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ASSISTANCE IN THE PRODUCTION OF VETERINARY DRUGS IN SADCC COUNTRIES

DP/RAF/86/012

TANZANIA

Technical report: The supply of veterinary drugs and vaccines in Tanzania*

Prepared for the Government of the United Republic of Tanzania
by the United Nations Industrial Development Organization,
acting as executing agency for the United Nations Development Programme

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INTRODUCTION

Tanzania is a country of some 880,000 sq.km. on the East Coast of Africa from 1^{0} and 12^{0} South of the Equator. The human population was estimated at 19million in 1980, growing at a rate of 3.1% per annum, expecting to reach 35M by the year 2000.

About 7% of the total land area is used for crops, 60% is infested by tsetse and one third is occupied by national parks.

There are an estimated 12.5million (see Graphs) cattle in Tanzania (1984) with an estimated annual population growth rate of 0.77% and a productivity (in terms of meat) growth rate of around zero.

Should the trends continue Tanzania will have to import more than half its requirement for beef for the year 2000, or allow beef consumption per capitum to drop to very low levels.

1. LIVESTOCK POPULATION AND PRODUCTION TRENDS

A consideration of recent changes in livestock numbers, together with the prospectives of the industry in the years ahead (as seen by the experts in the country) has been the basis of projected changes in livestock numbers over the next 15 years.

Two livestock census were carried out in recent years, one in 1978 and the latest one in 1984. With respect to cattle and poultry, the number of animals was divided between the traditional and commercial sectors of management. Within the commercial sector, numbers of dairy cattle were separated from those of beef, and in poultry layers and stock birds from broiler chickens. These distinctions between and within the sectors becomes necessary because of the difference of either accessability of stock to or its requirement for vaccination.

Livestock numbers for 1978 and 1984 respectively and the average changes per annum, expressed as a percentage of the 1978 numbers are summarised (Annex 1) together with projected increases by years 1990 and 2000.

The overall increase in the number of cattle over this six year period, between 1978-84, was very modest (0.59%) and fell below the yearly average of previous decades. The lowest increase was found in traditional beef cattle. The calculated 0.47 % p.a. increase, however, may be a slight underestimation since it is thought that the 1978 census probably overestimated the number of cattle since it was carried out right through the year. It was agreed, however, that due to a variety of constraints (see Marketing appraisal) the increases in the sector of the livestock industry is not likely to exceed 0.7% p.a. until the end of this century and the projected increases were calculated accordingly.

The number of dairy cattle increased by 7.3% p.a. over the same period, largely due to the attractive price of milk. Although the dairy industry should have plenty of scope for increase, yet it was agreed that this rate of increase is not likely to be sustained and will slow down to 6% p.a. due to the shortage of concentrates required by dairy cattle.

The number of commercial beef cattle was not available from the 1978 census, but it was thought that the increases were very modest, if at all. The number of cattle on the 15 ranches of the National Ranching Corporation (NARCO) occupying over 700,000 acres, varied between 1977 - 1985 from 90,000 to 100,000 head, not showing a sustained increase, although only four of the 15 ranches were considered fully stocked. The principal problems include water, care and improvement of pastures, road, paddocks, dips, etc. It was even suggested that the number of animals in commercial beef herds may not increase at all or, indeed, may fall. However, due to renewed emphasis on Livestock production in government policies, the view was expressed that the grade beef may increase at the rate of 2% p.a. Thus the overall increase in the number of cattle is likely to remain under 0.8% p.a., resulting in approximately 13 million head by 1990 and a little over 14 million by the year 2000.

The number of goats increased by 4.5% p.a. over the six years while that of sheep declined slightly. It is thought unlikely, however, that the number of goats would increase by more than 2.5% p.a. and that of sheep by 1% p.a. until the end of this century.

To obtain reliable information about the number of poultry, especially in the traditional sector, is notoriously difficult. Therefore, the numbers should be regarded with caution. Those in the commercial sector are more reliable. The number of layers increased by 3.3% p.a. and that of broilers by 11.8% p.a. These increases are unlikely to be sustainable due to a shortage of compounded fee and feed-supplements and drop to 2.5% and 5.0% respectively.

Considering the data presented in Annex 1 it should be borne in mind that the figures are the best available at the present time but were subject to the errors inherent in the livestock census, especially in the traditional sector. The projected increases until year 1990, then on to year 2000, may become increasingly inaccurate with the increase of time, since they were based on recent trends and present prospectives. Projected increases should be regarded, on the whole, as being on the modest, rather than over-optimistic side.

Due to severe under-investment in the livestock sector the present rate of meat consumption is in danger.

Total meat consumption per capitum per annum* (1983)

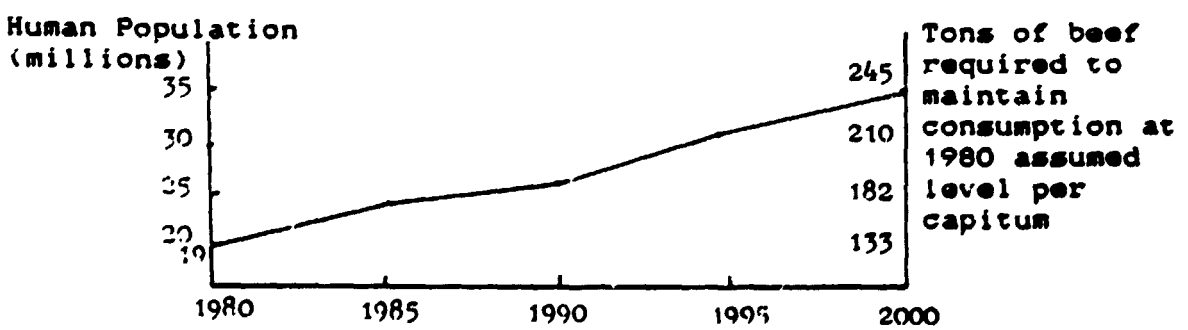
Beef	7kg
Mutton and Goat	1.4kg
Poultry	1.3kg
Milk	28 litres
Eggs	16.9

(Source: Livestock Policy of Tanzania, MLD June 1983)

* These figures are now believed to be an over-estimate, as the pre-1978 population growth projections were used.

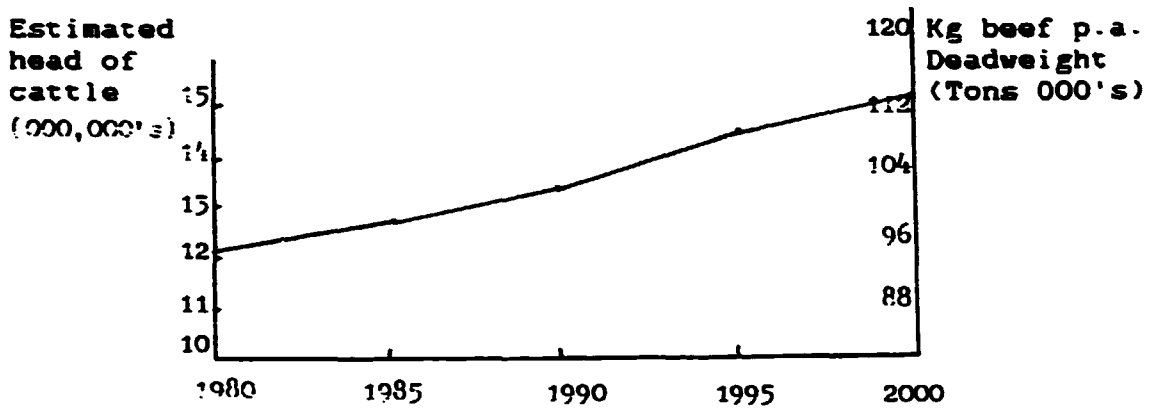
Graph 1

Projected increase in human population 1980-2000.



Graph 2

Tons of beef produced in Tanzania. Projections from 1980 to year 2000 assuming 0.7% cattle population growth, 8% culling rate and 100kg carcass deadweight.



From the above two graphs it would appear that the actual consumption of beef per capitum was about 5.3kg per head (not 7) in 1983 and that it will be necessary to import some 130,000 tons of beef per annum to satisfy the 7kg/capitum objective by the end of the century, unless human population growth trends and/or beef production trends change.

1.1 Constraints on Livestock Production in Tanzania

Over 80% of the people in Tanzania work in the agricultural sector many of them with livestock which play a key role in the national food strategy. This is because of their ability to convert low quality foods into high quality fats and proteins for human consumption.

99 per cent of cattle are kept by small farmers or nomadic tribes, are of poor genetic composition and are very poor producers.

The principal constraints to livestock development in Tanzania can be ranked as follows:

1.1.1 Land Land availability for grazing purposes is becoming ever more restricted as a result of 60% of the country being tsetse infested and the traditional pastures being encroached upon by mixed farming and catch crops. This results in the livestock being driven into poorer areas, with the resultant overgrazing, pasture deteriorates and ultimate desertification. This trend leads in turn to:

1.1.2 Poor nutrition (both water and grazing) so that most of the cattle population is under-nourished for most of its life. The calving index is 50%, calf mortality is 25-30%, adult mortality is 10% and cattle are culled for beef between 5-8 years old.

1.1.3 Management - land, pasture, husbandry. Although attempts have been made in the past to develop long-term ranching and land management schemes, they have largely failed in their purpose although some, such as the National Ranching Company, still exist but are so under-resourced as to make even survival a major achievement.

1.1.4 Animal Disease Superimposed on all these fundamental shortcomings is the effect of animal disease. It is impossible to quantify losses as a result of disease with any degree of accuracy but it must amount to at least 20 or 30% of total livestock production, as well as denying vast areas of the country to livestock use at all.

2. NATIONAL DISEASE CONTROL STRATEGIES

2.1 The following major disease groups are the subjects of specific control regulations.

2.1.1 Tsetse fly and trypanosomiasis
2.1.2 Tick-borne diseases

2.1.3 Rinderpest
2.1.4 Foot and Mouth Disease
2.1.5 Anthrax
2.1.6 Blackquarter
2.1.7 Newcastle Disease
2.1.8 Rabies
2.1.9 Brucellosis
2.1.10 Contagious bovine and caprine pleuropneumonia etc.

