OCCASION

This publication has been made available to the public on the occasion of the 50th anniversary of the United Nations Industrial Development Organisation.

DISCLAIMER

FAIR USE POLICY

CONTACT

Please contact publications@unido.org for further information concerning UNIDO publications.

For more information about UNIDO, please visit us at www.unido.org

UNITED NATIONS INDUSTRIAL DEVELOPMENT ORGANIZATION
Vienna International Centre, P.O. Box 300, 1400 Vienna, Austria
Tel: (+43-1) 26026-0 · www.unido.org · unido@unido.org

RESTRICTED

16330

DP/ID/SER.B/570
16 June 1987
ENGLISH

ASSISTANCE IN THE PRODUCTION OF VETERINARY DRUGS IN SADCC COUNTRIES

DP/RAF/86/012

Terminal report*

Prepared for the Governments of the Member States of the United Republic of Tanzania, the Republic of Zambia, the Republic of Malawi, the People's Republic of Mozambique, the Kingdom of Swaziland, the Kingdom of Lesotho, the Republic of Botswana, and the Republic of Zimbabwe
by the United Nations Industrial Development Organization,
acting as executing agency for the United Nations Development Programme

Based on the work of Mr. R. Menard, Team Leader of the Project, Dr. Laszlo K. Nagy, Dr. F. Gelencser, Experts in Production of Veterinary Vaccines, and Mr. H. Chappel, Expert in the Production of Veterinary Drugs

Backstopping Officer: Ms. Maria Quintero de Herglotz, Chemical Industries Branch

United Nations Industrial Development Organization
Vienna

* This document has been reproduced without formal editing.

V.87-86094

252

TABLE OF CONTENTS

ANNEXES

1. TEAM MEMBERS, COUNTRIES VISITED

Mr H Chappell (Veterinary Drugs)

Dr F Gelencser (Veterinary Vaccines)

Mr R Menard (Veterinary Marketing)

Dr L K Nagy (Veterinary Vaccines)

Mission Dates: July 11th - November 3rd 1986

Tanzania R.M. L.K.N.

Zambia R.M. L.K.N

Malawi R.M. L.K.N.

Mozambique H.C. F.G. R.M.

Swaziland H.C. F.C. R.M.

Lesotho H.C. F.G. R.M.

Botswana H.C. F.G. R.M.

Zimbabwe H.C. F.G. R.M.

The team intended to visit Angola but authority was not received in time for the mission dates. It is hoped that a team will be able to visit later and make a full report.

Messrs Chappel, Gelencser and Menard returned via Nairobi to meet authorities involved in regional disease control strategy.

2. OBJECTIVES

2.1 To determine:

1.1 Animal Disease Patterns

1.2 National and Regional Demand for Drugs and Vaccines

1.3 Possibilities for local manufacture.

1.4 Constraints on drug and vaccine usage and possibilities for enhanced consumption

2.2 To compare:

2.1 Importation of finished products

2.2 Importation of intermediate products for final processing

2.3 Local production

2.3 To recommmend:

3.1 Programme for local and regional manufacture

3.2 Licensing arrangements

3.3 Tariff systems

3. RECOMMENDATIONS

The following recommendations are made in respect of the various product groups:

1. ECTOPARASITICIDES

1.1. It is recommended that:

1.1.1 These should be produced locally

1.1.2 The existing facilities at Zimphos in Zimbabwe should be utilised as a regional supply source.

1.1.3 That SADCC representatives negotiate with Zimphos regarding production of acaricides for the region.

1.1.4 That SADCC representatives consider the building on the basis of current distribution arrangements (via Coopers Zimbabwe) for regional supply.

Comment

Zimphos has licencing agreements through Cooper to development and technical expertise, and scientific support.

The structure of the company Zimphos should be examined in relation to this proposed new role and steps taken to correct it if the present situation is not satisfactory.

1.2 Support Production Facilities

It is recommended that the Cooper facilities in Lusaka, Zambia be considered as a secondary supply-point within SADCC.

1.3 Strategic Plan

It is recommended that the TPI Plant in Arusha, Tanzania be considered as an additional production source for SADCC at around the year 1995.

2. VETERINARY PHARMACEUTICALS

2.1 It is recommended that:

2.1.1 There should be local production

2.1.2 The pharmaceutical facilities at CAPS in Zimbabwe should be utilised as a regional supply source.

2.1.3 That SADCC representatives negotiate with CAPS regarding regional supply arrangements.

Comment

CAPS is already manufacturing human and veterinary pharmaceutical products to the highest international standards.

Their production capacity is under-utilised and they have licencing arrangements with companies to produce a whole range of suitable veterinary pharmaceutical products.

2.2 Support Production Facilities

It is recommended that the LDA in Lesotho be considered as a secondary supply point within SADCC for a limited product range.

2.3 It is recommended that the TPI plant in Arusha, Tanzania be considered as an additional production source for SADCC at around year 1995.

3. VETERINARY BACTERIAL VACCINES

3.1 It is recommended that:

3.1.1 A veterinary bacterial vaccine production laboratory be established at Matsapa, Swaziland.

3.1.2 The initial objective would be to establish a centre of expertise in bacterial vaccine production and quality control based on deep culture technology (Annex 3). The facility should be established in two phases of development.

Phase I: Establishment of:

(i) formulation-filling-packaging unit (Filling Unit) for vaccines prepared from imported antigen concentrates.

(ii) Quality Control (QC) Laboratory.

Phase II: Establishment of:

(I) production of bacterial biologicals (liquid and lyophilised) for veterinary application.

(II) Quality Assurance (QA).

(III) Expansion of QC Laboratory.

3.1.3 Once established the laboratory could function as a training centre within SADCC for technical staff from other countries who would return to work in their own countries when suitable facilities had been established.

3.1.4 The laboratory would have a production capacity capable of meeting a substantial part (ca. 50%) of the SADCC requirements (Annex 1) over the next 10-15 years for priority bacterial vaccines.

Comments

With the problems of maintaining and operating the biological facilities in Angola and Mozambique, and the lack of suitable facilities in other countries, the most imortant and immediate objective must be to establish a reliable well-resourced and expertly staffed production laboratory to serve as a regional centre of expertise and training.

Technical collaboration with a commercial vaccine manufacturer of Veterinary Bacterial vaccines to be responsible for the project implementation and initial training is considered essential and names of appropriate companies are given in Chapter 6.

3.2 Support Production Facilities

It is recommended that the production facilities at Balmoral, Zambia be considered as a source of supply for SADCC of Contagious Bovine Pleuropneumonia vaccine,

and the necessary steps taken to ensure that the manufacturing facilities and standards conform to GMP and Eur.Ph. regulations.

3.3 Strategic Plan

It is recommended that the facilities in Mozambique and Angola be re-established when conditions permit.

Depending on the success of correcting the present resource limitations in the Veterinary Services in Tanzania, consideration can be given to the establishment of veterinary bacterial vaccine production facilities about 1990-1995, possibly at Arusha.

4. VETERINARY MAMMALIAN VIRAL VACCINES

4.1 It is recommended that:

4.1.1 These should be produced locally.

4.1.2 The existing facilities at the Botswana Vaccine Institute, Gaborone be used as a regional supply source.

4.1.3 That SADCC representatives negotiate with BVI regarding the range and quantities of viral vaccines to be produced and the timing of their introduction.

Comment

The excellent record of the BVI in producing Foot and Mouth Disease Vaccine within SADCC must be borne in mind, also their recent production of Rinderpest vaccine to the highest International Standards for strategic purposes.

The BVI has a technical agreement with a major commercial European veterinary viral vaccine producer, who should be approached about the feasibility and cost of producing the additional vaccines.

4.2 Support Production Facilities

Consideration should be given to the VPL Embakasi, Kenya as an additional source of viral vaccines, particularly Foot and Mouth Disease Vaccine.

4.3 Strategic Plan

No convincing case can be presented for an additional supply source of mammalian viral vaccines within SADCC.

5. POULTRY VACCINES

It is not recommended that poultry disease vaccines be produced within SADCC, prinicipally for reasons of economics and disproportionate resource requirements (See Annex 7).

6. PROTOZOAL VACCINES

These have not been included in the main discussion as no Industrial Process exists to produce them. However a watch must be kept on developments within the area, especially the ECF project in Lilongwe, Malawi with a view to the possibilities of developing an industrial process in the future.

4. PROGRAM FOR LOCAL AND REGIONAL MANUFACTURE

Commencement of local production or establishment of local production facilities where they do not already exist

PRODUCT GROUP	IMMEDIATE	INTERIM SUPPORT	STRATEGIC
ACARICIDES	ZIMBABWE	ZAMBIA	TANZANIA (1990-1995)
PHARMACEUTICALS	ZIMBABWE	LESOTHO	TANZANIA (1990-1995)
MAMMALIAN BACTERIAL VACCINES	SWAZILAND	MOZAMBIQUE ZAMBIA (CBPP Vaccine)	TANZANIA (1990-1995) ANGOLA (1995-2000)
MAMMALIAN VIRAL VACCINES	BOTSWANA		
AVIAN VACCINES			
PROTOZOAL* VACCINES			MALAWI (1995-2000)

* This has not been included in the introductory list as industrial technology to produce these vaccines does not exist at present.

Discussion

Reference to the reasons for choice of country for proposing the development/establishment of the various veterinary industries make certain decisions self evident.

For example Botswana is the obvious choice for mammalian viral vaccines and Zimbabwe the obvious choice for both veterinary pharmaceuticals and acaricides.

A study has been made of the cost and feasibility of producing poultry vaccines together with the likely market requirement as a result of which the case for local production cannot be supported.

In the case of bacterial vaccines there is a great need to develop the expertise within SADCC but the over-riding immediate requirement is for training and maintaining such skills that do exist within member countries. It is for this reason that Swaziland is recommended (in view of their training function) together with the fact that biological products are high-value/low volume products and distribution costs can be accommodated from that source within the region.

Once other interested countries (Mozambique, Angola and Tanzania) are in a position to develop or re-establish their own facilities a centre of expertise and training will already exist within SADCC to provide valuable support.

The protozoon immunology (ECF) project must not be forgotten and the long term objectives of industrial scale production is therefore included.

Recommendations

It is recommended that the plan presented on p. 8 be presented to SADCC to be formally adopted.

Overall the additional cost to SADCC of some of the products maybe above the imported value of the products concerned, but the development of local industry, personnel and new technologies, plus the control of production of essential medicines (e.g. Rift Valley Fever Vaccine, African Horse Sickness Vaccine, Clostridium botulinum vaccine etc.) is of great national and regional importance and must be considered in the context of their strategic value.

5. TARIFFS

Should the recommendations be accepted, some tariff protection may be desirable, notably in the following cases:

1.	Acaricide production, Zambia for local supply:	20%
2.	Veterinary pharmaceutical manufacture, Zimbabwe for regional supply:	20%
3.	Bacterial vaccine production, Swaziland:	15%
4.	Veterinary acaricide production in Zimbabwe, for export:	15%
5.	Rabies vaccine production, Botswana:	15%

It is believed that the production of both veterinary pharmaceuticals and acaricides in Zimbabwe will be price-competitive, domestically. The full costing of viral vaccine production in Botswana for strategic purposes has not been done, but it is likely that a high premium will be needed.

The question of bacterial vaccine distribution costs from Swaziland must be further examined and it is possible that some further protection may be necessary.

6. POSSIBLE LICENSORS FOR VETERINARY BACTERIAL VACCINE TECHNOLOGY (Alphabetical)

Coopers Animal Health
Berkhamsted Hill
Berkhamsted
Hertfordshire HP4 2QE
United Kingdom.

Hoescht A.G. Pharma Fabrik
Postfach 800320
D-6230 Frankfurt am Main 80
Federal Republic of Germany

Phylaxia
Veterinary Biologicals
Budapest X Szallas 5
Hungary

Rhone-Merieux
17, rue Bourgelat
69002 Lyon
France

Possible Suppliers/Licencors for Veterinary Acaricides and Pharmaceuticals (Alphabetical)

CAPS Veterinary (Private) Ltd
Manchester Road
Harare
Zimbabwe

Coopers Animal Health
Berkhamsted Hill
Berkhamsted
Herts HP4 2QE
United Kingdom

Tanzania Pharmaceutical Industries Ltd
P O Box 7063
Arusha
Tanzania

Zimphos (Zimbabwe Phosphates Corporation)
Harare
Zimbabwe

7. SADCC CONSOLIDATED REPORT

7.1 SADCC REGION 42,195,298Km^2

7.1.1. **Population Statistics**

	Millions	% Growth Rate p.a.
Human	71.67	2.6 - 3
Bovine	27.4	1 - 2
Sheep and Goats	18.9	2
Pigs	1.3	1 - 2
Poultry	100.0	5

7.1.1.1 From the above statistics it is obvious that livestock numbers (and also livestock production trends) are far from keeping pace with human nutritional requirements. The situation is even worse as certain countries, notably Botswana and Zimbabwe, have prospects of improved production which masks the true situation in some other countries.

7.1.2. **Main Animal Diseases**

Regionally these are dominated by Nutritional Disease, Ticks and tick-borne disease, Tsetse fly and Trypanosomiasis and Foot and Mouth Disease.

Endoparasitosis, bacterial disease (Anthrax, Blackquarter, Haemorrhagic septicaemia, Brucella, Tuberculosis) and infertility follow but many other diseases are also important such as rabies, contagious Bovine Pleuropneumonia, Newcastle disease etc.

7.1.3. **Organisation of Veterinary Services**

The basic infrastructure of veterinary services still exists in most countries but with a few notable exceptions there are huge constraints in their operation.

7.1.4. **The Veterinary Market**

The whole market in SADCC amounts to US $26.6million p.a. being dominated by acaricides (42%), Foot and Mouth Disease Vaccine (10.7%), Antibiotics (11.5%) and Anthelmintics (9%). Geographically the market is dominated by Zimbabwe (40%), Tanzania (28%), Zambia (14%) and Swaziland (9%).

The trend is towards greatly increased demand, but unless desperate measures are taken in Tanzania in particular and to a lesser extent in Mozambique, Malawi and Zambia the market could stagnate altogether - any improvement in Zimbabwe, Botswana, Swaziland and Lesotho being offset by decline or even total collapse in the other countries.

Should appropriate measures be taken in those countries where the veterinary services are in need of re-building, the veterinary market could rise to about US $60million by the year 2000. (Annex 8)

7.1.5. **Constraints on Drug and Vaccine Usage**

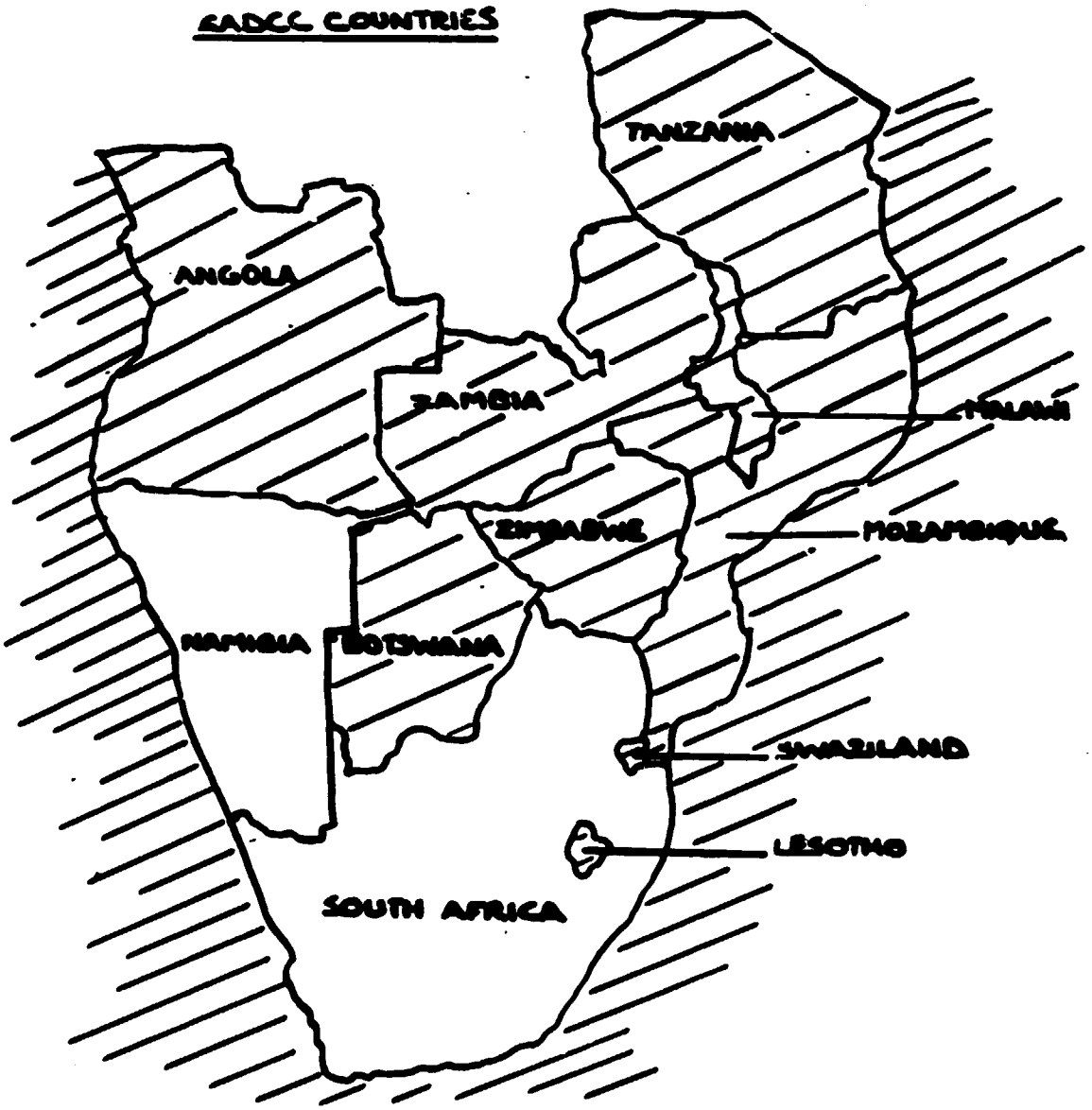
The initial constraint in all countries except Botswana, Lesotho and possibly Swaziland is availability of foreign exchange - even for raw material purchase where there are local production facilities.

However, this disguises the fact that with the notable exceptions of Zimbabwe, Botswana, Lesotho and Swaziland, even freely available drugs acaricides and vaccine would not automatically result in concommitant, pro-rata improvement in animal health and productivity.

Veterinary infrastructures are so under-resourced in the remaining countries that all aspects of animal health control are in need of radical improvement if greater availability of medicines are to be properly utilised. These shortcomings start with communications, diagnosis field campaigns, equipment, dip tanks, transport, distribution etc, and apply to all aspects of animal disease control, particularly manpower training and the staffing and running of the extension services.

7.1.6&7. **Drug and Vaccine Requirements to the Year 2000**

Details of these are given in Annex 1. Bearing in mind the constraints listed in 7.1.5. , the requirements should rise two and a half-fold in financial terms by the end of the century. It must be the resourcing of Veterinary Services, particularly in Tanzania (which contains about half the livestock population of all SADCC countries). If this is not done, increased drug and vaccine usage will essentially be limited to those countries with an adequate veterinary infrastructure, notably Zimbabwe, Botswana and Swaziland.


SADCC COUNTRIES
TANZANIA
ANGOLA
ZAMBIA
MALAWI
ZIMBABWE
MOZAMBIQUE
NAMIBIA
BOTSWANA
SWAZILAND
LESOTHO
SOUTH AFRICA

2. TANZANIA 880,000Km^2

2.1 Population Statistics

	Millions	% Growth Rate p.a.
Human	22	3.1
Cattle	12.5	0.7
Sheep and Goats	10.5	2.0
Pigs	0.15	5.0
Poultry	25	3.2

2.2 Main Animal Diseases and Control Measures

2.2.1 Malnutrition, tick-borne diseases, anaplasmosis, babesiosis, trypanosomiasis, foot and mouth disease, rinderpest, blackquarter, anthrax, Newcastle Disease, helminthiasis, infertility, brucella, CCPP, etc.

Scheduled infectious diseases, tick-borne diseases, tryponosomiasis and tsetse control are subject to official prophylactic control measures, notably dipping, prophylactic therapy and vaccination.

2.2.2 Contributory causes are lack of water, poor husbandry and pasture management, lack of education, competition with crops, etc.

2.3 Organisation of Veterinary Services

The basic veterinary infrastructure still exists but lack of resources has rendered it largely inoperable.

2.4 The Veterinary Market

The veterinary market is dominated by the government sector which amounts to about 90% by quantity and value. Purchases are made on a tender basis annually. The total value is in the order of US $7.8million of which ectoparasiticides account for about 50%, antibiotics 20%, trypanocides 16%, biologicals 13%, the rest being anthelmintics, minerals, etc (See Annex 1).

2.5 Constraints on Drug and Vaccine Usage

2.5.1 Availability of drugs and vaccines

2.5.2 Distribution, transport, storage, communication.

2.5.3 Extension services, diagnosis, trained personnel, farmer education, dipping tanks, equipment, monitoring of diseases and drugs, etc.

2.6 Projected Requirements for Drugs and Vaccines

These are summarised in Annex 1. It is estimated by the Department that the imediate requirement for drugs and vaccines is at least double current off-take, ie, US $ 16milion. However it is highly questionable whether such an increased availability could be used to the best advantage in the present circumstances.

By the year 2000, the use of biological products should increase, especially foot and mouth disease vaccine, but the whole Animal Health infrastructure needs re-building and together with it the systematic use of acaricides, drugs and vaccines.

2.7 Pharmaceutical Production

The Tanzania Pharmaceutical Industries (TPI) Plant at Arusha is a modern well equipped facility with good services, manufacturing to international standards. Powders, liquids, granules, and tablets are produced to standards largely according to GMP and EP, but antibiotic manufacture must be relocated in a separate building when convenient. The staff organisation and training is consistent with modern international requirement of qualification, structure, discipline etc.

