"To prevent packaging and labelling errors, a known number of labels should be issued and properly coded. Such issuance should be made against a written signed request that indicates the quantity and types of label required. Upon completion of packaging and labelling, the number of labels actually used should be carefully compared with the number issued and coded.
Destroyed and unused labels should also be checked".

Inasmuch as the labour remains rather unskilled, such process should be difficult to achieve.

(1) doc. A 22/P and B/12 - 6 June 1969 - WHO

DRUG QUALITY CONTROL IN KENYA

We refer to a report made by Professor ATTISSO (1) on the matter.

A laboratory control is provided for in the Pharmacy and Poisons ordinance of 1962 and in the Food, Drug and Chemical Substances Act of 1967.

These laws require that all products should conform to the standards laid down in the British Pharmacopoeia or British Pharmaceutical Codex ; but there is nowhere mention of an obligation for the Government itself to carry out such a test to check the required conformity.

Nevertheless one must point out that producers are actually doing some testing and that they are ready to undertake a real quality control. Yet the Ministry of Health is doing nothing so that they were made to do so.

The manufacturing of pharmaceutical products is liable to a licence awarded by the Ministery of Health. There is a law as well which requires that producers should be ensured that their products are of satisfactory quality and fit in with what the label says. Production is meant to be supervised by the Chief Pharmacist who himself should ask help from the Government Chemist in order to undertake the necessary testing. This testing should be carried through by the Government himself or done in a recognized laboratory from outside. To our knowledge this only happened once.

Finally, production and distribution of pharmaceutical products can be said to be under no control : the only guarantee being the "respectability" of the producing firm. Actually the amount of drugs sold in East Africa in the early sixties did not require any control, but as in 1970 it was raised up to 4 times what it was in 1960, it is quite reasonable to wonder whether - from an economical point of view - some control or at least some informative action - or both - are not being justified.

(1) WHO Document AFR/PHARM/5.

Kenya has two national laboratories able to undertake drug quality control.

- the Government Chemist's Laboratory
- The Medical Research Laboratory

THE GOVERNMENT CHEMIST'S LABORATORY

The laboratory undertakes analyses such as :

- drinking water and others
- foodstuffs and drinks
- various natural or synthetic products, locally manufactured or imported.

It carries out also :

- toxicological evaluations
- analysis of drugs in connection with evaluations or fraud biochemical and serological analysis for hospitals.

The present premises are extensive and well laid out, but already appear inadequate for the development of the laboratory.

The laboratory is equipped with modern apparatus particularly absorption spectrophotometry, chromatography, polarography, polarimetry, refractometry; its equipments include also all the usual implements such as balances, incubators, ph meters etc.

However, the specific equipment for the control of pharmaceutical product is lacking.

It is the Professor ATTISSO's view that "the Government's Chemist's laboratory could effectively undertake quality control of drugs, in view of its facilities, equipment and highly competent staff".

THE MEDICAL RESEARCH LABORATORY

This laboratory has been already inspected by Professor [illegible] and Dr. P. KOKKO (1). "This is the central laboratory in the country. It has been in existence for over 40 years. In its latest annual report (19[illegible]) the following typical public Health laboratory functions are [illegible] as part of its mission :

(a) serving as a reference laboratory for provincial laboratories;

(b) maintaining standards for medical laboratory [illegible] in the country;

(c) training of laboratory support for studies on food, water and milk contamination and for epidemiological studies on gastroenteritic disease and meningitis;

(e) it provides a clinical laboratory service to K[illegible] HOSPITAL.

In 1966, over 220,000 specimens were processed by the MRL constituting approximately 80 % of its total workload. M.L has also produced considerable quantities of high quality smallpox vaccine and serves as a blood bank.

Presently, the MRL's total staff (professional, technical and auxiliary) amounts to approximately [illegible]0 ...

Then D. KOKO mentions the next re-organisation move which "offers a logical opportunity to revitalise the public Health Laboratory functions in the MRL, which have become increasingly overshadowed by the rapidly growing clinical laboratory demand. The health laboratory service in KENYA faces a number of problems, the most important of which is the lack of competent scientific personnel... This problem, [illegible] indirect cause of [illegible] country (2) is particularly acute in the [illegible]

(1) WHO Document AFR/[illegible]/14

(2) underlined by ourselves

It is the opinion of the director of the Medical Research Laboratory and Dr. BLAND that, with the proposed new facilities, the laboratory would be able to undertake biological control of drugs in the following areas.

- Sterility control
- Biological titration of some antibiotics and vitamins
- Acute and chronic toxicity tests.

CONCLUSION: The professor ATTIWOO opinion is :

Pharmaceutical chemical and physico-chemical control tests could be carried out by the Government Chemist laboratories, sterility, biological titration (antibiotics and vitamins) and acute and chronic toxicity tests could be done in the expanded MRL premises.

At the time of his visit, Dr. TAYLOR, Senior Lecturer of Pharmacology was not yet arrived, but following his duties and supposing that Dr. TAYLOR has enough time left for undertaking laboratory work, it could be supposed that pharmacological tests could be carried out by Dr. TAYLOR and his assistants.

"Clinical Tests of new specialities should also be envisaged subsequently once the new MAKARERE UNIVERSITY HOSPITAL becomes operational.

Professor ATTIWOO suggests that "the type of organization suggested (for a drug control laboratory) would be national and not regional. In fact each of the three states of East African Community has at the moment a national chemical laboratory and a national laboratory of medical biology which are structured and could serve as a framework for systematic control.
The technical staff in KENYA, UGANDA and TANZANIA are very similar in number and quality. The equipment is also the same.

In the circumstances, it would seem unnecessary to create a regional laboratory".

Provided we follow Professor Attiso's suggestions there would be no less than three central laboratories in East Africa.

Should drug control, quality testing etc., be what matters in order to improve the pharmaceutical industry in East Africa, and should all tests be extremely simple and require no highly qualified staff, we would fully support Dr. A[illegible]'s views.

In fact, we suggest that there should be more than mere control, and despite the fact that the whole scale of tests including analysis and control that should be better left to national organisations, it would be anti-economical that so long and costly tests requiring such a highly qualified personnel as clinical testing does, were undertaken at a national level (provided it could actually be done on East African level).

Without going back to the details of the general chapter dealing with the East African Pharmaceutic Council (EAPC), we think it more economical to create in the first place ONE central control laboratory.

The ideal setting up will be discussed later on.

[illegible] SELECTION GUIDE

GUIDE FOR DRUG SELECTION

One of the first tasks of this laboratory would be by its own means or with the help of other correspondant laboratories to examine the most widely used drugs in East Africa. The result of such exercise would be published in a DRUG SELECTION GUIDE.

The general objective of the DSG would be to assist people to obtain presented pharmaceutical products of quality at a reasonable cost. This could encourage fair competition and more efficient method of distribution and utilisation of pharmaceutical preparation available to people.

This guide would require knowledgeable interpretation and would not be intended for general distribution. Therefore, circulation would be restricted to practitioners, pharmacists, hospitals and affiliated organization associated with the manufacture distribution and use of pharmaceutical preparation in order to serve as :

(a) a guide to practitioners in identifying quality products for prescribing;

(b) a guide to pharmacist in stocking comparable products for dispensing ;

(c) a guide to professional committee in the selection of pharmaceutical preparation recommended for use in hospitals.

Product listed in this guide should be selected by a committee on the following basis :

(a) Major drug categories and individual generic groups most commonly used in medical practices should be considered first;

(b) The products selected for listing should be therapeutically effective and manufactured under conditions which assure a continuance of good quality.

(c) The committe assessment should involve :

1. Examining manufacturing operations directly when in East Africa or abroad through consultants specially appointed for this purpose to determine the degree of responsability exercised in production and quality control.

2. Evaluating records and relevant data on formulation productions and control methods plus laboratory and clinical analysis attesting to quality and therapeutic efficacy.

3. When possible testing samples by the DQCL directly or indirectly through correspondant laboratory.

(d) The committee should be kept fully aware of the development following the release of a drug into the public in cas of new harmful effect, not come to light in the long process of testing a drug for safety.

BENEFITS TO BE EXPECTED FROM THE PUBLICATION OF A DRUG SELECTION GUIDE

The first benefit to be expected from the DSG is a fall in the cost of prescriptions.

On the matter we can refer to a country that yearly published a report comparing the cost of each tablet or capsule of one single product issued by different producers. It concerns 238 products or various conditionings.

As an example we have selected 13 among the most typical cases where price differences are the most noticeable.

We shall stress the point that, as far as active products are concerned, ratios varying from 1 to 5 are fairly common.

Ratios from 1 to 2 are very frequent and in the most cases, differences vary from 20 to 30 %.

If we consider a medium difference of 20 % as an average, and provided that doctors followed the DSG instructions in half of the cases, one can say that the DSG should reduce the expense costs by 10 % which would more or less mean a saving of 40 million shillings to East Africa.

One may object that products with similar chemical ingredients are not necessarily of equal quality or efficacy. Having this in mind they say they spended considerable effort in evaluating products and, on the basis of its investigations, they consider the chemically equivalent products listed in the index to be of comparable therapeutic value.

The given prices are calculated after the selling prices to the retailer.

Our suggestion is that the DQCL and so the DSG should in the first place consider the delicate problem of pharmaceutical products originated from countries newly thrown onto the market and whose products are sold at a better price although they are said to be of inferior quality. The latter assertion has yet to be proved after unprejudiciled testing.

It is important to point out that the publication of the DSG - in reference to a given therapeutic value - and the publicity for a drug fulfilling the requested aims at a lower cost, must not lead to the elimination of more expensive ones. Some freedom must be left to practitioners. A possible allergy to the drug is enough to justify such a warning.

WHOLESALE PRICE DIFFERENCES IN DRUGS

(costs per capsule or tablet (EA cents).

	Maximum	minimum	package size
PROPOXYPHENE - 65 mg	37	20	100
PHENYL BUTAZONE - 100 mg	36	5	100
PENICILLIN G (POTASSIUM) 500 000 IU (300 mg)	78	14	100
TETRACYCLINE - 250 mg	105	25	100
TETRACYCLINE - 125 mg/5 ml, Oral Liquid	94	39	60
NITROFURANTOIN - 100 mg	57	9	100
HYDROCHLOROTHIAZIDE - 50 mg	23	6	100
HYDROCHLOROTHIAZIDE - 25 mg	19	4	100
RESERPINE	18	4	100
TOLBUTAMIDE 0,5 g	48	-	100
TOLBUTAMIDE 0,5 g		9	50
CHLORDIAZEPOXIDE - 10 mg	45	16	100
MEPROBAMATE - 400 mg	39	-	50
MEPROBAMATE - 400 mg		6	100
PENTOBARBITAL SODIUM - 100 mg	22	9	100

ALLOCATION

The allocation of any activity inside an economic Community is one of the thorniest of all problem - and this is true fo Communities in general, not only of the East African Community.

Though it has nowhere been possible by political action to harmonise industrial activity, institutions can be allocated without too much difficulty, as has been the case in East Africa.

The E.A.P.C. may be regarded as an institution, and we believe that its allocation to one of the three countries will be less controversal than that of industry.

We have seen that each of the three countries already possesses the material facilities necessary to carry out partial tests.

Professeur ATTISO thinks the best thing would be to develop these facilities by adding to them. That is certainly a very reasonable approach.

There is however, a substantial negative factor -the almost total lack of qualified personnel to launch such an operation.

It is practically out of the question for the staff of the Medical Researsh Laboratory in Nairobi, on top of their routine work, to carry out tests that can be estimated to number in the region of 5 to 10 thousand.

Economic considerations also apply, and from this point of view it is better to have one laboratory performing three series of operations than three laboratories performing one each, but this is a minor matter compared with the first consideration

The second question is where the laboratory is to be established.

If there is intended to be more or less equal sharing of the pharmaceutical industry, then clearly Kenya cannot be chosen : in all likelihood a packaging plant will be set up in that country very shortly, and there is some chance of a gland extract manufacturing plant being built either at Nairobi or Mombasa in the same country. Kenya can also look forward to wider prospects in the growing of medicinal plants, but that is not a decisive factor since, at this stage in our enquiries, all three countries are on an equal footing.

Similarly, Tanzania has a good chance of getting its packging plant as well as a gland processing plant.

In the circumstances, Uganda seems the appropriate host country for the E.A.P.C.

There are further reasons in favour of this choice :

a) The E.A.P.C. needs a degree of independence from the packaging laboratories, which physical remoteness will provide.

b) The National Chemotherapeutics Research Laboratory (N.C.R.L.) at Kampala, whose vocation we see principally in discovering

useful compounds but not testing them, could very easily in our opinion get the D.Q.C.L. to carry out these preliminary tests and could offer foreign laboratories products that were already fairly well known.

c) A prostaglandines research laboratory is being built at Kampala under the aegis of Professeur KARIM, and the proximity of this with the D.Q.C.L. and the N.C.R.L. cannot fail to produce a highly profitable synergy.

d) It is recognized that East Africa definitely needs a School of Pharmacy; we believe it should initially be a single institution within Makerere University and the D.Q.C.L. should also take advantage of it.

e) Another determining factor is the affirmed will of the Ugandan Government to set up such an organisation.