N.B. Acute shortage of resources make the implementation of all but the most serious Disease Control Campaigns difficult to operate.

2.2 Animal Diseases in Economic Ranking

2.2.1 Trypanosomiasis. This one disease carried by the tsetse fly occurs in 60% of the country. Although long-term control must be achieved through tse'se control and eradication, this is quite impossible to contemplate at the present time for economic reasons.

However, animals can be protected against the disease carried by it by the use of Trypanocides, mainly Samorin, Berenyl and Novidium. Calculating the cost of the drug at Tsh. 16 per beast per year, the value of each beast saved would pay for the protection of 500. (Taking the average animal value at Tsh. 8,500).

2.2.2 Tick-borne Diseases. Although these include anaplasmosis, piroplasmosis and East Coast Fever (ECF) it is really the ECF which causes the most serious economic loss. The disease is carried by the three host tick Rhipicephalus appendiculatus which occurs widely in Tanzania. Unless animals at risk are dipped weekly, ECF which causes a high mortality in calves and exotic stock (even 50-100%), begins to occur. It is calculated that over 250 animals could be dipped for a year (in terms of ascaricide) for the cost of one animal saved.

2.2.3 Helminthiasis. Trematodes, cestodes, and nematodes in particular are common and cause losses in young animals, sheep and goats. Their effects are insidious and cause losses in production, but acute diseases will also kill young animals.

The production losses caused by these parasites must be in excess of 5% of production overall.

2.2.4 Bacterial diseases

In order to forecast future requirements for veterinary vaccines it is important:

(i) to consider the most important bacterial and viral diseases and the measure adopted for their control and,

(ii) to assess the number of livestock potentially at risk.

Among the diseases of bacterial ethiology:

Blackquarter/Blackleg caused by Cl.chauvoei, is considered to be the most important. It mainly affects cattle and much less frequently sheep. It is endemic in the country causing high mortality in infected animals. However due to a lack of diagnostic facilities its true economic significance cannot be assessed with any degree of certainty.

The official control policy of this disease is annual vaccination of all commercial cattle (ie, dairy and grade beef) and approximately 50% of cattle in the traditional sector.

This policy would appear to be adequate providing vaccine, intended for the traditional sector, is used very extensively in locations where the disease is known to occur. In other areas it should be used as ring vaccination around a new outbreak.

Anthrax caused by Bacillus anthracis is ranked as the second most important bacterial disease. It affects a wide variety of animals as well as man. Among the domestic animals cattle, goats and sheep are most frequently affected. It occurs sporadically across the country and is seen more frequently with the onset of the rainy season.

The official control policy is the same as that adopted for the prevention of Blackquarter but additionally some 10% of goats are also targets for vaccination. The shared vaccination policy with Blackquarter stems from the availability of a combined Blackquarter/Anthrax vaccine (Blanthax) which is much favoured for its efficacy and simultaneous applicability.

This policy is not ideal unless it is born in mind that vaccination against Anthrax is most effective when in heavily infected areas every animal at risk is vaccinated yearly until no anthrax death is diagnosed in that location for at least 3 to 5 years, when vaccination can be relaxed.

Haemorrhagic septicaemia caused by P.multocida serotype E, is believed to occur in many parts of the country. The outbreaks tend to be seasonal with the onset of rains. It mainly affects cattle and, in susceptible populations, mortality rates may be high. Due to the shortcomings of diagnostic facilities the true extent and economic important of this disease, like that of many other diseases, cannot be assessed reliably.

For the control of the disease vaccination of all cattle in areas where it is known to occur is advocated. An estimated 2-3 million head of cattle is thought to be at risk.

Assuming that the disease is as important as it is thought to be, this vaccination policy would be adequate providing vaccination is carried out on a campaign basis soon before the seasonal outbreaks of the disease is expected in the region. This is of great practical importance since protection, conferred by conventional inactivated whole culture vaccine, adjuvanted with aluminium salts, is not affective for more than 3-6 months on the whole.

Establishment of the true importance of this disease in the country may lead to a change in vaccination policies.

Bovine brucellosis caused by Br. abortus is one of the important causes of abortion in cattle, often associated with temporary infertility due to secondary infection of the genitalia. In dairy herds abortion may also reduce milk yields. Apart from the potential economic importance it is also zoonotic causing a highly dangerous disease, undulant fever, in man.

Although it is considered to be an important disease its true economic significance is not known. It may be pertinent however that in neighbouring Kenya an earlier survey of the disease in traditional herds found over 4% of females with titres indicative of natural infection (Nagy et al, 1969. Vet.Rec. 84, 65).

Currently adopted policy for control of the disease is calf-hood vaccination (betwee 4 and 8 months of age) for all female calves in dairy and grade beef herds using the live S19 vaccine.

This policy is adequate for the commercial sector until eradication of the disease may be considered. However, the same policy should be gradually extended to calves in the traditional sector, which would increase demand for the vaccine over tenfold.

2.2.5 Viral diseases

Of the viral infections:

Rinderpest is a highly contagious disease of cattle caused by a morbilli virus. In susceptible population mortality of infected animals is near 100%. Despite the existence

of effective live attenuated vaccine, due to economic and political difficulties, the disease is widespread in Africa. The last outbreak in Tanzania occurred in 1983-84 (before that in 1964)) first in wildlife which spread to Massay cattle. In 1985 the country resorted to mass vaccination. Due to late start of the vaccination campaign in that year, only 39% of cattle was vaccinated. In 1986 the aim is to vaccinate most of the national herd using 10 million doses of the vaccine. The campaign is to be maintained for two more years, using 10 million doses p.a. After that only yearlings shall be vaccinated (two injections) for three years.

Control of Rinderpest is subject of a Pan-African Rinderpest Campaign. It envisages erradication of the disease based on the following conditions.

(1) 100% or near 100% vaccination coverage of all cattle over a 4 year period. During that time every animal must be vaccinated twice in consecutive years. This is followed by calf vaccination for 3 years.

(2) Following this "vaccination phase" a "Consolidation phase" should follow lasting for six years. This phase would include setting up of control systems in enzootic areas ie. constant vigilance for outbreaks with a "stamping-out" policy in case of an outbreak plus vaccination of calves in the outbreak area for one year. This is coupled with ring vaccination of trade and nomadic cattle.

The policy adopted for the control of Rinderpest in Tanzania is in accord with the Pan-African policy provided that the "consolidation phase" shall be strictly observed.

Foot and Mouth disease is regarded as the second most important viral disease of cattle in the country. It is endemic in most regions and occurs every year. It causes a loss of condition, decrease or cessation of milk production, abortion and death is severe cases, particularly in young animals. Due to the relatively low mortality rates with this disease its economic importance is much underestimated in the traditional sector of the livestock industry.

For the control of the disease government policy includes twice a year vaccination of all dairy and grade beef cattle. Additionally once a year vaccination of trade stock (ie. cattle on the move, ca. 3% of total population). In case of an outbreak a "stand-still" order comes into force (limiting the movement of animals in or out of the zone of outbreak) in combination with ring vaccination of cattle in and around the area of the outbreak.

Whilst these policies and control measures may be adequate for the prevention of a major epizootic it cannot prevent the disease occurring sporadically.

For that end the same vaccination policy, adopted for commercial cattle, would have to be extended to cattle in the traditional sector. In addition importation of livestock from countries where the disease is known to occur should be prohibited and "buffer zones" of suitably vaccinated stock maintained in border areas endangered from neighbouring countries.

Lumpy Skin Disease is a malignant pox of cattle and has become a cause of increasing concern in recent years, not only to the veterinary profession but to livestock owners even in the traditional sector. Losses caused by the disease stems partly from the loss of condition and milk yield during the clinical phase of the disease and partly to the damage to the skin which can be so extensive as to ruin the hide.

Official policy for the control of this disease is vaccination of all dairy and grade beef cattle and cattle in the traditional sector on request. This may amount to 5% of traditional cattle.

Whilst extensive vaccination of cattle in the commercial sector is adequate, scanty and unplanned use of the vaccine in the traditional sector is clearly leaves much to be desired.

This disease is a vector-born disease spread by blood-sucking insects. Therefore it is important that affected animals are segretated sufficientlv from others, not to be a source of infection. All cattle in the same herd and, preferably is in nearby herds, should also be vaccinated at the first sign of an outbreak.

Rabies has been on the increase in recent years and is of major concern, not for its effect on livestock productivity but for the danger to human population.

Control policy is yearly vaccination of all dogs and cats in the country, free of charge.

This should be coupled with some means of indentification of certification of vaccinated animals, which has not been practised.

Newcastle is by far the most important of poultry diseases causing considerable losses especially in commercial flocks.

Government policy is to encourage vaccination of all commercial layers and stock birds three times p.a. on average, and all broilers once when a day old.

This policy should be extended so that every day old chick before leaving the hatchery should be vaccinated, followed by a second vaccination for broilers and three more vaccinations for layers and stock birds. This policy would be more readily executed if vaccine for purchasing was available together with the chicks. In the traditional sector, where the disease is of lesser importance, ring vaccination should be adopted in case of outbreaks so as to stop the spread of the disease.

Marek's disease is of considerable importance in the country, Control policy is vaccination of day old chicks intended for layers.

This policy should be extended to all day old chicks before leaving the hatchery.

Fowl Pox is the third of the economically important viral diseases of the poultry industry. Government policy only covers birds in the commercial sector where vaccination of layers and stock birds is encouraged at 10 weeks of age. Introduction of non-parental route of vaccination (in drinking water)at a very early age (day-old) makes it easier to extend vaccination so as to include all chicks leaving the hatcheries. Those birds, however which become layers or stock birds wold require a booster dose of the vaccine later in life.