The excellent all-round standards of the plant, equipment, personnel, etc. make the TPI plant worthy of serious consideration as a base from which to establish veterinary pharmaceutical manufacture, and possibly veterinary biologicals.

2.8. Veterinary Biological Production

2.8.1 The facilities at Mabibo are derelict and the vaccine laboratory at the CVL falls into the improvised bench-scale category.

2.8.2 The site, services, layout, plant, etc, are inadequate for the production of vaccines to international standards. The technology is rudimentary, the equipment is (mostly) old and improvements need to be made to the storage and distribution systems. There are insufficient staff and those available would need training if improved facilities were to be provided. Current local production is minimal.

2.9 Discussion

There is an urgent need for veterinary medicines in Tanzania both pharmaceutical and biological. The size of the National herd and the importance of the Livestock Industry socio-economically are such as to justify local production of both veterinary pharmaceuticals and biologicals. However, all aspects of animal disease control are in such a perilous state that it would be desirable to integrate investment in local production of drugs or vaccines with measures to determine and quantify animal disease on more reliable grounds than possible at the present time and to re-establish an effective infrastructure, especially communications and extension services, in order to carry out effective disease control policies.

2.10 Recommendations

2.10.1 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, communciations, storage and distribution, monitoring of drug concentrations and parasite resistance etc.

2.10.2 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.

2.10.3 Production of large demand bacterial vaccines should be established through a progression of development phases.

In Phase I establishment of a blending-filling-peckaging 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.

7.3. ZAMBIA

3.1 Population Statistics

742,000Km^2.

	Million	% Growth Rate p.a.
Human	7	3.1
Cattle: Commercial	0.4	2.5 - 3.0
Traditional	2	2.0 - 2.5
Sheep and Goats	0.42	2.5 - 3
Pigs	0.15	4.0
Poultry Total	12.5	4.0
Layers	0.8	-
Broilers	2	-

3.2 Main Animal Diseases

3.2.1 Ticks, tick-borne diseases, theileriosis, anaplasmosis, babesiosis and heartwater, trypanosomiasis and tsetse control, foot and mouth disease (control), malnutrition, CBPP (control), Rinderpest (control), Newcastle disease, Helminthiasis, brucellosis, blackquarter, anthrax, haemorrhagic septicaemia, lumpy skin, rift valley fever.

3.2.2 Contributory causes; poor husbandry and lack of education.

3.3 Organisation of Veterinary Services

There is a Department of Veterinary Services and tsetse control, the Veterinary Department being sub-divided into Field, Diagnostic Research and Vaccine Production Departments.

3.4 The Zambian Veterinary Market

There is significant local formulation - 50% of ectoparasiticides by the private sector, and veterinary biologicals by the Veterinary Department (bacterial and some rabies).

3.5 Constraints on Drug and Vaccine Usage

Apart from having to rely on (unpredictable) donations from agencies for drug purchases, there are fundamental deficiencies in the traditional livestock sector, including all aspects of extension services, diagnosis, disease monitoring, education, maintenance of dips, transport and availability of sufficient trained extension staff. Although the policy of charging livestock owners for veterinary attention is generally acceptable, it must be combined with efficient extension services and incentives to production.

3.6 Projected Requirements for Drugs and Vaccines

These are summarised in Annex 1. There is a large increased requirement in the traditional sector where up to 10 times more acaricide would be needed to fulfil stated disease control policies; increased acaricide use would be accompanied by better and increased use of anthelmintics, antibiotics and biologicals. The estimates given (Annex 1) have been made on the assumption that the other products are imported under government licence. There is no registration. There is official control of FMD, Rinderpest and CBPP vaccination, but all other drug and vaccine purchases are made either by private traders or as a result of aid donations, when they may or may not be incorporated into national disease control strategies. The unco-ordinated Aid Donations and the government's "auction" policy for foreign exchange have had extremely disruptive effects on the veterinary drug market.

Estimates of current value put the market at about US $4million of which ectoparasiticides account for about 27%, antibiotics and antibacterials 16%, trypanocides 16%, anthelmintics 12%, biologicals 20% and the rest by feed supplements etc.

The great majority of the market is in the private cattle sector, in spite of it only comprising 20% of the cattle population.

Although there is a national strategy to dip cattle in the Northern, Eastern provinces and some other districts hardly any of the traditional animals are dipped regularly because of shortage of acaricide, and because the cattle owners have to pay a fee. A quite separate issue is tsetse and trypanosomiasis control. Previous schemes have ceased and trypanosomiasis is increasing. There is an urgent need for effective implementation of the regional tsetse and trypanosomiasis control scheme based on fly baiting and the use of anti-trypanosomal drugs.

The requirement for veterinary drugs and biologicals is dependent on correcting the constraints listed above, co-ordination of Aid Donations, re-building extensions services and adequate funding of disease control programmes. The total market should be more than double in units and value by the year 2000 should these actions be taken.

3.7 Consideration for Local Manufacture

3.7.1 Acaricides

Two private organisations are formulating acaricides, disinfectants and other products to international standards of quality and GMP and there is considerable excess capacity. There are technical support staff available from the companies within SADCC with the availability to offer technical advice on product use and to investigate field problems.

3.7.2 Biologicals

There is a Veterinary Biologicals Laboratory at Balmoral which would fall mainly into the "improvised bench-scale production" category (Annex 3). Offtake is variable but actual production in 1985 was 39,800 doses of S19 538,200 doses of haemorrhagic septicaemia and 378,406 doses of blackquarter vaccines. There is also some out-dated rabies vaccine production.

An EEC scheme to construct new facilities to produce a greater range of biologicals for the domestic market including egg-origin poultry and rabies vaccines is in progress. It is not clear whether these facilities would meet present-day international standards of GMP production and quality control.

3.8 Discussion

There is an urgent need to protect local acaricide production from the effects of the auction of foreign exchange and unco-ordinated Aid Donations. Tariff protection, registration of products and channelling aid through local producers (where appropriate) would be desirable. Biological production at Balmoral can only be considered on a local (Zambian) basis. Should the new (EEC funded) laboratory be considered as a source of supply of vaccines outside Zambia a thorough appraisal of the proposed building, plant, equipment, staffing and quality control is recommended.

3.10 Recommendations

3.10.1 Acaricides

Steps be taken immediately to protect local acaricide production (as listed under 7.3.8)and building on this to expand the local production of veterinary pharmaceuticals, with possibility of exporting to neighbouring countries.

3.10.2 Biologicals

Should there be a desire to consider the facilities currently under construction as a regional supply source, the necessary steps should be taken to see that they meet international standards of manufacture, quality control and product specification. This is especially relevant to the production of CBPP vaccines where Zambia could be considered as the supply point of this vaccine for the SADCC countries.

7.4 MALAWI 118,484Km^2

4.1 Population Statistics

	Millions	% Growth Rate p.a.
Human	9	2.9
Cattle	0.95	2 - 3
Sheep and Goats	0.89	2.0
Pigs	0.19	1.0
Poultry	14	15.0

4.2 Main Animal Diseases

4.2.1 Tsetse and trypanosomiasis, ticks and tick-borne disease, foot and mouth disease (control), malnutrition, fascioliasis, African Swine Fever, tuberculosis, brucellosis, rabies, Newcastle disease, lumpy skin, blackquarter.

4.2.2 Contributory causes; pressure on land from competition with agriculture and human population.

4.3 Organisation of Veterinary Services

Animal health control is exercised by the Department of Health and Industry Veterinary Investigation Services (and Research) Field Services and Administration.

4.4 The Malawi Veterinary Market

The Malawi Veterinary Market amounts to only some US $576,000 per annum, most of it being government purchases through the Malawi Pharmacies and some direct purchases by the DOAMI from (e.g.) The Botswana Vaccine Institute (FMD Vaccine). The breakdown is approximately:- FMD Vaccine 37% ectoparasiticides 13%, antiprotozoons 8%, feed supplement 10%, antibiotics 7%, anthelmintics 5%, rabies vaccine 5.6%, blackquarter vaccine 0.4%, the rest by other vaccines, rinderpest, pasteurella, lumpy skin, NDV etc.

4.5 Constraints on Drug and Vaccine Usage

The completely over-riding constraint to drug and vaccine usage is shortage of foreign exchange. With the exception of prophylactic FMD and rinderpest vaccination schemes, all animal health schemes are collapsing for lack of drugs. Even then, some of those drugs which are available (e.g. arsenic and toxaphene) are dangerous and of doubtful efficacy.

Second to the availability of effective drugs as a constraint come efficient diagnosis, transport and extension services. All are in need of considerable improvement. There is a specific impediment to the development of the poultry industry - availability of compounded foods. This has prevented

development, but should it be resolved, the requirement for poultry vaccines would be markedly increased.

4.6 **Project Requirements for Drugs and Vaccines to the Year 2000**

These requirements are summarised in Annex 1. There is at least a three-fold increase in requirement, particularly in acaricides and trypanocides. However, this increased availability could not be used to the best advantage unless the measures mentioned in paragraph 7.4.5to improve diagnosis, transport and extension services, are also taken.

4.7 **Possibilities for Local Manufacture of Veterinary Pharmaceuticals and Biologicals**

It would not be realistic to propose any local production at this stage. The primary livestock industry is small (in regional terms) and in urgent need of basic health care. Attention should be devoted to this in order to reduce animal diseases losses.

4.8 **Discussion**

The ECF Immunisation Project at the CVL is of great regional interest and could assist in developing strategies in the future.

4.9 **Recommendations**

4.9.1 Should the ECF Immunisation project prove effective under field conditions an appraisal should be carried out to examine the feasibility of scaling up production to a commercial basis.

4.9.2 Production of egg-derived viral vaccines for poultry should not be established.

7.5. MOZAMBIQUE 800,000Km^2.

5.1 Population Statistics

	Millions	% Growth Rate p.a.
Human	14	2.6
Cattle	0.75	-10
Sheep and Goats	0.6	-
Pigs	0.15	-
Poultry	0.3	-

5.2 Main Animal Diseases

Trypanosomiasis, ticks and tick-borne disease, reproductive disease, helminthiasis disease, foot and mouth disease, rabies, African Swine Fever, Newcastle disease, blackquarter, tuberculosis, anthrax, lumpy skin and bluetongue.

5.3 Organisation of Veterinary Service

All drug and vaccine purchases are made by the state through the parastatal company MEDIMOC and distributed through BOROR to the Veterinary Department. The total market value has declined from US $4million in 1981 to US $87,000 in 1986 because of a lack of funds. When funds are available the market breakdown is:- ectoparasiticides 20-35%, veterinary pharmaceuticals (trypanocides, feed supplements, antibiotics, anthelmintics) 40-45%, the rest (25-35%) being biologicals. Locally-produced biologicals reached a peak of $185,000 in 1982, but diminished to $38,000 in 1986.

5.6 Projected Requirements for Drugs to the Year 2000 (Annex 1)

With the cessation of hostilities and re-creation of the veterinary infrastructure, diagnosis, and animal disease control campaigns, the requirement for drugs coud come up to about half the 1981 level (US $4million) by the year 2000.

5.7 Possibility of Local Manufacture

5.7.1 Pharmaceuticals

Unrealistic at the present time.

5.7.2 Biologicals

The present laboratory is not suitable for production of veterinary biologicals to international standards, either manufacturing conditions or finished product specifications and quality control. In most respects it falls into Category 1 (improvised bench-scale, see Annex 3).

5.8 Discussion

The immediate reason for the lack of biological production is lack of money for raw materials and routine operation. There is, however, a centre of expertise and trained staff which should not be lost. Only the provision of new facilities would overcome the inherent shortcomings of design, disease security and operation to enable the INVI to produce to International Standards.

5.9 Recommendations

5.9.1 A bridging project to enable the INVI to continue any manufacture at all should be introduced as a stop-gap measure to prevent the total dissemination of the staff and the collapse of all activities at the laboratory.

5.9.2 A new laboratory, built to international standards using classical technology (see Annex 3) should be planned for construction when conditions permit. Ability to produce the following products should be included:

5.9.2.1 Anthrax	5×10^6	
5.9.2.2 Blackquarter	2×10^6	
5.9.2.3 Brucella	0.5×10^6	Capacity
5.9.2.4 Brucella Antigen	2×10^6	per
5.9.2.5 Tuberculin	2×10^6	annum

The production of egg-origin vaccines should cease.

7.6. SWAZILAND 17,364Km^2.

6.1 Population Statistics

	Millions	% Growth Rate p.a.
Human	0.67	3.4
Cattle	0.63	-
Sheep and Goats	0.35	-
Pigs	0.014	-
Poultry	0.7	-

6.2 Main Animal Diseases

6.2.1 Ticks and tick-borne diseases, anaplasmosis, pyroplasmosis, heartwater, foot and mouth disease, (prophylactic vaccination), nutritional disease, helminthiasis, rabies, Newcastle disease, blackquarter, brucella.

6.3 Organisation of Veterinary Services

The Director of Veterinary Services heads up both production and health; there are four regional veterinary centres, each with 3-4 sub-centres. Animal disease control policies revolve around the dip-tanks.

6.4 The Swazi Veterinary Market

This is dominated by Government purchase (over 90%) in relation to disease control campaign. The annual market value is estimated at US $2.3million (Annex 1), of which ectoparasiticides amount to 70%, FMD vaccine and other biologicals 9%, antibacterials 6.5%, anthelmintics 2%, the rest being growth promoters, coccidiostats, etc.

6.6 & 6.7 Projected/Optimum Requirements for Drugs and Vaccines to Year 2000

These requirements are presented in Annex 1. As animal diseases programmes are well-established and functioning satisfactorily, no greatly increased demand is foreseen, particularly as the policy is to encourage de-stocking in the traditional sector.

6.8 Consideration for Local Manufacture

In the case of Veterinary pharmaceuticals there is no wish to establish local production. However, the general level of technical expertise is high and ancillary industries (milk processing and meat packing) are well operated and efficiently run.

The role of Swaziland in co-ordination of training should be borne in mind for any regional animal health strategies, and in this context should be considered as a training base in bacterial vaccine production, quality control and quality assurance.

7.7 LESOTHO 30,355Km^2

7.1 Population Statistics

	Millions	% Growth Rate p.a.
Human	1.5	2.3
Sheep	1.2	-
Goats	0.8	-
Cattle	0.5	-
Pigs	0.03	-
Chickens	1.0	-
Dogs	0.165	-

7.2 Main Animal Diseases

Sheep scab, nutritional disease, helminthiasis, rabies, Newcastle Disease, anaplasmosis, pyroplasmosis.

7.3 Organisation of Veterinary Services

There is a good coverage of extension services based on the sheep dip (202 dip tanks) network. There is a system of livestock improvement centres, livestock attendants and veterinary clinics.

7.4 The Veterinary Market

Over 90% of the drugs and acaricides are bought by the Veterinary Department.

The annual requirement is about US $270,000, of which acaricides amount to 39%, anthelmintics 36%, antibiotics 7%, biologicals 6%. The rest is made up of feed supplements, antiprotozoals, etc.

7.5 Constraints on Drug and Vaccine Usage

There are no outstanding limitations but communications, transport and training (especially livestock attendants) need strengthening.

7.6 & 7.7 Projected/Optimum Requirement for Drug and Vaccine Usage to the Year 2000

Details are summarised in Annex 1 . It is anticipated that there will be a general increase in drug and vaccine requirement to the year 2000 consequent on the policy of improved livestock production.

Acaricides and anthelmintics will continue to dominate, but the use of rabies vaccine should be increased two to four times.

7.8 Consideration for Local Production

7.8.1 Pharmaceuticals

The Lesotho Dispensary Association is producing a range of basic pharmaceuticals but could be expanded and modified suitably to process high-value low-volume veterinary drugs.

7.8.2 Biologicals

The Government laboratory produced Lasota Newcastle Disease vaccine on the basis of imported SPF eggs. The yield is 3×10^6 doses per year, under "improved bench-scale" (see Annex 3) conditions. The buildings and technology, staffing, in-process and final Q.C are inadequate, and no tests are carried out in the target species.

7.9 Discussion

Considering the size, geographical location and range of animal diseases in Lesotho it does not represent a realistic option for the production of veterinary biologicals or pharmaceuticals. Should the LDA introduce the production of sterile injectables, consideration could be given to the production of veterinary equivalents, e.g. antibiotics and steroids.

7.10 Recommendations

Certain modifications to LDA premises and procedures have been recommended.

7.8. BOTSWANA 582,000Km^2

8.1 Population Statistics

	Millions	% Growth Rate p.a.
Human	0.85	3.1
Cattle	2.6	-
Sheep and Goats	1.1	-
Chickens	0.85	-

8.2 Main Animal Diseases

Nutritional disease, foot and mouth disease, tick-borne disease, anthrax, blackquarter, rabies, brucellosis, hydatidosis, ecchinococcosis, botulism and trypanosomiasis.

8.3 Organisation of Veterinary Services

All veterinary activities and trypanosomiasis control come under the Director of Veterinary Services. Animal Production is separate.

8.4 The Veterinary Market

All purchases are made by the Veterinary Department for the country, the main disease control campaigns being run free of charge to the livestock owners (FMD, anthrax, rabies and blackquarter vaccination).

The Veterinary Market amounts to US $1.72million (Annex 1) of which FMD vaccine comprises 73%, antibiotics 4%, blackquarter vaccine 8%, anthrax vaccine 4%, anthelmintics 3%, the rest being made up mainly of vaccines.

8.5 Constraints on Drug and Vaccine Usage

Transport and road conditions form the most serious physical constraint. However, the principal consideration is the harsh climate and periodic droughts which completely over-ride all other factors.

8.6, 8.7 & 8.8 Projected/Optimum Drug and Vaccine Requirements to the Year 2000

These requirements are summarised in Annex 1. The likely reduction in the use of prophylactic vaccination against FMD, with the success of current policies, means that the total veterinary market in Botswana is unlikely to expand significantly by the year 2000 in view of the dominance of this one product in the total veterinary market.

8.9 Possibilities for Local Manufacture

8.9.1 Veterinary pharmaceuticals.

There is no local production.

8.9.2 Biologicals

The Botswana Veterinary Institute is an excellent modern virus vaccine laboratory producing Foot and Mouth Disease and Rinderpest vaccines to the highest International Standards.

There is considerable excess capacity in the FMD laboratory and the rinderpest vaccine production unit could be utilised for the production of other vaccine on a campaign basis.

There is also ample space for additional high-security virus-vaccine production units on site.

8.10 Discussion

Within SADCC this virus vaccine Laboratory is in a class of its own, both in plant and equipment and the technical competence and discipline of the staff.

8.11 Recommendations

It is recommended that the B.V.I. be further developed as a regional laboratory.

8.11.1 To expand the regional Foot and Mouth Disease Control Programmes.

8.11.2 To supply inactivated tissue-culture rabies vaccine to the SADCC region on a progressive basis, labelling imported vials, followed by local filling from bulk and eventual local production.

8.11.3 Other viral vaccine of strategic importance within SADCC.

To carry out a feasibility study and costing to produce Blue tongue, African Horse Sickness, lumpy skin, goat pox, sheep pox, Rift Valley Fever and ephemeral fever vaccines for the SADCC region.

A comparison of the cost feasibility of producing these in a totally new unit on the B.V.I. site should be made with production on a campaign basis in the rinderpest vaccine suite.

7.9. ZIMBABWE

9.1 Population Statistics

	Millions	% Growth Rate p.a.
Human	8.25	2.4
Cattle - Communal	3.4	4
Commercial	1.7	0.5
Sheep and Goats	1.4	2
Pigs	.1	-
Poultry - Broilers	15	
Layers	1.5	5
Backyard	30	
Dogs	1.3	-

9.2 Main Animal Diseases

Ectoparasites and tick-borne diseases, trypanosomiasis, foot and mouth disease, malnutrition, anthrax, blackquarter, rabies, brucellosis, helminthiasis, Newcastle disease.

9.3 Organisation of Veterinary Services

There is a good veterinary infrastructure with emphasis on the extension services, backed up by diagnosis and research laboratories.

9.4 The Veterinary Market

The veterinary market is divided roughly equally in value terms between the Government sector concentrating on scheduled diseases and the private sector. Apart from vaccines, most veterinary medicines (drugs and vaccines) are locally formulated. Government purchases are made on a tender basis, usually annually.

The veterinary market value is approximately US $10.4million (Annex 1') of which acaricides account for 46%, anthelmintics 14%, foot and mouth disease vaccine 11%, antibiotics 6%, antiprotozoal drugs 1.5%, poultry vaccines 1.6%, the rest being other vaccines such as rabies, anthrax, brucelia etc.

9.5 Constraints on Drug and Vaccine Usage

Foreign exchange is difficult but there is no over-riding constraint over animal disease control. Steps are being taken to improve the extension services to promote animal health in the communal sector.

9.6 &
9.8 **Projected/Optimum Drug and Vaccine Requirements to the Year 2000**

App. 1/8 gives a summary of these requirements. It is anticipated that the animal disease control policies will continue to be implemented effectively and that the total market will approximately double by the year 2000. There will be a relative increase in drugs associated with livestock production, especially anthelmintics, antibiotics and feed additives.

9.9.1 Veterinary Pharmaceuticals and Acaricides

Zimbabwe has a number of International-class pharmaceutical companies producing a whole range of human and veterinary pharmaceutical products to the highest standards.

A number were inspected, as a result of which two are proposed as suitable for consideration as sources of wider supply within SADCC, namely:-

CAPS Pharmaceuticals, Harare - Pharmaceuticals

Zimphos, Harare - Acaricides.

9.10 Discussion

In the case of both these companies they have licensing agreements with Third Parties with access to research development and technical services, and in the case of Zimphos with a Company for distribution and Technical Servicing.

9.11 Recommendation

It is recommended that SADCC explore the possibilities of using these companies as possible sources of supply within SADCC, and the suitability of maintaining existing licensing arrangements between these companies and licensors of tehcnology and distribution arrangements.