It may be noted, however, that there is no physical obstacle to establishing the pharmaceutical complex at Nairobi or Arusha, and that considerations of independence from manufacturers or the existence of the N.C.R.L. -in present circumstances - are of little weight compared with considerations of national independence. Still, we believe that if the development of a pharmaceutical sector were to proceed haphazardly, the Community would have missed a great opportunity, and - bearing in mind the way the E.A.C has for the last 4 years succeeded in surmonting the formidable obstacles thrown up by political differences and outside influences - we confidently expect that economic considerations will prevail and Uganda will get her proper share of the cake.

RECOVERY OF ANIMAL AND HUMAN BY-PRODUCTS

1 - MANUFACTURING PROCESSES AND PROFITABILITY LIMITS

1.1 - By-products from animal origin

The slaughter-house by-products likely to be used are :

- skins
- bones
- blood
- squaring waste
- fats
- glands

1.1.1 - Gelatin

It is obtained from bones and skins (one uses what is no good in tannery) through sulphuric destructive action, then by neutralizing the obtained liquid with lime. This process is discontinuous and refuses are taken over twice by sulphuric acid. The successively obtained broths have various qualities characterized by their bloom measuring the coagulating speed.

The first broth (the best one) is used in pharmacy (gels ...) and photography.

The second one goes to alimentary industry (iced-creams, sweets, hams, soups, ready-made dishes ...).

As to the third one, it is used for the making of glues.

7 kilos of skins or 5 kilos of bones give one kilo of gelatin : 50 % for the first broth and 50 % for the two following ones.

The world production amounts to some 150 000 tons a year and there are not many issuers.

The developed country [illegible] (from India among others) [illegible] the supplies go down, this may be an opportunity to value African bones. But the production limit - [illegible] tons of gelatin a year at SOMAGEL TANANARIVE that is 1 000 tons of fat [illegible] 100 000 bovines a year (this is the amount the TA[illegible] will be able to cope with). This limit stands below what the [illegible] slaughter houses in East Africa (ATHI RIVER, [illegible], TA[illegible]) are likely to be in reference to meat developing production

. [illegible], the whole [illegible]

and one cannot consider any project before dealing with a [illegible].

1.1.2 - Meals

Products such as blood meals, meat ones and meals made of [illegible] bones or not, we only quote for they are obtained through physical processes entirely. These meals are used either in food cattle or as manure [illegible] is no technical manufacturing limit, for the equipment is very simple, but there are commercialization limits.

1.1.3 - Fat bodies

These are animal fats either recovered as they actually are or obtained through the water cooking of bones (before possible [illegible] per extracting gelatin-. Those tallows are used in soap industry [illegible] in food consuming or foot oil recovered through water cooking [illegible] in watch making and mechanics.

1.1.4 - Glands

Liver and pancreas are the most commonly used glands, but hypophysis, ovaries, surrenal glands and lungs are used too.

Liver is used for the making of liver extracts to be injected. But this [illegible] commes into competition with food consuming. The sale prices to pharmaceutical usage are very low - something around [illegible] per kilo, so it is a meat nourishment usually less expensive than meat itself. One must not forget that meat remains a luxury for most populations.
Pancreas is also used in the making of insulin but this is a complicated process. It can also give digestive enzyms, among which trypsin.

The richest pancreas for insulin is the calf's that gives 100 gr. insulin a ton, the oxe's only gives 50 gr. a ton. One kilo of insulin costs some 70 000 CFA francs and one gets two kilos of pancreas per ton of carcass. Insulin extraction is completed through watery alcohol set in acid : one then must purify it through precipitations and successive re-dissolution. Those processes require much care.

Enzym obtaining is more simple : one can manufacture industrial pancreatin at low costs and low value as well, used in tannery. But extracting equipment by way of a solvent is expensive.

By purification one gets a pharmaceutical pancreatin used in the making of proteolysats after blood. Finally one can obtain isolated enzyms (pancreatin contains several enzyms) via a succession of precipitations set in water or alcohol re-dissolution, dialysis, etc... all delicate and costly processes.

Lungs give heparin : one ton of lungs yields 30 gram heparin and one has about 1 kilos of lungs per ton of carcass. Heparin costs about [illegible] per kilo. The making process consists in completing lung digestion by way of an usual enzym and then extracting soluble heparin from water. It has then to be purified. After they have been pounded, lungs are put into many great reagents ; for extraction and purification one uses usual machinery.

Various products are extracted from the other glands too, but in very small quantities.

Two kinds of production can be thought of :

- the taking of glands, their solidification and sending without treatment to European pharmaceutical laboratories. It is unlikely that we could have enough liver to do so. This could only be done with lungs and other glands. The taking requires some qualified staff. The slaughtering conditions must meet with the required sanitary standards and one must have cold storage equipment. In order to consider such an operations, it appears that the production limit of a slaughter-house should reach some 40 to 50 000 bovine units a year.

- treatment of pancreas and lungs : the limit is of some hundred thousand bovine units a year. This figure could be attained provided that the three East African Slaughter-houses were grouped.

1.2 - By-products from human origin

Human placentae are used in preparing gamma-globulins. Extracting them requires a succession of complicated processes, technically difficult to carry through. Here they are :

- pounding and reducing congealated placentae into powder
- solution hold in salt water
- filtration and centrifugation : only the liquid is kept
- precipitation via alcohol
- centrifugation : the precipitate - accumulation of globulins - is kept
- precipitation via PH modification down to 6
- centrifugation : liquid is kept
- precipitation via alcohol (30 % in volume)
- precipitate hold in solution in salt water again
- last precipitation via alcohol with very definite dosage

Here are the technical difficulties :

- all these operations are undergone at 5° minus (1/10° margin degree). Now when alcohol is poured for precipitation, some heat occurs. One must then mix it all up to avoid local overheating. The whole process is undertaken in 2 000 liter containers. Hovener 600 liters of alcohol have to be poured in in less than an hour.

- centrifugations are very elaborated : one only gets one kilo of precipitate out of 50 solution likers. ALFA LAVAL alone makes this kind of centrifugation machinery.

- the whole process must take place in a perfectly sterilized environment.

Pulps are recovered, and out of them do we extract raw material for cosmetics. What is eventually left can be used in cattle food.

After the extracting process has been discribed one is led to conclude that so far East Africa is not ready to consider doing anything like it.

What could be considered is : gathering, congealating and exporting. But then the profitability limit lies around 40 000 new born babies a year. There is no African hospital that reaches such a figure.
Howener would the demand increase, the limit could be cut down to 15 - 20 000.

1.3 - Market and prospects

So far the placenta export countries are : East European Countries, South-American, Asian and North. African countries.

The seling price of placentae is shs 4.7 per kilo. Europe delivered - 100 kilos of placentae give approximately 1 kilo crude gamma-globulin which it self gives 30 gr. of dried gamma-globulin sold at shs 1 000 per gram.

2 - EAST AFRICAN MARKETS

East African markets of the studied products (gelatin, animal glands and their product extracts, gamma-globulins) can be said non-existent.

The only point worth considering is the export markets.

All these products will have to undergo further transformation before final dispatching. Their production and market are within the hands of a few European, American and Japanese firms ; production processes require subtle techniques. Apparently nothing can be done before technical and commercial deals with those firms.

3 - PRODUCTION MACHINERY AND PLANS

There is already one factory treating slaughter-house wastes in a fairly complete way.

Since 1967 PROCHIMAD in Tananarive has been carrying through the treatment of locally re-covered bones and issuing tallows and bone meals sold as manure. PROCHIMAD executives have been able to make a deal with the French firm ROUSSELOT some two years ago and have just started, close to the slaughter-house to be in Tananarive intended for 100 000 bovine units a year, a new factory known after the name SOMAGEL witch will be issuing 600 tons of gelatine a year (the three kinds of gelatine previously described).
This is actually the single unit really belonging to pharmaceutical industry.

CONCLUSION

The only trade channel of the products obtained through the treatment of slaughter-house wastes and placentae through chemical process is exportation towards developed countries.

Building two if not three gelatine factories seems quite possible : one in MOMBASA/NAIROBI, another in DAR ES SALAAM.

The gathering and congelation of lungs and small glands (except for liver) could be completed in DAR ES SALAAM, MOMBASA/NAIROBI whose slaughter-houses can cope with more than 50 000 animals.
Along with this the gathering of placentae and their congelation can only be achieved in places where there are from 40 to 50 000 new born babies a year. Alone the NAIROBI district might be adequate as it has a population of around on million inhabitants with the more or less required figure of new born babies, provided they were born in hospitals or welfare centres.

The treating of animal glands, lungs and pancreas can be thought of in NAIROBI or MOMBASA only. Even though one should probably no face the requirements, and supplies coming from TANZANIA and perhaps MADAGASCAR would have to be considered.

PLANT EXTRACTS

EXECUTIVE SUMMARY

For plant extracts and essential oils, the three East African countries offer a number of advantages, e.g. -

1. A wide variety of climates, from arid desert in Northern Kenya to the eternal spring of Nairobi and including the mild tropical climate of the Tanzanian central highlands.

2. Virgin land in great abundance; though this needs to be qualified by the consideration that the highland areas between about 4000 and 7500 feet are for the most part heavily populated and it will be difficult to introduce there a new crop, probably less rewarding than coffee or pyrethrum.

3. Cheap labour.

4. Comparatively well developed communications.

5. A political and economic system that lends itself to this kind of operation (cf. the success of pyrethrum).

6. Each of the three countries already has a solvent extraction plant either working, though not full capacity, or else closed down or operating occasionnaly.

7. The managements of both the Kenya and the Tanzanian plants have expressed their intention to diversify production to include other things than pyrethrene, and have even carried out tests (TANGANYIKA EXTRACT Co).

8. The NATURAL CHEMOTHERAPEUTIC RESEARCH LABORATORY has already produced 5 plant extracts with attractive properties.

THE PYRETHRUM INDUSTRY

GENERAL

Pyrethrum is extracted from the flower of pyrethrum (Chrysanthemum Cinerariae Folium). This plant, just like a China aster, grows at altitude above 6500 feet in the regions of Kisii, Nyandarua, Rift valley, and the Aberdares, in Kenya; and in the region of Iringa Songea, Njombe, Mbeya, and on the slopes of Mount Meru, near Arusha, in Tanzania.

The plant needs at least 48 inches of rain, extending over the whole year, and a fairly wide range of temperature over the day.

The flowers are picked individually, at regular intervals, as frequent as possible and never more than two weeks. The biggest crop is in November, December and January, and the smallest in April and May, in Kenya. In Tanzania, where the main growing areas are some 600 miles further South, production is at its peak in November an February, with a slump in June and July.

After being dried, either naturally in the sun, or artificially in a heated drier, the flowers are bagged and taken to the processing plant at Nakuru (Kenya) or Arusha (Tanzania).

On arrival, each consignment is inspected, a sample is taken, ground, and its pyrethrine content measured, to determine what price is to be paid to the grower.

Content ranges between 1.2 and 3 per cent and averages 1.3 per cent.

Processing includes grinding and extraction with a solvent (ISO-HEXANE).

In both countries, pyrethrum production was started by European (chiefly British) settlers, but very soon taken over by Africans.

The main qualities of pyrethrum are :

- its knock-down effect, acting on the insect's nerve-centres,
- of all insecticides, it is one of the least harmful to mammals,
- practically no insect can withstand it,
- pyrethrine degrades rapidly under the impact of air and sun, it has no remanent effect,
- it repels insects for a long time after it has been applied,
- there is as yet no evidence of acquired resistance.

It was feared for a time that the natural product might be replaced by synthetic substitutes, the pyrethroids. However, while it is true that these are more efficient per unit of weight, field tests have shown that their spectrum is not so wide as that of natural pyrethrine : some are effective against flies, less against beetles, cockroaches ,or mosquitoes. Natural pyrethrum is effective against all insects.

So <u>in the short run</u> there is no reason to fear competition from synthetic products.

A long-term venture, including for instance the construction of a new plant, might be more hazardous. Fortunately, each of the two countries already has a plant and can regard the near future as being safe and very favourable.

THE PYRETHRUM INDUSTRY IN KENYA AND PLANT EXTRACTS

The PYRETHRUM BOARD, which runs the whole of the pyrethrum industry, is already very interested in the idea of processing other things besides pyrethrum flowers.

The Board is concerned both :

(a) to use its plant to full capacity, and

(b) to diversify operations and reduce its dependence on a single product (despite the present situation, there is no guarantee against the eventual discovery of a broad-spectrum pyrethroid that would push out the natural product).