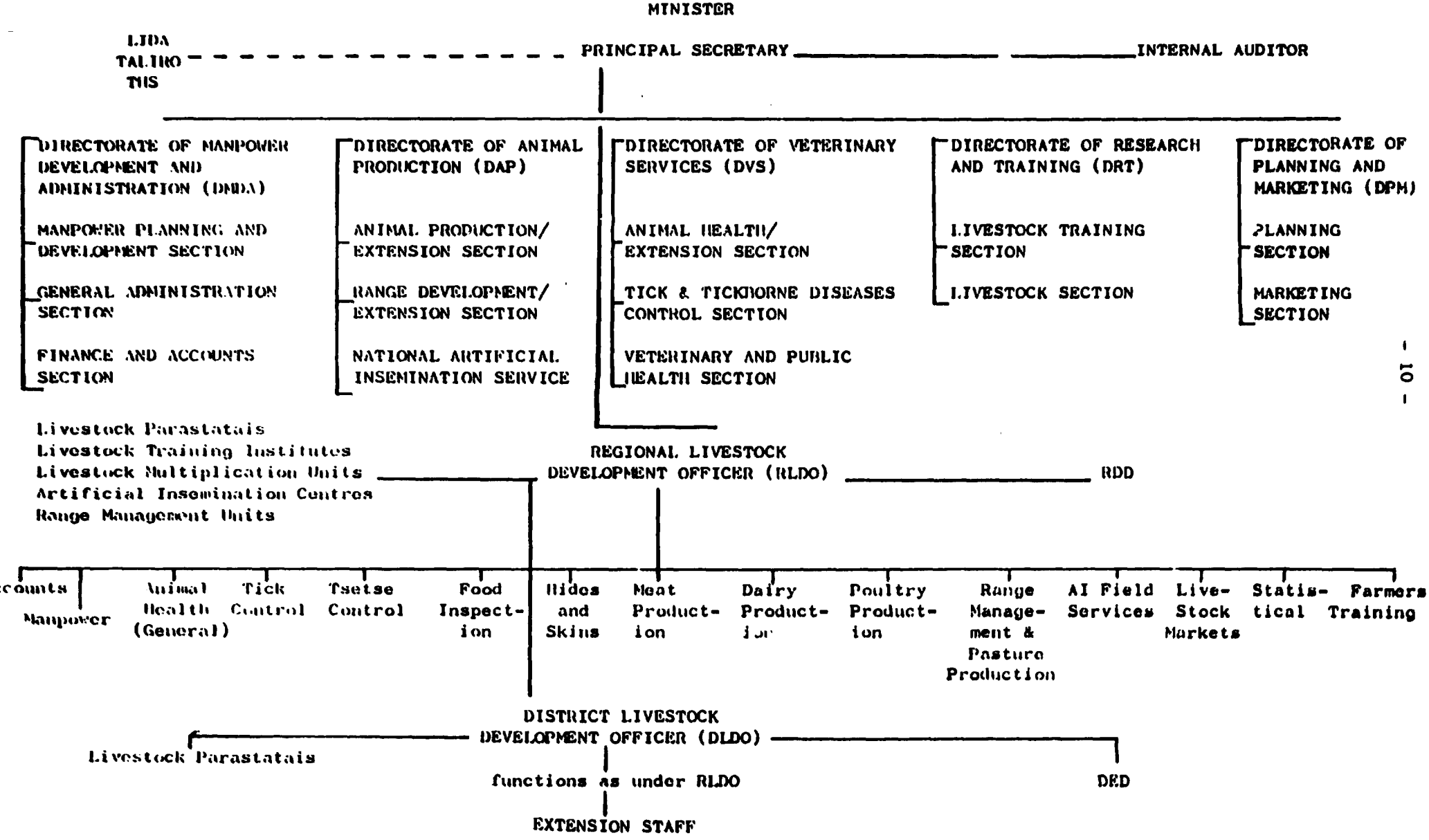
Although government adopted policies and preventative measures for the control of bacterial and viral diseases of livestock are adequate (with those exceptions noted in connection with each disease) execution of these measures leaves much to be desired. It may be stated that hardly any of the vaccination policies are fully implemented. This observation will be borne out by a comparison of actual vaccine usage, and the requirement to meet the demands of policies, if fully executed. Perhaps the only exception at the present time is the Rinderpest vaccination campaign, where adequate vaccine is available from France, purchased by donation of EEC countries. In contrast, less than half of the dogs in the country and hardly any cats are vaccinated against Rabies. By far the most important reason for the shortfall of implementation of vaccination policies is a severe shortage of funds, not only for the purchase of vaccines, but for their administration via the extention services.

3. ORGANISATION OF VETERINARY SERVICES

These come under the principal secretary, Ministry of Livestock Development (Table 1).

TABLE 1

ORGANISATION STRUCTURE AND FUNCTIONS OF THE MINISTRY OF LIVESTOCK DEVELOPMENT (MLD)



4. VETERINARY DRUG AND VACCINE MARKET (1985/86) AND ESTIMATED FUTURE REQUIREMENTS (1990 and 2000)

4.1 Virtually all veterinary medicines are imported into Tanzania by the Ministry of Livestock Development who are also responsible for their distribution and use. A nominal charge on all drugs and medicines (except Rinderpest vaccine) is made on the owner.

Additional drugs can be imported by NAPCO (National Pharmaceutical Company) when foreign exchange controls permit.

These are for the private sector such as poultry raising and cattle ranching, but private imports only amount to about 10% of current importations at present.

The Tanzanian Pharmaceutical Market

Although the year-to-year importations have vaired enormously depending on foreign exchange availability, the ratio of the principal product areas remain roughly similar. An approximate breakdown being:

Product	Units	Value (US $000's)
Ectoparasiticides	Litres	
Toxaphene	2,600,000	2,900
Delnav	80,000	600
Antiprotozoan	Doses	
Samorin	2,100,000	1,050
Berenyl	300,000	150
Antibiotics	Doses	
Tetracycline	5,000,000	1,400
Other (Pen/Strep)	1,250,000	160
Anthelmintics	Doses 325,000	65
Minerals, vits. etc.	N.A.	110

4.2 The requirement for drugs

In the recent past the range and quantity of drugs used has been dictated by the availability of foreign exchange for drug purchase. Repeatedly, the drugs obtained were less than those required, sometimes with disastrous effects (eg., deaths from Trypanosomiasis rising to reported 27,800 * following a shortage of trypanocides one year).

Estimates of drug usage and projections for 1990 and 2000 are attached. (Table 2)

On the basis of the historical value of drug and vaccine importation over recent years and the projected requirement to the year 1990 (demand forecast) the shortfall is at least 50% of requirements. However it is doubtful whether the extension services could utilise such an increased availability to the maximum advantage.

Furthermore, estimates for acaracides (amounting to some 50% by value of all the drugs used) have been based on the continued use of Toxaphene. This is now banned in most countries, and parasite resistance is bound to emerge in Tanzania. Provision has been for changes in acaracides in forward projections, which have a highly significant effect on anticipated drug costs.

* More than 20 times the reported average for the decade 1970-80.

TABLE 2

ESTIMATES OF VETERINARY DRUG REQUIREMENTS IN TANZANIA

DRUG/BIOLOGICAL	YEAR 1986		1990		2000	
	Units	Value	Units	Value	Units	Value
		(Values US $000's without inflation)				
Ectoparasiticides (Immersions)						
Toxaphene	130 M*	2,900	100 M	2,200		
O.P.	6 M	600	100 M	10,000	150 M	15,000
Amidine/pyrethroid					100 M	10,000
Endoparasiticides	1,200,000	250	2,400,000	500	4,800,000	1,000
Antibiotics (Doses)		1,500		2,000		3,000
Tetracyline	3,000,000		6,250,000		9,400,000	
Other	1,250,000		1,550,000		2,300,000	
Antiprotozoans						
Samorin	2,000,000	1,000	4,000,000	2,000	6,000,000	3,000
Berenyl	300,000	250	1,550,000	500	900,000	750
Sutelex				100		500
Others Minerals Vitamins etc.		150		200		250
Total		6,750		17,500		33,500

* M = million units

4.3 Current Use and Estimated Optimal Requirements for Vaccines

In preparing these estimations, it was assumed that adequate vaccines were available for use and correct vaccination policies adopted for their application. In Annex 2 estimated national requirements for years 1990 and 2000 are presented together with use of these vaccines during recent years.

Blackquarter

To carry out government policy of vaccination of all dairy and grade beef cattle, in addition to vaccinating approximately one half of cattle in the traditional sector, 6.8million doses of the vaccine would be required by 1990 increasing to 7.5million doses by 2000. This compares to the use of 1.5million doses in 1985/86 and to a demand forecast for 5.0million doses for 1986/87. The difference between recent usage (1.0-1.5million doses p.a.) and the demand (6.8-7.3 million doses p.a.) implicit in the vaccination policy is well over 5.0million doses. Even at $0.06 per dose the cost of 5.0million doses is $300,000, equivalent to the price of 1200 head of cattle at $250 per head. The question arises, are the losses, due to this disease, in proportion to the cost of the vaccine, which is only a part of the cost of vaccination. The answer to the question can only come from much improved diagnostic services.

Anthrax

The current concept of using anthrax vaccine, much the same way of using Blackquarter vaccine, needs to be revised. Vaccinating animals in affected herds or even limited ring vaccination, leads to preventing losses in that small locality but does not reduce disease incidence in the larger region, therefore vaccination must be maintained indefinitely. Vaccination against this disease is most effective when applied to all susceptible animals in large regions for as long as there is any death due to the disease. This normally takes from 3 to 5 years, after which vaccination can be relaxed. Application of this vaccination policy calls for monovalent vaccine and use of the bivalent Anthrax-Blackquarter vaccine is only justified when both diseases occur in the same region. To meet the demands of this vaccination policy it is estimated that ca. 7.5million doses would be required by 1990 increasing to 8.3million by the end of the century. Such judicious and extensive use of the vaccine should lead to near eradication of the disease in the country with consequential reduction in demand for the vaccine.