7.10. ANGOLA ca. 950,000Km^2

10.1 Population Statistics

	Millions	% Growth Rate p.a.
Human	8.4	2.3
Cattle	2.0	(-10%)
Sheep and Goats	1.6	-
Pigs	.5	-

10.2 Main Animal Diseases

Malnutrition, trypanosomiasis, ticks, tick-borne disease, contagious bovine pleuropneumonia, foot and mouth disease, rabies, ecchinococcosis, African Horse Sickness, brucellosis, tuberculosis.

10.3 The Organisation of Veterinary Services

Apparently little structure remains.

10.4 The Angolan Veterinary Market

There is no information.

10.5-10.7 Market Constraints and Projections to the Year 2000

Until the security situation improves there is no prospect of improving animal health and increasing drug usage.

10.8 Local Manufacture

There was a small veterinary biologicals unit at Huambo, producing mainly poultry biologicals. It has not produced anything for several years.

10.9&10.10 Discussion and Recommendations

Until the security situation improves, little can be done to help. When there is stability the facilities at Huambo will need to be examined to determine the feasibility of repairing and re-commissioning them.

8. ANIMAL DISEASE PATTERNS

Animal diseases are dominated by three of four over-riding conditions common within the SADCC region.

1 Nutritional Disease

2 Ticks and tick-borne disease

3 Trypanosomiasis and tsetse control.

4 Foot and mouth disease

Also widespread and of secondary importance, but nevertheless of great economic significance are:

5 Endoparasitosis, nematodes, trematodes and cesstodes

6 Miscellaneous bacterial infections causing pneumonia, diarrhoea, mastitis, septicaemia, etc.

7 Infertility, usually resultant on a combination of factors, including specific disease, nutrition management etc.

Of lesser overall importance, but nevertheless important, strategically, localy or sporadically are:

8 Newcastle disease

9 Blackquarter

10 Anthrax

11 Bovine pasteurellosis

12 Brucellosis

13 Tuberculosis

14 Rabies

15 Contagious Bovine Pleuropneumonia

16 Rinderpest

17 African Swine Fever

18 Blue tongue

19 African Horse Sickness

20 Sheep/Goat pox

21 Lumpy skin disease

22 Rift Valley Fever

23 Malignant catarrhal fever.

SADCC - ANIMAL DISEASE PATTERNS

DISEASE \ COUNTRY	TANZANIA	ZAMBIA	MALAWI	MOZAMBIQUE	SWAZILAND	LESOTHO	BOTSWANA	ZIMBABWE	ANGOLA
NUTRITIONAL	+ + +	+ +	+ + +	+ +	+ + +	+ + +	+ + +	+ +	+ + +
ECTOPARASITE/ TICK BORNE	+ + +	+ + +	+ + +	+ + +	+ +	+ + +	+	+ +	+ +
TSETSE/ TRYPONASOMIASIS	+ + +	+ + +	+ + +	+ + +	-	-	+	+ +	+ + +
FOOT AND MOUTH DISEASE	+ + +	+ + +	+ + +	+ + +	+	-	+	+	+ + +
ENDOPARASITES	+ + +	+ +	+ + +	+ +	+ +	+ + +	+	+ + +	+
MISCELLANEOUS BACTERIAL	+ + +	+ +	+ +	+ +	+	+	+	+	+
BLACK QUARTER	+ +	+ +	+ +	+	+ +	+ + +	+ +	+ +	+ +
ANTHRAX	+	+	-	+	-	+	+	+ +	+
BRUCELLOSIS	+	+ +	+	+ +	+ +	+	+ +	+ +	+ +
PASTEURELLOSIS	+	+	+	+	+	-	+	-	+
RINDERPEST	+	-	-	-	-	-	-	-	-
CBPP	-	+ v	-	-	-	-	-	-	+ +
NEWCASTLE DISEASE	+ +	+ +	+ + +	+ + +	+ + +	+ + +	+ + +	+	+
RIFT VALLEY FEVER	-	+	+	+	-	-	-	+	-
SHEEP POX/LUMPY SKIN	+	+	-	-	-	-	-	+	-
RABIES	+ +	+ +	+ +	+ +	+ +	+ +	+ +	+	+ +

+++ high incidence
++ medium incidence
+ low incidence
- free of disease

TABLE I.

Figure 1

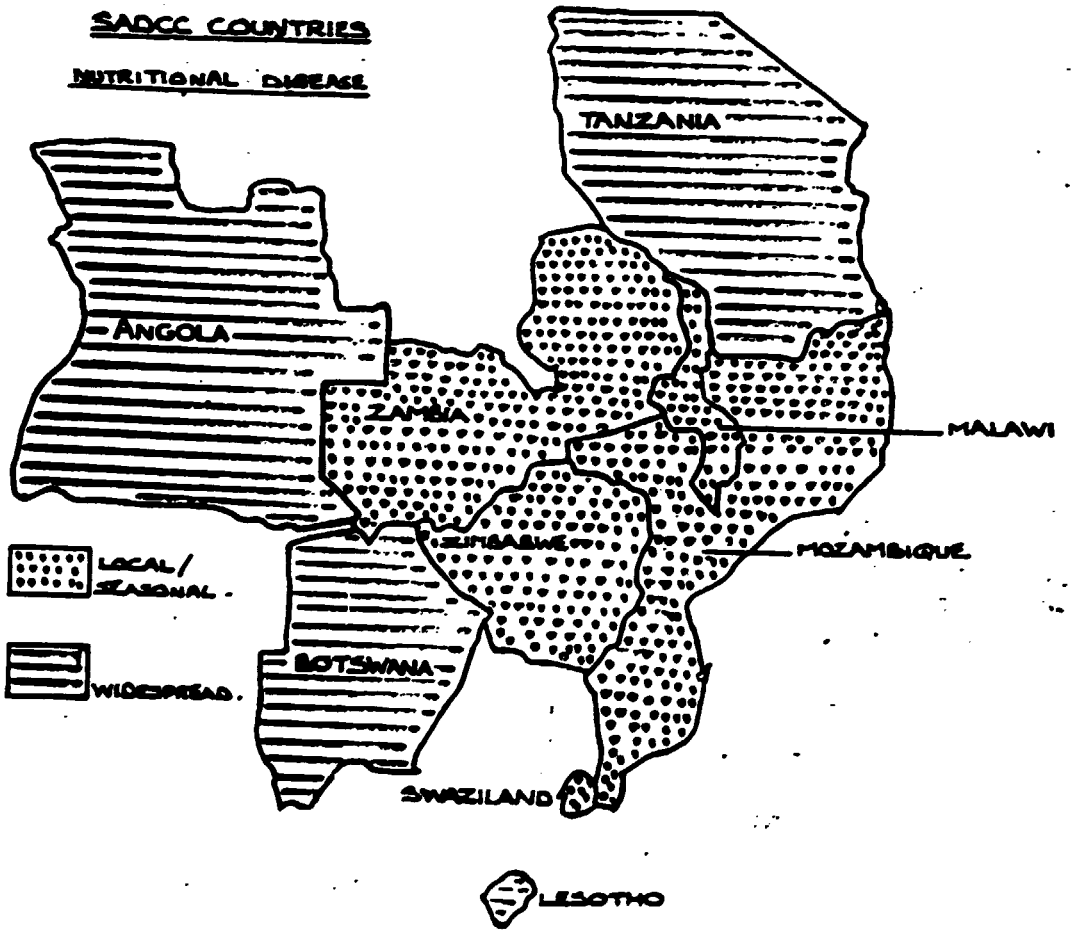

SADCC COUNTRIES
NUTRITIONAL DISEASE
TANZANIA
ANGOLA
ZAMBIA
MALAWI
ZIMBABWE
MOZAMBIQUE
LOCAL/ REGIONAL
WIDESPREAD
BOTSWANA
SWAZILAND
LESOTHO

Figure 2

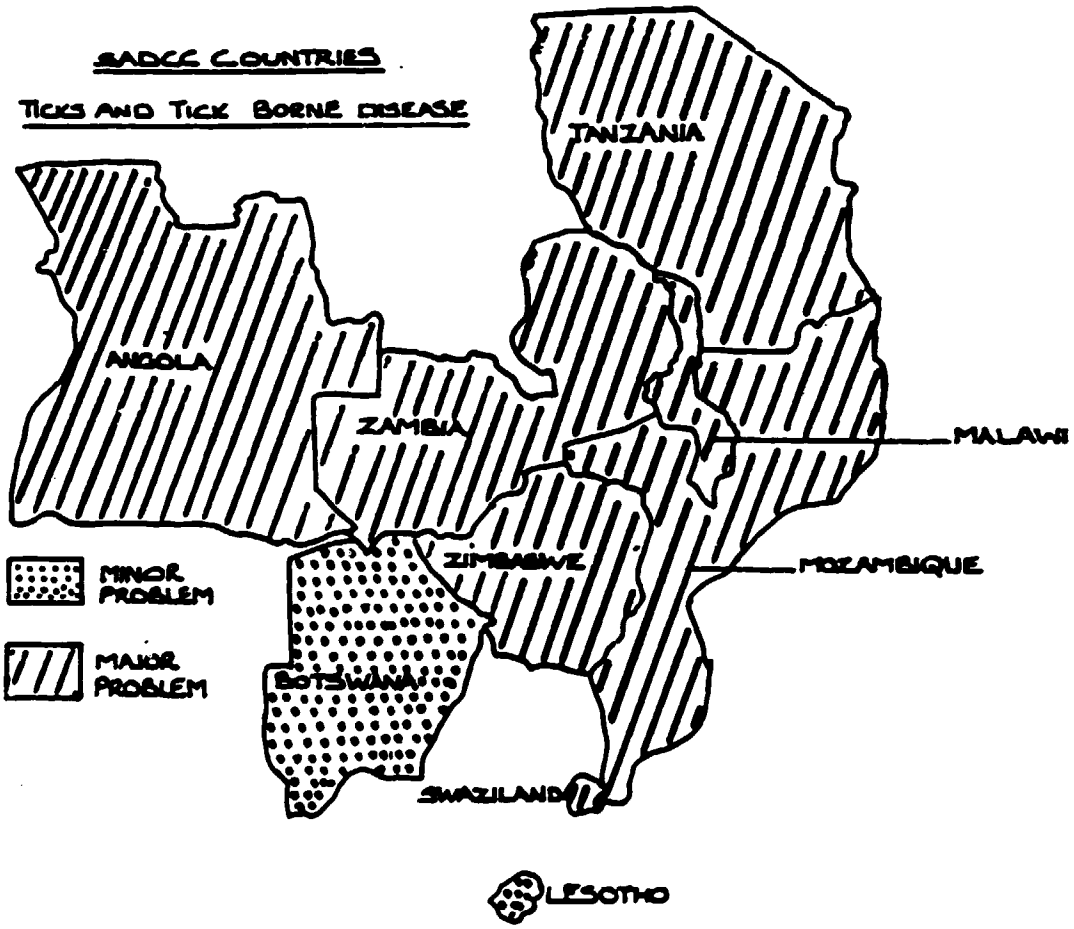

SADCC COUNTRIES
TICKS AND TICK BORNE DISEASE
TANZANIA
ANGOLA
ZAMBIA
MALAWI
ZIMBABWE
MOZAMBIQUE
MINOR PROBLEM
MAJOR PROBLEM
BOTSWANA
SWAZILAND
LESOTHO

Figure 3

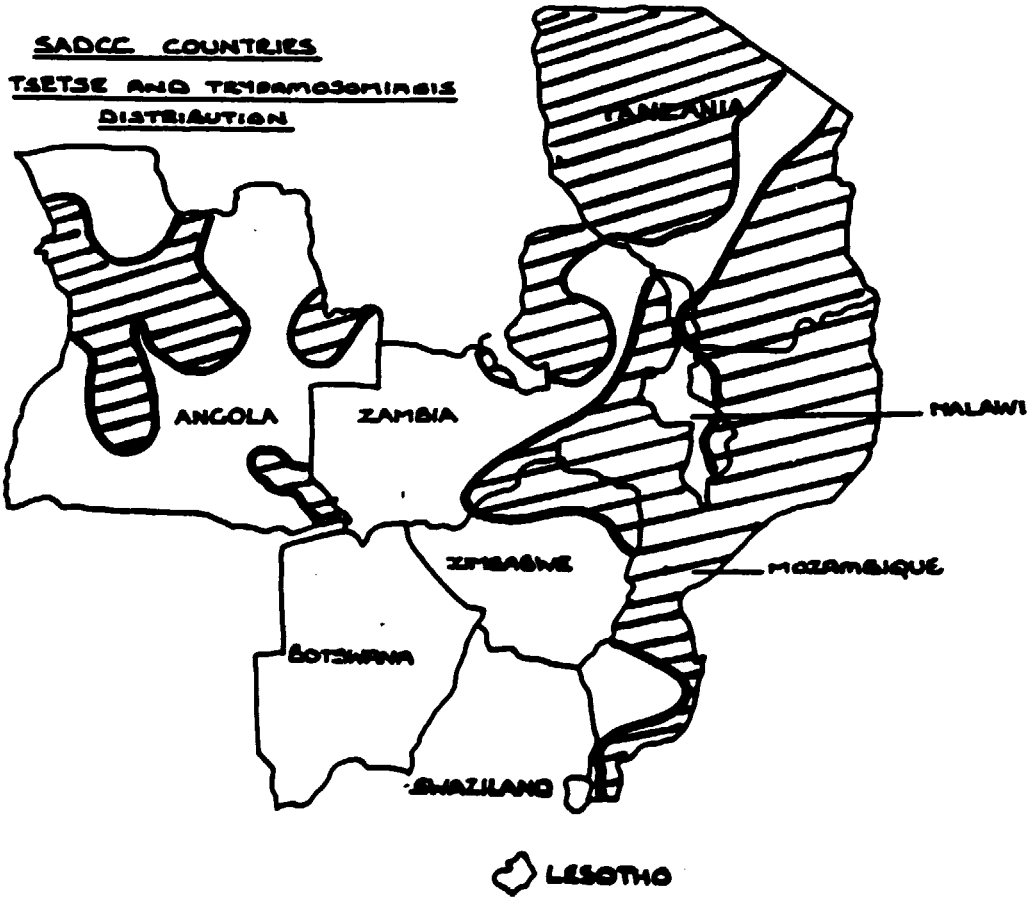

SADCC COUNTRIES
TSETSE AND TRYPANOSOMIASIS
DISTRIBUTION
TANZANIA
ANGOLA
ZAMBIA
MALAWI
ZIMBABWE
MOZAMBIQUE
BOTSWANA
SWAZILAND
LESOTHO

Figure 4

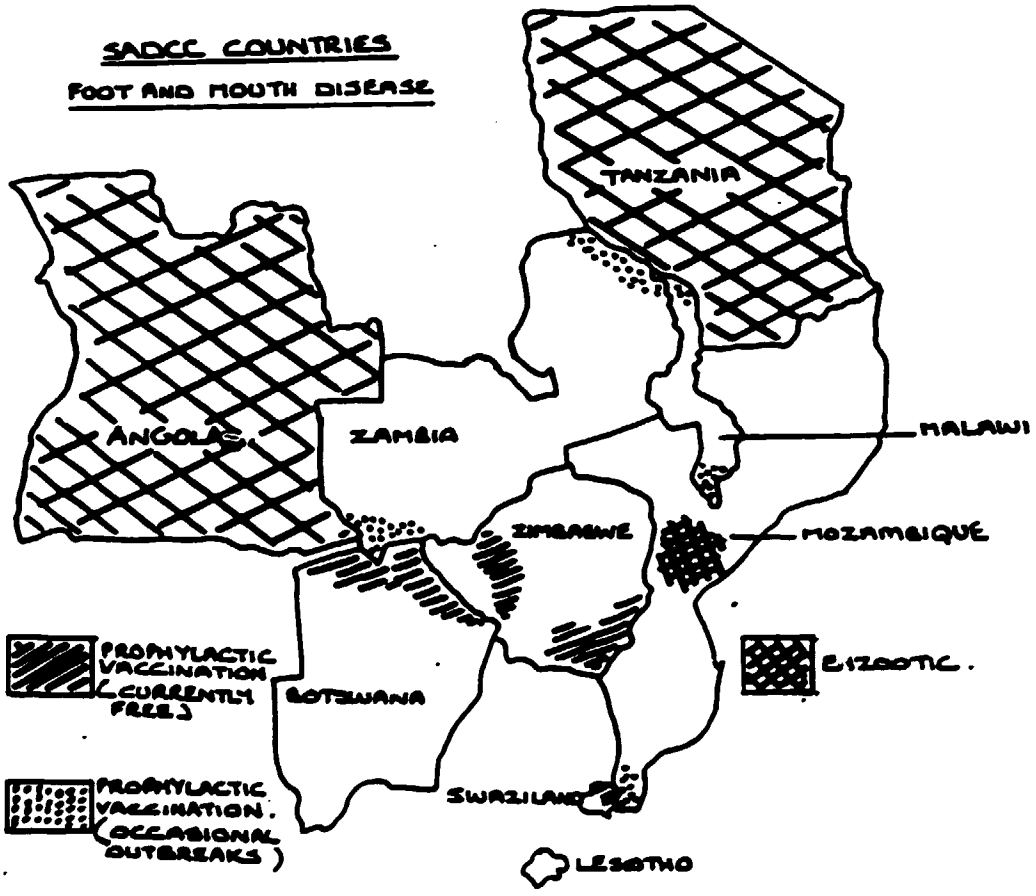
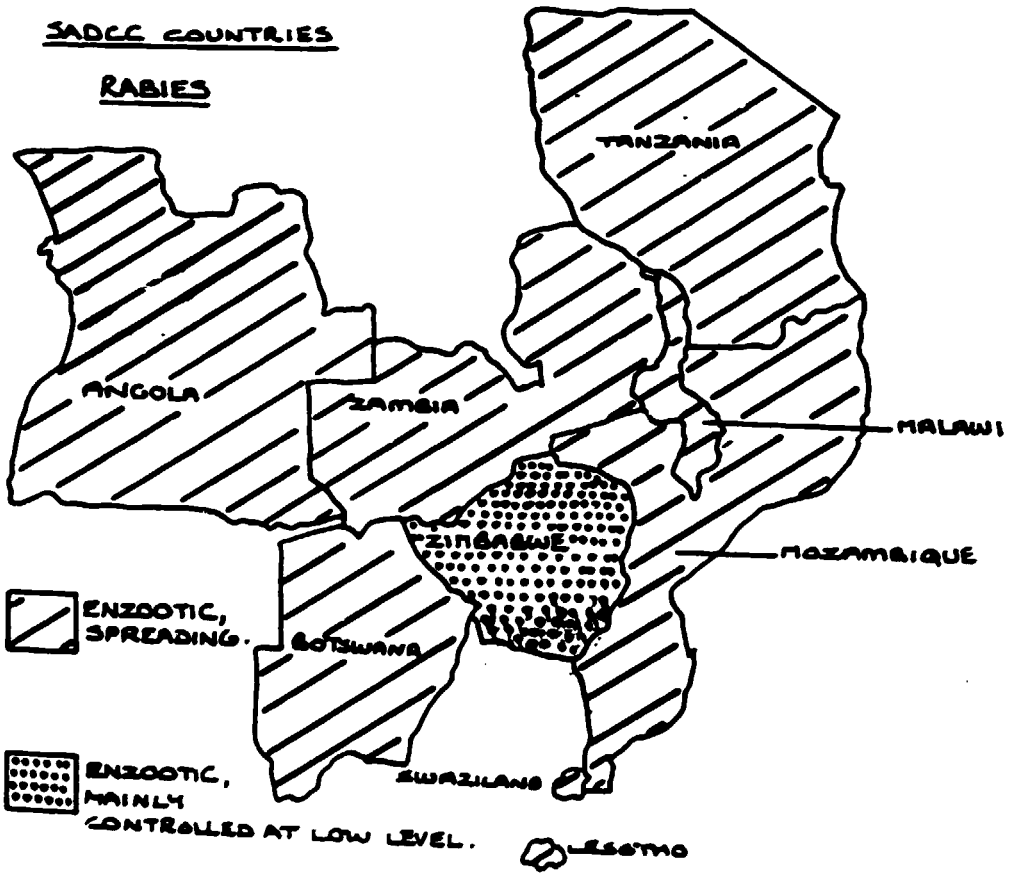

SADCC COUNTRIES
FOOT AND MOUTH DISEASE
TANZANIA
ANGOLA
ZAMBIA
MALAWI
ZIMBABWE
MOZAMBIQUE
PROPHYLACTIC VACCINATION (CURRENTLY FREE)
ENZOOTIC.
BOTSWANA
PROPHYLACTIC VACCINATION. (OCCASIONAL OUTBREAKS)
SWAZILAND
LESOTHO

Figure 5


SADCC COUNTRIES
RABIES
TANZANIA
ANGOLA
ZAMBIA
MALAWI
ZIMBABWE
MOZAMBIQUE
ENZOOTIC, SPREADING.
BOTSWANA
ENZOOTIC, MAINLY CONTROLLED AT LOW LEVEL.
SWAZILAND
LESOTHO

9. REGIONAL STRATEGIES FOR ANIMAL DISEASE CONTROL WITHIN SADCC

There are a limited number of infectious diseases where a Regional Control Strategy is highly desirable, if not an absolute necessity.

These include the following:-

Foot and Mouth Disease

Rabies

Contagious Bovine Pleuropneumonia

Rinderpest

In respect of each of the above diseases the need for a regional approach has long been recognised, and in the case of Foot and Mouth Disease and Rinderpest, the control policies well established.

Contagious bovine pleuropneumonia has been confined to Angola until recently when it spread to Zambia in 1970 and is also threatening Namibia. Since then a sanitary cordon with animal vaccination in the Western Province, and strict movement control has prevented any further outbreaks. The situation in Angola is unknown.

9.1 Foot and Mouth Disease

Great strides have been made within the SADCC within the last 5 years in the regional strategy to control Foot and Mouth Disease.

At the time of writing there is no clinical disease in the domestic livestock in Swaziland, Lesotho, Botswana, Zimbabwe or the Republic of South Africa. Furthermore, Botswana, Zimbabwe and Swaziland are recognised as disease-free countries to the extent that meat exports are permitted to the EEC.