A senior official handed us a list of the products that have been considered by the Board :

LEPTOSPERM OIL
CITRONELLA
GERANIUM OIL
EUCALYPTUS OIL
STROPHANTUS KOMBE
RAUWAULPHIA SERPENTINA (source of reserpine)
RAUWAULPHIA ACUTIFOLIA
CEDAR OIL
QUININE

Our talks showed that, if extraction requires a solvent facility, the PYRETHRUM BOARD is certainly the organisation on which any new operation should rely. Likewise, the experience of the PYRETHRUM MARKETING BOARD will be extremely valuable for the marketing of output.

THE PYRETHRUM INDUSTRY IN TANZANIA AND PLANT EXTRACTS

The growing areas are practically all in the South. But the production plant is in the North, at ARUSHA, where only per cent of the throughput is grown.

The plant originally handled the crops of European settlers' estates in the immediate vicinity. But these crops levelled off and then fell, while the less developed South the crop was introduced successfully and output quickly rose until it accounted for almost the total supply, despite the flowers having to be transported over more than 300 miles.

For our purposes, it is unlikely that a new crop could be introduced in the ARUSHA region where coffee and tea growing, wheat, meat and milk farming, and jobs in the new industries, hotels, and the offices of the Community, are much more attractive propositions.

The General Manager of the TANGANYIKA EXTRACT COMPANY (MITCHELL COTTS & Co 51%, NDC 49 %) therefore thinks that, if a new plant were to be built, it would be in the South rather than at ARUSHA.

The present plant has a capacity of 7000 tons (three shifts a day, 300 days per year) and is currently processing about 3000 tons.

Efforts have already been made to diversify, and the plant has produced or processed :

GERANIUM OIL
LEMON GRASS
NINDE (successfully cultivated in MALAWI)
LAVENDER
THYME

UGANDA AND PLANT EXTRACTS

UGANDA has two major assets for a venture in this field :

THE NATURAL CHEMOTHERAPEUTIC RESEARCH LABORATORY, and
THE INSTANT TEA MANUFACTURING PLANT AT PORT BELL.

THE NATURAL CHEMOTHERAPEUTIC RESEARCH LABORATORY

This Laboratory was set up in 1964 for research into local medicinal plants. It has fairly complete facilities for extraction and analysis, and can carry out tests on animals.

As the Laboratory has not been able to get all the money hoped for, work has concentrated on three compounds :

- fungicides,
- antibiotics, and

Five extracts have been obtained and one of them, [illegible] is being studied *in vivo* after successful tests *in vitro*. In addition to possible uses in human medicine, this extract has been found to be effective against Coffee Berry Disease (CBD).

There is nothing to prevent this organization seeking such contract for a foreign Company.

We consider that it is along these lines that the Laboratory should mainly work.

It is perfectly sound economically, in our views, that the laboratory should make discoveries, investigate local medicinal products, select the most effective produce extracts, and make a few tests *in vitro* and *in vivo*; but we do not think it would be an economic proposition to test products completely for use on the local market, even if the local market were to include the whole of Africa, which would imply having overcome all difficulties due to national particularisms.

Measuring and testing the efficacy and safety of a new drug calls for extraordinarily expensive efforts, requiring a hospital and laboratory system that does not exist and which, to be developed would cost far more than UGANDA can afford within the limits of balanced growth.

Proving a drug is one of the most difficult tasks of modern science, calling for broad knowledge, inventiveness, meticulousness.

The causes of the difficulties are several. First of all, most patients recover from their ailments whether they get drugs or not. Many others recover as a result of the psychological effect of receiving treatment, even when the "drugs" they receive are placebos, totally innocuous substances that do not affect physiological processes.

Often, it is impossible to predict that a drug will not harm the patient, let alone cure him. For preliminary trials on animals can be misleading (animals react differently from humans) and tests on a few volunteers are inconclusive (people vary widely in their reactions).

The modern drug tester draws on the accumulated knowledge of half a dozen scientific disciplines, as :

- chemistry
- pharmacology
- physiology
- psychology - because drugs can affect the body through the mind as well as directly in the body
- statistics.

It is not uncommon that a pharmacologist may spend seven years evaluating a new drug - trying it on several species of animal, administering it to successively larger groups of people, analysing his findings -before he finally convinces governmental authorit' that the drug should be admitted to medical respectability.(1)

And after a drug has won acceptance, its ation still cannot stop, for prolonged and widespread use may turn ffects that no testing programme, even if it includes thousands o. bjects and lasts several years, could predict.

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(1) The following examples illustrate the expense and difficulty of the pharmaceutical research :

- One speciality cost $ US 120,000 before being marketed. An antibiotic required 200,000 strains being observed, and 3,484 of them examined.

- Out of 200 new salts elaborated by a research team over one year, 50 are selected at the stage of physiological testing, 10 at the stage of chemical tests, and only 2 have a serious chance of being marketed.

  According to American industry, 3 products reach the market out of every 1000 that are studied, i.e. after getting beyond the stage of pharmacological analysis.

  In these circumstances it is clear that, left to its own devices, the NCRL has little chance of operating economically with its 5 products already selected.

The kind of effort the Government is prepared to make in this field is sufficiently apparent from the small amount of funds made availible to the Laboratory for the current fiscal year, viz. £ 7000.

We feel it would be more reasonable - as being immediately profitable- for the Laboratory to look abroad and agree to work under contract for foreign firms.

There is a striking contrast within the space of a few hundred years, between the activity of the unit under the leadership of Professor KARIM (1) and the comparative inactivity of those we are discussing.

We see here an example to be followed.

This would involve the Laboratory circulating its findings -after they had been properly patented - and bringing them to the notice of all bodies in a position, either to ensure the fundings of research into new extracts (for the greater benefit of the Laboratory), or to further develop the 5 products already available (for the benefit of mankind).

This would assume a change in the attitude of management, whose secretiveness prevented us from having access to their findings.

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(1) Professor KARIM is cooperating with an American pharmaceutical firm, and has obtained quite remarkably quickly one million US dollars to finance a prostaglandines research institute.

PREVIOUS ATTEMPTS OR RECOMMENDATIONS

As a landlocked country more than 600 miles from the sea, UGANDA is destined by nature to be a producer of high-cost low-weight goods whose price is little affected by transport and which can, if necessary, be carried by air freight.

Pharmaceutical extracts and essential oils are such goods.

It has already been suggested that plants such as following might be processed : VANILLA, PELARGONIUM ODORATISSIMUM, CARDAMOM, HOT CHILLIES, GINGER, GERANIUM, and ROSES. Roses Grow very well in UGANDA; the present varieties are not those that produce the oil required, but there should be no difficulty in changing over.

The Ministry of Cooperation is attempting to introduce the growing of SENNA in collaboration with COLEMAN (U.K.). This plant provides L-DOPA, which is effective against Parkinson's disease, and it is still produced in the Sudan. With a view to diversification, the British firm wishes to develop the growing of SENNA in UGANDA.

The ideal would be to produce enough to permit processing locally .

AROMATIC PLANTS

CITRUS AND CONSORTIUM

A citrus processing plant was set up in 1970 by the IVORY COAST CITRUS AND AROMATIC PLANTS CONSORTIUM (COCI), whose shareholders are the Ivory Coast Government (50 %), SIAN (10 %), and private persons (40 %).

The plant is situated at SASSANDRA, 150 miles west of ABIDJAN, on the coast. It is supplied by 4,000 acres of plantations (441,000 trees) in the neighbouring regions.

The plant processes lemons, which are utilised fully (oil, peel, and pulp), bergamots for oil and peel, and Seville oranges for oil, juice and pectine.

The juices and oils are sold in FRANCE, the dried peel in ITALY and GERMANY.

The capacity of the plant, supplied initially by the existing 4,000 acres of plantations, representing 37,000 tons a year, is 170 tons of essential oils, 1260 tons of concentrated fruit juice, and 2150 tons of pectine.

The investments amount to 11 million shillings.

A further 1250 acres is to be planted over the years 1970-75 at a cost of 15 million shillings, and it is planned to grow other aromatic plants (basil, palmarosa, ambrette) if the conditions of vegetation are satisfactory and if circumstances are appropriate.

OTHER MEDICINAL PLANTS REQUIRED

The following list, obtained in one of the three countries of EAST AFRICA, indicates the plant species that a European firm would be ready to buy (see Annex).

SOME MEDICAL PLANTS REQUIRED BY EUROPEAN FIRM

NAME AND SPECIES	QUANTITIES REQUESTED	OBSERVATIONS
BARK OF CHINA TREES (CHINCHONA BARK)	150 - 200 tons/year	
RAUWOLFIA VOMITARIA	All quantities	BARK AND ROOTS Grows in wilderness local extraction could be made
STROPHANTUS	All quantities	
DATURA INNOXIA	All quantities	Leaves dry
DATURA STRAMONIUM		
ALBA	All quantities	Leaves dry
METEL	All quantities	Leaves dry
DIGITALIS LANATA		Leaves dry : could be grown in plantations
SOLANUM LACINIATUM or ANCOLORA		Leaves dry
VINCA ROSEA		ROOTS - raw material for the obtention of VINCRISTINE SULPHATE end of the newest and most effective anticancer drug. Fifteen tons of wild periwinkle leaves and 16 weeks of processing yield only one ounce of VINCRISTINE.

PAPAINA

Papaina in an enzyme extract obtained through the treatment of latex, the latter being gathered from incision of the pawpaw tree fruit not yet riped.

Papaina is mostly used for :

- the softening of meats
- the clarifying and steadying of beers

It is also used in tannery for peeling off the fur in textile industry (recovery of wool and silk treatment), in malt-houses (in order to improve the yields), in rubber industry (for the treatment of latex meant for casting), in pharmaceutical industry (drugs for gastric or duodenal deficiencies), in the making af cattle food (pre-digestion of oil cakes) and finally in bacteriology for preparing sets of bacteria (culture).

The main issuers of papaina are Uganda, Kenya, Zaire and Ceylon.

This product world exports vary from 150 to 400 tons a year for a value going from shs mn 5.5 upto shs mn 16. The world market is one hand very narrow and on the other very difficult to analyse because of the many fluctuations due to speculation. Prices actually fluctuate between shs 2,000 and 5,500.

The main consumers of papaina are the United States - they use 35 % to 40 % of the world market sales -, Western Europe and Japan.

The papaina world market remains too limited and thus cannot yet be of any noticeable profitability to the East African countries concerned.

Provided that a new usage of this product was found so that it would meet with greater demands, the three East African countries should be the first to take profit from this increase in production.

Let us point out that the Ivory Coast is presently thinking over the industrial channels it would be given from exploiting the pawpaw tree.

PRODUCTION OF PHARMACEUTICAL PRODUCTS

The main characteristic of pharmaceutical products is their variety. The number of used types (under their various shapes) in the East African countries amounts to approximatly 10 000, this figure can be cut down to 2 000 for basic drugs. The latter figure remains impressive; one can then understand that within the limits of this survey, it is impossible even to consider describing the manufacturing process of those 2 000 basic drugs, and all the more so as a few of them are the more or less exclusive monopoly of a very small number of industrial firms.

Although it is impossible to give a description of the manufacturing processes of all basic drugs, we shall endeavour to supply you with general.

1 - MANUFACTURING PROCESSES - PROFITABILITY LEVELS (LIMITS)

Several great processes may be considered for the obtaining of basic components. There are :

- vaccine manufacturing
- antibiotic manufacturing
- extraction from plants
- extraction from animals
- organic synthesis.

Then come the formulating, preparing and packaging processes.

1.1 - Vaccine manufacturing

The manufacturing process first requires micro-organic culture in a specific bacteria set, living animal or rather animal tissue, the recovery of microbes by way of centrifugation or filtration and inactivation by means of ultra-violet rays or chemical reagents. One must then test the obtained vaccines on animals, which requires knowing all about their past and so making sure that they are thoroughly free from the disease one is attempting to fight against. The manufacturing in itself is fairly easy but requires much care.
The most important is finding and then renewing the animals, they may be of two kinds : those used as bacteria sets when this is the case and those used for testing, as the latter must be completely free from any infection, a sanitary barrier must be set up.

There is hardly any technical limit in production, but there is one where staff qualification is concerned.

1.2 - Antibiotic manufacturing

First of all there are two types of antibiotics, along with two types of bacteria named Gram+ and Gram- ; The wall of the Gram + is pervious enough to let antibiotics act upon them. As for the Gram-bacteria it is impermeable and so far colimycine alone can act destructively upon them.

The manufacturing process first includes the culture of yeast hold in vat and set in a sterilized and apyrogeneous water with an admixture of mineral salts and nutritive components (galactose, proteins, etc ...). The water producing is technically difficult.