Brucella S19 vaccine

As for S19 vaccine for the control of bovine brucellosis, if vaccination should be restricted to cattle in the commercial sector, the requirement by 1990 is ca. 82,000 doses increasing to 150,000 by year 2000. If vaccination policy is extended to incorporate the whole of the national herd the requirement increases very sharply over 1.22 and 1.31 million doses by years 1990 and 2000 respectively. In calculating these requirements it was assumed that one half of the national herd was female, calving rate was 50% ca, one half of the calves born were female and mortality rate was 25%.

Haemorrhagic septicaemia vaccine

In calculating national requirement for vaccine against Haemorrhagic septicaemia it was assumed that the disease was as important as presently perceived. A change in the perception of the significance of this disease could lead to a substantial difference in vaccination policy and reduce requirement for the vaccine from 2.5 -3.0 million doses, as indicated presently for 1990 and 2000 respectively.

Rinderpest

The need for Rinderpest vaccine remains high(ca.10million dosefor 1985/86 and 1986/87. In the ensuing years only the new calf crop needs vaccination (2.5 - 2.7 million doses). Calculating the likely number of calves requiring vaccination, a calving rate of 50% and a calf mortality rate of 25% was assumed.

Foot and Mouth Disease vaccine (FMDV)

The demand for FMDV very much depends on what particular vaccination policy is adopted for control of this disease. Using it at the present rate, between 150,000 - 300,000 doses p.a., costs $100,000 - 200,000 and it is only sufficient for the prevention of an epizootic.

Mounting a major campaign of twice a year blanket vaccination of the national herd for two years would require ca. 26 million doses of the vaccine p.a. This would have to be followed by the maintenance of a buffer zone in the border areas, in which cattle would be routinely vaccinated twice a year with the appropriate vaccine. Combined with these measures, importation of cattle and products of countries where the disease is endemic would have to be strictly controlled and a slaughter and ring vaccination policy adopted for the control of an outbreak in the country. It is highly doubtful however, if this, or any similiar measures could be introduced in the near future without major international involvement. In the meanwhile increasing vigilance for recognising an outbreak, needs to be maintained together with the typing of strains isolated from outbreaks anywhere in the region so that the appropriate vaccine may be ordered as soon as possible for ring vaccination. A strategic reserve for this and for maintenance of the buffer zones in the border areas would require ca. 9 - 10million doses of vaccine p.a.

Lumpy Skin vaccine

Use of between 0.2 to 0.73million doses of this vaccine in recent years has not stopped spread of the disease. Therefore it is necessary to extend vaccination to include not only all commercial cattle but a higher proportion of cattle in the traditional sector. Use of ring vaccination should be more promptly and more extensively applied than at the present time. It is estimated that ca. 1.0million doses of the vaccine would be required by 1990 increasing to 1.2million doses by year 2000. However these figures should be revised in the light of experience.

Rabies Vaccine

The use of 100,000 doses of Rabies Vaccine per annum has failed to prevent spread of the disease. Although the exact number of dogs and cats in the country is not known, it is thought that the use of 500,000 doses of the vaccine p.a. increasing to 700,000 by the year 2000 should be adequate. Yearly vaccination should be coupled with an extermination policy of stray dogs and of those not vaccinated.

Newcastle vaccine

Use of 4.0-5.0million doses of this vaccine p.a. was inadequate to meet the demands even of the 6.0million broilers and 1.2million layers in the commercial sector. It is therefore not supprising that Newcastle disease remained the most severe poultry disease in the country. To provide vaccine for safer vaccination policies than curently in use, in the commercial sector alone, ca. 22.6million doses of it would be required by 1990 increasing to over 30.6million doses by year 2000. These requirements depend on an annual projected increase of 2.5% and 5.0% p.a. in the number of layers and broilers respectively till the end of the century (Annex 1).It is suggested that the vaccine should be available at the

hatcheries so that its use would be encouraged beyond its first application by the hatchery.

Marek's Disease Vaccine

The problem with the use of the currently available vaccines is that they need to be administered by the subcutaneous route. New generation of Marek's vaccines are under investigation which can be applied by inhalation. Availability of such non-parenteral vaccine should greatly facilitate its popularity. To provide sufficient vaccine for chicks from the hatcheries, prinicipally going to the commercial sector, and have some vaccine also available for the traditional sector, ca. 9.3million doses would be required by 1990 going up to 13.3million doses by the year 2000.

Fowl Pox Vaccine

Vaccine of the non parenteral type is available now. This vaccine can be administered in the drinking water and may be applied before the chicks leave the hatchery. Alternatively if the vaccine is available at the hatchery, together with the chicks, it may be administered by the customer. For layers and stock birds a second dose of this type of vaccine is necessary, bringing up the requirements to ca. 13.0 and 14.0million doses by 1990 and 2000 respectively.

Use of vaccines in the past, has been erratic (Annex 2) principially because of the lack of funds for their purchase. With the exception of a small quantity (0.25 million doses) of Anthrax and Blackquarter vaccines from the Animal Disease Research Institute, all other vaccines were imported as finished products. Funds for them came from either donations (EEC, individual countries) or from the government. However, foreign exchange has not been allocated for these purchases in adequate amounts. A comparison of values of vaccine used in 1985/86 to those in demand by 1990 (at 1985/86 prices) are shown in Annex 3.

The difference is over seven and one quarter-fold. Since the requirement by 1990 is only 3% higher than at the present time, it may be concluded that, taking the money value of priority vaccines as a whole, over seven times the currently available currency would have to be made available to meet the national requirements.

5. CONSTRAINTS ON DRUG AND VACCINE USAGE

The problems are fundamental and relate to cumulative effect of under-investment in the livestock and related areas.

In the animal health area the principal constraints to profitable drug and vaccine usage include the following:

5.1 Field intelligence and diagnosis. There has been a disastrous neglect of the diagnostic services with a lack of equipment and reagents necessary to carry out an efficient service. This in turn means that it has not been possible to monitor the animal disease position accurately. The lack of help in diagnosis from the Livestock Department has an additional negative effect in that farmers are less willing to report disease, partly as they know that the necessary drugs may also not be forthcoming.

5.2 Extension services. These too have fallen into very poor conditions. All aspects are very under-resourced, with the possible exception of manpower and it is very much to the credit of all the Extension Officers that it is functioning at all.

There is a stifling shortage of basic communications, principally transport, at all levels. Maintenance of cattle dips, crushes and stockades have all been neglected and essential

support such as the ability to measure dip wash concentrates of the acaricide is often absent. Basic ancillary requirements such as water or fences are often not available, as well as simple equipment for drug administration such as syringes.

As a corollary of the lack of diagnosis and the ability to implement disease control strategies it is impossible to monitor and quantify drug resistance of parasites and changes in epidemiological patterns of infectious diseases. Even simple routine serology of the most important diseases is beyond present resources (with the possible exception of Rinderpest).

5.3 The lack of resources also make the imposition of movement control restrictions, quarantine and supervision of stock routes difficult to operate.

5.4 Distribution. Not to be overlooked is the need to re-create an efficient drug and vaccine distribution network with reliable cold stores and efficient handling facilities, with attention paid to conditions in transit of the heat-labile products.

6. PROPOSALS FOR INCREASED DRUG AND VACCINE USAGE

These depend almost entirely on foreign exchange availability and remedying the constraints listed in paragraph 5.

Until both these matters have been resolved no meaningful animal health strategy can be developed. (See paragraph 8, Recommendations).

Although the fundamental basis of animal disease control must revolve around ectoparasite control and the dip-tank network, other strategies can be built up.

In the case of infectious disease control, the national policy must fit into the regional policies where relevant. For example rinderpest and the prophylactic use of vaccine. Foot and mouth disease control must be built up on the basis of field information of the disease including typing, and the setting-up of a local serological laboratory. Once the epidemiological situation is clarified, larger quantities of vaccine can be used, concentrating on protection of improved animals and the vaccination of mobile populations.

Rabies control, too, should be tackled as part of a regional policy in view of the danger to the human population. The control of Bacterial diseases such as anthrax, blackquarter and bovine pasteurellosis should form part of the overall animal disease control strategy established on the basis of improved diagnosis and field information.

Trypanosomiasis control is such a mammoth undertaking that little can be said in this report other than to support the use of more prophylactic therapy as a stop-gap measure pending definitive solutions.

7. CONSIDERATIONS FOR LOCAL MANUFACTURE

7.1 Pharmaceuticals

A detailed study has recently been carried out by TISCO a local firm of business consultants.

In this, they have considered the possibility of local production of veterinary pharmaceuticals at the two human pharmaceutical plants, Keko outside Dar es Salaam and Tanzania Pharmaceutical Industries at Arusha.

7.1.1. The Keko plant is rather old and already committed to other uses. (Annex 6)

7.1.2 Tanzania Pharmaceutical Industries

Location, site, buildings, services and utilities. TPI is situated on the outskirts of Arusha in an Industrial complex well served with roads, rail and air communications.

There is reliable water and electricity supply. Imported raw materials can be brought by rail from Tanga.

The site is some 100,000sq. metres, gently undulating and is well drained. (See site plan, Annex 7).

The main production area is approximately 65 metres square with adjoining warehouse, cool store and cold store. Also on site are control laboratory, maintenance workshop, laundry, boiler, canteen, office block, gate house and stand-by generator. There is ample space for a separate veterinary pharmaceutical production area and inflammables store.

The central utilities (steam water, deionised water, compressed air, electricity etc.) are supplied via an underground tunnel to the main production areas.

7.1.2.1 Manufacturing Standards

The manufacturing standards are in line with those set out in the Guide to Good Pharmaceutical Manufacturing Practice (1983).

7.1.2.2 Production Specifications

Product Range	Capacity p.a. 000's
Tablets (pieces)	420,000
Capsules (pieces)	75,000
Granules (bottles)	4,000
Mixing (for tablets Kg)	460
Liquids (litres)	140
Injectables (litres)	12

A range of antimalarials, antibiotics, analgesics, expectorants, antacids and vitamins is produced including sterile solutions and suspensions for injection.