In Zambia, regular prophylactic vaccination campaigns are carried out twice a year along the Tanzanian border and near the Caprivi strip. The last clinical cases were reported in 1982, until an outbreak in September 1986.

In Malawi the main threat is on the Northern boundary with Tanzania, the last two outbreaks being in 1981 and 1982.

In the south of the country there is a constant risk of introduction of FMD from neighbouring Mozambique, the last outbreak occuring in 1985. Prophylactic vaccination twice a year is practised along the two boundaries.

Mozambique. Although Foot and Mouth Disease has not been diagnosed for the last few years in the south of the country, the Kruger Park is regarded as a constant threat and vaccination along the border is practised when possible. A low enzootic state is believed to persist in the Zambezi valley.

Swaziland last suffeed an outbreak in 1969. Regular barrier-vaccination along the Mozambique border, together with zoosanitary measures have maintained the country disease-free since then.

Lesotho is free from FMD and surrounded by RSA, itself free. Tanzania is the one country within the SADCC which is suffering from enzootic Foot and Mouth Disease, with occasional epizootics. At least four virus types are known to occur there, and large moving cattle populations present a constant risk both to the spread of disease within Tanzania and re-infection of neighbouring countries, especially Malawi and Zambia.

Proposed Regional Strategy

In view of the EEC meat import regulation, Botswana, Zimbabwe and Swaziland have little option to continuing systematic barrier vaccination in defined high-risk areas (e.g. round game parks) coupled with strong zoosanitary measures as a basic policy, together with emergency plans for stamp-out, ring-vaccination and stand-still measures should outbreaks occur.

In both Malawi and Zambia little further protection could be provided other than, possibly, to carry out more effective FMD control measures in the Capr'·i strip (to assist Zambia) and to provide effective buffer vaccination and movement control on the Mozambique side of the border with Malawi.

Therefore, on a SADCC regional basis the only country where additional effective action can be taken is Tanzania. In Tanzania, Foot and Mouth Disease is recognised as the fourth most important animal disease (after nutritional deficiency, trypanosomiasis and tick-borne diseases). The cattle population is about 13,000,000 head.

It is recommended, therefore, that, for FMD control, Tanzania be identified as a priority animal health objective within SADCC, and that a progressive strategy in its control should be developed along the following lines:

1) Gaining field information on outbreaks, geographical, seasonal class of animal, etc.

2) Collection of virus samples and their despatch for laboratory examination.

3) Laboratory support to type the viruses responsible and carry-out serological examinations.

4) Establish a local FMD diagnostic laboratory under the technical guidance of an appropriate regional laboratory.

5) In parallel with 1, 2 and 3 (above) increase the use of vaccine in the high risk classes of animals including:

5.1 Commercial dairy cattle.

5.2 Commercial ranch cattle
(These vaccination should be carried out twice a year with polyvalent vaccines, at least until more epidemiological knowledge is available).

5.3 The vaccination of trade cattle prior to movement, coupled with physical examination and quarantine.

5.4 The regular mass vaccination of nomadic cattle (principally Masai).

6) This phase of the strategy would take up to 5 years and should be accompanied by an economic study (benefit/costs analysis) and a detailed long-term plan regarding country-wide control (Phase 2).

7) At this stage the decision could be taken on the desirability of local production versus bulk imports of vaccine or final product.

8) It is suggested that Phase 1 would take 5 years and Phase 2 would take the following decade.

9) It is likely that the BVI would have capacity to meet the requirements for Phase I without any additional capital investment.

10) The ability of the Kenya FMD Laboratory to supply vaccines containing strains of FMD virus antigen appropriate for Tanzania must be borne in mind especially in relation to the Masai cattle.

Likely FMD Vaccine Off take 1986-2000 from BVI with/without Tanzania Campaign

	1986		1990		2000	
Country	000's Mono Dose	US $ 000's	000's Mono -equiv.	US $ 000's	000's Mono Dose	US $ 000's
BOTSWANA	3,600	1,080	2,400	960	2,400	1,200
ANGOLA	-	-	150	60	150	75
LESOTHO	-	-	-	-	-	-
ZIMBABWE	3,900	1,170	3,900	1,560	3,900	1,750
MOZAMBIQUE	30	30	900	300	900	300
MALAWI	190	209	300	330	360	396
ZAMBIA	350	175	385	192	470	235
SWAZILAND	140	40	140	50	140	60
TANZANIA	300	210	9,000	4,500	10,000	5,000
S.AFRICA	30	15	30	15	30	15
STRATEGIC RESERVES EST.	1,000	300	1,000	400	1,000	500
TOTALS	9,530	3,229	18,205	8,367	19,350	9,531
(WITHOUT TANZANIA)	9,230	3,019	9,205	3,865	9,350	4,531

9.2 **Rabies**

With the possible exception of Zimbabwe rabies is a growing problem within SADCC, in part due to the increasing urbanisation within the region.

Vaccination of dogs is the basis of control campaigns, together with destruction of strays and, sometimes, wild vectors.

In almost all cases the control campaigns are under-resourced and a variety of vaccines of greatly varying quality are used. Some countries produce small quantities of vaccines in unpredictable amounts or quality.

It is recommended that a regional strategy to the control of rabies be adopted and that all campaigns be based on good quality tissue culture vaccine containing at least 3 I.U per dose, thus affording three years protection. Such vaccines are also highly stable.

In view of the expertise currently existing at the BVI it is proposed that the possibility of regional supply from this laboratory be examined for:

1) Price of competitiveness

2) Feasibility

The regional requirement for rabies vaccine is great, but bearing in mind current resources limitation, the following are believed to be realistic estimates of offtakes by 1990 and projection for 2000.

COUNTRY	1986 Doses	1990 Doses	2000 Doses
Tanzania	100,000	500,000	700,000
Zambia	37,000	250,000	250,000
Malawi	56,000	200,000	250,000
Mozambique	20,000	100,000	200,000
Swaziland	50,000	70,000	100,000
Lesotho	20,000	40,000	60,000
Zimbabwe	380,000	700,000	1,000,000
Botswana	50,000	50,00	50,000
Angola	0	0	0
TOTALS	713,000	1,910,000	2,610,000

It is recommended that the development of the BVI as a regional centre to supply rabies vaccine to the SADCC should be made a strategic objective.

Three phases shoud be studied:

1) The importation of finished vials for local labelling and distribution.

2) The importation of bulk concentrate for local filling.

3) The local production of rabies vaccine.

In any agreement to Phase I there must be a simultaneous commitment to Phases 2 and 3.

9.3 Rinderpest

Rinderpest control is a subject of Pan African Policy and therefore it is not subject of this report.

9.4 Contagious Bovine Pleuropneumonia (CBPP)

An ongoing well-established policy is in operation to contain and eventually eliminate CBPP.

10. PRODUCTION OF SMALL VOLUME VIRAL VACCINES FOR THE SADCC REGION

There are a number of viral diseases of sporadic and/or local importance within SADCC, for which vaccines are not readily available from any source due to the lack of regular demand on the world market, moreover the volume of products is small. These include:

	Assumed Annual offtake for Planning Purposes
Sheep pox Goat pox Lumpy skin	2×10^6 doses
Blue tongue	1×10^6 doses
Rift Valley Fever	0.5×10^6 doses
African Horse Sickness	0.2×10^6 doses
Malignant Catarrhal Fever	0.1×10^6 doses
Ephemeral Fever	0.1×10^6 doses

It is recommended:

That a feasibility study be carried out at the BVI to produce these vaccines for the SADCC region.

a) Using the rinderpest-vaccine suite on a campaign basis.

b) Constructing dedicated high-security production facilities on the BVI site adjacent to the present building for producing these vaccines.

c) A combination of campaign production in the present rinderpest vaccine production suite and dedicated new facilities.

11. CONSTRAINTS ON DRUG AND VACCINE USAGE WITHIN SADCC

With the specific exceptions of the private sector in Zimbabwe, Zambia and Swaziland, the application of veterinary drugs, acaricides and vaccines within SADCC almost entirely exercised by the Government Veterinary Authorities of the Member Countries. Within these three countries the private sector may purchase drugs through commercial channels, but their usage for scheduled diseases is controlled by government regulation.

With a few notable exceptions, the constraints on drug and vaccine usage within SADCC reflect the low priority afforded to animal disease control by the respective governments. The acute financial constraints imposed on the Veterinary Authorities in the majority of countries means that they are unable to carry out essential animal health activities such as maintaining good communications, adequate diagnostic services, disease monitoring systems, quarantine, or stock movement control.

At national level the difficulties of implementation of animal disease control policies represent the major impediment to disease control and hence the appropriate use of veterinary drugs and vaccines.

Within the Veterinary extension services the lack of investment has caused major difficulties at all levels. From transport and distribution of drugs, the availability of equipment, the repair and maintenance of dip-tanks, the staffing of extension services, training of livestock attendants, monitoring dip wash concentrates, parasite resistance monitoring, farmer education etc., all aspects are sadly lacking in many countries.

The unavailability of drugs in certain countries may represent the over-riding constraints to drug and vaccine usage at the present time. But any long-term scheme to establish local production of veterinary drugs and biologicals must be linked to rational properly resourced animal disease control policies throughout the Member Countries.

The question of Regional Strategies is largely outside the scope of this report as it impinges on Pan-African strategies in the case of infectious diseases such as Rinderpest control, or other areas such as vector control, in the case of trypanosomiasis, (which is already the subject of a regional control policy). Regional Policies will therefore only be referred to in the cases of Foot and Mouth Disease and Rabies control.

The constraints on drug dn drug and vaccine usage are illustrated in Table II. The number of crosses are indicative of the severity of the problem which cannot be reliably quantified, and they are deducted by team members on the base of information given by the national authorities.

Table 11

CONSTRAINT \ COUNTRY	TANZANIA	ZAMBIA	MALAWI	MOZAMBIQUE	SWAZILAND	LESOTHO	BOTSWANA	ZIMBABWE	ANGOLA
FOREIGN EXCHANGE FOR DRUG PURPOSE	+ + + +	+ +	+ + + +	+ + + +	-	-	-	+	+ + + +
LOCAL BUDGET	+ + + +	+ + + +	+ + + +	+ + + +	+ +	+	-	+	+ + + +
DIAGNOSIS	+ + + +	+ +	+ +	+ + + +	+	-	+	+	+ + + +
DISEASE QUANTIFICATION	+ + + +	+ +	+ +	+ + +	+	-	+	+	+ + + +
DISEASE MONITORING	+ + + +	+ +	+ +	+ + + +	+	-	+	+	+ + + +
INFRASTRUCTURE	+ + +	+ +	+ +	+ + + +	+	+	+	+	+ + + +
STAFFING	+ + +	+ +	+ +	+ + +	+	+	+	+	+ + + +
COMMUNICATIONS	+ + + +	+ +	+ +	+ + + +	+	+ +	+	+	+ + + +
TRANSPORT	+ + + +	+ +	+ + +	+ + + +	+	+ +	+ + +	+	+ + + +
DISTRIBUTION	+ + +	+ +	+ +	+ + + +	-	+ +	+	+	+ + + +
FUNCTIONAL DIP TANKS	+ + +	+ +	+ +	+ + +	-	+	-	+	+ + + +
EQUIPMENT	+ + +	+ +	+	+ + +	-	+	-	+	+ + + +
FARMER INCENTIVES	+ +	+ + +	+	+ + +	+	+	-	+	+ + +
SECURITY	-	-	-	+ + + +	-	-	-	-	+ + + +

12. POSSIBLE LICENSING ARRANGEMENTS FOR THE ACQUISITION OF LOCAL VETERINARY PHARMACEUTICAL, ACARICIDE AND BIOLOGICAL MANUFACTURE WITHIN SADCC COUNTRIES

It is strongly recommended that candidate licensors should be reputable commercial veterinary acaricide or biological manufacturers with appropriate qualifications

Veterinary products and acaricides to be produced within SADCC should be manufactured under conditions as dictated by good manufacturing practice and final product specifications should comply with international standards of safety, potency, efficiency etc., e.g., Eur.Ph; B.Vet.C.

Type of Licensing Arrangement

Various types of licensing arrangements could be considered.

1) A turnkey project whereby the licensor is totally responsible for establishing local production and either hands over the going operation at an agreed point, usually with a consultancy agreement, or continues on a management control basis.

2) A technology-transfer contract whereby the local partner (Government, parastatal or private) concerned assumes the role of main contractor being directly responsible for the site, services, buildings and utilities including the provision of test animals where necessary, under the direction of the licensor.

   The licensor is responsible for providing the outline specifications of the buildings and ancillary services and utilities and the detailed design and specifications of all process plant and equipment. He is also technically responsible for all aspects of the production process and quality control, including the provision of suitable raw materials for production and control, and the training of key staff. The licensor is responsible for the procurement, shipping, installation and commissioning of all process plant and equipment. In the case of the process, which includes the provision of suitable seed materials (cells, viruses, bacteria, etc.) and challenge strains of organisms where necessary. As in the case of a turn-key project, the completion of commissioning can be followed by a management contract or hand-over with or without a consultancy contract.

3) Another option would be to invite commercial companies with suitable qualifications to produce locally for SADCC. This would be less onerous and cheaper in the short-term but a careful study would have to be made regarding long-term implications of such a course.

Recommendation

It is recommended that licensing arrangements along the lines of Option 2 be pursued in the case of biologicals and either Option 2 or 3 in the case of both pharmaceuticals and acaricides.

13. ANCILLARY REASONS FOR ESTABLISHING LOCAL VETERINARY PHARMACEUTICAL AND BIOLOGICAL PRODUCTION FACILITIES

1) To establish new national industries.

2) To develop new technologies.

3) To develop centres of expertise and training which can be used in other areas.

4) To be in control of the production of veterinary drugs and vaccines which are of strategic importance to the National Economies and which may not be available elsewhere.

5) By the creation of new technologies, to reduce the dependency on outside sources for essential drugs and vaccines and possibly to save on foreign exchange.

6) To be able to trade with foreign countries in additional product areas.

14. CONSIDERATIONS FOR CHOICE OF LICENSOR FOR COLLABORATION WITH SADCC IN ESTABLISHING LOCAL VETERINARY PHARMACEUTICAL PRODUCTION FACILITIES

1) The licensor should be a reputable commercial veterinary pharmaceutical company with wide experience in animal-disease control.

2) The licensor should be technically-based with a strong development activity and access to new products.

3) The licensor should be familiar with the animal diseases and the range of veterinary products and formulations suitable for the region.

4) The licensor should be able to offer technical support in production development and quality control and prepared to accept trainees of technical and management staff of Licence.

5) The licensor should also be able to offer technical support to products in the field and additional laboratory support where appropriate.

Considerations for Choice of Licensor for Collaboration with SADCC in Establishing Local Veterinary Acaricide Production Facilities

1) The licensor should be a reputable veterinary acaricide commercial company with wide experience in animal-disease control.

2) The licensor should be technically-based with a strong development activity and access to new products.

3) The licensor should be familiar with the animal diseases and the range of veterinary products and formulations suitable for the region.

4) The licensor should be able to offer technical support in production, development and quality control.

5) The licensor should also be able to offer technical support to products in the field and additional laboratory support where appropriate.

Considerations for Choice of Licensor for Co aboration with SADCC in Establishing Local Veterinary Biological Production Facilities

1) The licensor should be a reputable Commercial Veterinary Biological Company with wide experience of the biological control of animal diseases.

2) The licensor should be technically-based with a strong development activity and access to new products.

3) The licensor should be familiar with the animal diseases and the range of veterinary vaccines suitable for the region.

4) The licensor should be able to offer on-going technical support in the production, development and quality control of veterinary biologicals and offer technological and managerial training to employees of licencee.

5) The licensor should also be able to offer technical assistance to biological products in the field and additional laboratory support where appropriate.

15. CRITERIA FOR ESTABLISHMENT OF LOCAL PRODUCTION FACILITIES

In the following two tables (Table III-IV) scores from - to +++ are indications of merit on a comparative basis. No score denotes lack of adequate information.

Table III

CRITERIA FOR THE ESTABLISHMENT OF LOCAL PRODUCTION FACILITIES FOR VETERINARY PHARMACEUTICALS

CONSIDERATION \ COUNTRY	TANZANIA	ZAMBIA	MALAWI	MOZAMBIQUE	SWAZILAND	LESOTHO	BOTSWANA	ZIMBABWE	ANGOLA
1. Domestic requirement	+++	+	+	+	+	+	+	++	
2. Disease control campaigns	+	++	+		+++	+++		+++	
3. Diagnostic facilities	+	++	+		+++	+	+++	+++	
4. Extension services	+	++	+		++	++	++	+++	
5. Communications system	+	+	+		++	+	+	++	
6. Storage and distribution system	+	++	+		+++	++	+++	+++	
7. Available premises/land for expansion	+++	+			+++	+++		+++	
8. Available technology to utilise	++				+	+		+++	
9. Trained personnel available	++				+	+		+++	
10. Site, services, utilities, to be shared	++				+	++		+++	
11. Ability to carry-out quality control	++				+	+++		+++	
12. Reliable raw material supply					+				
a) Imported					+++			+++	
b) Local								+++	
13. Availability of ancillary industries, eg. electronics, glassware, packaging	+	+			++	+		+++	

Table IV

CRITERIA FOR THE ESTABLISHMENT OF LOCAL PRODUCTION FACILITIES FOR VETERINARY BIOLOGICALS

CRITERIA \ COUNTRY	TANZANIA	ZAMBIA	MALAWI	MOZAMBIQUE	SWAZILAND	LESOTHO	BOTSWANA	ZIMBABWE	ANGOLA
1. Domestic requirement	+++	+	+	+	+	+	+	++	
2. Disease control campaigns	+	++	+		+++	+++	+++	+++	
3. Diagnostic facilities	+	++	+		+++	+	+++	+++	
4. Extension services	+	++	+		++	++	++	+++	
5. Communication system	+	+	+		++	+	+	++	
6. Storage and distribution system	+	++	+		+++	++	+++	+++	
7. Available premises/land for expansion	+++	+++	+	+++	+	+	+++	+	
8. Available technology to utilise	+	++	-	+	-		+++		
9. Trained personnel available	+	++	-	+	-		+++	+	
10. Site, services, utilities, to be shared	+++	++	-	+	+	+	+++	+	
11. Ability to carry-out quality control	+	++	-	+	-		+++		
12. Reliable raw material supply									
a) Imported	+	+	-		+		+++	++	
b) Local	+	+	-		+++			+	
13. Availability of ancillary industries, e.g. electronics, glassware, packaging	+	+	+		++			+++	

Annex I

VETERINARY DRUGS AND VACCINES: CONSOLIDATED USE (1986) AND ESTIMATED OPTIMAL REQUIREMENTS (1990 and 2000) *

COUNTRY: SADCC REGION**

DRUG/BIOLOGICAL	YEAR					
	1986		1990		2000	
	UNITS	VALUE US$000's	UNITS	VALUE US$000's	UNITS	VALUE US$000's
Ectoparasiticides		11,211		15,677		21,448
Anthelmintics		2,498		3,335		9,200
Antibiotics		3,051		4,170		6,585
Antiprotozoons		1,711		3,714		5 814
Feed Additives		2,220		2,848		4,670
SUB-TOTAL		20,691		29,744		47,087
Biologicals (doses x 000)						
FMD	8,660	2,858	17,025	6,469	18,170	8,722
Rinderpest	4,726	331	2,575	206	2,795	279
Rabies	713	466	1,922	1,095	2,620	1,312
çPoultry vaccines	91,519	274	158,000	474	221,200	723
Other viral vacc. (Rift Valley Fever African Horse Sickness etc)	1,283	385	3,500	1,225	4,000	1,800
Blackquarter	4,999	500	10,874	1,305	12,053	1,687
Anthrax	7,285	728	14,905	1,789	16,401	2,296
Brucella	1,006	201	2,429	559	2,712	813
Pasteurella	675	67	3,240	389	3,750	525
Botulism	1,000	100	1,000	120	1,000	140
SUB-TOTAL		5,910		13,631		18,897
TOTAL		26,601		43,375		65,984

ç Mainly NDV
* Taking 'optimistic' viewpoint on the requirements of Tanzania, Zambia, Malawi and Mozambique
** Assuming US$ inflation at 15% to 1990 and a further 30% to 2000

VETERINARY DRUGS AND VACCINES USED (1986) AND ESTIMATED OPTIMAL REQUIREMENTS (1990 and 2000)

COUNTRY: TANZANIA

DRUG/BIOLOGICAL	YEAR 1986 UNITS	1986 VALUE US$000's	1990 UNITS	1990 VALUE US$000's	2000 UNITS	2000 VALUE US$000's
Ectoparasiticides	IMMERSIONS		IMMERSIONS		IMMERSIONS	
Toxaphene	130M*	2,900	100M	2,300		
Organo-phosphorous	6M	600	100M	2,500	150M	4,000
Amidine pyrethroid					100M	3,000
Anthelmintics	DOSES		DOSES		DOSES	
	1,200,000	250	2,400,000	500	4,800,000	1,000
Antibiotics	DOSES	1,500	DOSES	2,000	DOSES	3,000
Tetracycline	5,000,000		6,250,000		9,400,000	
Other	1,250,000		1,550,000		2,300,000	
Antiprotozoons						
Samorin	2,000,000	1,000	4,000,000	2,000	6,000,000	3,000
Berenyl	30,000	250	15,000,000	500	900,000	750
Butelex		0		100		500
Feed Additives						
		150		200		250
SUB-TOTAL		6,750		10,030		15,500
Biologicals (doses)						
FMD	300,000	210	9,000,000	4,500	10,000,000	5,000
Rinderpest	4,856,000	325	2,500,000	167	2,700,000	181
Rabies	100,000	60	500,000	330	700,000	420
Poultry vaccines	5,000,000	30	40,000,000	240	60,000,000	360
Other viral vacc. (Rift Valley Fever African Horse Sickness etc)	732,000	190	999,000	257	1,180,000	307
Blackquarter	1,500,000	90	6,800,000	408	7,539,000	452
Anthrax	1,500,000	135	7,461,000	671	8,298,000	747
Brucella	0		1,220,000	366	1,318,000	395
Pasteurella	0		2,500,000	500	3,000,000	600
Botulism	0		0		0	
Others	0		0	20	0	25
SUB-TOTAL		1,040		7,429		8,487
TOTAL		7,790		17,459		23,987