During the growing of the yeast, the antibiotic is released : in a way this antibiotic is the toxin secreted by the yeast. One must then extract it from the liquid via several precipitations, centrifugation or filtration, re-dissolution, and purification of the last liquid on activated carbons. One thus obtains a precipitate that will be dried up and changed into powder :one has thus got a basic product that will then be packaged either into tablets (mouth absorption) or into a solution within water or ofl (intra-muscular injection).

The packaging - that is the making of definite doses - is simple enough but requires being done within a thoroughly sterilized environment.
Producing powder is a highly automatized operation requiring few employees while packaging requires five times as many.

Before finishing with the sole technical matters, it is necessary to give an idea of what the supply is like. There are many anti-biotic issuers of Gram^{+} bacteria (penicillin, tetracyclin) in the world, because producing then is an easy job.
Therefore there is surplus production and their export price is a dumping one. There is no doubt that so far, would East Africa start issuring them, its cost prices would increase by two or three times those usually practised on the world market.

Obtaining antibiotics for Gram- bacteria is a technically more difficult job and besides their manufacturing is protected by patents.

Is it worthwhile considering packaging ? No doubt, the difference of prices between loose antibiotics and packaged antibiotics is big enough, but along with it goes a big technical problem, nowhere equipment complexity is concerned but in reference to staff conscientiousness.

(1) An apyrogeneous water is a water free from all substance likely to provoke fever - a toxin usually secreted by bacteria water.

1.3 - Extraction of vegetal and animal substances

Please refer to specialized chapters.

1.4 - Organic synthesis

There are many organic synthesis products used in pharmaceutical field. The most important ones are :

- cyanogen chloride
- chloroacetates
- acetyle/chloracetyl chloride
- acetyl-acetates
- acetyl-acetone
- cyanacetates

- chlorure alkyl-amino ethanol chlorides
- chlorido benzile
- chloraniline
- chlorobenzenes
- bromobenzenes
- orthoand para-toluene-sulfochlorides
- bromopyridines
- naphtols
- methyl/ethyl sulfate
- diaethyl - sulfoxyde
- ketene
- phosgene
- hydrides and amidrides

The chemical reactions that must be set out are very different : chlorination, sulphonation, acetylation, oxidation, bromination etc...

Two equipements can be used :

- one multivalent unit : all reactions can be achieved in view of small or average quantities. The cost of such a unit is of some shs mn 15.

- specialized units for large issues, each of them equipped for producing a small amount of components, most of pharmaceutical laboratoires are equipped with those.

  a) because they are of small or average importance and specialised in a small range of products.

  b) because they are large issuers and so require specialised installations.

In any case such installations require highly qualified staff and being close to research laboratories: the E.A. Community Countries cannot consider such an industry without the technical commercial help of pharmaceutical firms. Now the latter are not willing to do so.

1.5 - Formulation

Formulation is the making up of a drug after the basic products obtained either by way of organic synthesis or extraction. This is the job research pharmaceutical laboratories are mostly concerned with and which requires highly qualified personnel and great experimentation means.

Those laboratories have mostly been working on developed country diseases. But even when research on specific African country diseases is concerned (Bilharziosis), it has been undertaken in those laboratories because of the required necessary means.

At present considering building real research laboratories in the E.A. Community countries is unthought of.

1.6 - Pharmaceutical shaping and packaging

The job consists in putting products in shape of :

- solids : sugar coated pill
  tablet
  pill
  gel
  suppository
  etc ...

- liquids : bottle for drinkable solution
  container for " "
  container for injection
  dropping tube bottle
  atomiser
  collyre
  lotion
  etc...

- gas : aérosol

It is necessary to achieve solution sets in various liquids (if water is the required liquid, it must be pure and sterile something difficult to get in Africa as there are very few underground water-levels free from all infection) drying, filtrating, powder mixing, lozenge making. This requires :

- means of treating water
- air conditionning (unless the factory is situaded in NAIROBI or ARUSHA)
- working in sterilized settings

One must also be supplied with packages : cardboard boxes, tin boxes, plastic under various shapes, glass (of special quality for certain liquids) and rubber caps.

Finally one must be able to control the manufacturing :

- testing of raw materials
  unless warranted by issuer
- testing in the course of manufacturing
- testing of finished products.

Equipements are fairly simple, technical limits are relatively low : 10 million tablets a year per one lozenge machine.

On the other hand there should be an economical limit : one must share out overhead expenses (installation and running of general departments, stocking at cool temperature, control laboratory) and qualified personnel costs amongst an adequate sales volume. If we attempt working out this limit through experience (the sales volume of a few packaging laboratories in Africa) one should be given the figure of some 3 million shillings a year.

1.7 - Various concerns

As we shall see later on, there are but two activities among those previous by talked of in East Africa :

- vaccine manufacturing :
  Medical research laboratories in Nairobi, 3 veterinary vaccine laboratories in Kenya and a newly set up one in DAR-ES-SALAAM.

- preparing and conditionning
  half a dozen in Kenya, one in Tanzania and two in Uganda.

We shall now think over the possibilities of working out a small preparing and packaging industry in some countries (in as far as it may be profitable in terms of local added value). The added value in as far packaging -changes a lot according to the drug cost and in Europe impels the policy of the issuer.

- considering expensive raw materials issued in small quantities, the packaging costs represent a minute percentage of the cost price. The issuer will then be likely to package the product.

- condidering a common product, packaging will then cost more than producing. The issuer will so package the products and get most of his profit margin out of it.

- as far in-between products one has better sub-contract packaging as it costs a lot.

One must understand that pharmaceutical issues are the monopoly of industrial firms (some small very specialized (1) ones : others very large ones with a wide range of products) all investing alot into research and new drug development. There is then much competition. One then can think of several methods for the setting up of a large packaging unit in East Africa.

- one single laboratory provided it has an adequate market.
- the coming up together of a few laboratoires which result in a wider range of manufacturing.

(1) The animal sales volume of a laboratory depends on the vulgarisation of the manufactured product. (Specific product or common one) but for a "in-between product" it can amount to Shs 400 - 600 000.

- someone working on request without any commercializing concern.
- and last it could be a state organization with hospitals and welfare centres being its biggest customers.

The first one exists in East Africa : besides the fact that the market is very narrow, such a method gives a dim view on the sale prices of raw materials from the Mother Establisment to its subsidiary.

The second one is very difficult to under take : competitive firms cannot easily come to an agreement.

The third one exists in East Africa on a very small scale. It requires someone who holds capital (1 to 2 million shillings) as well as some technic and qualified personnel in order to offer adequate warrantee.

Therefore there is no ideal solution. But we fell sure that the first two are the most likely to fit in with East Africa countries : a neutral, private, public (or both) industry working on request.

We will discuss this point in chapter.

STRATEGY FOR THE SETTING UP OF A PACKAGING INDUSTRY

STRATEGY FOR THE SETTING UP OF A PACKAGING INDUSTRY

INTRODUCTION

We have seen that the only industry that can be thought of in economical terms is the packaging one : one must leave out -as far as economy is concerned - the possibility of an integrated pharmaceutical industry within such a small market as the EAST AFRICAN one and more especially in a country where there are very few technicians - or even none - able to help the launching of an integrated pharmaceutic industry : we will find, in these three countries, plans that will be more profitable than this one whatever the standards one is refering to .

The packaging industry can be outlined in the following :

-a) compared with the turnover, investment is low (1)

-b) the added value is low : raw materials are imported, there is no import tax, a great amount of packaging material is imported; foreign management staffing is highly needed to supervise local labour.

-c) there is no hope of new connected industries before a long time.

-d) industry offers few new jobs.

(1) PFIZER is thinking of investing one million dollars in the Kenyan plan.

It is easy to understand that ill-negociated setting up of a pharmaceutical industry can be of no benefit to the country and can even result in a loss for the economy of the country.

Various strategies

The most prejudicial eventuality would be that of a single investor who, in return for the setting up of such an industry in the Community, would gain the sole rights in the supplying of drugs that could be conditioned in this own factory.

In this case the promoter will give advantage to his own products against other makes although the latter might be more efficient. Little by little the other manufacturers will lose interest in such a cornered market, and a few years ahead one single make will remain available on the market. It will remain that the promoter will have to buy some of the products he will not be manufacturing, but nothing can prevent him from buying them on the world market at their lowest rate and taking them back to his own factory to be packaged at the highest : we have seen in the chapter concerning the EAEC the huge margin there is between the highest and the lowest prices in reference to a given product.

Would this solution be adopted the only way to dwindle its bad effects would be setting up a second packaging factory in another country. A competitive element would thus be introduced on the market to the benefit of the Community.

Another alternative would be to make a deal not with a single manufacturer, but with a cartel such as PFIZER-HOECHST, PHONE-POULENC and its subsidiaries (THERAPLIX, SPECIA, ROGER BELLON, INSTITUT MERIEUX) (1), IFF (5 partners), PHARMA (22 partners) (2) etc... This enables to enlarge the product scale without acting upon prices.

The third and most favourable possibility with regard to both the product scale and the action upon prices would be giving raw material to an executer that would condition them on request.

Under the present circumstances it is the most difficult one, for it understates the existence of an "entrepreneurial skill" in this particular field, and governments - they may be right - rather trust a powerful organisation from outside than a private individual often unreliable.

In this case the "executer" does not have to bother about commercialising his products : the outside firm has its own medical salesmen, its dispatching network and agents but knows that packaging is ensured by an independant firm. In the same way the dispatching firms of petroleum products bring crude petroleum to MOMBASA OR DAR ES SALAAM refineries - and though a settled conditioning margin - receive finished goods. It is fairly more complicated here, for there is a packing problem as well.

This process gives warranty for the quality of the finished goods because the latter will only be accepted when leaving the packaging factory, if they meet the specialisations spelt out by the commercialising firm.

(1) According to the laws regulating the East African Common Market this could be done.

(2) We have chosen these firms as examples only : they have let us known that they had no interest in any plan with the East African Community.

(3) This could be a state controlled or owned company working on profit basis.

Another improvement would consist in having 2 packaging factories. Such an organisation might then enable the government to have the products for Hospitals or Health Centers conditioned under more interesting conditions.

Would the "entrepreneurial skill" not be lacking, this last solution would be the easiest to achieve for it can be set up without the help of foreign organisations.

The first contacts we had, made us realize that very few pharmaceutical firms were interested in setting up a firm in Africa:

1) the managing executives we have come in touch with are hardly interested in this continent which they think of as "unpredictible"
2) the African market is a small and competitive one with low price products, while they are only interested in expensive and sophisticated products.

Plus the fact that, as far as French firms are concerned, drugs used in EAST AFRICA are labelled in English and that most doctors have received an English training.

Under such circumstances, it is easy to figure out that a foreign firm will find interest in this market provided it is given the same advantages as those talked of at the beginning. This of course hardly makes the process worthwhile.

united nations industrial development organization

04458 (2)

establishment of a pharmaceutical industry sector in the east african community

part II : interim report
market and drug distribution

sema

UNITED NATIONS INDUSTRIAL DEVELOPMENT ORGANISATION

ESTABLISHMENT OF A PHARMACEUTICAL INDUSTRY SECTOR IN THE EAST AFRICAN COMMUNITY

INTERIM REPORT

PART II : THE PRESENT SITUATION :

MARKET AND DRUG DISTRIBUTION CHANNELS

UNIDO CONTRACT N° 71/44
Project n° SIS 70/784 AFR 10
Phase II

SEMA (METRA INTERNATIONAL)
Division "Marketing and Industrial Development"
P A R I S

April 1972

C. 32 448

TABLE OF CONTENTS

1. THE MARKET

Our first task was to ascertain the E.A. Market. As our terms of reference did not include the local manufacturing plants or vaccine production units both for human and veterinairy uses, at first, we did not take them into consideration and felt this was not an important aspect of the EA drug industry.

The result of the compilation of Trade Statistics is amazing and demonstrates that the local production plays an important role, as shown in TABLE II :

TANZANIA seems to consume more than twice as much as KENYA does and UGANDA is a larger consumer than KENYA.

This is a surprising result when one considers the GNP, per head income and population figures.

So, the local drug production far from being negligeable is an important fact of the E.A. drug scene. So, we feel a comprehensive survey should include this aspect, as shown in table III.