7.1.2.3 Technology

The technology is modern Western European provided under a Technical and Management contract by M/S ORION of Finland.

7.1.2.4 Plant and Equipment

The plant and equipment is of good European origin and has been correctly installed and maintained (Annex 8).

7.1.2.5 Warehouse and distribution

There are well organised warehouse facilities with due segregation of Goods Inwards, Materials Pending and Finished Products. There are also ample cool store and cold store facilities and good road and rail communications.

7.1.2.6 Staffing and qualifications

TPI has an organisational structure consistent with Good Pharmaceutical Manufacturing Practice. Key professional staff have been trained in Europe and foreign specialists are still providing additional assistance.

Discussion

There is no doubt that it would be advantageous and teachnically feasible to manufacture Veterinary Pharmaceuticals at TPI, from the point of view of sharing overheads, management, services, utilities etc.

Also there could be some synergism between trained staff performing similar functions.

However there are a number of important points to be borne in mind.

1. The economic and marketing data presented in the TISCO report are no longer valid as the marketing projections were based on assumptions now known to be invalid, and all foreign currency elements (including raw materials) have to be revised in the light of the recent devaluation of over 100%.

2. Any recommendation to invest in Veterinary Pharmaceutical Production at TPI must be within a long-term technology and management contract with an appropriate foreign organisation.

3. Together with the commitment to capital investment for construction, commissioning and staffing the facilities, must be the commitment to foreign exchange for the purchase of raw materials, spare parts and foreign technical assistance for a protracted period.

4. The decision to invest in local Veterinary Pharmaceutical Production in Tanzania must depend on the appropriate measures to be taken to remove the present constraints on drug usage. (See Chapter 5 above).

Two private companies in Tanzania have expressed interest in the local production of veterinary pharmaceuticals and should also be considered, especially as recent Government policy stresses the importance of the private industrial sector. One laboratory had already carried out a survey on the Commercial Veterinary Markets in Tanzania and a full costing and feasibility study for local manufacture.

It also has technical links with an overseas Pharmaceutical Company.

It is suggested that the importance of Veterinary Medicines in Tanzania should be looked at, not so much in the profit and loss of the Pharmaceutical Industry but in its contribution to animal health in the national herd.

The combined effects of lack of water, malnutrition, poor pasture management and animal husbandry, and constant disease losses are resulting in a slowing of the growth rate and productivity of the livestock industry in Tanzania.

Only improved animal health care for these four major constraints can yield short term benefits. With the prospect of importing over 100,000 tons of beef annually to maintain 1980 beef consumption levels in the human population, it would appear that a crash campaign to develop animal health is a virtual necessity. Should this policy be adopted, then all the necessary aspects would have to be catered for.

It is in this context that the value of veterinary medicines should be judged.

The TPI plant at Arusha is suitable for the production of those veterinary drugs proposed in the TISCO document but further thought should be given to the 70% by value of drugs which are not included (Trypanosides and ectoparasiticides) and up-grading of the product range in due course.

The most compelling reasons for local production are to develop national industry, to introduce new technologies, to develop national trained staff and to play an active part in the support of an industry of critical national importance - the livestock industry.

Short-term commercial benefits should not be expected. On no account should the establishment of a National Veterinary Pharmaceutical Industry be prejudicial to the livestock industry in terms of cost, quality or availability of Veterinary Medicines.

7.2 Biologicals

At the present time there are two establishments in the country which warrant consideration for this purpose (i) Mabibo and (ii) Animal Disease Research Institute.

(i) Mabibo

Located some 15km from the centre of Dar es Salaam was established in 1971 for the production of Smallpox and BCG vaccines. Production of smallpox vaccine came to an end in 1978 when WHO declared that smallpox was globally eradicated. The production of BCG vaccine to WHO standards never succeeded and was eventually abandoned in 1982.

In 1980, Mabibo was handed over to National Chemical Industries (NCI) with a view of rehabilitation/re-orientation. In 1984 it was considered as the most suitable solution for housing the Extended Program of Immunisation (EPI) in Tanzania and in October of that year all but three of the buildings were handed over to the Ministry of Health for the use of EPI.

EPI had had plans for adaptation of all the buildings and consequently in July of 1986 the last three of the buildings were handed over by NCI for the use of EPI (Source of information: Dir. of Finance and Planning NCI).

Although the whole of the Mabibo Institute has found an alternative use, and consequently is not available for vaccine production any longer, one half of the 12 hectar area is available for future development.

(ii) Animal Disease Research Institute (ADRI)

Near Dar es Salaam is the only establishment where a very small quantity of each of the two vaccines for veterinary use have been produced, the only vaccines of any kind produced in the country.

In 1970 it was decided that veterinary vaccines should be produced in Tanzania. On the grounds of ADRI a building was erected between 1971-75 for that purpose and some equipment was provided by GTZ. In 1973 a veterinarian from Burundi was engaged and between 1975-77 worked on the development of Anthrax, Blackquoter and Fowl typhoid vaccines. This work was taken over in 1977 by the present head of vaccine production who completed development of Anthrax and Blackquoter vaccines and production started in late 1980.

Since then between 0.15-0.25million doses of each of these two vaccines have been produced per annum. Although somewhat larger quantities of them could be manufactured within the existing facilities and currently used technologies, but significant extension of production is bared by the lack of space for expansion and the fact that ADRI is a research orientated establishment.

Although the site and building at ADRI are not appropriate for the expansion of vaccine production in Tanzania, the staff, expertise in production and quality control and, in a much smaller degree, equipment, would have a significant bearing on future developments of production of veterinary biologicals. For that reason only these two requisits of vaccine production shall be described and discussed here in some detail.

Staffing consists of an Officer in Charge (Doctor of Vet.Med) who spent three months at the Commonwealth Serum Laboratories, Melbourne, and six weeks in Mapato, Mozambique, studying vaccine production methodology. In addition he has been responsible for completing development work on the two existing vaccines and for their production and quality control since 1980.

He is aided by four technicians with diplomas in laboratory technology (a four year, full-time course) and three auxilliary staff without formal qualifications. Practical experience of staff is confined to that associated with production of the two vaccines.

Undoubtedly one of the major obstacles of expansion of vaccine production in the country is the scarcity of suitably qualified staff. Curriculum for a diploma course in microbiology and immunology is medically orientated and graduates find employment in the health services. There is no scope for technical training in vaccine production other than what is offered at ADRI which is clearly very limited in every sense of the word. Thus training at the present time can only be acquired abroad in the face of a lack of incentives for industrial manufacturers to provide training. Unless a way can be identified by which a well established industrial manufacturer of biological products finds it in its own interest to accept trainees, the problem of a lack of qualified staff remains.

At ADRI all aspects of vaccine production, including media preparation, production of cultures, blending and filling of vaccines and quality control are carried out by the same staff. All aspects of production relys on very basic technologies employed in a small building containing a few "general purpose" laboratories in addition to media preparation room, a walk-in incubator, small cold room, some offices and a store room.

Preparation of Anthrax Spore Vaccine

Aims to meet the Standards of the Brit. Vet. Codex. 1965.

The avirulent B.anthracis is grown on Tryptone yeast extract medium in Roux flasks. Twenty flasks would represent a typical batch and 3 to 5 batches p.a. may be produced. Each Roux flask yields 2000-3000 doses and the yearly output varies between 150,000 to 250,000 doses. (Detailed description of production and quality control are appended as Annex 4).

Briefly, Original Culture of B.anthracis $34F_2$ was obtained from Weybridge, England from which a Master Seed Culture (Seed Lot Culture) was prepared and lyophilised. From Master Seed Culture, Production Seed Culture is prepared which is used for the inoculation of production cultures in Roux flasks. Each of 20 or so Roux flasks is inoculated with ca. 5ml of Production Seed Culture and incubated at 37°C for up to 7 days. From the 4th day of incubation growth from some of the flasks are sampled and tested for sporulation. When it exceeds 60% (usually 6th-7th day) growth is harvested and two pools of harvests formed. If these are pure they are pooled and inactivated by the addition of twice its own volume of glycerol and incubated at 37°C for 2 days. Following spore counts the spore suspension is diluted in saline-glycerol mixture (containing 0.5% saponin) to give 1×10^7 spores per 1ml dose and filled out in glass containers of 100 or 150 doses per pack.

The following comments and suggestions are offered:

(1) Production of this vaccine in Roux flasks involves a great deal of handling and therefore it is very laborious and runs a high risk of contamination. Since the size of a batch is also limited by this propogation technique the cost of quality control is proportionately high. To meet the country's requirement for this vaccine it would need to be produced by more modern and economical large scale technology.

The Quality Control and tests employed would require the following modifications to satisfy Brit.Vet.Codex and WHO requirements.

(i) The Master Culture (prepared from Original Seed) would need to be tested (in addition to identity and purity tests) for Safety in Sheep (WHO Tech.Rep.Ser.No.361. 1967, p.36), Immunogenicity (WHO Tech.Rep.Ser.No. 361, 1967 p.38). These later two tests are statutory tests and may be satisfied by applying them to the first production batch of the vaccine prepared with the new Master Culture.

(ii) Culture should be harvested when sporulation is in excess of 80% (rather than 60% as presently used).

(iii) Bulk vaccine is currently tested for extraneous organisms on nutrient agar and Sabouraud medium. The former (used for the detection of contaminating bacteria) should be replaced with Thioglycollate broth (B.P. (Veterinary) 1985, App.XVIA, A126) supplemented with 2% agar.

(iv) Filling lot should also be tested for number of culturable spores and stability.

(v) In the course of the guinea-pig potency assay only a single inoculation can be given (not two) and the challenge culture should be standardised to 200 MLD_{50}.

Preparation of Blackquarter Vaccine

Aims to meet the requirements of the Brit.Vet.Codex 1965.