* M million units

VETERINARY DRUGS AND VACCINES USED (1986) AND ESTIMATED OPTIMAL REQUIREMENTS (1990 and 200)

COUNTRY: ZAMBIA

DRUG/BIOLOGICAL	YEAR 1986		1990		2000	
	UNITS	VALUE US$000's	UNITS	VALUE US$000's	UNITS	VALUE US$000's
Ectoparasiticides						
Organo phosphorous Amidines Pyrethoid		1,100		2,655		4,000
Anthelmintics	LITRES					
	6,000	500	12,000	1,000	1,800	1,500
Antibiotics	DOSES					
Tetracycline	500,000	650	1,000,000	1,000	1,500,000	1,500
Others	150,000					
Antiprotozoons						
Samorin	680,000	340	1,000,000	500	1,000,000	500
Berenyl	320,000	160	500,000	250	500,000	250
Feed Additives						
		450		600		800
SUB-TOTAL						
		3,200		6,005		7,050
Biologicals (doses x 000)						
FMD	350,000	175	385,000	192	470,000	235
Rinderpest	40,000	12	44,000	13	58,000	17
Rabies	37,000	66	250,000	150	250,000	150
Poultry vaccines	643,000	106	31,900,000	528	41,000,000	714
Other viral vacc. (Rift Valley Fever African Horse Sickness etc)						
Blackquarter	1,200,000	144	1,350,000	162	1,750,000	210
Anthrax	485,000	73	544,000	81	703,000	105
Brucella	240,000	72	264,000	79	316,000	95
Pasteurella	250,000	37	250,000	37	250,000	37
Botulism Others & PPLO		20		25		35
SUB-TOTAL						
		799		1,267		1,598
TOTAL						
		3,999		7,272		8,648

VETERINARY DRUGS AND VACCINES USED (1986) AND ESTIMATED OPTIMAL REQUIREMENTS (1990 and 2000)

COUNTRY: MALAWI

DRUG/BIOLOGICAL	YEAR 1986		1990		2000	
	UNITS	VALUE US$000's	UNITS	VALUE US$000's	UNITS	VALUE US$000's
Ectoparasiticides	LITRES					
Arsenic and Toxaphene	120,000	63				
OR						
Amidine	5,000	15	125,000	340	250,000	680
Anthelmintics	DOSES					
	150,000	30	300,000	60	600,000	120
Antibiotics						
	120,000	40	240,000	80	480,000	160
Antiprotozoons						
Samorin	47,000	13	150,000	15	150,000	15
Berenyl		34				
Feed Additives						
		55		90		90
SUB-TOTAL		250		720		1,200
Biologicals (doses)						
FMD	190,000	209	300,000	330	360,000	396
Rinderpest	100,000	6.7	31,000	2	87,000	2
Rabies	56,000	33.6	200,000	120	250,000	150
Poultry vaccines	3,589,000	12.1	9,700,000	47	17,800,000	80
Other viral vacc. (Rift Valley Fever African Horse Sickness etc)	240,000	60	250,000	67	350,000	94
Blackquarter	26,000	2.4	300,000	27	300,000	27
Anthrax	0	0	100,000	11	100,000	11
Brucella	6,000	1.8	115,000	34	138,000	41
Pasteurella	0		50,000	7	50,000	7
Botulism	0		0		0	
Others	0			10		12
SUB-TOTAL		326		655		820
TOTAL		576		1,375		2,020

VETERINARY DRUGS AND VACCINES USED (1986) AND ESTIMATED OPTIMAL REQUIREMENTS (1990 and 2000)

COUNTRY: MOZAMBIQUE *

DRUG/BIOLOGICAL	YEAR 1986		1990		2000	
	UNITS	VALUE US$000's	UNITS	VALUE US$000's	UNITS	VALUE US$000's
Ectoparasiticides			500,000	261	500,000	712
Anthelmintics		10		50		100
Antibiotics		15		50		100
Antiprotozoons		15		400		600
Feed Additives		10		50		50
SUB-TOTAL		50		811		1,562
Biologicals (doses)						
FMD	30,000	30	900,000	300	900,000	300
Rinderpest						
Rabies	20,000	2	100,000	20	200,000	40
Poultry vaccines						
Other viral vacc. (Rift Valley Fever African Horse Sickness etc)	100,000	5	1,000,000	20	2,000,000	40
Blackquarter	0	0	500,000	50	500,000	50
Anthrax	0	0	300,000	30	300,000	30
Brucella	0	0	20,000	5	30,000	75
Pasteurella	0	-	-	-	-	-
Botulism						
Others	10,000	1	20,000	2	30,000	3
SUB-TOTAL		38		427		470.5
TOTAL		88		1,238		2,032.5

*These figures are highly speculative as they depend on stability in the country and re-establishment of the veterinary services and disease control campaigns.

VETERINARY DRUGS AND VACCINES USED (1986) AND ESTIMATED OPTIMAL REQUIREMENTS (1990 and 2000)

COUNTRY: SWAZILAND

DRUG/BIOLOGICAL	YEAR 1986		1990		2000	
	UNITS	VALUE US$000's	UNITS	VALUE US$000's	UNITS	VALUE US$000's
Ectoparasiticides		1,600		1,700		1,800
Anthelmintics		50		60		80
Antibiotics		150		180		200
Antiprotozoons		5		5		10
Feed Additives		295		200		320
SUB-TOTAL		2,100		2,245		2,410
Biologicals (doses)						
FMD	140,000	40	140,000	50	140,000	60
Rinderpest						
Rabies	50,000	50	70,000	70	100,000	100
Poultry vaccines						
Other viral vacc. (Rift Valley Fever African Horse Sickness etc)		20		20		20
Blackquarter	70,000	14	70,000	14	70,000	14
Anthrax						
Brucella	10,000	2			10,000	2
Pasteurella						
Botulism						
Others		24		24		24
SUB-TOTAL		150		180		210
TOTAL		2,250		2,425		2,630

VETERINARY DRUGS AND VACCINES USED (1986) AND ESTIMATED OPTIMAL REQUIREMENTS (1990 and 2000)

COUNTRY: LESOTHO

DRUG/BIOLOGICAL	YEAR 1986		1990		2000	
	UNITS	VALUE US$000's	UNITS	VALUE US$000's	UNITS	VALUE US$000's
Ectoparasiticides	LITRES					
Diazinon	11,200	116	11,200	120	12,000	130
Anthelmintics		108		120		130
Antibiotics		21		25		25
Antiprotozoons		1		1		1
Feed Additives		5		8		10
SUB-TOTAL		251		274		296
Biologicals (doses)						
FMD						
Rinderpest						
Rabies	20,000	8	40,000	16	60,000	30
Poultry vaccines						
Other viral vacc. (Rift Valley Fever African Horse Sickness etc)						
Blackquarter	68,000	3	80,000	4	80,000	4
Anthrax						
Brucella						
Pasteurella						
Botulism						
Others		7		8		10
SUB-TOTAL		18		28		44
TOTAL		296		304		340

VETERINARY DRUGS AND VACCINES USED (1986) AND ESTIMATED OPTIMAL REQUIREMENTS (1990 and 2000)

COUNTRY: BOTSWANA

DRUG/BIOLOGICAL	YEAR 1986		1990		2000	
	UNITS	VALUE US$000's	UNITS	VALUE US$000's	UNITS	VALUE US$000's
Ectoparasiticides						
Amitraz	2,000	17	2,500	21	3,000	26
Anthelmintics	36,000	50	40,000	55	50,000	70
Antibiotics		75		85		100
Antiprotozoons						
Feed Additives						
-		50		50		50
SUB-TOTAL		192		211		246
Biologicals						
(Mono doses)						
FMD*	3,600,000	1,080	2,400,000	960	2,400,000	1,200
Rinderpest+	3,000,000	100	3,000,000	100	3,000,000	100
Rabies**	50,000	25	50,000	25	50,000	25
Poultry vaccines						
Other viral vacc. (Rift Valley Fever African Horse Sickness etc)						
Blackquarter	1,400,000	136	1,000,000	100	1,000,000	100
Anthrax	1,500,000	67	2,500,000	100	2,500,000	100
Brucella	500,00	75	500,000	75	500,000	75
Pasteurella	400,000	14	400,000	14	400,000	14
Botulism						
Others	500,000	36	500,00	36	500,000	36
SUB-TOTAL		1,533		1,423		1,663
TOTAL		1,725		1,634		1,909

* To this must be added exports of some 6.3million monovalent-equivalent doses for a value of about US$ 2million.

** These figures would change dramatically if the regional rabies strategy (See Appendix) were adopted.

+ These are intended for export.

VETERINARY DRUGS AND VACCINES USED (1986) AND ESTIMATED OPTIMAL REQUIREMENTS (1990 and 2000)

COUNTRY: ZIMBABWE

DRUG/BIOLOGICAL	YEAR 1986		1990		2000	
	UNITS	VALUE US$000's	UNITS	VALUE US$000's	UNITS	VALUE US$000's
Ectoparasiticides						
Amidine						
O. Phosphorous	190	4,800		5,800		8,800
Pyrethroid						
Anthelmintics						
Round						
Flukicide	5	1,500	5	1,800		7,000
Combination						
Antibiotics						
Tetracycline						
Pen/Strep	2	600	2	750	4	1,500
Suphas + Comb.						
Antiprotozoons						
Samorin		60				
Berenyl		80		150		200
Others		20				
Feed Additives						
Coccidiostats		1,200		1,500		3,000
Growth Promoters						
SUB-TOTAL		8,260		10,000		20,500
Biologicals						
FMD	3.9	1,170	3.9	1,560	3.9	1,750
Rinderpest	-	-	-	-	-	-
Rabies	0.38	76	0.7	161	1 0	300
Poultry vaccines	76	166	0.85	213	100.0	326
Other viral vacc. (Rift Valley Fever African Horse Sickness etc)	0.22	66	0.25	90	0.3	100
Blackquarter	0.8	38	0.85	50	0.9	65
Anthrax	3.8	125	4.0	152	4.5	222
Brucella	0.35	32	0.4	41	0.5	67
Pasteurella	0.025	10	0.04	18	0.05	30
Botulism	0.5	25	0.5	29	0.5	37
Others		474		637		914
SUB-TOTAL		2,182		2,951		3,811
TOTAL		10,442		12,951		24,311

SADCC PROGRAMME FOR ESTABLISHMENT OF REGIONAL PRODUCTION OF VETERINARY ACARICIDES

	1987	1988	1989	1990	1991	1992	1993	1994	1995	2000
TANZANIA				- - - - -	- - - - -	- - - - -	- - - - -	- - - - -	——→	
ZAMBIA	——→									
MALAWI										
MOZAMBIQUE										
SWAZILAND										
LESOTHO										
BOTSWANA										
ZIMBABWE	——→									
ANGOLA										

——→ Established or should be established

- - - - - - - - - - → Time frame for establishment

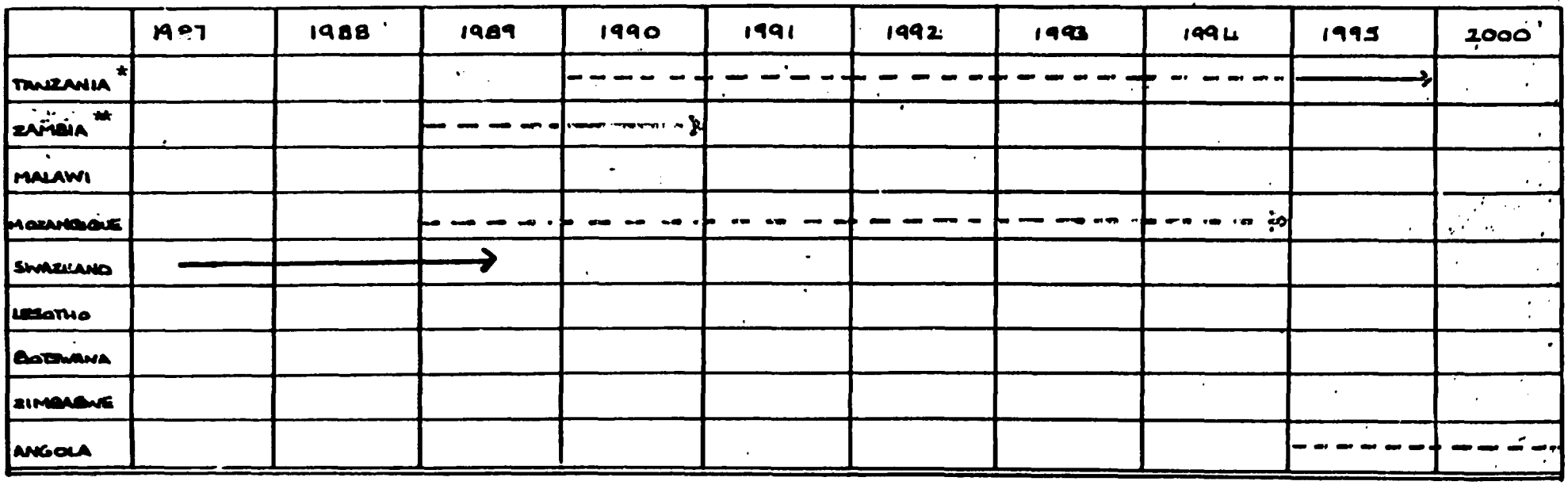
SADCC PROGRAMME FOR ESTABLISHMENT OF REGIONAL VETERINARY PHARMACEUTICAL FACILITIES.

	1987	1988	1989	1990	1991	1992	1993	1994	1995	2000
TANZANIA				- - - - -	- - - - -	- - - - -	- - - - -	- - - - -	——→	
ZAMBIA										
MALAWI										
MOZAMBIQUE										
SWAZILAND										
LESOTHO		· · · · ·	——→							
BOTSWANA										
ZIMBABWE	——→									
ANGOLA										

——→ Established or should be established

- - - - - - - - - - - - - - → Time frame for establishment

SADCC PROGRAMME FOR ESTABLISHMENT OF REGIONAL PRODUCTION OF VETERINARY MAMMALIAN BACTERIAL VACCINES



———————— Established or should be established

---------- Time frame for establishment

* National production programme can start in 1988

** CBPP vaccine

SADCC PROGRAMME FOR ESTABLISHMENT OF REGIONAL PRODUCTION OF VETERINARY VIRAL VACCINES

	1987	1988	1989	1990	1991	1992	1993	1994	1995	2000
TANZANIA										
ZAMBIA										
MALAWI										
MOZAMBIQUE										
SWAZILAND										
LESOTHO										
BOTSWANA	→									
ZIMBABWE										
ANGOLA										

→ Established

Annex 3

VETERINARY BIOLOGICAL PRODUCTION

DEFINITIONS

1) Improvised Bench Scale

1.1 Building Design and Purpose

This is usually quite unsuitable to meet any present-day standards of operation, disease security, working procedures, discipline etc, and is quite often shared with other activities e.g. diagnosis.

1.2 Manufacturing Standards

These are usually totally inadequate to meet international standards, in-process control batch reproducibility, quality control, security from cross contamination. Animals and test facilities are usually inadequate.

1.3 Technology

The Technology is usually rudimentary and improvised, leading to a high failure rate, intermittent production, or the issuing of sub-standard products.

1.4 Equipment

Equipment is usually bench-scale and inappropriate for routine production, for example lacking means of validation, and often in a poor state of repair.

1.5 Staff Training and Organisation

Staff are usually lacking in expert training, have to perform several tasks, sometimes quite different, eg. diagnosis.

VETERINARY BIOLOGICAL PRODUCTION

DEFINITIONS

2) Classical Production Methods

2.1 Building Design and Purpose

The building is correctly designed with proper segregation of activities and types of products with separate quality control and animal facilities all to international standards.

2.2 Manufacturing Standards

Product specifications, manufacturing conditions, discipline and quality control are all to international standards.

2.3 Technology

The technology is well-proven, simple, reliable and capable of regular batch production.

2.4 Equipment

The equipment is unsophisticated, dependable and readily maintained. It does not require highly skilled staff to operate or to service.

2.5 Staff Training and Organisation

Senior posts are filled by trained graduates with dedicated activities, and are supported by trained technicians. On-site training is continuous with expatriot involvement during commissioning and periodically thereafter.

VETERINARY BIOLOGICAL PRODUCTION

DEFINITIONS

3) Sophisticated Technology

3.1 Building Design and Purpose

The building is correctly designed with proper segregation of activities and types of products, with elaborate support utilities. Separate quality control and animal facilities are provided to international standards.

3.2 Manufacturing Standards

Product specifications, manufacturing conditions and efficiency, discipline and quality control are all to international standards.

3.3 Technology

The technology is sophisticated with delicate ancillary (e.g. electronic) equipment. It is capable of producing high-quality vaccine on a regular basis to international standards.

3.4 Equipment

The equipment is sophisticated and requires expert operation and servicing.

3.5 Staff Training and Organisation

Considerable overseas and on-site training is necessary for the key staff. Intermediate staff require both biological and mechanical training. Senior staff have dedicated functions and training is continuous. Ex-patriot installation, commissioning and continued supervision is needed.

Annex 4

OPTIONS ON VETERINARY BACTERIAL VACCINE SUPPLY WITHIN SADCC

OPTION 1: Local Formulation and Filling*/Quality Control

SUMMARY OF CAPITAL COST ESTIMATE**

			US $ 000's
1.3	Plant and Major Equipment		370
1.4	Buildings		
1.4.1	Administration	101m^2	91
1.4.2	Blending-Filling Cold Store	194m^2	227
1.4.3	Preparations, storage, incinerator	224m^2	196
1.4.4	Quality Control	83m^2	82
1.4.5	Animal Testing	214m^2	213
	TOTALS	816m^2	813
1.5	Manpower/Training/Technical Assistance		
1.5.1	Training		78
1.5.2	Ex-patriot Technical Assistance		96
	GRAND TOTAL		1,357

Estimated budget cost US $ 1,357,000

N.B. Due to the highly variable cost of transfer of production technology from a third party it is excluded from this estimation.

* For Products and Quantities see 1.1, and for Production Processes 1.2 in Annex 4

** Excluding taxes and duties.

1.1 **Products and Quantities**

For these considerations 50 per cent of the SADCC's estimated regional requirements of bacterial vaccines (to theyear 2000) were taken as a basis.

1.1.1 Anthrax Vaccine
(Bacillus anthracis, live avirulent spores in liquid)

Annual requirement: 8million doses, 8000L bulk vaccine prepared in 8 x 1000L batches.

Pack size 50 x 1ml and 100 x 1ml per pack

Total no. of packs: 80,000 x 50ml packs (4000L)
40,000 x 100ml packs (4000L)

1.1.2 Blackquarter/Blackleg Vaccine
(Inactivated Cl.chauvoei culture adjuvanted with aluminium salt)

Annual requirement: 7million doses, 14000L bulk vaccine prepared in 14 batches.

Pack size 50 x 2ml and 100 x 2ml per pack

Total no. of packs: 70,000 x 100ml packs
35,000 x 200ml packs

1.1.3 Haemorrhagic septicaemia Vaccine
(Inactivated P.multocida type E culture adjuvanted with aluminium salt)

Annual requirement: 2million doses, 4000L bulk vaccine representing 4 batches.

Pack size: 50 x 2ml and 100 x 2ml per pack

Total no. of packs: 20,000 x 100ml packs (2000L)
10,000 x 200ml packs (2000L)

1.1.4 Diluent
(for lyophilised Br.abortus S19 vaccine)

Annual requirement: for 1.4million doses, 1400L diluent, representing 4 batches and 16 filling lots.

Pack size: for 10 doses, nominal 10ml/pack

Total no. of packs: 140,000 x 10ml packs.

1.2 Production Processes

All processes are implemented on a campaign basis, ie only one vaccine is handled at any one time, followed by decontamination before beginning a new campaign.

1.2.1 Antigen concentrate is imported in bulk and stored at 2-8°C til required.

1.2.2 Preparation of bulk vaccines

These are prepared from antigen concentrates which are supplied complete with blending instructions.

2 x 1200L jacketed, blending vessels are installed in the blending room. These are used in parallel but one lagging 7 days behind the other with respect to the stage of preparation of the same vaccine.

Following preparation of bulk vaccine (Day 1) it is held in blending vessel for 11 days (Days 2-11) and kept at 2-8°C using chilled water via the jacket of the vessel. On day 12 bulk is filled out directly and on days 13-14 the vessel is washed, sterilised and made available for new batch. One batch of bulk vaccine is prepared per week.

To calculate a time frame of the blending campaign and occupancy of blending room each vaccine is considered under the following headings.

Name of vaccine: volume of batch; number of batches; utilisation of blending vessel by each batch; duration of blending-filling campaign using two vessels.

Anthrax Vaccine: 500L; 16 batches; 14 days; 18 weeks.

Blackquarter Vaccine: 1000L; 14 batches; 14 days; 16 weeks.

Haemorrhagic septicaemia Vaccine: 1000L; 5 batches; 14 days; 7 weeks

Diluent for S19 Vaccine: 400L; 3 batches; 24 days; 8 weeks.

Because of the use of the two blending vessels the blending room is occupied for 49 calendar weeks in the year for the preparation of three vaccines and one diluent. Remaining weeks are taken up by holdiays and decontamination procedures between production campaigns.

1.2.3 Filling and Closing

To save on storage vessels (ca. $12,000 for a 250L vessel) and cold storage space for bulk vaccine pending on tests, calculated risk is taken and vaccine is filled out directly from the blending vessel after a provisional sterility test at 11 days. To save on cost of quality control of filling lots the aim is to fill out the batch in a single day.

One person feeds containers to automatic filling machine with a capacity of 1000-1200 packs per hour. A team of three people required; work in two shifts may need to be considered.

Vaccine containers are polyethylene packs of 25,50, 100, 250 or 500ml capacity which are delivered sterile by the manufacturers.