TABLE I - DRUG IMPORTATIONS

UGANDA - NET IMPORTS OF DRUGS FROM OVERSEAS

	1966 £		1967 £		1968 £		1969 SHS		1970 SHS	
Vitamins and Provitamins	16 769		8 168		7 477			188 276		422 562
- Government		595		23		0	16 665		86 753	
- Private sector		16 174		8 145		7 477	171 611		335 809	
Antibiotics and their derivatives	66 672		43 177		58 805			1 876 613		2 486 364
- Government		38 183		411		0	15 082		194 842	
- Private sector		26 489		48 766		58 805	1 861 531		2 991 522	
Opium, alkaloids and derivatives	29 453		41 327		49 843			1 135 205	878 738	
- Government		524		2 456		297	57 848		69 034	
- Private sector		28 929		38 871		49 546	1 077 357		809 704	
Hormones	1 854		2 666		2 420			115 611		243 694
- Government		576		0		0	0		96 800	
- Private sector		1 278		2 666		2 420	115 611		146 694	
Glycosides and their derivatives					1 220			35 259	5 332	
- Government						0	0		25 648	
- Private sector						1 220	35 259			
[illegible]	38		239	95	9	0	0	725		
- Government		38		144		9	725			
- Private sector		0								
Biological products, sera, vaccines	37 176		54 275		41 789			1 924 717		3 190 653
- Government		10 592		26 734		15 076	2[illegible] 896		2 436 300	
- Private sector		26 584		27 541		26 713	1 624 821		754 353	
Medicaments	999 517		545 785		665 166			14 061 547		24 965 9[illegible]
- Government		[illegible]		75 3[illegible]		40 704	1 112 535		4 912 44[illegible]	
- Private sector		54[illegible]		471 [illegible]		624 462	12 94[illegible] 012		20 053 52[illegible]	
[illegible]										
- Government										
- Private sector										

TANZANIA - NET IMPORTS OF DRUGS FROM OVERSEAS

	1966 £		1967 £		1968 £		1969 SHS		1970 SHS	
Vitamins and provitamins	24 575		23 635		22 202			439 678		643 [illegible]
- Government		2 260		710		1 284	57 587		329 081	
- Private sector		23 315		22 925		20 918	382 091		313 981	
Antibiotics and their derivatives	97 900		100 765		105 141			3 093 540		4 198 [illegible]
- Government		10 435		25 792		8 125	505 406		2 258 489	
- Private sector		87 465		74 973		97 016	2 588 134		1 940 103	
Opium alkaloids and their derivatives	88 178		100 507		111 987			2 395 202		2 117 [illegible]
- Government		30 [illegible]		5 [illegible]		2 066	149 963		170 027	
- Private sector		57 [illegible]		95 532		109 921	2 145 239		1 947 708	
Hormones	2 908		1 604		3 918			46 271		20 [illegible]
- Government		774		853		54	49 464		13 893	
- Private sector		2 187		751		3 864	26 817		6 456	
Glycosides and their derivatives					935			57 336		192 [illegible]
- Government						0	2 921		12 619	
- private sector						935	54 415		179 560	
Organo-therapeutic glands, organs	66x		112		61			7 122		
- Government		0		64		45	5 436		5 216	
- Private sector		66x		46		16	1 684			
Material products, cats, ligatures	47 171		67 112		65 967			1 839 277	0	4 860 [illegible]
- Government		4 [illegible]		3 [illegible]		11 935	228 802		3 306 334	
- Private sector		42 [illegible]		53 331		53 631	1 610 475		1 553 [illegible]	
Medicaments	719 716		609 660		999 801			20 757 914		30 241 [illegible]
- Government		273 227		188 [illegible]		253 [illegible]	6 263 041		9 940 488	
		445 491		421 [illegible]		746 461	14 494 873		20 301 240	
[illegible]										
- Government										
- Private sector										

KENYA - NET IMPORTS OF DRUGS FROM OVERSEAS

	1966 £		1967 £		1968 £		1969 Shs		1970 Shs	
Vitamins and Provitamins	33 539		38 484		42 881			1 306 718		2 7[illegible]
- Government		625		463		403	72 607		82 309	
- Private sector		32 914		33 951		42 47[illegible]	1 234 111		2 629 131	
Antibiotics and derivatives	61 945		30 881		38 390			1 386 099		1 819 0[illegible]
- Government		71 103		30 706		31 771	1 187 193		933 752	
- Private sector		9 2[illegible]		173		6 619	198 906		885 343	
[illegible], alkaloids and their derivatives	9 368		35 970		33 778			328 862		1 75[illegible]
- Government		1 7[illegible]		1 012		6 170	29 887		15 222	
- Private sector		11 154		34 958		27 608	298 975		1 744 679	
Hormones	1 092		4[illegible]		3 018			31 413		255 [illegible]
- Government		1 [illegible]		37[illegible]		1 107	36 312		208 110	
- Private sector		2 [illegible]		[illegible]		4 125	5 1[illegible]		47 554	
Glycosides and their derivatives					6 720			93 603		83 5[illegible]
- Government						0	0		0	
- Private sector						1 720	93 603		83 530	
Opotherapeutic glands, organs	822		218		18			3 443		27 1[illegible]
- Government		0		232		43	0		20 780	
- Private sector		822		14[illegible]		25	3 443		6 357	
Bacterial products, sera, vaccines	107 226		74 624		148 037			3 926 465		3 651 [illegible]
- Government		3 670		4 581		3 125	36 0[illegible]		125 [illegible]	
- Private sector		103 5[illegible]		70 043		144 912	3 890 437		3 526 [illegible]	
Medicaments	1 303 883		1 480 330		1 757 906			[illegible] 677		41 0[illegible]
- Government		167 042		1[illegible]		144 [illegible]	[illegible]		5 605 [illegible]	
- Private sector		1 136 [illegible]		1 313 [illegible]		1 613 [illegible]	[illegible]		35 [illegible]	
TOTALS										
- Government										
- Private sector										

IMPORT OF LOCAL DRUGS FROM TANZANIA AND UGANDA

currency : [illegible]

	1966		1967		1968		1969		1970	
	ORIGIN									
	TANZANIA	UGANDA	TANZANIA	UGANDA	TANZANIA	UGANDA	TANZANIA	UGANDA	TANZANIA	UGANDA
Vitamins and provitamins	-	-	-	-	-	-	-	-	-	-
Antibiotics and their derivatives	-	-	-	-	-	820	-	-	650	-
Opium, alkaloids and their derivatives	-	2 280	720	2 620	220	28 760	12 589	36 795	197 [illegible]14	41 368
Hormones										
Glycosides and their derivatives										
Organo-therapeutic glands, organs										
Bacterial products, sera, vaccines	260	-	-	-	-	-	-	-	1 000	-
Medicaments	51 160	102 000	87 520	153 660	63 720	225 400	155 697	205 862	75 [illegible]72	242 23[illegible]
TOTAL DRUGS	51 420	104 280	88 240	156 280	63 940	254 980	168 286	242 65[illegible]	275 366	2[illegible]3 6[illegible]

IMPORTS OF LOCAL DRUGS FROM TANZANIA AND KENYA

current : SHS

	1966		1967		1968		1969		1970	
	ORIGIN									
	KENYA	TANGANYIKA	KENYA	TANGANYIKA	KENYA	TANZANIA	KENYA	TANZANIA	KENYA	TANZANIA
Vitamins and provitamins	500	-	-	-	-	-	-	-	1 540	-
Antibiotics and their derivatives					15 380	-	-	-	880	3 000
Opium, alkaloids and their derivatives	240	-	400 520	-	46 400	-	314 106	-	932 583	1 650
Hormones										
Glycosides and their derivatives										
Organo-therapeutic glands, organs										
Bacterial products, sera, vaccines	15 080	-	24 30	-	81 900	-	296 862	-	329 827	-
Medicaments	3 855 620	32 320	4 341 12	8 220	5 202 760	78 640	5 441 35	31 170	8 469 84	6 262
TOTAL DRUGS	3 872 360	32 32	4 765 94	8 220	5 346 44	78 640	6 052 31	31 170	9 734 60	10 912

TANZANIA

IMPORTS OF LOCAL DRUGS FROM KENYA AND UGANDA

Currency : Shs

	1966		1967		1968		1969		1970	
	O R I G I N									
	KENYA	UGANDA	KENYA	UGANDA	KENYA	UGANDA	KENYA	UGANDA	KENYA	UGANDA
Vitamins and provitamins	1 320	-	-	-	-	-	-	-	-	-
Antibiotics and their derivatives	-	-	-	-	25 560	-	-	-	-	-
Opium, alkaloids and their derivatives	55 500	1 [illegible]	274 500		151 180	15 [illegible]	387 674	1 620	544 840	[illegible]
Hormones	-	-	-	-	-	-	6 000	-	-	-
Glycosides and their derivatives										
Organo-therapeutic glands, organs										
Bacterial products, sera, vaccines	19 250	-	-	-	[illegible] 240	-	254 345	-	1 154 [illegible]	[illegible]
Medicaments	6 115 80[illegible]	[illegible]	5 632 [illegible]	[illegible] 040	7 537 50[illegible]	343 700	[illegible]	224 752	10 161 [illegible]	71 [illegible]
[illegible]	6 [illegible]	[illegible]	6 [illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]

THE E.A. MARKET

a) without regards to the local production — TABLE II
b) considering the local production — TABLE III

TABLE II

KENYA MARKET

Without regard to local production

E.A. Shs

Net imports	51.653.373
+ imports from EAC	558.971
	52.212.344
- exports to EAC	- 21.695.813
	30.516.531

TANZANIA MARKET

Net imports	58.380.957
+ imports from EAC	11.991.881
	70.372.838
- exports to EAC	- 286.278
	70.086.560

UGANDA MARKET

Net imports	32.608.658
+ imports from EAC	9.745.596
	42.354.240
- exports to EAC	- 384.457
	41.969.891

KENYAN MARKET

TABLE III

		1966	1967	1968	1969	1970
Origin						
Foreign drugs	**Gross imports**					
	- gross imports of end products					
	- imports of raw materials					
	Reexport to partners					
	- Uganda					
	- Tanzania					
	Net imports	30 313 780	31 980 100	39 637 860	46 854 280	51 653 373
	- Government	4 [illegible] 140	2 882 340	3 741 740	6 [illegible] 394	7 [illegible]
	- Private sector	25 [illegible] 640	29 037 760	35 896 120	40 [illegible] 769	44 [illegible]
East African drugs	**Local production**					
	Imports of east African products					
	- Tanzania	51 420	88 240	63 940	168 256	275 [illegible]
	- Uganda	104 280	156 280	254 980	242 657	283 [illegible]
						558 971
	Imports of local products					
	- Tanzania	6 262 900	5 107 420	5 722 480	8 983 009	11 961 [illegible]
	- Uganda	3 872 360	4 765 940	5 346 440	6 052 328	9 [illegible]
	- Others					
	Total east African drugs available in local market					21 495 813
TOTAL	Total drugs available in local market for consumption					

TANZANIAN MARKET

TABLE III

Currency Shs

Origin		1965	1967	1968	1969	1970
Foreign drugs	Gross imports					
	- Gross imports of ends products					
	- Imports of raw materials					
	Reexport to partners					
	- Kenya					
	- Uganda					
	Net imports	17 803 520	18 069 960	25 748 200	28 636 340	58 380 957
	- Government	5 819 680	4 344 720	5 511 320	7 332 622	16 022 234
	- Private sector	13 [illegible] 520	13 725 240	20 236 880	21 303 798	42 358 723
East African drugs	Local production					
	Imports of East African products					
	- Kenya	6 252 900	6 107 420	8 722 480	8 993 000	11 361 [illegible]
	- Uganda	180 220	165 040	359 640	226 [illegible]	[illegible]
						11 981 881
	Exports of local products					
	- Kenya	51 420	88 240	63 [illegible]	168 256	[illegible]
	- Uganda	32 320	6 220	78 640	31 [illegible]	[illegible]
	- Others					286 278
	Total East African drugs available in local market					
TOTAL	Total drugs available in local market for consumption					