The vaccine is produced in a liver-meat broth in glass bottles each containing 10L medium. Two strains of Cl.chauvoei isolated locally and one strain imported from Ethiopia are used for production. A strain imported from Mozambique is used for challenge culture in the potency assay. For the production of 150,000-250,000 x 2ml doses, 300-500L of Cl.chauvoei culture is produced p.a.

For details of production and quality control see Annex 5.

Briefly, the Original Cultures, whether imported or locally isolated, was inoculated each into a host animal which was killed in extremis. Some of its muscle tissue was sliced in strips and air dried before storing it in glass bottles at room temperature serving as Master Seed Culture (equivalent of Seed Lot in a Seed Lot System). From muscle tissue Cl.chauvoei is isolated on blood agar to serve as inoculum for Seed Culture then Production Seed Culture to inoculate the Production Culture in 10L bottles. These are incubated at 37°C for 7 days before inactivation with 0.5% formalin. Suitably inactivated strains are adjuvanted with 1% potassium aluminium sulphate to give single strain vaccines made up of a number of ca. 10L aliquotes. These are sampled to form an experimental blend which is tested. Pending on satisfactory tests these are used for blending the bulk vaccine which consists of equal parts of the imported Ethiopian strain and one or other of the local strains depending on the destination of the particular batch in the country. A filling lot consists of 20L bulk filled out semi-automatically into 50 dose glass bottles and plugged and crimped by hand. Release depends on suitable sterility test on a 2% sample of a filling lot.

The following comments and suggestions are offered:

(i) Preparation and maintenance of Master Seed Culture in the form of dried muscle tissue is undesirable since it cannot be adequately standardised. It should be replaced by a lyophilised or meat broth culture stored at 2-8°C. Such a culture would require all the tests appropriate to a Master Seed Culture (equivalent of Seed Lot Culture) (purity, identity, viability, safety and potency).

(ii) Current production technology involves a lot of handling and therefore it is labour intensive and is prone to a high risk of contamination.

(iii) The batch size is also limited by same technology making quality control proportionately more expensive.

(iv) Yield of immunogens is also on the low side and would require improvements.

(v) These shortcomings can be eliminated by the adaptation of fermentation technology.

Quality control and tests employed would benefit by the following changes:

(i) Master Seed Culture should be changed and tested on lines already indicated.

(ii) Adoption of Master Seed Culture (as above) would make biochemical tests of Seed Culture unnecessary.

(iii) Sterility test/2 employed on inactivated single strain cultures is inadequate and should be replaced by the direct inoculation method (B.P. Veterinary 1985, App.XVIA) using Robertson's meat broth and Soyabean casein digest medium.

(iv) Final Bulk vaccine should be tested for Sterility (B.P. Veterinary 1985, App.XVIA), Safety (B.P. Veterinary 1985, p.159), and Potency (B.Vet.Code. 1970 Supplement p.116).

(v) Potency test as used presently would need to increase the number of control guinea-pigs from 2 to 5 and demand 100% survival of vaccinates (instead of 80%) for a "pass".

Discussion

From the foregoing description of production methods and testing it is apparent that it is not only small scale but also relys on outdated and uneconomical technologies requiring not so much changes and adjustments but complete replacement if it is to meet even some of the country's demand for veterinary vaccines.

However, apart from manufacturing, there are other means of acquiring vaccines to meet the country's demands. These are:

(i) importation of finished products

(ii) importation of bulk concentrates for local formulation

(iii) local production

(iv) a combination of (i)-(iii).

(i) Apart from the local production of small quantities of Anthrax and Blackquoter vaccines, importation of finished products has been the practice in the country. This has not found favour because it is regarded as the most expensive way of procuring vaccines, combined with chronic shortage of foreign exchange for vaccine purchases; implicit dependence on external supplies, and it tends to inhibit development of new skills and technologies.

(ii) Importation of bulk concentrates for local formulation would offer a number of advantages which would not only answer some of the objections leveled against importation of finished products, but would also have a certain logic from the point of view of development. It would help to save some foreign exchange, but more importantly it would offer opportunities of developing new skills and experience in some aspects of vaccine manufacturing, especially if combined with establishment of Quality Control. Successful establishment of local formulation and quality control would serve as a most valuable basis for the development of

(iii) local production of vaccines, with its greater demands on resources, technologies and expertise. However, even local production of veterinary vaccines may not

provide every kind of vaccine that may be necessary and

(iv) a combination of local production with some importation of bulk or finished vaccines would be still called for.

Tanzania's requirements for the four priority bacterial vaccines (Anthrax, Blackquarter, Brucella S19 and Haemorrhagic septicaemia) are very great due to the fact that its cattle population of 12.5million represents almost 46% of cattle and its 10.5million sheep and goats 60% of those in the whole of SADCC.

At the present time there are no realistic grounds for the large scale production of vaccines to internationally recognised standards. However, to aid the country to become self sufficient at a later date (perhaps during the last decade of this century) in high volume, low technology bacterial vaccines, it is suggested that, as a first stage, local formulation of bacterial vaccines from imported bulk concentrates should be established together with establishment of appropriate quality control laboratory.

8. RECOMMENDATIONS

8.1 An integrated animal disease control plant should be drawn up starting with the re-establishment of an effective diagnostic service, followed by disease monitoring and quantification.

Veterinary infrastructures and all aspects of extension services should be built up, paying attention to training, repairs to dips, transport, communications, storage and distribution, monitoring of drug concentrations and parasite resistance etc.

8.2 Within this overall strategy, the plans for local veterinary pharmaceutical and biological production should be included, so as to come on-stream with appropriate quantities and quality of products in phase with the maximum growth of the animal health market.

8.2.1 Productionof large demand bacterial vaccines should be established through a progression of development phases.

In Phase 1 establishment of a blending-filling-packaging unit (utilising imported antigen concentrates) and Quality Control Laboratory is recommended.

In Phase II production of bacterial biologicals is established and Quality Assurance, Quality Control Laboratories expanded.

ANNEX 1

Estimated number of livestock and poultry and projected increases (1978 - 2000)

	Numbers (000)		% Annual Changes		Projected increases(000)	
	1978*	1984*	Past*	Projected	1990	2000
Cattle						
Traditional	11,929	12,161	0.47	0.70	12,672	13,559
Dairy	96	139	7.50	6.00	189	302
Commercial beef	N/Av	149	N/Av	2.00	167	200
TOTAL	12,025	12,449	0.59	0.77	13,028	14,061
Goats	5,500	7,000	4.50	2.50	8,050	10,176
Sheep	3,565	3,500	-0.30	1.00	3,710	4,081
Poultry						
Traditional	15,500	18,000	2.60	2.50	20,700	25,875
Layers	1,000	1,200	3.30	2.50	1,476	1,815
Commercial Broiler	3,500	6,000	11.80	5.00	7,800	11,700
TOTAL	20,000	25,000	4.16	3.20	29,976	39,390

* 1978 and 1984 Livestock census

ANNEX 2

Recent usage and estimated national requirements for priority vaccines (Tanzania 1984 - 2000)

Vaccines	USED (000 doses) 1983/84	1985/86	ON ORDER (000 doses) 1986/87	ESTIMATED REQUIREMENTS (000 doses) 1990	2000
Anthrax	973	1500	5000	7461	8298
Blackquarter	106	1500	5000	6800	7539
Brucella S19	20	0	80	1221	1318
Haemmorr. Septic	10	0	50	2500	3000
Rinderpest	5500	4856	10000	2500	2700
FMDV	156	300	150	9000	10000
Lumpy skin	N/Av.	732	740	990	1180
Rabies	100	100	300	500	700
Newcastle	4000	5000	5000	22584	30660
Fowl Pox	1000	0	1000	10000	14000
Marek's	N/Av.	0	0	9276	13315

ANNEX 3

Values of priority veterinary vaccines used in Tanzania in 1985/1986 and that required by 1990

Vaccines	Used (000 doses) 1985/86	Price per dose (US $)	Value (US $) 1985/86	Requirement (000 doses) 1990	Price per dose (US $)	Value (US $) 1990
Anthrax	1500	0.09	135000	7461	0.09	671500
Blackquarter	1500	0.06	90000	6800	0.06	408000
Brucella S19	0	0.30	0	1220	0.30	366000
Haemorrh. sepic	0	0.20	0	2500	0.20	500000
Rinderpest	4856	0.067	325352	2500	0.067	167500
FMDV	300	0.70	210000	9000	0.50	4500000
Lumpy skin	732	0.26	190320	990	0.26	257400
Rabies	100	0.60	60000	500	0.60	300000
Newcastle	50000	0.0015	7500	22584	0.0015	33876
Fowl Pox	0	0.0082	0	9276	0.0082	76063
Marek's	0	0.0143	0	9276	0.0143	132600
TOTAL VALUES			1018172			7412939

ANNEX 4

ANTHRAX SPORE VACCINE (Live)
(Animal Disease Research Institute)

STARTING MATERIALS

1 **Master Culture**

A) Origin: B.anthracis 34 F_2 (production strain) from Weybridge U.K.
B.anthracis 17 JB (challenge strain) from Weybridge, U.K.

B) Maintenance: Lyophilised and stored at 4-8°C.

2 **Master Seed Culture**

A) Preparation

	Freeze-dried Master Culture held at 4-8°C.
	Master Culture reconstituted with Nutrient Broth.
	Inoculated on to Nutrient agar and nutrient broth.
	Incubated at 37°C for 24hrs.
Identity Purity Test	Nutrient broth is sampled and stored at 4-8°C pending on microscopic examination and purity test. If satisfactory culture is lyophilised to be MASTER SEED CULTURE.
Identity	Suitable colonies from Nutrient agar are selected and sampled.

3 Media and Solutions

3.1 Media: Tryptone-yeast extract medium containing KH_2PO_4, K_2HPO_4, Ca Cl, $MgSO_4$, $MnSO_4$, $FeSO_4 7H_2O$, distilled water. Sterilised by heat in Roux flasks, to give Production Media.