To calculate the time frame for filling campaigns, and occupancy of filling room, these are considered under the following headings.

Name of vaccine: volume of bulk vaccine for filling; pack volume; number of packs filled out per day; occupancy of filling room in each working week; duration of each filling campaign;

Anthrax: 500L; 50ml; 10,000; 1 day; 8 weeks;
500L; 100ml; 5,000; 1 day; 8 weeks

Blackquarter: 1000L; 100ml; 10,000; 1 day; 7 weeks
1000L; 200ml; 5,000; 1 day; 7 weeks

Haemorrhagic septicaemia: 1000L; 100ml; 10,000; 1 day; 2 weeks
1000L; 100ml; 5,000; 1 day; 3 weeks

Diluent for S19 Vaccine: 100L; 10ml; 10,000; 4 days; 3 weeks

Filling room is thus occupied one day per week for 35 weeks (for vaccines) and for 4 days per week for 3 weeks for diluent, 38 weeks in all.

1.2.4 Labelling, inspection and packaging

Applicable for any vaccine or diluent originating from one batch.

Number of packs for labelling: 5,000 - 10,000

Number of packs for packaging: 5,000 - 10,000

Time taken by one person in each working week: labelling 1 day, inspection and packaging 2-3 days.

1.2.5 Storage of filled products pending on tests (2-8^{o}C)

Each batch of a product requires storage, whilst pending on tests for its release for use. Since several batches are produced during the time of testing of the first batch, these accumulate til the first batch is released. Stocks, pending on release, stabilise at that level before depleting after the production of the last batch.

For storage space of filled products three times its bulk volume was taken, allowing for passages (eg, 1000L, 3m^3 requiring 3m^3 storage space). For calculating floor area, products are stored 1.5m high.

Before release, storage space requirements of products are sequential in time, with some overlap.

Anthrax vaccine must be adequately segregated in storage from all other products.

Time frame for occupancy and storage space requirements in cold store is considered as follows.

Duration of storage for each batch: total storage time for each product before release; storage space per batch; maximum storage space for each product; maximum floor area for each product.

Anthrax: 5 weeks; 21 weeks, 1.5m^3; 7.5^3; 5m^2.

Blackquarter: 6 weeks; 20 weeks; 3m^3; 18m^3; 12m^2

Haemorrhagic septicaemia: 3 weeks; 8 weeks; 3m^3; 9m^3; 6m^2

Diluent for S19 vaccine: 2 weeks; 6 weeks; 0.8m^3; 2.4m^3; 2m^2

Since the cold storage requirement of vaccine, before release, is sequential in time, maximum demand is determined by the most voluminous product, ie, Blackquarter vaccine, occupying 12m^2 floor area. The 5m^2 area for Anthrax segregated from other products is additional.

1.2.6 Storage of released products (2-8^{0}C)

Released products require same storage space as before release. However, their requirements are not necessarily sequential in time. For maximal safety cold storage facility is planned for concurrent storage of all products requiring a total of 58m^2 (Anthrax 16m^2; Blackquarter 28m^2, Haemorrh.septic. 10m^2, Diluent 4m^2).

1.3 PLANT AND MAJOR EQUIPMENT

DESCRIPTION	QTY	SPECIFICATION	JUSTIFICATION	EST.COST (US $)
Water deioniser plant complete with automatic regenerator	1	Output 500-3000L/h depending on water hardness. Effluent purity: 0.05ppm, silica and oil ppm CO_2, pH6.5-7.	To demineralise water for distillation (required for vaccine blending), generation of steam and for rinsing of glassware.	8,000
Holding tank	1	2000L polypropilane tank.	For storage of deionised water	2,500
Boiler	1	Oil-fired, water tube, steam boiler, fed with deionised water, generating 200kg/h particulate matter-free steam.	Steam is required for sterilisation of blending vessel (150kg/h) via the jacket.	23,000
Oil tank	1	1000L mild-steel tank.	For storage of fuel for boiler.	1,200
Fully automatic water still	1	Electrically heated, fully automatic still requiring deionised water. Example: Finn Aqua 75E-4. Capacity: 75kg/h. Conductivity: 0.5-2.0uS/cm. Consumption of electricity/h 15.6Kw. Feed water at 15.2 100kg/h	To provide pyrogen-free distilled water for vaccine preparation and vaccine diluent.	25,000
Water storage tank complete with insulation	2	1000L each, stainless steel tank complete with absolute filters at in and outlets. Temp. maintained at 80°C.	Preparation of bulk vaccines from antigen concentrates requires the use of pyrogen-free sterile distilled water, which has been stored under defined conditions.	12,000
Heaters for water tanks	2	Thermastatically controlled emersion-type electric heater.	To maintain temperature of stored water at 80°C.	500
Stirrers	2	Electrically propelled.	To aid maintenance of even temperature of water in storage tanks.	1,200

1.3 PLANT AND MAJOR EQUIPMENT (Cont'd)

DESCRIPTION	QTY	SPECIFICATION	JUSTIFICATION	EST.COST (US $)
Water chiller	1	Electrically operated water chiller. Refridgerator capacity: Kcal/hr 1000x8.5. Example: ACRO-KOOL model RTC300	To reduce temperatue of pyrogen-free distilled water (stored at 80°C) for vaccine dilution and to maintain temperature of vaccine at 2-8°C whilst stored in blending vessel.	10,000
Cold room	1	Sectional pre-fabricated. Divided into two chambers and fitted with two sets of refridgeration equipment, each capable of providing 60% of required duty. Total area: ca 80m^2 200m^3.	To hold antigen concentrates and vaccines (at 2-8°C), of which Anthrax needs to be segregated, from all other biological products.	30,000
Refridgerator	3	General purpose, front loading, electrical, adjustable thermostat push button defrost. Capacity: 215L. Shelf area 1m^2.	For samples of vaccines, adjuvants, diluents, culture media in petri dishes, bact. culture in QC Laboratory and Filling Unit.	900
Hot air oven	1	Standard, electrically heated. Capacity: 1000-1500L. Example: Haraeus STUH 100/150. Connected load:KVA:15.	For sterilisation of glass and metal laboratory equipment for blending/filling unit and QC Laboratory	9.000
Autoclave	1	Electronically managed, quadrangel, double door, steam autoclave. Chamber size: 80x80x125cm. Horizontal sliding doors at each end. Capacity: 800L. Demand for steam: max 120kg/h, avar.o5kg/h. Example: Fedegari FOF3.	For sterilisation of solids, liquids, filtering systems used in relation to production and quality control of vaccines.	65,000
Blending vessel	2	1200L stainless steel, jacketed, complete with stirrer, in and outlet ports. Internal finish: mirror polish and crevice-free welding. Design pressure: 2.3 bar	For blending and storage of Haemorrhagic septicaemia, Anthrax and Blackquarter vaccines. vaccines (one vessel is occupied for 11 days with every batch produced at 14 days intervals).	48,000

1.3 PLANT AND MAJOR EQUIPMENT (Cont'd)

DESCRIPTION	QTY	SPECIFICATION	JUSTIFICATION	EST.COST (US $)
Automatic filling and closing machine	1	Electrically operated, three-phase 415V/ 50H2, for polyethylene or poly propylene packs of up to 500ml volume. Filling speed: 1000-1250pcs/hr. Example: Schubert's Pharmic VSF100	For filling of vaccines and vaccine diluent into final containers and closing and sealing such containers.	90,000
Laminar flow isolator	1	1200x1800mm biological safety cabinet to provide Class II operator (US Standard N.S.F.49) as well as product protection.	To provide appropriate conditions for filling and closing of vaccines and diluent.	7,500
Labelling machine	1	Fully automatic. Label size 25x50mm. Output: up to 4000/hr.	For labelling final containers of vaccines and vaccine diluent.	10,000
pH meters	2	Fully automatic, temperature compensated Accuracy to 0.01pH. Range pH 0-14. For redox/oxidation work: range 0-1999v, resolution 1uV.	For measuring pH of diluents, vaccines and reagents at Filling Unit and QC Laboratory	800
Centrifuges	2	Laboratory-type MSE Super-Minor max. RCFxg from 2460 to 6990.	For bench-scale sedimentation of particulate matter in liquids and vaccines at Filling Unit and QC Lab.	1,540
Microscope	2	For research, routine light microscopy with interchangeable objectives, complete with 12V 100W light source, transformer and control unit. Example: Olympus B2 Series.	For use by QC Laboratory and Filling Unit to assess morphology, purity, etc of microbiological specimens.	5,500
Balances (Gallenkamp)	2	Electronic, analytical, weighing range 82g. Readibility 0.1mg, precision 0.1mg. For 110-250v, 50-60 H2 single phase supplies supplies. 2nd mechanical, top loading, weighing range 2000g, readibility 0.1g, precision 0.2g.	For weighing chemicals for preparation of reagents, buffers etc (1), and for microbiological media in QC Laboratory and Filling Unit.	2,500 1,600

1.3 PLANT AND MAJOR EQUIPMENT (Cont'd)

DESCRIPTION	QTY	SPECIFICATION	JUSTIFICATION	EST.COST (US $)
Water bath	1	General purpose water bath. Temp. range up to 100°C. 15L capacity. Power rating 500W. Temp. variation 0.1°C.	For incubation of serological reactions in QC Laboratory.	500
Deep freezer	1	Top loading, min.temp. -20°C, 260L capacity. 220-240v, 50H2 single phase supplies	For below freezing point storage of biological specimens in QC Laboratory.	400
Spectrophotometer	2	Solid state, wavelength range 340-1000 , 220-240v, 50-60H2 single phase supplies.	For assessment of bacterial suspensions in QC Laboratory and Filling Unit.	3,000
Laminar flow biological	1	Bench mounted, Class II. Working area 120x64x86cm.	To aid aseptic handling of specimens, media, inoculation in QC Laboratory	
Incubators	3	Electrically heated (220-240v) thermostatically controlled (0.1°C), 250L, shelf area 1m². Temp. range 5°C over ambient to 100°C (2), or -10°C to 50°C (1).	For incubation of serological reactions (1), and bacterial cultures at the different temperatures (2) in QC Laboratory.	4,500
			TOTAL:	364,500

1.4 BUILDING REQUIREMENTS

1.4.1 Administration

Ref. No. to layout A		Dimensions (m)	Area (m^2)	Cost/m^2 (US $)*	TOTAL COST (US $)
3	Head of Filling Unit/Manager	4 x 5	20		
4	Secretary	3.2 x 5	16		
6	Typist	2.2 x 5	11	900	
5	Administration Office	5 x 5	25		
2	Reception/Tel. Exchange	2.2 x 4	8.8		
1	Accounts	5 x 4	20		
	TOTALS		ca. 101		90900

1.4.2 Vaccine Blending Filling, Storage

9	Blending Room	7.2 x 5	36	1500**	54000
10	Filling Room	7.2 x 5	36	1500**	54000
11	Labelling/Packaging	7.2 x 5	36	900	32400
7&8	Cold Rooms (2)	7.2 x 6	86.4	1000***	86400
	TOTALS		ca. 194		226800
Ref. No. to layout B					
18	Incinerator	6 x 5	30	700	21000

* - "Budget cost" figures for planning subject to ±20% error.

** - Inclusive of air conditioning

*** - Exclusive of cooling plant

1.4.3 Preparations

Ref.No. to layout A		Dimensions (m)	Area (m^2)	Cost/m^2 (US $)	TOTAL COST (US $)
15	Washing up	7.2 x 6	43.2		
14	Sterilisation	7.2 x 3	21.6		
13	Water treatment and storage	7.2 x 4	28.2	900	
12	Store	7.2 x 6	43.2		
16&17	Changing rooms (2)	7.2 x 4	57.6		
	TOTALS		ca. 194		174600

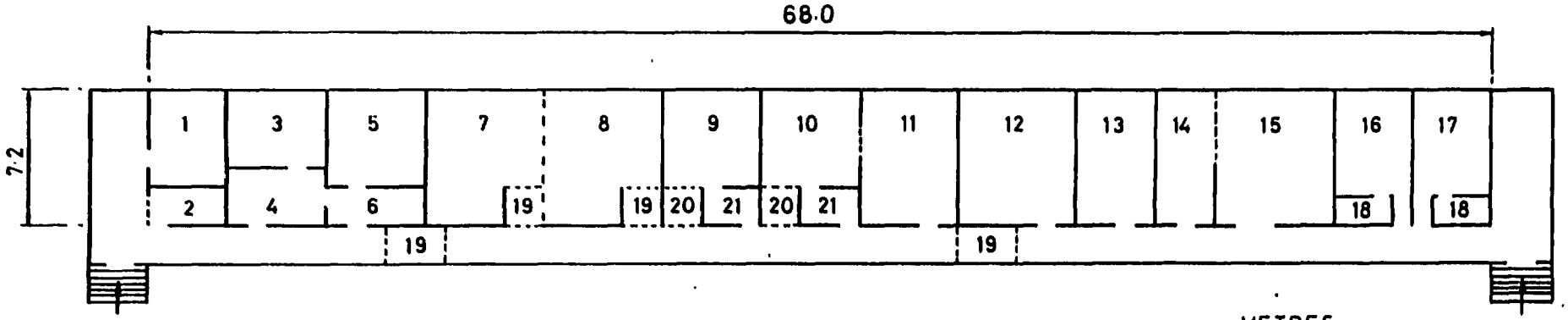
1.4.4 Quality Control

Ref.No to layout B					
2	Head	5.5 x 4	22	900	19800
1	General Office	5.5 x 4	22	1050	19800
3	Laboratory	7 x 5.5	38.5	1050	42350
	TOTALS		ca. 83		81950

1.4.5 Animal Testing

Ref.No. layout B					
4&5	Changing rooms (2)	3 x 5.5	33		
6	Guinea pigs	4 x 5.5	22		
7	Mice	4 x 5.5	22		
8	Rabbits	4 x 5.5	22	900	
9	Inoculation room	4 x 5.5	22		
10	Cage cleaning/sanitisation	4 x 5.5	22		
11	Store	4 x 5.5	22		
12	Goats	3 x 5.5	16.5		
	TOTALS		ca. 181		163500
13	Guinea pigs Anthrax (High security)	3 x 5.5	16.5	1500	49500
14	Sheep	3 x 5.5	16.5		
	TOTAL		33		49500
	GRAND TOTAL		816m^2		$808250

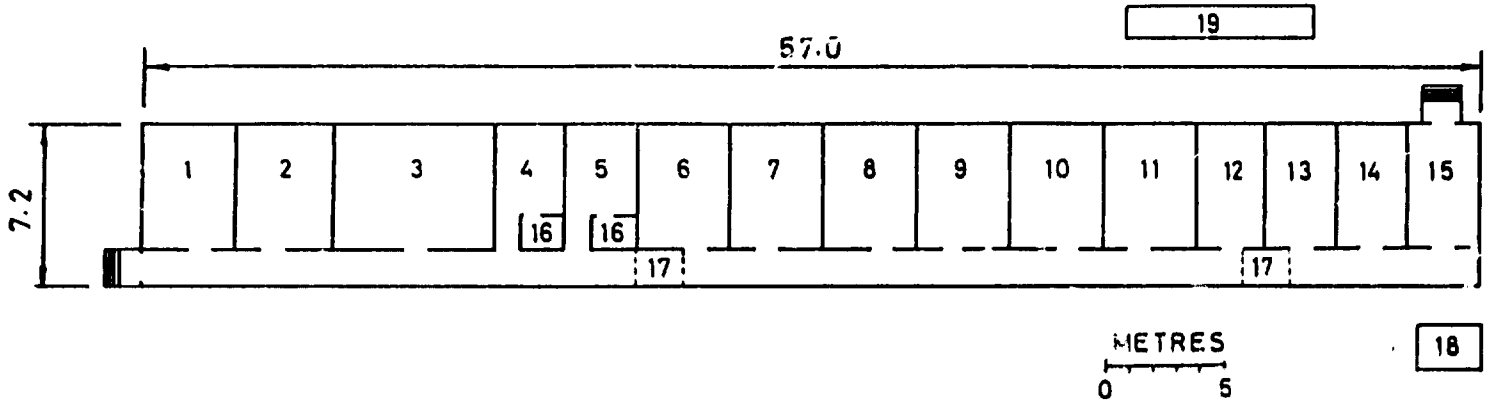
ADMINISTRATION - FILLING UNIT - STORAGE - PREPARATION.



13. STORE
13. WATER TREATMENT AND STORAGE
14. STERILISATION
15. WASHING
16. FEMALE SHOWER AND LOCKERS
17. MALE SHOWER AND LOCKERS
18. W.C.
19. AIR LOCK
20. CONTROLLED AIR LOCK
21. PERSONNEL AIR LOCK

Layout A

QUALITY CONTROL ANIMAL TESTING.



1. GENERAL OFFICE Q.C.
2. HEAD OF Q.C.
3. QUALITY CONTROL (Q.C.) LABORATORY
4. MALE LOCKER ROOM
5. FEMALE LOCKER ROOM
6. GUINEA-PIG ROOM
7. MOUSE ROOM
8. RABBIT ROOM
9. INOCCULATION ROOM
10. CAGE CLEANING AND STERILIZATION
11. FOOD STORE
12. GOAT ROOM
13. GUINEA-PIGS (ANTHRAX)
14. SHEEP ROOM (ANTHRAX)
15. PERSONNEL AIR LOCK AND SHOWERS
16. W.C.
17. AIR LOCK
18. INCINERATOR
19. CHEMICAL TREATMENT

Layout B

1.5 Requirements for Manpower, Training and Ex-patriot Technical Assistance

1.5.1 Manpower and Training

	Number	Training abroad Man mths	Cost (US$)
Head of Filling Unit/Technical Manager (Graduate)	1	6	12000*
Head of Quality Control and Quality Assurance (Graduate in Microbiology)	1	9	18000
Personal Secretary	1		
Secretary/Typist	3		
Receptionist/Tel. Exchange	1		
Administration Manager	1		
Accountant	1		
Senior Laboratory technicians (filling 1, QC 1)	2	12	24000
Laboratory technicians (filling 2, QC 2)	4		
Laboratory attendants	6		
Animal house attendants	2		
Instrument technician/electrician	1	6	12000
Maintenance engineer	1		120[illegible]
TOTAL COST OF TRAINING			**78000**

1.5.2 Ex-patriot Technical Assistance

Ex-patriot Technical Manager (fielded for 6 months in 2 years)	1		48000**
Ex-patriot Head of Quality Control (fielded for 3 months in 2 years)	1		24000
Ex-patriot maintenance technician (fielded for 3 months in 2 years)	1		24000
TOTAL COST OF EX-PATRIOT ASSISTANCE			**96000**

* US $ 2000/month
** US $ 8000/month

Services of three ex-patriot staff is envisaged for a time following commissioning of Filling Facility. Ex-patriot Technical Manager should be experienced in all aspects of bulk vaccine preparation, filling, and regulations affecting these activities. His understudy (Head of Filling Unit/Technical Manager), a microbiologist, should have received six months training prior to commissioning of the Facility at the premises of supplier of bulk antigen. They should work in parallel for six months in all after commissioning of Filling Unit.

Ex-patriot head of Quality Control should be experienced not only in the technical aspects of various tests but all aspects of regulations affecting Quality Control and Quality Assurance. The understudy, a graduate in microbiology, veterinarian or biologist, should receive nine months training in all aspects of quality control and quality assurance at the premises of supplier of bulk antigens before taking up the post at the new Facility. They should work in parallel for up to three months following commissioning of Filling Unit.

The two senior laboratory technicians, one heading the team of 6 technicians in the blending and filling unit, the other in Quality Control with two technicians, should also receive six months training each at the premises of supplier of bulk antigen.

Instrument technician and maintenance engineer are key personnel in the smooth operation of equipment and plant and each should receive three [illegible] training abroad.

OPTIONS ON VETERINARY BACTERIAL VACCINE SUPPLY WITHIN SADCC

OPTION 2 Establishing Local Production*

SUMMARY OF CAPITAL COST ESTIMATE**

			US $ 000's
2.3	Plant and Major equipment		1,281,000
2.4	Buildings (Also see Appendices 8B and C)		
2.4/1	Administration/Staff Facilities	584m^2	525,600
2.4/2	Preparation/Stores	533m^2	479,700
2.4/3	Deep Culture Suite No.1	252m^2	305,100
2.4/4	Deep Culture Suite No.2	252m^2	284,400
2.4/5	Blending/Filling/Cold Storage/Water Plant	406m^2	466,900
2.4/6	Support Services	612m^2	550,000
2.4/7	Quallity Control(Layout B)	60m^2	63,500
2.4/8	Animal Testing (Layout B)	214m^2	213,000
	TOTALS	2913m^2	2,889,000
2.5	Manpower/Training/Technical Assistance		
2.5/1	Manpower-Training: personnel: 53 (Cost of traiing: 111 man months @ $2000/month)		222,000
2.5/2	Ex-patriot Technical Assistance (24 man months @ $8000/month)		216,000
	Estimated budget cost:		US$ 4,608,000

* For products and quantities see 2.1 and for Production Processes 2.2 in Annex 4.

** Excluding taxes and duties.

2.1 Products and Quantities

The products included here are the most important bacterial vaccines required in the SADCC region. The quantities indicated represent approximately one half of that required in the region by the year 2000. Exception is Brucella S19 vaccine of which the entire requirement is included due to its demand for lyophilisation, not readily available even in countries producing their own vaccines.

2.1/1 Anthrax Spore Vaccine for veterinary use
(Standard: WHO Tech.Rep.Ser.No. 361)

Fluid preparationof live spores of an attenuated, non-capsulated strain of Bacillus anthracis 34F2.

Dose size: 1ml (containing 2-10 x 10^6 viable spores)

Annual requirement: 8.0mill. doses originating from 1600-2400L culture (3.5-5 doses per ml of culture) used for the preparation of 8000L bulk vaccine prepared in 8 x 1000L batches.

Pack sizes: 50 x 1ml, 80,000 packs (4000L)
100 x 1ml; 40,000 packs (4000L) 120,000 packs in all.