UGANDAN MARKET

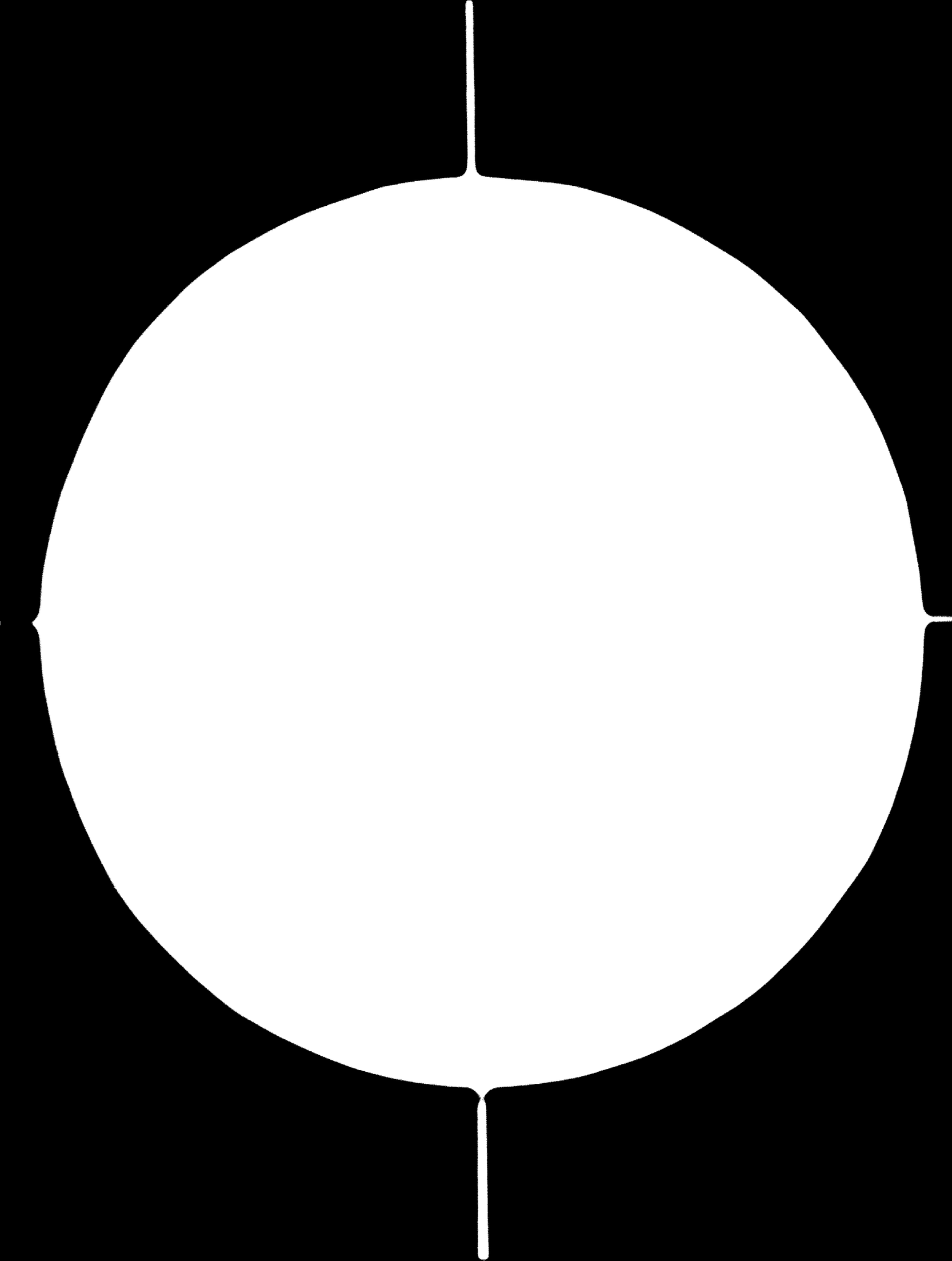
TABLE III

Currency SHS

Origin		1966	1967	1968	1969	1970
Foreign drugs	**Gross imports**					
	- Gross imports of end products					
	- Imports of raw materials					
	Reexport to partners					
	- Kenya					
	- Tanzania					
	Net imports	15 109 580	13 932 760	16 385 000	19 325 228	32 608 652
	- Government	2 165 460	2 102 360	1 121 540	1 501 026	7 821 825
	- Private sector	12 944 120	11 830 400	15 263 520	17 834 927	24 786 827
East African drugs	**Local production**					
	Imports of East African products					
	- Kenya	3 872 360	4 765 940	5 346 440	6 052 318	9 734 684
	- Tanzania	32 320	8 220	78 640	31 170	10 912
						9 745 596
	Exports of local products					
	- Kenya	104 280	156 280	254 980	242 657	283 605
	- Tanzania	180 220	165 040	359 640	226 378	39 852
	- Others					324 457
	Total East African drugs available in local market					
TOTAL	**Total drugs available in local market for consumption**					

I-659

81.11.30



II. DRUG CONSUMPTION

DRUG EXPENSES

It is very difficult to estimate drug expenses in developped countries. In East Africa, it is even worse, if not impossible, because :

- the whole statistical system on the subject of health is very poor,

- it is impossible to isolate the amount of drugs bought out of the total amount of purchases made by the government medical stores,

- the private sector's commerce of pharmaceutical products is in such a state of confusion that the real margins and actual prices paid by consumers are impossible to determine.

This last remark is especially valid for Kenya and Uganda, as Tanzania's centralized structure allows a better estimation of private sector affairs.

We do dispose of the following factors to estimate drug expenses :

- amount of annual imports of finished pharmaceutical products at CIF price,

- amount of local annual production,

- amount of annual exports of local products,

- estimation of margins between CIF prices and retail prices,

- purchases and sales of the medical stores (sometimes including equipment and dressings).

Amongst the factors which can influence the level of consumption of drugs, the most important are :

For the paying sector :

- the consumer's purchasing power,
- the retail prices of drugs,
- the number of prescriptors,
- the geographical distribution of prescriptors.

For the free-of-charge sector :

- definition of the free-of-charge system,
- the importance of sums voted for the purchase of drugs by the public sector (block grant system),
- the importance of the central medical stores' working capital,
- the organisation of the purchase and distribution system which tends towards a better of worse use of allotted sums.

For the free-of-charge or public sector, the number and geographical distribution of prescriptors (health centres, dispensaries) can also be of importance, even though the approved expenses for medical stores create the real bottleneck. In fact, when new health units are opened, there are usually two consequences :

- the distribution of scarcity is harder to define,
- the working capital must be increased to allow for additional stocks.

This always brings about an increase in working expenses, or a better use of the money, and this usually means that more drugs are consumed.

1. [redacted]

Apart from the particulars of foreign commerce and production given in the earlier chapters, we do have the book-keeping statistics on purchases (and sometimes sales) of the medical stores.

[redacted]

KENYA - PURCHASE OF STORES, PLANT AND EQUIPMENT

	Stores, plant and equipment estimates		Medical stores only estimates
1966/67			
1967/68	846,000	749,557	
1968/69	902,000	991,621	
1969/70	950,000	1 351,694	
1970/71	1,315,150	1,513,638	
1971/72	1,300,000	-	1,122,450

[illegible]

[illegible]

1 - [illegible]

19[illegible]	-	T. Rs.	[illegible]
19[illegible]	-		[illegible]
19[illegible]	-		[illegible]
19[illegible]	-		[illegible]
19[illegible]	-		[illegible]
1964/65	-		[illegible]
19[illegible]	-		[illegible]
1966/67	-		[illegible]
1967/68	-		[illegible]
1968/69	-		[illegible]
1969/70	-		[illegible]
1970/71	-		[illegible]

2 - Total purchases - [illegible]

1969/70	-	T. Rs.	81,01[illegible]
1970/71	-		33,09[illegible]

[redacted]

[redacted] - GOVERNMENT EXPENDITURE ON STORES, DRUGS AND EQUIPMENT

	Stores, Drugs, Equipment		Drugs only
	Estimates	Actual	Actual
1966/67		7,964,000	
1967/68	6,840,000	9,500,000	
1968/69	10,668,000	13,139,000	
1969/70	16,360,000		13,700,000
1970/71	24,190,000		15,700,000

2. GEOGRAPHICAL DISTRIBUTION OF DRUG EXPENSES

This distribution is only partially possible and this, only for the public sector.

It is nevertheless useful to appreciate the rural zones' comparative under-consumption, where the private sector plays a very small part.

It is possible to complete this information by a regional distribution of the prescriptors, which of course has a direct effect on the distribution of consumption.

For more precise information on the distribution of health personnel in each country, see appendix.

[illegible]

[illegible]

[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	

[illegible]

[illegible]	[illegible]	[illegible]	[illegible]	
Pharmacist	[illegible]	[illegible]	-	[illegible]
Assistant pharmacist	[illegible]	[illegible]	[illegible]	[illegible]
Physician	[illegible]	[illegible]	73	[illegible]
Medical Assistant	[illegible]	[illegible]	[illegible]	[illegible]
Health assistant	[illegible]	[illegible]	[illegible]	[illegible]
Dentist	[illegible]	[illegible]	-	

[illegible]

[illegible]

[illegible]	[illegible]
[illegible]	[illegible]
[illegible]	[illegible]
[illegible]	[illegible]
[illegible]	[illegible]
[illegible]	[illegible]

[illegible]

[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]		[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	-	-	[illegible]
Total	[illegible]	[illegible]	[illegible]	[illegible]

(1) [illegible] full time teaching doctors at the University of DAR ES SALAAM.

(2) excluding [illegible] Medical Personnel practising in up country stations and rural areas

(3) on training and local authority

[illegible]

[illegible]

[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]

3. ESTIMATION OF THE PER HEAD DRUG CONSUMPTION AT THE CONSUMER LEVEL (VALUE)

This is nothing but a rough indication of the per head consumption at the consumer level.

One cause of distorsion in the existence of stock - which we do not take into consideration in our calculation - at different levels. Another one is the 10 % distribution margin taken by the Medical stores which certainly does not reflect the true distribution cost by the Medical stores : the distribution of drug is certainly subsidized in a certain extent by the Government by the way of both running and development expenses.

The third one is the errors on the distribution margin in the private sector. These have been obtained by the way of interviews and the distributors were not quite willing to release such information and that obtained is eventually biaised.

Amongst other possible causes of distorsion let us note :

The small proportion of drugs purchased by the three Medical Stores estimeed at about 2 % by the heads of the three Medical Stores but no accurate figure is available.

	1966	1967	1968	1969	1970
Total drugs available in local market 1. Government sector Expenditure in public sector - CIF price medical stores margin Expenditure in public sector - selling price 2. Private sector Expenditure in privatesector - CIF price Customduties Total Average margin of private sector Expenditure in private sector - selling price.					
TOTAL EXPENDITURE AT ITS SELLING PRICE					

STRUCTURE OF DISTRIBUTION

I. KENYA AND UGANDA

II. Private Sector

The structure of drug distribution is very much alike in both countries. And this, mainly because of their financial ties in imports and wholesale businesses, strengthened by the fact that imports into Uganda from overseas pass through Kenya.

In these two countries, the commerce of drugs has hardly any structure because of the pluralism of most importers, wholesalers and retailers, also because of very incomplete legislation. In fact, apart from the classic separation between private sector and government sector, there are no clearly defined distribution circuits. The tables below only show main tendencies; reality is much more complex

III. Importers

Import licences (Part I and Part II) can be obtained by any authorised vendor. This means that most wholesalers and retailers are also importers, which further increases the amount of imported patent medicines.

IV. Wholesalers

In Kenya, there are about [illegible] wholesalers, [illegible] of which are also manufacturers and packers, and [illegible] more also packers or manufacturers of liniments and foodstuffs. Some of these wholesalers have several agencies : Mackenzie-Dalgety ([illegible]), Howse and McGeorge, and Phillips, Harrisons and Crosfield ([illegible]), Old East Africa Trading Co, Sterling Winthrop, Mason and Barry, Hoechst East Africa ([illegible] each).

Geographically, the wholesalers' agencies are divided as follows :

- Nairobi	35
- Mombasa	6
- Other towns	6
Total	47

113. Retailers

a. Kenya

In Kenya, the retailers are divided as follows :

	Licence Part 1	Licence Part 2
Nairobi	31	70
Provinces	13	260 (1)
TOTAL	54	330 (1)

(1) estimed

To these figures, one must add the authorised vendors of products for agriculture (especially cattle dips). These are mainly the agencies of the Kenya Farmers Association. They represent about 250 selling points all over the country.

b. Uganda

There are about 20 retailers in Uganda, most of which are importers and wholesalers.

To give an idea of the complexity of the circuits, both in Kenya and Uganda :

- not all foreign companies have a subsidiary on the spot and some of their representatives are local importers,

- the foreign companies' subsidiaries do not necessarily import themselves all their own patent medecines and products, and can use local importers in a better position to sell certain goods,

- local manufacturers sometimes try to sell products they make or pack on the spot,

- there are many authorized parallel circuits (dispenser doctors) or non-authorized (resalers).

114. Stocks

According to the importers' statements, these take from 3 to 12 months. As an average, stocks take 5 to 6 months : 1/3 ordered, 1/3 floating, 1/3 delivered. This means that the actual stock delivered is of 2 months. As the supplier's credit is usually of 6 months, the working capital is reduced to a bare minimum.

Some importers do consent to have larger stocks so as to be in a better position to meet local tenders or to supply the government in urgencies, e.g. NAKIVUBO at Kampala.

115. Commercial promotion

The market is very competitive and sales are irregular. Commercial promotion has an essential role and sales are "led" by the importers. Few importers, however, invest by themselves. Commercial promotion is usually financed by the manufacturer. It includes, as anywhere else, medical visitors, samples, literature, personal contacts for "ethical" products. As for the other products (household and proprietory) they are usually promoted by samples at first given to the chemists, and later sold.

12. Public Sector

The Medical Stores, both in Kenya and Uganda, distribute all drugs in all the government's health units. In Kenya, the Medical Stores also supply the missions when this arrangement offers better prices. In Uganda, the Medical Stores also supply the local authority dispensaries and health centres, but these can make their own decisions.