3.2 Inactivating agent: Glycerol

3.3 Preservative: None

3.4 Adjuvant: 1% Saponin (stored as 10% solution)

3.5 Diluent: Sterile saline and glycerol in equal proportions.

SCHEMATIC OUTLINE OF PRODUCTION AND QUALITY CONTROL PROCEDURES

Preparation of Seed Culture

MASTER SEED CULTURE is removed from 4-8°C.

Reconstituted in nutrient broth.

Inoculated into nutrient broth.

Incubated at 37°C for 24hrs to give PRODUCTION SEED CULTURE.

Identity Test

Purity Test

Production Seed Culture is sampled and if satisfactory used to inoculate culture medium.

Preparation of Production Culture

Suitable PRODUCTION SEED CULTURE added to Roux flasks, ca. 5ml per flask.

Incubated at 37°C for 7 days.

Test for Sporulation

On the 4th day of incubation a proportion of the Roux flasks are sampled.

After 7 days of incubation ca. 30ml of sterile saline, containing glass beads is introduced into each Roux flask and growth washed off and removed. Harvest of 10 flasks is pooled.

Test for Purity

Pooled harvest is sampled

If pooled harvest is pure contents of 20 Roux flasks, ie. 2 pools, are blended and glycerol, twice the volume of harvest, is added to cell suspension.

Incubated at 37°C for 48hrs.

Test for Spore Count

Pooled concentrate is sampled and stored at 4-8°C till required for dilution and filling out.

Preparation and testing of bulk vaccine

Pooled concentrate is removed from 4-8°C.

Pooled concentrate is diluted, in a mixture of 50% saline, 50% glycerol, to give 1 x 10^7 spores per 1ml.

Test for Purity Identity

Spore counts

Diluted bulk is sampled and kept at 4-8°C pending on tests.

Suitable diluted bulk vaccine is removed from 4-8°C and sterile saponin is added to a final concentration of 0.1% to give BULK VACCINE.

Test for Contamination

Potency

Inocuity

Bulk vaccine is sampled and stored at 4-8°C til required for filling out pending on test results.

Test for Contamination

Suitable Bulk Vaccine is filled out in 100 or 150 dose glass containers and 1% of a filling lot is taken for test.

Tests on Anthrax Spore Vaccine (living)

Identity Test

Microscopic examination of Gram stained smear.

Pass: "Typical" cell morphology.

Purity Test

Culture suspension is plated onto each of 2 nutrient and Sabouraud agar plates and aerobically and anaerobically at 37^{0}C for 24hr.

Pass: Absence of contaminating colonies.

Test for Sporulation

Smears stained by Ziehel-Nielsen stain and proportion of spore bearing cells counted and calculated.

Pass: if 60% or more of the cells have sporulated culture is inactivated after 7 days of incubation.

Test for Spore Counts

Serial doubling dilutions of pooled concentrate is prepared and 0.1ml per dilution is inoculated onto nutrient agar. After 4 days of incubation counts are carried out.

6-12 x 10^{6} spores/ml are normally found.

Test for Potency

10 healthy guinea-pigs 250-300g in weight are injected with 1ml of the vaccine S/C and 2 left for challenge control. 21 days later injections are repeated. Seven to 10 days later each of the guinea-pigs are challenged with 0.2ml of an overnight nutrient broth culture of B.anthracis 17JB.

Pass: Both controls should die but none of the vaccinates. Observed for 7 days.

Inocuity Test

Each of 2 goats are inoculated S/C with 2ml of the vaccine. Rectal temperatures are taken daily for 7 days and local reactions looked for.

Pass: No clinical signs of ill health. In case either animal fell sick test is repeated. In case of any sign of ill health on re-test, batch is discarded.

ANNEX 5

BLACKQUARTER VACCINE (ADRI)

STARTING MATERIALS

1 **Master Cultures**

A) Origin: Cl.chauvoei - Awasa strain from Ethiopia

Cl.chauvoei - Tukuyu strain from Tanzania

Cl.chauvoei - Tabora strain from Tanzania

Cl.chauvoei - Ch 22 strain from Mozambique (used as challenge culture)

B) Maintenance : lyophilised and stored at 4-8^{o}C.

2 **Master Seed Culture**

A) Preparation: Each of four strains was inoculated into experimental animals respectively which were sacrificed in-extremis and their muscle tissues were air-dried.

B) Maintenance: Each strain is kept as dried muscle tissue in glass bottles at ambient room temperature.

C) Verification (purity, identity): none carried out at that stage.

3 **Media and Solutions**

3.1 Composition: Pepsin digest of meat-liver broth, filtered and sterilised by autoclaving. Stored in 10L jars at 37^{o}C before use as production media.

3.2 Tests done on production media:

a) Sterility

b) pH adjusted to pH7.6-7.8

3.3 Inactivating agent used: 0.5% formaldehyde

3.4 Preservative in use: None. Formalin is regarded in the inactivated culture as a preservative.

3.5 Adjuvant: Potassium aluminium sulphate

SCHEMATIC OUTLINE OF PRODUCTION AND CONTROL PROCEDURES

Preparation of Seed Cultures

Master Seed Culture removed from storage at room temperature and the dried muscle is placed into nutrient broth.

Nutrient broth inoculated onto blood agar and nutrient agar.

Incubated aerobically and anaerobically for 48hrs at 37°C.

Microscopic examination of colonies BA plate

From anaerobically incubated blood agar plate colonies are selected to inoculate 5ml liver-meat infusion broth.

Biochemical tests on colonies from BA plates

Incubated at 37°C for 18hrs to give SEED CULTURE.

Test for Purity

If biochemical and microscopic tests were satisfactory Seed Culture is inoculated into 50ml of liver-meat infusion broth incul ated at 37°C for 18hrs to give PRODUCTION SEED CULTURE.

Preparation of Production Culture

50ml of suitable Production Seed Culture is added to 10L liver-meat infusion broth.

Incubated at 37°C for 7 days with periodical shaking.

Test for Purity

Sample taken on day 7.

0.5% Formaldehyde added, and shaken well.

Incubated at 37°C for 5 days.

Sterility Test/2

Inactivated whole culture held at 37°C for 3 days pending on results of Sterility Test.

Microscopic Examination

Preparation and Testing of Bulk Vaccine

	Suitably inactivated whole culture is removed from 37°C and calculated volume of potassium aluminium sulphate is added to a final concentration of 1%.
	Incubated at 37°C for 7 days.
Sterility Test/1	Single strain vaccine is sampled and stored at 2-8°C till required for blending and filling.
	Every 2nd of the 20 x 10L bottles is sampled and equal volume of each is used to make a very small trial blend of vaccine for testing.
Sterility Test/1 Inocuity Potency	Pooled sample is tested.
	10L volume of the inactivated Awasha strain of the vaccine and 10L of either Tukuyu or Tabora strains of the vaccine are poured for blending into a 25L glass container in the filling room.
	20L of the vaccine is filled into glass bottles, 100ml per bottle, semi-automatically, plugged and crimped by hand.
2 containers per filling lot is tested Sterility/1	This is considered as a filling lot and is stored (4-8°C) separately pending on results of sterility test.

Tests on BlackquarterVaccine

Sterility/1

A "small volume" each of Thioglycollate and Sabourauds media are inoculated with few ml of sample and incubated at 37°C aerobically as well as anaerobically (5-7 days) and inspected for signs of growth.

Pass: lack of visable growth.

Biochemical tests

"Fermentation tests are carried out characteristic for the strains used".

Purity Test

Blood and nutrient agar (B.A. and N.A.) plates are inoculated with sample and incubated at 37°C aerobically for 1 day and anaerobically for 2-3 days.

Pass: homogeneity of colonies.

Sterility/2

Blood and nutrient agar and nutrient broth are seeded and incubated at 37° aerobically as well as anaerobically for 3 days.

Pass: lack of visable growth.

Potency Test

Each of 10 guinea-pigs are inoculated S/C with 2ml of the vaccine and 2 are left as challenge controls. 21 days later injections are repeated and 10 days after 2nd injection guinea-pigs are challenged with an 18hr culture of Cl.chauvoei Ch22 strain using 0.2 or 0.4ml of the culture I/M depending on "the health condition" of guinea-pigs prior to challenge.