2.1/2 Blackquarter/Blackleg Vaccine
(Standard: B.P. Veterinary 1985)

Formalin inactivated, liquid culture of Clostridium chauvoei adjuvanted with potassium aluminium sulphate.

Dose size: 2ml

Annual requirement: 7.0mill. doses originating from ca. 7000L of culture (1ml culture per dose) used for the preparation of 14,000L bulk vaccine prepared in 9 x 1600L batches.

Pack sized: 50 x 2ml: 70,000 packs (7000L)
100 x 2ml: 35,000 packs (7000L); 105,000 packs in all.

2.1/3 Haemorrhagic septicaemia Vaccine
(Standard: B.Vet.Codex)

Formalin inactivated whole culture of encapsulated and virulent strain of Pasteurella multocida Robert's type I (Carter's type E) adjuvanted with alhydrogel.

Dose size: 2ml (containing not less than 1 x 10^{10} organisms)

Annual requirement: 2.0mill. doses originating from 1000L of culture (0.5ml culture per dose) used for the preparation of 4000L bulk vaccine prepared in 4 x 1000L batches.

Pack sizes: 50 x 2ml: 20,000 packs (2000L)
100 x 2ml: 10,000 packs (2000L)
30,000 packs in all.

2.1/4 Brucella abortus S19 Vaccine
(Standard: WHO Tech.Rep.Ser.No.594)

Lyophilised culture of low virulence Brucella abortus S19. The vaccine is freeze-dried and reconstituted before use with a suitable diluent.

Dose size: 2ml (containing 4-12 x 10^{10} live cells)

Annual requirement: 2.6mill. doses originating from ca. 1300L culture (0.5ml culture per dose) produced in 13 batches.

Pack sizes: 10 dose packs; 260,000 packs in all.

2.1/5 Diluent for Brucella S19 Vaccine

Sterile pyrogen-free distilled water.

Dose size: 2ml

Annual requirement: for 2.6mill. doses originating from 5200L of distilled water.

Pack size: 10 x 2ml packs; 260,000 packs in all.

2.2/1 Production of and time required for ANTHRAX (live) SPORE VACCINE

Flow Sheet of Production

CONTROLS	PROCESS
	SEED LOT
Number of culturable spores	
Safety test in sheep	
Test for immunogenicity/identity	
Freedom from extraneous organisms	
	SEED NO.1
Microscopic examination	
	SEED NO.2
Microscopic examination	
Purity	
	MEDIUM
Sterility	
	CULTIVATION
Optical density	
Sporulation	
	SINGLE HARVEST
Purity	
Sporulation	
	CONCENTRATION
	INACTIVATION OF VEGETATIVE CELLS
Number of culturable spores	
Freedom from extraneous organisms	
	FINAL BULK
Freedom from extraneous organisms	
	FILLING LOT
Microscopic examination/identity	
Freedom from extraneous organisms	
Safety	
Number of culturable spores	
Immunogenecity	
Stability	

Time required for production of one batch

	Process Stage	Duration (Days)	Remarks
1	Cleaning, sterilising filling of fermenters(2)	3	This can take place in parallel with preparation of Seeds No.1 and 2.
2	Seed No.1	1	In shake flasks
3	Seed No.2	1	Concurrently with preparation of fermenter for inoculation. 40L medium in 75L fermenter
4	Production Culture	1-1.5	1000L fermenter producing 400L culture.
5	Concentration	7	At 18-20°C in 2 x 250L settling vessel. Yielding 2 x ca. 20L concentrate
6	Inactivation	14	At 18-20°C, 1 part cell conc., plus 2 parts glycerol, ie. 2 x 60L in 250L vessel
7	Storage of Spore concentrate	14	At 2-8°C pending on spore counts and test for extraneous organisms.
8	Blending of Bulk Vaccine	2	400L culture yields ca. 2.0mill. doses. Dose size 1ml therefore bulk vaccine is 2000L prepared as 1 x 2000L bulk.
9	Storage of Bulk Vaccine pending tests	11	At 2-8°C in blending vessels (extraneous organisms)
10	Filling	3	10,000 x 100ml packs (1000L) 20,000 x 50ml packs (1000L) 30,000 packs in all.
11	Release of filled vaccine	120 (31)	Pending on tests for contamination, spore counts, safety, immunogenicity and stability.

It follows from the foregoing that:

1. Production cycle, including release of filled vaccine, may take ca. 174 days if stability test on every batch is included, otherwise it is 55 days inclusive of filling.

2. One production batch of anthrax culture can be grown in a little under five working days including preparation of the culture vessel for use. However, due to demands on blending vessels and because there is sufficient time available, one batch per two weeks is produced.

3 Production of 6 400L culture takes 12 weeks, plus replacements of say 25% failure 2 x 400L would take 4 weeks, 16 weeks in all ca. 4 months.

4. Filling would take at the rate of 10,000 packs per day, 3 days per 2000L batch in every two weeks.

5. Duration of Anthrax vaccine production campaign may be up to five months.

2.2/2 Production of and time required for BLACKQUARTER/BLACKLEG VACCINE

Flow Sheet of Production

CONTROLS	PROCESS
	SEED LOT
Test for immunogenicity (identity)	
Safety test in cattle/sheep	
Viability	
Freedom from extraneous organisms	
	SEED NO.1
Microscopic examination	
	SEED NO.2
Microscopic examination	
Purity	
	MEDIUM
Sterility	
pH	
	CULTIVATION
Opacity	
	SINGLE HARVEST
Purity	
pH	
Opacity	
	INACTIVATION
	BULK ANTIGEN
Sterility	
Opacity	
Potency	
Freedom from abnormal toxicity	

	FINAL BULK VACCINE
Sterility	
Sterility	FILLING LOT
Safety	
Free formaldehyde	
Freedom from abnormal toxicity.	
Potency	

Time required for production of one batch

	Process Stage	Duration (Days)	Remarks
1	Cleaning, sterilising, filling of fermenter	3	This can take place in parallel with preparation of Seeds No.1 and 2.
2	Seed No.1	1	Concurrently with preparation of fermenter for inoculation.
3	Seed No.2	1	50L medium in 75L fermenter
4	Production culture	0.5-1	800L medium in 1000L fermenter.
5	Inactivation	5	In 4 x 250L holding vessel at 37°C
6	Storage of inactivated culture	42	In 4 x 250L holding vessels at 2-8°C pending on sterility tests and potency assay of experimental blend.
7	Blending of Bulk Vaccine	1	800L culture makes ca. 1600L vaccine
8	Storage of Bulk Vaccine	11	In 2000L blending vessels pending sterility tests.
9	Filling	3	16,000 x 200ml packs (800L) 8000L x 200ml packs (800L) 24,000 packs in all.
10	Release of filled vaccine	42	Pending sterility, safety, abnormal toxicity and potency tests.

It follows from the foregoing that:

1. Production cycle, including release of filled vaccine is 107 days, otherwise it is 65 days inclusive of filling.

2. One production batch of Cl.chauvoei culture can be produced in 4 working days including preparation of fermenter (3) and growing of culture (1). However, due to pressure on blending vessel one batch per two weeks is grown.

3. Production of the minimum 9 x 800L culture takes 18 weeks, plus replacement of say 20% failure 2 x 800L would take 4 weeks. 24 weeks ca. 6 months in all.

4. Filling would take, at the rate of 8000 packs per day, 3 days per batch in every 14 days.

5. Duration of Blackquarter vaccine production campaign may be up to six months.

2.2/3 Production of and time required for HAEMORRHAGIC SEPTICAEMIA VACCINE

Flow Sheet of Production

CONTROLS	PROCESS
	SEED LOT
Viability	
Freedom from extraneous organisms	
Safety	
Identity	
Immunogenicity	
	SEED NO.1
Microscopic examination	
Iridescence/purity	
	SEED NO.2
Microscopic examination	
Iridescence/purity	
	MEDIUM
Sterility	
	PRODUCTION CULTURE
Optical density	
	SINGLE HARVEST
Microscopic examination	
Iridescence/Purity	
Viability	
Optical density	
	INACTIVATION
Sterility	

BULK VACCINE

Sterility

Free formaldehyde

FILLING

Sterility

Freedom from abnormal toxicity

Safety

Potency

Free formaldehyde

Time requirement for production of one batch

	Process Stage	Duration (Days)	Remarks
1	Cleaning, sterilising filling of fermenter	3	This can happen concurrently with preparation of seeds No.1 and 2.
2	Seed No.1	0.3	In shake flasks Concurrently with preparation of fermenter for inoculation
3	Seed No.2	0.3	70L medium in 150L fermenter
4	Production culture	0.4	250L medium in 500L fermenter
5	Inactivation	5.0	At ambient room temperature in each of a 250L holding vessels.
6	Sterility testing	14.0	1 x 250L inactivated whole culture stored at 2-8^{0}C
7	Bulk vaccine formulation	1.0	250L culture make[illegible] ca. 1000L vaccine left for adsc[illegible]n at room temperature for 18-24hrs.
8	Holding Bulk vaccine pending on tests	11.0	At 2-8^{0}C in [illegible]ing vessel (sterility).
9	Filling	1.0	5000 x 100ml p[illegible] (500L) 2500 x 200ml packs (500L) 7500 packs [illegible]il
10	Release of filled vacine	21.0	Pending sterility, safety, potency and abnorm[illegible] toxicity tests.
	TOTAL	55	

It follows from the foregoing that:

1. One production batch of the culture may be conveniently grown per calendar week since "turn round" time of fermenter is 3 days and growth takes another day. However, due to pressure on blending vessels one batch per 2 weeks is grown.

2. The whole production cycle, including release of filled vaccine, takes 55 days (lead-in time).

3. Production of the minimum 4 x 250L culture takes 8 weeks, plus replacement, say for 25% failure ie, 1 x 250L would take another 2 weeks, 10 weeks in all ca. 2.5 caiendar months.

4. Filling would take at the rate of 8000 packs per day, ca. 1 day per batch.

5. Duration of production campaign ca. 2.5 months.

2.2/4 Production of and time required for BRUCELLA ABORTUS S19 VACCINE

Flow Sheet of Production

CONTROLS	PROCESS
Consult WHO Tech.Rep.Ser 594 (1976) Annex 3 p.77-82	SEED LOT
Microscopic examination	SEED NO.1
Acriflavin Test	
Microscopic examination	SEED NO.2
Acriflavin Test	
Purity	
Sterility	MEDIUM
pH	
Optical density (as required)	CULTIVATION
Microscopic examination	SINGLE HARVEST
Acriflavin Test	
Purity	
Dissociation	
Viability	
Viability	CONCENTRATION BY FLOCCULATION
Viability	FINAL BULK
Bacterial and mycotic contamination	

FILLING AND CLOSING

FREEZE-DRYING

FINAL LOT

Identity

Bacterial and mycotic

Contamination

Dissociation

Viability

Stability (of selected filling lots)

Reactivity in Guinea-pigs* (Safety)

Antigenicity and Immunogenicity* (Potency)

*These tests on the first batch of the vaccine, prepared from a new Seed Lot, may be taken as the verification of the Seed Lot. However, these tests are optional for standard production batches produced within the framework of the Seed Lot System.

Time required for production of one batch

	Process Stage	Duration (Days)	Remarks
1	Cleaning, sterilising, filling of fermenter	3	This can take place in parallel with preparation of Seeds No. 1 and 2.
2	Seed No.1	1	Concurrently with preparation of fermenter for inoculation.
3	Seed No.2	1	
4	Production Culture	3	100-120L medium in 150L fermenter (yield 1×10^{11} viable cells/ml)
5	Concentration	3	In a 200L settling vessel at 2-8°C.
6	Storage of Concentrate	3	ca. 10L concentrate at 2-8°C pending on viable counts (ca. 10^{12}/ml ≈ 10 doses).
7	Blending of Bulk Vaccine	1	30-40L bulk vaccine in small blending vessel (100L).
8	Storage of Bulk Vaccine	14	In blending vessel pending on tests (viability, extraneous organisms)
9	Filling		Batch should yield ca. 200,000 doses. In 10 dose packs, this is 20,000 packs. Lyophilised at the rate of 2000 packs per day.
10	Lyophilisation		
11	Release of filled vaccine	91	Pending on tests. If potency assay and stability tests are carried out, release takes 91 days, otherwise it takes 14 days.

It follows from the foregoing that:

1. The whole of the production cycle, including release of filled vaccine takes 128 days.

2. One production batch of S19 can be grown in every 6 working days ("turn round" time 3 days, growth 3 days). However, lyophilisation of 100L production batch takes 10 working days ie 2 calendar weeks. Therefore to avoid undue delays in lyophilisation of the culture, one batch in every TWO weeks should be grown.

3. Production of the minimum 12 x 100L culture takes 24 weeks plus replacement, say for 25% failure 3 x 100L would take another 6 weeks. 30 weeks, ca. 8 months in all.

2.2/5 Production and time required for DILUENT for Brucella S19 Vaccine

Approximately 180L of sterile pyrogen-free distilled water is drawn from the reservoir (temperature of which had been maintained at 80°C and monitored for freedom of pyrogens) into a sterile blending vessel which is delivered for filling at the rate of ca. 8000 x 10 dose packs (20ml per pack) per day.

The filling lot is tested for sterility and pyrogenicity. The yearly requirement is for 260,000 10 dose-packs requiring ca. 32 filling days p.a.

Filling of the diluent should be fitted in with the other demands on the filling unit in a complementary way.

Comments to Production Processes

Considering the time requirement of these four vaccines, it would be feasible to produce Haemorhagic septicaemia and Brucella S19 vaccine on a time sharing basis (in that order, 2.5 and 8 months respectively) in the same production suite, and Blackquarter and Anthrax vaccines (6 and 4 months respectively) in a different production suite.

To meet the demands of these vaccines for blending and filling it would be necessary to produce Blackquarter and Haemorrhagic septicaemia vaccines concurrently, using the two 2000L blending vessels for Blackquarter and the 1000L vessel for Haemorrhagic septicaemia vaccine. Using a single 1000L vessel the later vaccine would require some storage of bulk antigen since the tank could only be turned around in ca. 3 weeks.

These two vaccines would release blending and filling facilities after ca. 7 months leaving just sufficient time (up to five months) for blending and filling of Anthrax vaccine.

Blending, filling and lyophilisation of Brucella S19 vaccine would take place in its own suite.

Filling of 260,000 x 10ml packs of diluent for Brucella S19 vaccine would take, at the rate of 10,000 pack per day, 26 working days in the year, fitted in with other commitments of filling facility in a complementary way.

2.3 PLANT AND MAJOR EQUIPMENT

DESCRIPTION	QTY	SPECIFICATION	JUSTIFICATION	EST.COST (US $)
Water deioniser plant complete with automatic regenerator	1	Output: 500-3000L/hr (depending on water hardness). Effluent purity : 5μS/cm	To demineralise water for distillation and generation of industrial and pure steam	8,000
Holding Tank	1	2000L polypropylene tank	For storage of deionised water	2,500
Boiler	1	Oil-fired, watertube steam boiler. Feed water: deionised (5μS/cm) Output: 400kg/hr particulate matter free steam.	Industrial quality steam is required for operating water still, pure steam generator, heating of fermenters, cauldrons and an autoclave.	40,000
Oil Tank	1	1000L mild steel tank	Fuel storage for boiler	1,200
Water Still	1	Steam operated: 100kg/hr at 8 bar Output: 220kg/hr. Feed water: 245kg/hr deionised, max. conductivity 5μS/cm Example: Finn Aqua 100-H-3	To provide pyrogen free distilled water for vaccine blending, reconstitution of lyophilised vaccine production of pure steam preparation of certain reagents requiring pyrogen-free distilled water.	60,000
Water Storage Tank (insulated)	2	1000L each, stainless steel tank, complete with absolute filters at in and outlets. Temp. maintained at 80°C.	For storage for pyrogen free sterile distilled water	12,000
Heater for Water Tanks	2	Thermostatically controlled emersion-type electric heater.	To maintain temperature of sterile pyrogen free distilled water.	500
Stirrers	2	Electrically propelled	To aid maintenance of even temperature of sterile pyrogen-free distilled water in tanks.	1,200
Pure Steam Generator	1	Output: 200kg/hr ultra pure pyrogen-free steam Source of energy industrial steam. Feed water: demineralised, conductivity 5μS/cm. Example: Stilmas Ultra Pure Generator	For sterilisation of non-jacketed stainless steel vessel used in production and for operation of autoclave.	33,000

2.3 PLANT AND MAJOR EQUIPMENT (Cont'd)

DESCRIPTION	QTY	SPECIFICATION	JUSTIFICATION	EST.COST (US $)
Water Chiller	1	Electrically operated water chiller. Refridgeration capacity: Kcal/hr 1000x8.5. Example: ACRO-KOOL model RTC300	To reduce temperature of pyrogen-free distilled water (stored at 80^{0}C) for vaccine dilution in blending vessels and to maintain temperature of vaccine stored in blending vessels.	10,000
Hot Rooms	2	2.5x2.2m prefabricated hot room (20m^{3}). Heating duty: 25-40^{0}C	For preparation of seed cultures in each of two vaccine production suites.	15,000
Cold Rooms	2	Sectional, prefabricated, fitted with two sets of refridgeration equipment each capable of providing 60% refridgeration duty of 2-8^{0}C. Total area 120m^{2}(300m^{3})	To hold antigen concentrates and vaccines, of which Anthrax needs to be segregated from all other biological products.	45,000
Freeze dryer	1	For aseptic processing, steam sterilisable equipped with internal vacuum sealing system. Shelf area: 3m^{2} Cycle process time: 2.5 days.	For lyophilisation of Brucella S19 vaccine. (20,000x25ml vials need to be freeze-dried in 10 working days, ie, in not more than 4 batches).	200,000
Refridgerators	5	General purpose, front loading, electrical, adjustable thermostat. Capacity 200-300L. Shelf area 1-1.5m^{2}.	For samples of vaccines, adjuvants, diluents, reagents in QC Laboratory (2) for samples of vaccines in Blending Unit (1) and for cultures, culture media etc. in Production Suites (2).	2,000
Autoclave	1	Electronically managed, programable, quadrangle, double horizontal sliding doors, steam autoclave. Chamber size: 30x80x125cm. Capacity: 800L.: Demand for steam: pyrogen-free. Max. 120kg/hr. Av. 65kg/hr. Example: Fedegari FOF3	For sterilisation of solids, liquids, filtering systems etc. used in relation to vaccine production and QC, demanding sterilisation in a pyrogen-free environment.	6,500

2.3 PLANT AND MAJOR EQUIPMENT (Cont'd)

DESCRIPTION	QTY	SPECIFICATION	JUSTIFICATION	EST.COST (US $)
Bio-fermenter	1	1200L stainless steel, jacketed culture vessel complete with stirrer, pH, 0_2 and heater control. Internal finish: mirror polish, welds ground smooth and crevice-free. Manufactured to Brit. Stand. 5500. Design pressure: 2.3 bar Design temp: 150°C	For production of Cl.chauvoei and B.anthracis cultures.	26,000
Bio-fermenter	1	75-100L stainless steel, jacketed culture vessel as above.	For scaling up of Cl.chauvoei and B.anthracis inoculate for 1200L Bio-fermenter.	12,000
Bio-fermenter	1	500L stainless steel, jacketed culture vessel as above.	For production of Pasteurella culture for Haemorrhagic septicaemia vaccine.	21,000
Bio-fermenter	1	150L stainless steel, jacketed culture vessel as above.	For scaling up of Pasteurella inocula for 500L Bio-fermenter and for the production of Br.abortus culture for Brucella S19 vaccine.	14,000
Settling Vessel	1	250L stainless steel vessel with conical bottom and outlet port. Integral finish mirror polish, crevice-free weldings. Design pressure: 2.3 bar	For concentration of Br.abortus cells in the culture medium by precipitation and sedimentation. (Vessel is required for 3 days per batch of culture produced every 14 days).	6,000
Settling Vessels	4	250L stainless steel vessel as above.	For concentration of B.anthracis cultures. (2 vessels for 10 days are required for each batch, which is produced at 14 day intervals.	24,000
Storage Vessels	4	100L stainless steel storage vessel complete with magnetic stirrer and ports. Internal finish: mirror polish, crevice free weldings. Design pressure: 2.3 bar	For inactivation and storage of B.anthracis cultures. (One vessel for 5 weeks is required per batch, which is produced at 14 day intervals).	18,000
Storage Vessels	4	250L stainless steel as above.	For inactivation and storage of P.multocida cultures for Haemorrhagic septicaemia vaccine. One vessel for 4 weeks is required per batch, produced at 14 day intervals.) In case of time-drift with blending vessel 1 extra storage vessel is included.	24,000

2.3 PLANT AND MAJOR EQUIPMENT (Cont'd)

DESCRIPTION	QTY	SPECIFICATION	JUSTIFICATION	EST.COST (US $)
Storage vessels	20	250L stainless steel as above.	For inactivation and storage of Cl.chauvoei cultures. (4 vessels for 8 weeks are required per batch, produced at 14 day intervals).	120,000
Storage vessels	3	200L stainless steel tanks complete with in and outlet ports for liquids, steam. Internal finish, mirror polish, crevice-free weldings. Design pressure: 2.3 bar.	For diluent (dist. water) for Brucella S19 vaccine. ca. 160L is filled out per day, turn around time is ca. 3 days.	12,000
Blending vessels	2	2300L stainless steal, jacketed, steam sterilisable complete with stirrers, in and outlet ports. Internal finish: mirror polish and crevice-free weldings. Design pressure: 2.3 bar	For blending and storage of Anthrax and Blackquarter vaccines. (One vessel is occupied for 11 days per batch of vaccine, produced at 14 days intervals).	60,000
Blending vessels	1	1200L stainless steel, jacketed, steam sterilisable complete with stirrers, in and outlet ports. Internal finish: mirror polish and crevice-free weldings. Design pressure: 2.3 bar	For blending and storage of Haemorrhagic septicaemia vaccine. (One vessel for 11 days is required per batch produced at 14 day intervals. To counteract time-drift with the use of blending vessel extra storage vessel for antigen is available).	24,000
Storage vessels	3	100L stainless steel, steam sterilisable complete with stirrer and ports. Internal finish: mirror polish and crevice-free weldings. Design pressure: 2.3 bar	For Brucella S19 vaccine. (One vessel is is occupied for 3 weeks per batch, produced at 14 days intervals).	13,500
Freeze dryer	1	For aseptic processing, steam sterilisable, equipped with internal vacuum sealing system. Shelf area: $3m^2$. Cycle process time: 2.5days.	For lyophilisation of Brucella S19 vaccine vaccine. (20,000 x 25ml vials need to be freeze-dried in 10 working days, ie, in not more than 4 batches).	200,000