121. Organization and Distribution of Stocks

Each health unit writes out its own orders for drugs, but these orders are usually transmitted to the Medical Stores by the District Medical Officer. A list of the various health units which stock drugs will be found as an appendix to this report.

In Uganda :

The stock of drugs held by a district is roughly that of the amount used in 2 months. In Health centres and dispensaries it represents the needs for 1 month or 1 week. In Government hospitals, the stock has been reduced from 6 months to 2 months after improvement of the ordering and delivery process.

In Kenya :

The Central Medical Stores have a 6 monthsstock. All government hospitals and departments used to make their orders twice a year (6 months stock - see appendix). This process will probably be changed too. In fact, in october 1971, the reorganization of stock management was being studied (costing, entering, laying out, packing, dispatching). Besides, there is no adequate accommodation in Nairobi nor in hospitals. Time to deliver drugs from central stores is too long. Because of this, there is talk of opening nine regional stores which would directly supply the health units. In a first step, may be in 1972-1973, four of these centres could be opened in Nairobi, Mombasa, Kisumu and Nakuru.

2. TANZANIA

21. Private Sector

Since March 1970, a "pharmaceutical products" department has been opened in the State Trading Corporation which controls a large amount of the imports and distribution in Tanzania.

211. STC's "Pharmaceutical Products" Department

STC has concentrated all import and distribution operations above the retailer. Only a few isolated importers still use their license.

STC has a Central Store in Dar Es Salaam and regional stores which act as wholesalers. Only a few regional stores seem to be really active : DAR, MOSHI, MWANZA, TANGA, MBEYA. An imposed price system has been established so that STC might indirectly control the retail stage. Actually, STC's working capital isn't sufficient to avoid

discontinuation of stock. Examination of stock forms has shown that some essential products are missing 2 or 3 times a year at the Central Stores. The effect of this is of course increased at the regional stores and even more so at the retail chemist shops.

As a remedy, the working capital is to be increased to 2 months' needs, which would be a minimum, and also the amount of distributed products and especially patent medecines is to be limited, as they often duplicate with eath other.

It is also important that in Tanzania, distribution of drugs is mainly carried out by the public sector, the private sector, including STC, only distributes a small amount of the drugs used. STC imported 24,000,000 Shs worth of drugs in 1971.

212. Private Importers

A few big retail chemists import and distribute some patent medecines not controlled by STC.

22. Public Sector

The Tanzanian Central Medical Stores are organized along the same lines as those of Kenya and Uganda. However, their action is more widespread as they also supply nearly all missions and voluntary agencies.

All health units order directly through the closest district or regional hospital.

The following stocks are kept by the various units :

Central Medical Stores

Safety stock + stock on hand + stock in order : 6 months

Safety stock + stock on hand : Abt. 3 months.

According ot the Fund's regulations, value of stocks held at any one time should not exceed shillings five million, i.e. one month and a half of the amount of drugs used in 1970-1971.

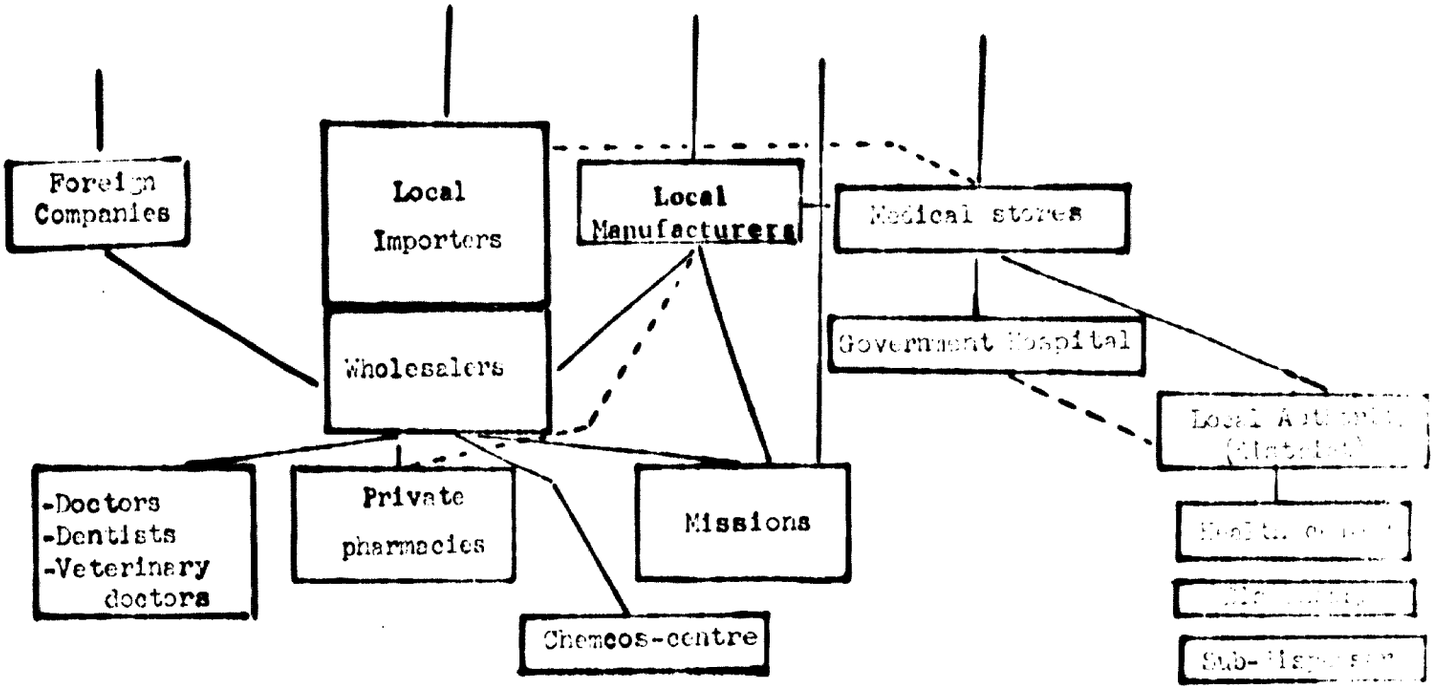
Muhumbili Hospital

4 month stocks (3 orders per year)

Regional and District Hospitals

3 months, but can fall to a few weeks.

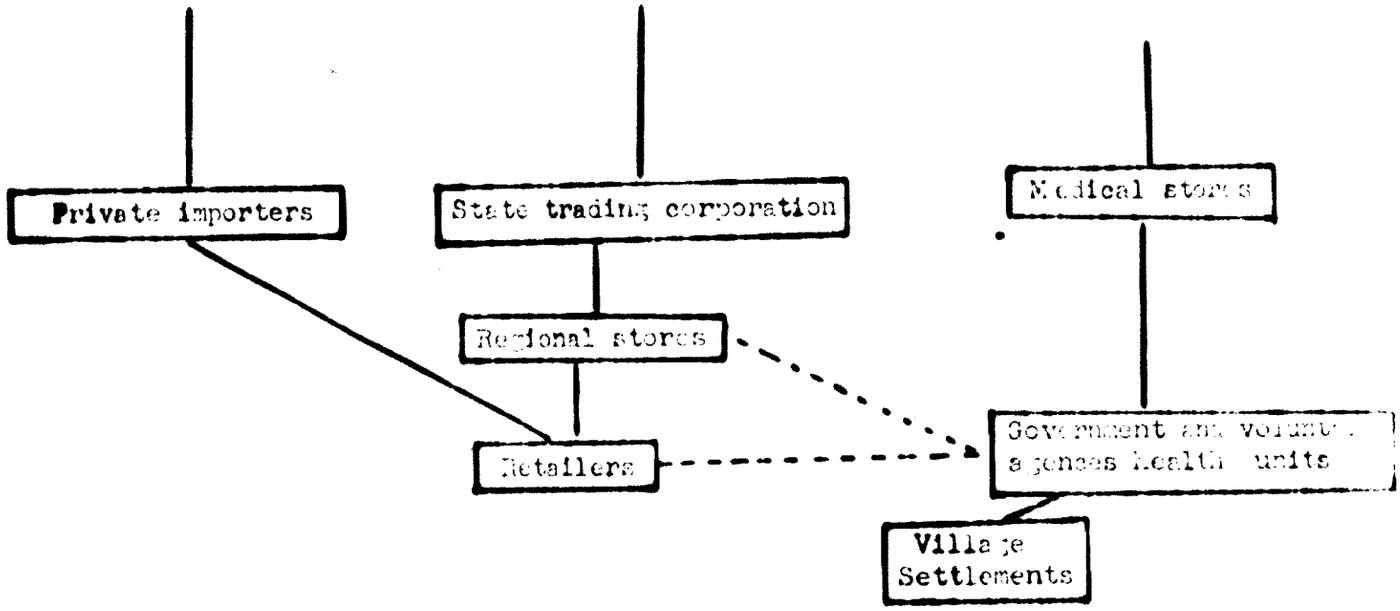
UGANDA - MAIN DISTRIBUTION CHANNELS



—— Scheduled connection

- - - Occasional connection

TANZANIA - MAIN DISTRIBUTION CHANNELS



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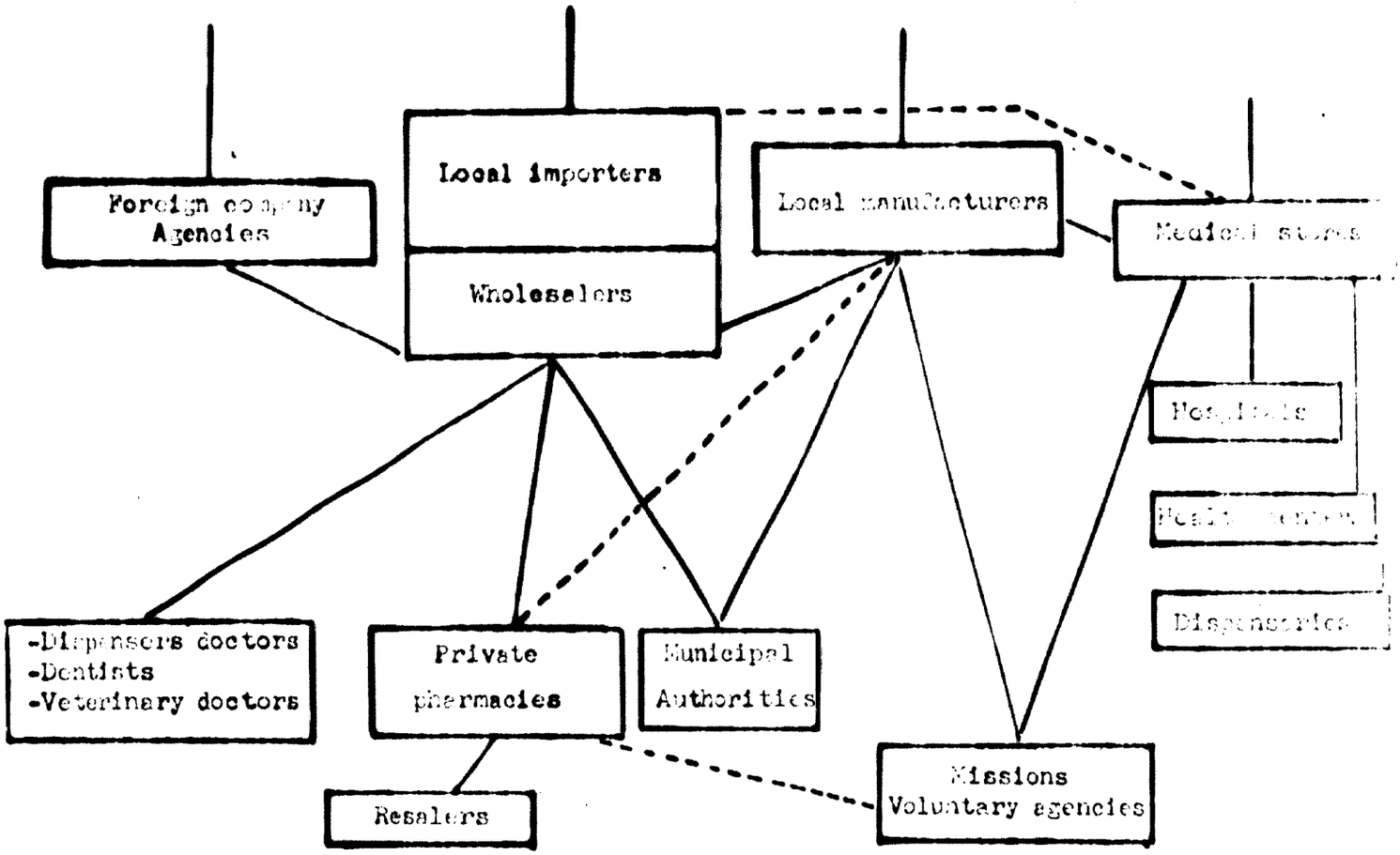
KENYA - MAIN DISTRIBUTION CHANNELS



——— Scheduled connections

- - - - Occasional connections

IV. PURCHASING ORGANIZATION

BUYING ORGANIZATION

In the private sector, the buying organization has nothing remarkable. The importers are somewhat specialized : the subsidiaries of foreign companies import their own products, and local importers share :

- the products of western firms which do not have subsidiaries,
- the products of eastern countries,
- Indian products.