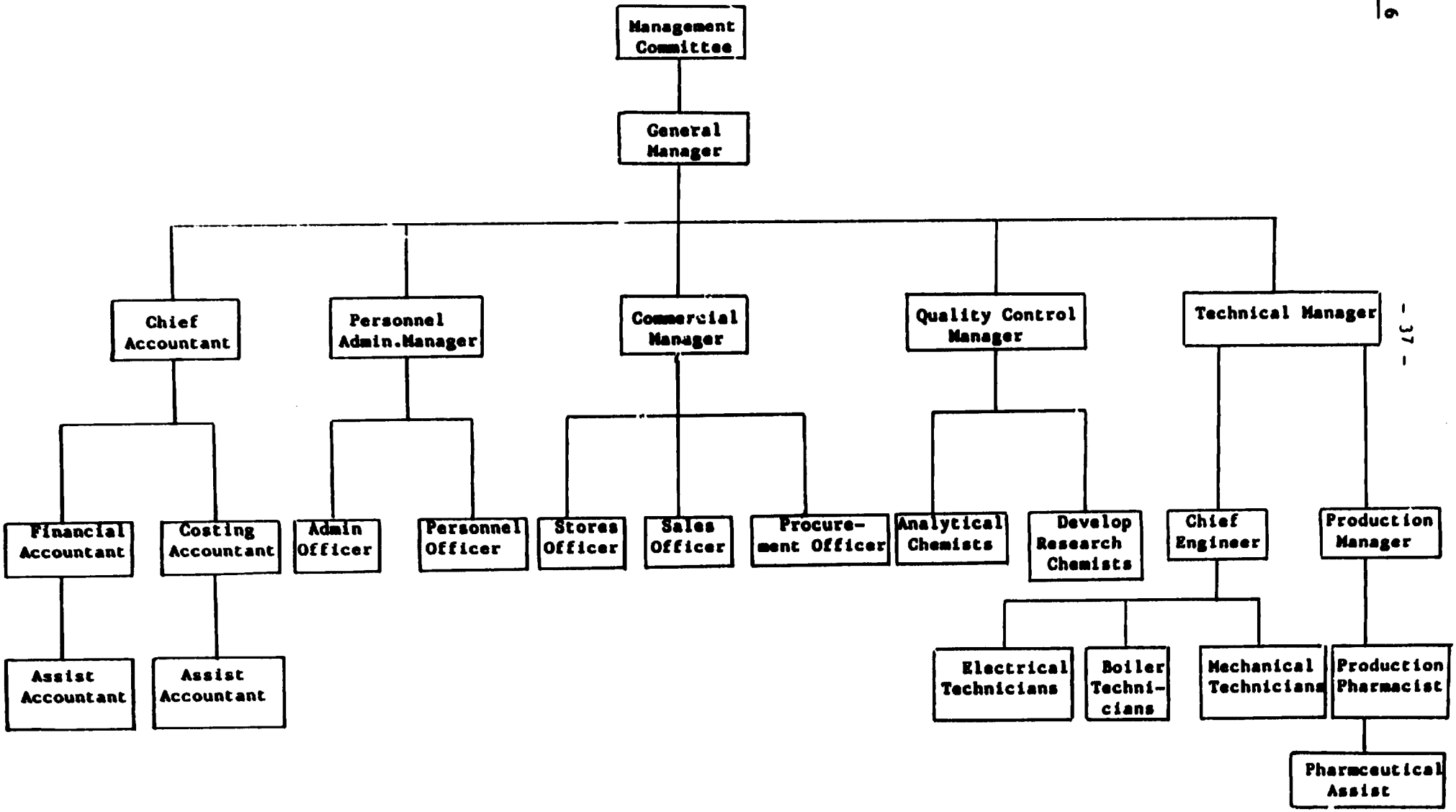
Pass: both controls should die and 8 of 10 vaccinates to survive.

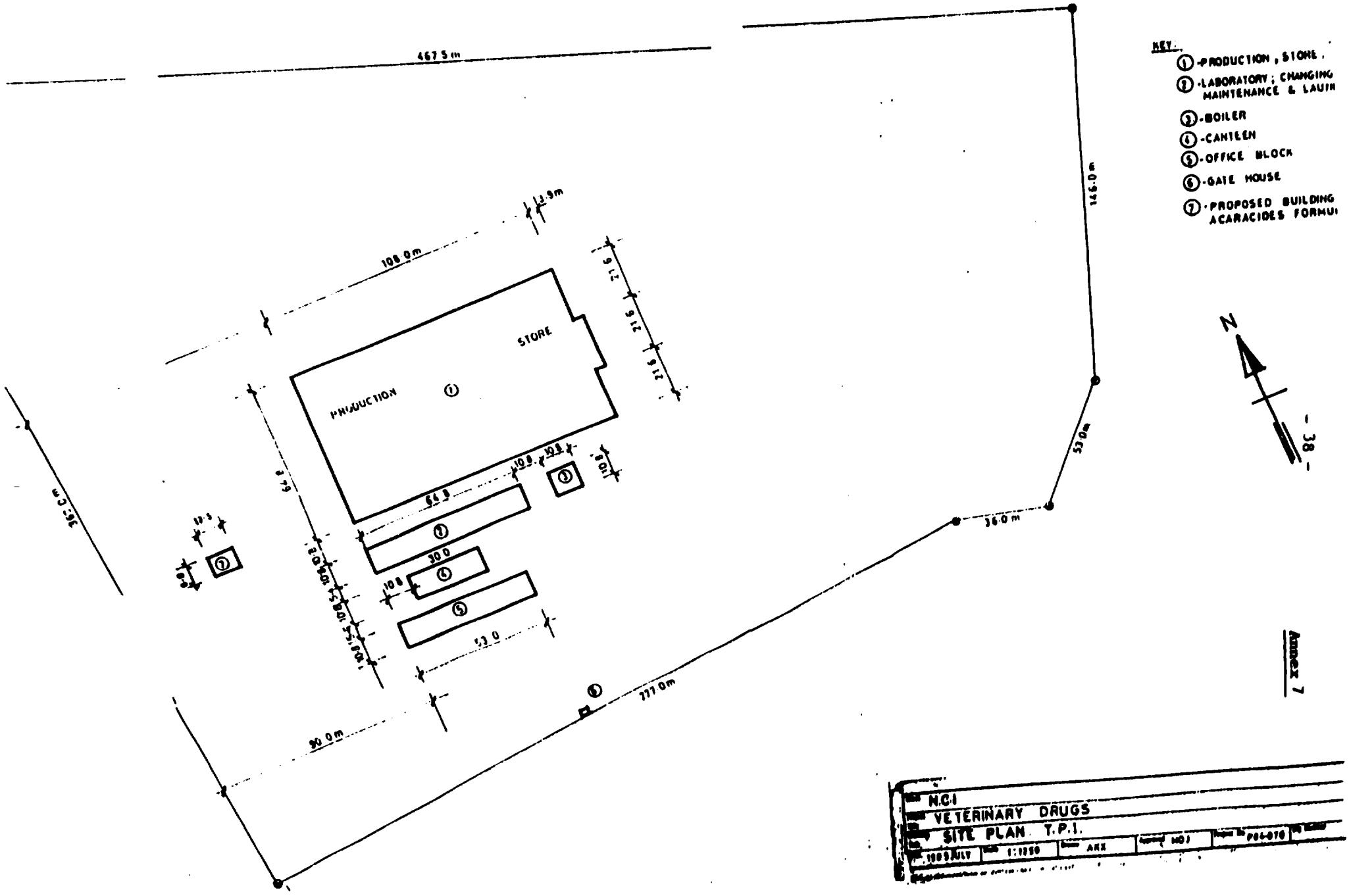
Inocuity Test

Twice the recommended dose, i.e. 4ml, is inoculated S/C into each of 2 goats. Morning and evening temperatures are recorded for 7 days and animals kept for 14 days.

Pass: survival of both animals without clinical signs of ill health. Tempertures are not considered.

THE EXISTING ORGANIZATION STRUCTURE FOR KEKO PHARMACEUTICAL INDUSTRIES LIMITED




467.5 m
KEY.
① - PRODUCTION, STORE.
② - LABORATORY; CHANGING MAINTENANCE & LAUN
③ - BOILER
④ - CANTEEN
⑤ - OFFICE BLOCK
⑥ - GATE HOUSE
⑦ - PROPOSED BUILDING ACARACIDES FORMU
PRODUCTION ①
STORE
108.0m
13.9m
21.6
21.6
21.6
146.0m
53.0m
36.0m
277.0m
90.0m
36.0m
64.8
30.0
10.8
10.8
10.8
10.8
10.8
10.8
10.8
10.8
53.0
N
- 38 -
Annex 7
N.C.I
VETERINARY DRUGS
SITE PLAN T.P.I.
1:1250
ARK
P01-070

Annex 8

LIST OF MAIN PRODUCTION MACHINERY & EQUIPMENT AT TPI

S.NO.	MACHINERY/EQUIPMENT	MODEL	CAPACITY	QUANTITY	REMARKS
	BOILER SECTION				
1	Steam boiler	Minipak	Steam output: 567 kg/h pressure: 6.8 bars	2	
	PACKAGING SECTION				
2	Labelling machine	Newman 24V	40/min	2	For tins & bottles
4	Labelling machine	Frewitt up IRP		1	for bottles
5	Counting machine	Prazi Blitz 4		1	for powders and tablets by weight
6	Strip sealing machine	Uhlman HS 3S		1	
7	Roller conveyor			1	
8	Belt conveyor			1	
	INJECTION SECTION				
9	Mixer	Turbula T 100		1	
10	Milling Machine	Condux Gm 100		1	
11	Balance	Scale MTT 3		1	
12	Balance	Sauter AC		1	
13	Oven	Hot air Lytzen J1800		2	
14	Autoclave	Autoclave 1-67-IL	650x1250x1250mm	1	
15	Autoclave	Autoclave 1-63	450x450x650mm	1	
16	Bottle washing machine	Faw 500		2	
17	Drying oven	Futurum FU 22		1	
18	Laminar flow cabinet	Laminar LIV 5021		1	
19	Tank	Seitz tank	131 l	1	
20	Balance	Scale Bosch S-200		1	
21	Powder dosing	Dos Mikro		1	

S.NO.	MACHINERY/EQUIPMENT	MODEL	CAPACITY	QUANTITY	REMARKS
22	Boiling pan	Metes finking 1255		1	
23	Tabletting Machine	Rotapress MK 1145	120,000-240,000/h	2	
24	Tabletting	Betapress 16	30,000/h	1	
25	Granulator	Lodige MGL 600 G IMZ	Wet granulating 200Kg per charge	1	Used for wet granulation for anti-biotic
26	Granulator	Drais T 1000 A	Wet granulating 300kg/charge Dry mixing 450kg/charge	1	Used for wet granulation
27	Granulator	Glatt WSG 120	120kg/2-3h	2	Use: Mixing, granulation, drying
28	Drying oven	Lytzen JI 1800		4	
29	Capsulating machine	Capsulating MG2	30,000 Caps/h	1	
30	Balance	Sauter	2.5-20kg	1	
31	Balance	Bosch		1	
32	Balance	Sartorius	Up to 500g, readibility 0.001 g	2	
33	Balance	Sartorius	Up to 220g readibility 0.001g	2	
34	Mixer/sifter	Frewitt MGI F624	Output 1000kg/h	1	For determining granule size uniformity
35	Milling machine	Stokes Tornado mill		1	
	LIQUIDS SECTION				
36	Bottle washing	Strunck RNDA01	580-800 bottles/h or 1600 ampoules/h	1	
37	Storage and mixing tank		500l	1	
38	Storage and mixing tank		2000l	1	
39	Filling machine	Schuco filler 1000A		1	