Terms of delivery are from 2 to 6 months and Indian products often take longer than western products.

In the public sector, the Medical Stores of all three countries send out tenders. An international tender is used in the three states, as well as urgency local tenders. The tender is sent out from the Central Tender Board and not from the Medical Stores themselves, who only specify their needs. These are mostly written in generic terms.

For 1970/71, purchases were made as follows :

KENYA :
- Crown Agents 80 %
- local tenders 20 %

UGANDA :
- Crown Agents 98 %
- local tenders 2 %

TANZANIA :
- STC : items purchased in bulk from overseas agents
- open publics tenders : common preparations
- local purchases (East Africa) : non scheluded specialities.

In all three countries, the obligation to go through the Central Tender Board is felt to be a rather inadequate process for drugs. To-date, one year to one year and a half can pass between the time the need is expressed and the goods received. In Kenya, as in Uganda, the people responsible for the medical stores would like to establish their own tender board to shorten the buying process and make more sophisticated selection tests.

Between the time of the order and the delivery from the works, the ordered quantities can be adjusted by $\pm$ 20 %.

[redacted]

[redacted]

The structure of the distribution will of course have a strong influence on the prices. Because of this, Kenya and Uganda will be dealt with on one case, and Tanzania on another.

1. [redacted]

The structure of distribution described above brings about a very confused price system. To speak of wholesale or retail prices in one must be nothing.

There is no imposed price schedule, and one can only give average margins.

The are three main circuits, however, leading to different prices :

- government imports,
- private sector imports of patent medecines,
- private sector imports of standard drugs.

According to some importers, average margins can be estimated as follows :

(index 100 for CIF price)

	PRIVATE SECTOR		GOVERNMENT SECTOR
	Specialities	Standard drugs	
CIF	100	100	100
Landed cost	110	110	110
Agent commission	132	154	
Wholesale	172		
Retail	237		
Dispenser doctor		230 ?	
Medical stores			115 ?

2. [redacted]

Medical Stores and State Trading Corporation prices are the following :

C I F	S T C (%)	MEDICAL STORES (%)
STC purchasing price	100	
Selling price to government cooperatives	121	107
Selling price to chemist shop :		
- in large quantities	126	
- in small quantities cash	132	
- in small quantities credit	136	
Selling price to consumer	176	
Medical stores selling price		?

3. [redacted]

For some drugs which are not essential, there is a 30 % duty, also, but rarely, for certain vitamines and alkaloids.

The price levels above correspond to duty-free products. In Kenya and Uganda, the price of patent medecines with customs duty should be multiplied by about three for the retail price (instead of 2.5 for a duty-free product).

4. RESPECT FOR PRICES

Except for Tanzania and the Government distribution systems, there are no imposed prices in East Africa.

Thus, dispenser doctors can sell the products they have in stock to their patients at whatever price they wish, and chemists frequently apply 10 to 25 % discount to their best customers.

3. SOME EXAMPLES OF PRICES

[illegible] 1

	Kenya	Tanzania	Uganda	OBSERVATIONS
FOB				
CIF - private				
- medical stores				
Landed cost				
Wholesale price				
Consumer price (private sector)				
Selling price medical stores				

VI. THE PRESCRIPTORS' ROLE

THE PRESCRIPTORS'ROLE

Private Sector

The main prescriptors of drugs for human use are doctors and also, to a slighter degree, dentists.

All doctors have a more or less important stock :

- First-class doctors have a small urgency stock which enables them to give their patients first aid.

- Dispenser doctors with more popular patients have an important stock they resell to their patients. The resell prices seem to be extreemly variable and this process is made even easier because there is no packaging to recognise the administred product.

- Between these two extreme categories, there is an intermediate one of doctors who prescribe and sell certain drugs themselves, but do not answer to "dispenser doctors". Here, we can class doctors who have a stock "to compensate the deficiencies of the distribution system". This is an argument frequently used by private doctors in Tanzania.

The prescriptions of private doctors are of course very much influenced by the origin of their diplomas and by the kind of patients they have. In the private sector, there are two categories :

- the doctor who has studied in Europe and whose patients are well-to-do will prescriba almost nothing but western products from well-known laboratories,

- the doctor whose patients are popular, who is often Indian and prescribes cheap products, often Indian themselves.

The medical visitors' work tends to increase the cleavage between the two very different types of doctors.

Public Sector

The states' policies have of course a great influence on the quantities and kinds of drugs used. Each country has three policies :

- a system of free medical treatment
- restraints imposed in government doctors' prescriptions
- a policy to bring about standardization of drugs.

a. Systems of Free Medical Treatment

KENYA

Government health services are financed by :

- treasury
- hospital insurance schemes
- individual payment at hospitals

The system of free medical treatment can be defined as follows :

BENEFITS	KENYA	UGANDA	TANZANIA
- Full provision for hospital care			x
- Partial provision for hospital care	x		
- Surgical expenses when surgery is performed in hospital	x	x	x
- Surgical expenses when performed outside of hospital			
- Medical attention in hospital	x		
- out-patient medical care	x		
- Doctor's care in public clinics	x		
- Doctor's care in doctor's office			
- Doctor's house calls			
- Orthopedic devices			
- Eyeglasses			
- Dentistry			
- Dentures			
- Prescription medecines (in government units only)	x	x	x
- Proprietary medecines (in government units only)			
- Convalescent or rest homes Following illness			
- Nursery care			
- Nursery home			
- Maternity care	x	x	x
- Confinement in mental institution	x		

Out patients

Medical attention is free for all outpatients in government clinics.

In patients

Taxable incomes of less than 600 £ a year : small fee of £ 1 is charged for adult inpatients, but not for children in government hospitals.

Taxable incomes of at least £ 50 a month (or £ 150 in the previous three months, or £ 600 in the previous year) are required to contribute compulsorily to the National Hospital Insurance Scheme.

"Benefits consist of daily allowances, depending upon the hospital at which treatment is obtained, towards the cost of hospital treatment received by a contributor, his named wife (or husband) or any child of his under the age of 18 years, except that no benefit is payable in respect of treatment received by a child within 10 days of the birth of that child. In maternity cases resulting in confinement of the named wife of a contributor, other than in an approved hospital, a benefit of up to Sh 150 may be paid in respect of expenses necessarily incurred for services rendered by a registered or enrolled midwife or registered medical pratitioner in connexion with that confinement".

The cost of a day in hospital varies from 35 to 120 shs, depending on the hospital's category, and whether it is a private of public hospital. (35 to 40 Shs in a private hospital, 55 Shs in a private maternity). The Fund refunds 40 Shs per day.

The NHIS's role is especially important for private hospitals.

As for drugs, they are only completely free for people with low incomes. They are partially refunded for the others up to the limit of the NHIS's contribution. However, civil servants can obtain additional facilities from their administrations.

b. Drugs Prescribed by Government Doctors

In all three countries, there are two lists of drugs (see appendix) : scheduled drugs and non-scheduled drugs.

The second list is mainly one of expensive drugs for use by consultants and specialists or doctors controlled by the head of the health unit.

In Tanzania, the use of drugs in dispensaries, where the prescriptor is most often only a medical assistant, has been studied with special care. The following classification has been used since 1969 :

A. Drugs authorized by the Ministry for grade A dispensaries only,

B. Drugs authorized by the Ministry for grade B dispensaries only,

S. Drugs on the supplementary list of the Ministry, which can be authorized by the District Medical Officer;

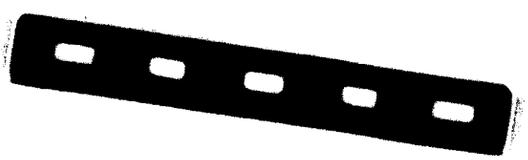
E. Extra drugs, which are not on the Government list, but which are suggested in this booklet. According to authority if the Ministry, District Medical Officers may use their discretion to approve the use of these drugs in individual dispensaries. They will give you full information on properties, use and dosage of these extra drugs.

In addition, the Rural Medical Aids get special training and the Health Ministry's services draw up a list of "recommended" drugs for the dispensaries which still further limits lists A and B in order to simplify prescriptions and meet most common cases without any risks.

c. Standardization of Drugs

As we have seen, tenders sent out by the Medical Stores are written in generic terms, but the private sector remains of course much attached to trade names.

Standardization is still only at the study stage, except in Tanzania where, as we mentioned earlier, it is being applied more and more in the public sector. The STC also intends to reduce to 1,500 to 2,000 products it is now importing. The Dutch Research Institute is apparently also studying the matter in Nairobi.

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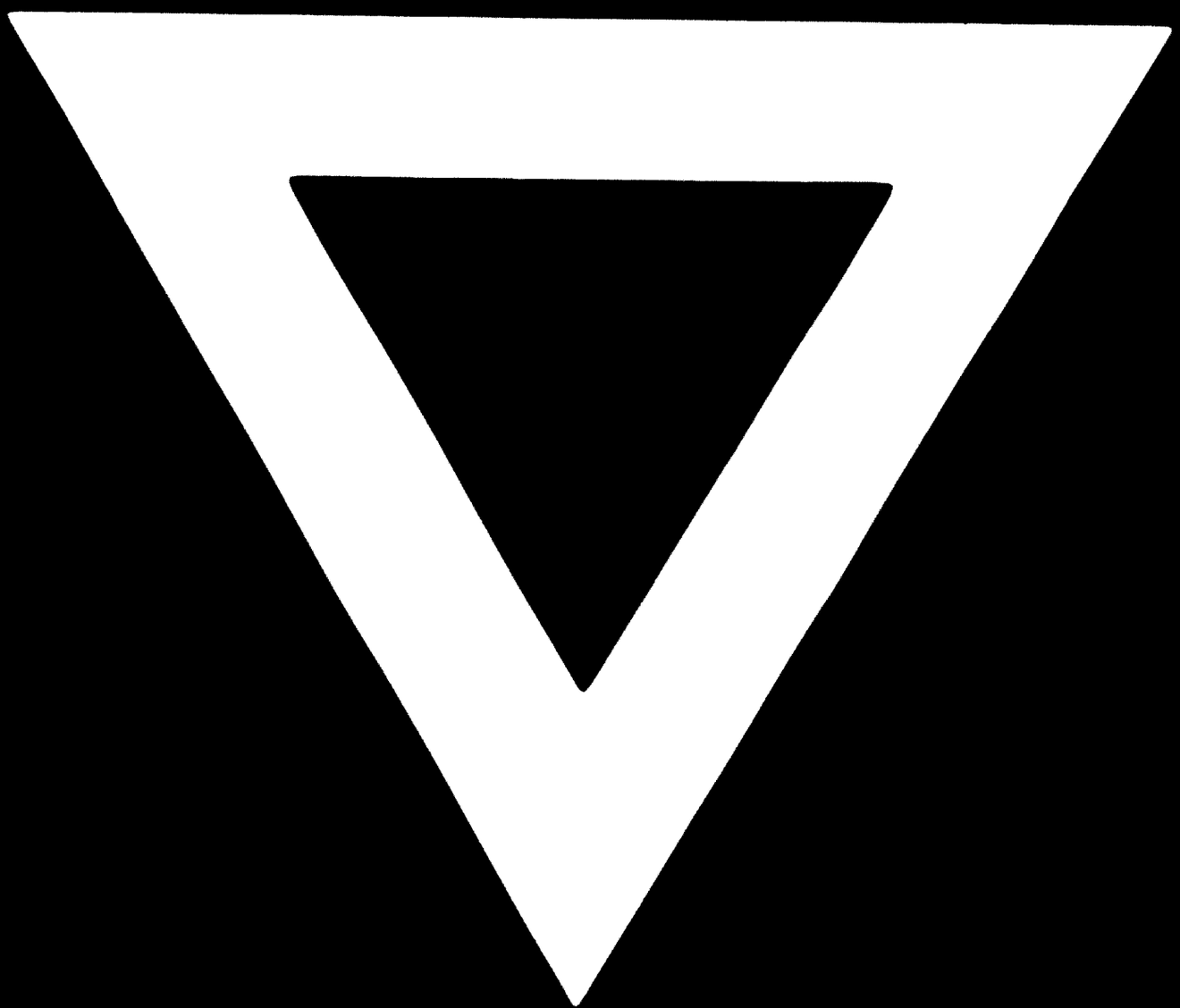

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