2.3 PLANT AND MAJOR EQUIPMENT (Cont'd)

DESCRIPTION	QTY	SPECIFICATION	JUSTIFICATION	EST.COST (US $)
Filling Machine		Semi-automatic microprocessor controlled peristaltic filling machine. Range of volumes 0.1-100ml. Accuracy: 0.2%. Output: up to 1000L. Example: SHUBERT PF100	For filling Brucella S19 vaccine into vials for lyophilisation.	6,000
Laminar flow isolator	1	750x1200mm biological safety cabinet to provide Class II operator protection (US Standard N.S.F.49) as well as product protection.	To provide appropriate conditions for filling Br. S19 vaccine and manual placement of stoppers into vials prior to lyophilisation.	6,000
Laminar flow isolator	1	1200x1800mm biological safety cabinet to provide Class II operator (US Standard N.S.F.49)as well as product protection.	To provide appropriate conditions for filling and closing of Anthrax, Blackquarter, Haemorrhagic septicaemia vaccines and diluent for Brucella S19 vaccine.	7,500
Automatic filling and closing machine	1	Electrically operated three-phase 415v/ 50H2, for polyethylene and polypropylene packs between 25-500ml packs. Filling speed up to 1250/hr. Example SCHUBERT's Pharmic VSF100	For filling and closing Anthrax, Blackquarter, Haemorrhagic septicaemia vaccines and diluent for Brucella S19 vaccine.	90.000
Labelling machine	1	Fully automatic, label size 25x50mm. Output up to 4000units/hr.	For all vaccines and diluents.	10,000
Cauldrons	2	1500L haemispherical, half-jacketed, steam-heated stainless steel boiling pan complete with mechanical stirrer and temperature control.	For preparation of media including meat-infusion medium. Preparation of infusion-type medium requires 2 vessels in conjunction with clarification/filtration.	28,000
Extraction cabinet	1	5 x 2ft wall mounted hood complete with extraction fan.	For weighing very fine powdery substances, peptones, enzymes etc., used in media production	600

2.3 PLANT AND MAJOR EQUIPMENT (Cont'd)

DESCRIPTION	QTY	SPECIFICATION	JUSTIFICATION	EST.COST (US $)
Storage vessels	5	300L pressurised stainless steel vessels. Internal finish: mirror polish, crevice-crevice-free weldings. Design pressure: 2.3 bar	Although bulk media is filtered directly into the fermenters, in case of dislocations, bulk media needs to be stored until used.	32,500
Cryogenic refridgerators	2	Castor-mounted, cabinet type. Storage temp. -196°C. Capacity: 3000x2ml vials. Liquid nitrogen capacity 40L, nominal evaporation rate 2.5L/day.	For dependable storage of working seed cultures used for vaccine production (1) and for challenge cultures in Q.C. lab (1).	2,000
Rotary shakers	2	Orbital flask shakers with infinitely variable speed 0-300rpm controlling a 25mm orbital circular stroke, inter-changeable shaker platforms. Power supply: 220-240v.	For aeration of seed cultures in each of two vaccine production suites.	2,000
pH meters	4	Fully automatic temperature compensation. Accuracy to 0.01pH. Range pH0-14. For redox/oxidation work milli-volt 1ml resolution between 0-1999.	For measuring pH of media, cultures, diluents etc., in vaccine production (2), Filling Unit (1) and Q.C. Laboratory (1)	1,600
Centrifuges	4	Laboratory type, bench mounted, max RCF x g up to 7000. Example: MSE Super-Minor	For bench-scale sedimentation of particulate matter in liquids, cultures and vaccines in vaccine production (2), Filling Unit (1) and Q.C. Laboratory (1)	3,100
Microscopes	4	For research/routine light microscopy, interchangeable objectives, complete with 12v 100W light source, transformer and control unit. Example: Olympus B2 series	For assessment of morphology and purity of microbiological specimens in vaccine production suites (2), Filling Unit (1) and Q.C. Laboratory (1).	11,000
Balance	1	Electronic analytical, range: 82g. Readibility 0.1mg, precision 0.1mg.	For weighing chemicals for reagents, buffers etc., in Q.C. Laboratory.	2,500
Balance	1	Mechanical, top loading weighing range 10,000g, readibility 0.1g, precision 0.2g.	For use in media kitchen.	2,000

2.3 PLANT AND MAJOR EQUIPMENT (Cont'd)

DESCRIPTION	QTY	SPECIFICATION	JUSTIFICATION	EST. COST (US $)
Water bath	1	General purpose. Temp. range up to 100°C. 15L capacity, power rating: 500w. Temperature variation: 0.1°C.	For incubation of serological reactions in Q.C. Laboratory.	500
Deep freezer	1	Top loading, min. temp -20°C. Capacity: 260L. Mains: 220-240v.	For below freezing point storage of biological specimens in Q.C. Laboratory.	400
Spectrophotometers	4	Solid state, wave length long: 340-1000mm, 220-240v, 50-60H2 single phase supply. Example: Banshand Lamb spectronic, model MV	For assessment of bacterial suspensions in vaccine production suites (2), Filling Unit (1) and QC Laboratory (1).	6,000
			TOTAL COST:	1,281,600

2.4 Building Requirements
(Also see Appendices 8B & 8C)

2.4/1 Administration/Staff Facilities

Ref.No. to Layout	C	Dimensions (m)	Area (m^2)	*Cost/m^2 (US $)	TOTAL COST US ($)
1	Director	5 x 6	30		
2	Director's Secretary	5 x 4	20		
3	Head of Production	5 x 5	25		
4	Head of Quality Control	5 x 5	25		
5	Reading/Meetings Room	7 x 6	42		
6	Administration	7 x 6	42	900	
7	Accounts	7 x 7	49		
8	Production Office	5 x 5	25		
	"	5 x 7	35		
9	Reception/Tel.Exchange	4 x 4	16		
10	Staff facilities (changing rooms, showers, rest rooms, WC's)	-	275		
	TOTALS		584m^2		525,600

2.4/2 Preparation/Stores

11	Media Preparation	7 x 13	91		
12	Media Stores	7 x 6	42		
13	Chemical Stores	7 x 6	42		
14	Receiving/Washing	9 x 8	72		
15	Sterilisation/Sorting	9 x 11	99	900	
16	Stores/Vessels-glass etc.	9 x 13	117		
36	Sterilisation	7 x 3	21		
37	Washing	7 x 7	49		
	TOTALS:		533		479,700

* Exclusive of air conditioning to "comfort" standard which would add to cost ca. $150/$m^2$

Building Requirements (Cont'd)

2.4/3 Deep Culture Suite No. 1

Ref.No to Layout		Dimensions (m)	Area (m^2)	Cost/m^2 (US $)	TOTAL COST (US $)
20	Autoclave Room	6 x 5	30	1050	31,500
21	Seed Preparation	6 x 7	42	1050	44,100
22	Deep Cultures (Pasteurella, Brucella)	6 x 8	48	1500	72,000
23	Downstream Processing	6 x 6	36	1050	37,800
24	Blending/Filling (Brucella only)	6 x 7	42	1500	63,000
25	Lyophilisation (Brucella only)	6 x 9	54	1050	56,700
	TOTALS		252		305,100

2.4/4 Deep Culture Suite No. 2

26	Autoclave Room	6 x 5	30	1050	31,500
27	Seed Preparation	6 x 7	42	1050	44,100
28	Deep Culture (Clostridium, Anthrax)	6 x 10	60	1500	90,000
29	Downstream Processing	6 x 12	72	1050	75,600
30	Stores	6 x 8	48	400	43,200
	TOTALS		252		284,400

2.4/5 Blending/Filling/Cold Storage

31	Cold Room	7 x 16	112	1000*	112,000
32	Water deionisation, distillation and storage plant	7 x 14	98	1050	102,900
33	Blending Rooms(2)	7 x 6	84	1500	126,000
34	Filling Room	7 x 6	42	1500	63,000
35	Stores (stainless steel vessels etc)	7 x 10	79	900	63,000
	TOTALS		406		466,900

* Exclusive of cooling plant

Building Requirements (Cont'd)

C-2.4/6 **Support Services**

	Dimensions (m)	Area (m^2)	Cost/m^2 (US $)	TOTAL COST (US $)
Goods Inwards Storage Despatch Boiler House/Power Plant	9 x 68	612	900	500,800
TOTALS		612		550,800

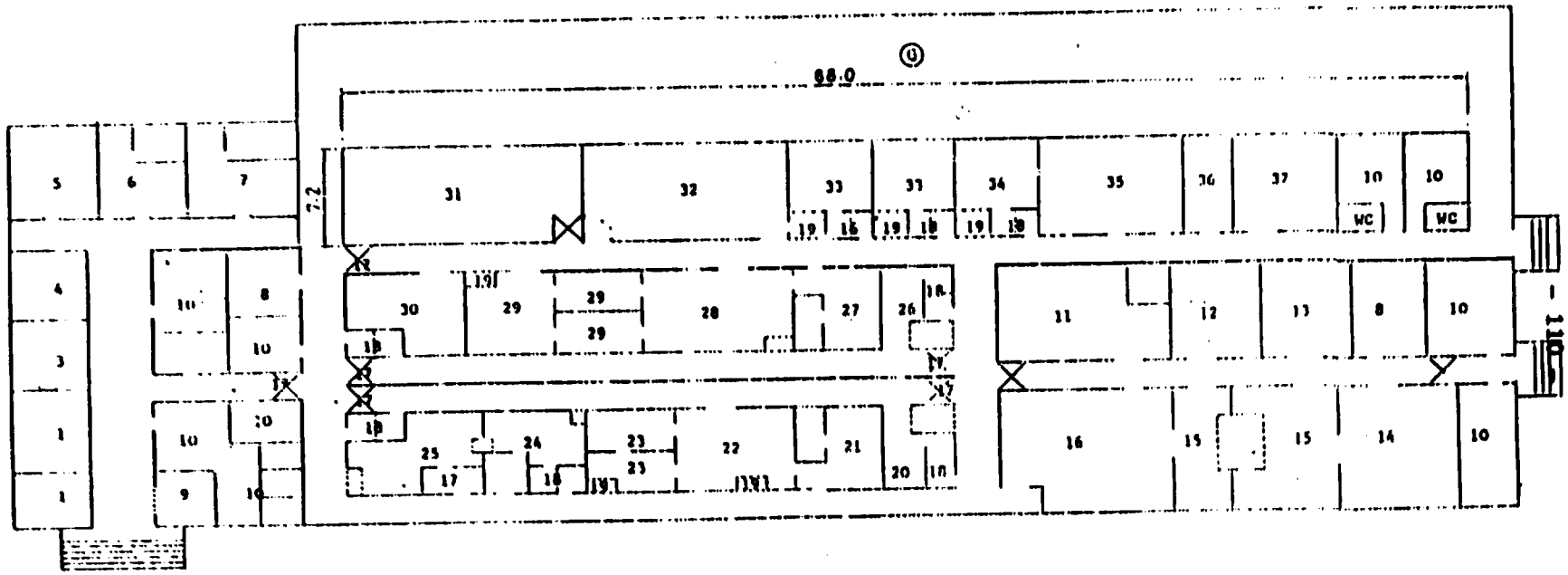
2.4/7 **Quality Control** (Layout B)

General Office	5.5 x 4	22	1050	23,100
Laboratory	5.5 x 7	38	1050	40,425
TOTALS		60		63,500

2.4/3 **Animal Testing** (Layout B)

Changing Rooms(2)	5.5 x 3	33		
Guinea Pigs	5.5 x 4	22		
Mice	5.5 x 4	22		
Rabbits	5.5 x 4	22	900	
Inoculation Room	5.5 x 4	22		
Cage Cleaning/Sanitisation	5.5 x 4	22		
Store	5.5 x 4	22		
Goats	5.5 x 3	16.5		
TOTALS		ca. 181		163,500
Guinea pigs Anthrax	5.5 x 3	16.5	1500	49,500
Sheep high sec.	5.5 x 3	16.5		
TOTALS		33		49,500
GRAND TOTALS		2913m^2		2,889,000

VETERINARY BIOLOGICALS PRODUCTION FACILITY



ADMINISTRATION/STAFF FACILITIES

1 Director(6x5m)
2 Director's Sec.(4x6)
3 Head of Production(5x5)
4 Head of Qual. Assur.(5x5)
5 Reading/Meetings Rm(7x6)
6 Administration(7x6)
7 Accountancy(7x7)
8 Production Offs.(5x5&5x7)
9 Reception/Tel.Exchange(4x4)
10 Staff facilities(275m²)

(584m²)

N.B. All measurements in m

PREPARATION/STORES

11 Media Prep.(7x13)
12 Media Store(7x6)
13 Chemical Store(7x6)
14 Receiving/Washing(9x8)
15 Steril./Sorting(9x11)
16 Store Vessels-Glass(9x13)

(463m²)

LOCKS

17 Air Locks
18 Personnel Locks
19 Formalin Locks

DEEP CULTURE SUITE NO.1

20 Autoclave Rm (5x6)
21 Seed Prep.(7x6)
22 Fermenters(8x6)
(Brucella,Pasteurella)
23 Downstream Process.(6x6)
24 Blending/Filling(Brucella)(7x6)
25 Lyophilisation Plant(9x6)
(252m²)

DEEP CULTURE SUITE NO.2

26 Autocl. Rm(5x6)
27 Seed Prep.(7x6)
28 Fermenters(10x6)
(Clostridium,Anthrax)
29 Downstream Process.(12x6)
30 Stores(8x6)
(252m²)

BLENDING/FILLING/COLD STORAGE

31 Cold rooms(7x16)
32 Water Plant(7x14)
33 Blending Rms(2)(7x6)
34 Filling Room(7x6)
35 Stores
36 Sterilisation(3x7)
37 Washing(7x7)
(476m²)

SUPPORT SERVICES (G)

Goods Inwards
Storage
Despatch
Boiler House/Power Plant

(612m²)

Layout C

2.5 Requirements for Manpower, Training and Ex-patriot Technical Assistance

2.5/1 Manpower and Training

Title	Number	Training Abroad (Man/mths)	(Cost US$)
General Manager (Graduate)	1	6	12,000
Head of Production (Graduate in Microbiology/Biotechnology)	1	12	24,000
Head of Quality Assurance/Control (Graduate in Biology or associated fields)	1	12	24,000
Administration Manager (Graduate)	1	3	6,000
Chief Accountant (Graduate)	1		
Accounts Assistant	1		
Supplies Assistant	1		
Library Assistant	1		
Secretaries	3		
Secretaries/Typists	3		
Receptionist/Tel. Exchange	1		
Senior Laboratory Technicians:			
Media Preparation	1	3	6,000
Production	2	24	48,000
Quality Control	1	12	24,000
Blending/Filling	1	6	12,000
Lyophilisation	1	6	12,000
Animal House	1	3	6,000
Laboratory Technicians:			
Media Production	1		
Production	4		
Quality Control	2		
Blending/Filling	3		
Laboratory Attendants	11		
Animal House Attendants	2		
Instrument Technician	1	12	24,000
Maintenance Engineers	2	12	24,000
Electrician	1		
Security Guards	3		
Drivers	3		
TOTALS	55	111	222,000

Total number of personnel: 55

Duration of training abroad: 111 man/months

Cost of training abroad (at the rate of US$ 2000/month): US$ 222,000

2.5/2 Ex-patriot Technical Assistance

Expert in production (Fielded for 12 months in 2 years)	96,000
Expert in Quality Assurance and Control (Fielded for 9 months in 2 years)	72,000
Ex-patriot maintenance technician (Fielded for 6 months in 2 years)	48,000
TOTAL of 27 man/months.	
TOTAL COST OF EX-PATRIOT TECHNICAL ASSISTANCE (US$ 8000 per man/months)	216,000

2.6 Transport Vehicles

Saloon Car	1
Landrover	1
Minibus	1
Lorry (3 tonnes)	1

Annex 5

ESTIMATED RUNNING COST OF BIOLOGICALS PRODUCTION FACILITY WITHIN SADCC

OPTION 1 Local Formulation and Filling/Quality Control

SUMMARY OF RUNNING COST ESTIMATE

		US$ 000's
1.1	Amortisation of Buildings at 4% (See Annex 4 ; Capital cost estimate $813,000)	33
1.2	Amortisation of Plant and Equipment at 12.5% (See Annex 4 ; Capital cost estimate $370,000)	46
1.3	Salaries/Wages/Ex-patriot Experts (See Annex 4 for personnel)	
	Salaries/Wages	28
	Ex-patriot experts	48
1.4	Materials	
1.4.1	Antigen Concentrates (See Annex 4 for 17million doses at $25/1000 doses	425
1.4.2	Adjuvants and Diluents (See Annex 4 ; 22000L bulk vaccine)	
	Adjuvant: Aluminium salt at 20% 4400L, $8.0/L	35
	Diluent: Pyrogen-free sterile water estim. 15000L; $2.0/L	02
1.4.3	Filling/Packaging (Also see Annex 4)	127
1.5	Quality Control	10
1.6	Services (Electricity, steam, water, telephone estimated)	30
1.7	Repairs and Maintenance (estimated)	20
1.8	Transport : 1 vehicle	7
	GRAND TOTAL	801

1/3-A Salaries/Wages/Ex-patriot Experts

Status	Nos. in Group	Salary p.a. (US $)	Total
Graduates	2	3,500	7.0
Senior Laboratory Technician	2	1,300	2.6
Laboratory Technician	4	850	3.4
Attendants/Lab. Animal	6	600	3.6
Administration Manager	1	2,700	2.7
Accountant	1	2,700	2.7
Personal Secretary	1	1,300	1.3
Secretories/typists etc	4	600	2.4
Instrument Tech./Electrician	1	1,300	1.3
Maintenance Engineer	1	850	0.9
TOTAL			**27.9**
Ex-patriot technical experts fielded for six months in the year		96,000	48.0

1/4.3-A Filling/Packaging

Packs: Polyethylene, ½ -irradiated

Sizes		Numbers	US $.../1000	TOTAL US $ 000's
20ml	x	140,000	150	21
50ml	x	80,000	180	14
100ml	x	130,000	230	30
250ml	x	45,000	300	13
Stoppers-collars		500,000	20	10
Cardboxes for 400,000 packs, aver.20 packs/box		20,000	1200	24
Labels, leaflets		500,000	estimate	15
TOTALS				127

1/5-A Quality Control

(only bulk vaccines and filling lots tested)

Vaccine (No. of batches)	Animal species* (Total nos.)	Keep-days	Total Cost (US $)
Anthrax (8)	Sheep (16)	160	400
	Guinea-pigs (104)	1920	1300
Blackquarter (14)	Calves (28)	204	1600
	Mice (60)	190	280
	Guinea-pigs (220)	7056	4100
Haemorrh.septic. (4)	Cattle (8)	64	1700
	Mice (80)	812	450
TOTAL			9830

*Cost US $:

Cattle $ 200; $1/keep day
Calf $ 50; $ 1/keep day
Sheep $ 20; $0.5/keep day
G-pig $ 3; 0.5/keep day
Mice $ 1;

ESTIMATED RUNNING COST OF BIOLOGICALS PRODUCTION FACILITY WITHIN SADCC

OPTION 2: Local Production

SUMMARY OF RUNNING COST ESTIMATE

		US$ 000's
2.1	Amortisation of Buildings at 4% (See Annex 4; Capital cost estimate $2.9mill.)	116
2.2	Amortisation of Plant and Equipment at 12.5% (See Annex 4 ; Capital cost estimate $1.1mill.)	132
2.3	Salaries/Wages/Ex-patriot Experts (See Annex 4)	
	Salaries/Wages	62
	Ex-patriot Tech. Experts	97
2.4	Materials	
2.4/1	Media (See Annex 4)	70
2.4/2	Adjuvant (See Annex 4 for 26,000L bulk vaccine)	
	Adjuvant: Aluminium salt at 20% 5200L $8.0/L	52
	Diluent: Pyrogen-free ster. water 15000L $2.0/L	2
2.4/3	Filling/Packaging (See Annex 4)	231
2.5	Quality Control	31
2.6	Services Electricity, steam, water, telephone (estimated)	50
2.7	Repairs and Maintenance (estimated)	30
2.8	Transport: 4 vehicles	30
	GRAND TOTAL	903

2.3-A Salaries/Wages/Ex-patriot Experts

Status	Nos.in Group	Salaray p.a. (US $)	TOTAL (US$ 000's)
Graduates	5	3,500	17.5
Senior Lab. Tech.	7	1,300	9.1
Lab. Tech.	10	850	8.5
Attendants: Lab/Animal	13	600	7.8
Accounts, Supply, Library Assistants	3	850	2.6
Secretaries	3	1,300	3.9
Typists/Tel. Exchange	4	600	1.3
Maint. Engineers/Electricians	3	850	2.6
Drivers 3	850	2.6	
Security Guards	3	600	1.8
TOTAL			62.2
Ex-patriot Technical experts (fielded for 13.5 man/months)		96,000	97.2

2.4/1-A Media,Chemicals

	$/1L	TOTAL (US $)
Anthrax 2400L	3.6	8,600
Blackquarter 7000L	5.9	41.300
Haem.Septic. 1000L	12.2	12,200
Brucella S19 1300L	4.8	6,200
Diluent 15000L	0.1	1,500
TOTAL		69,800

2.4/3-A Filling/Packaging

Packs: Polyethylene, γ-irradiated

	Sizes		Numbers	US $../1000	TOTAL(US $)
Anthrax	50ml	x	80,000	180	14,400
	100ml	x	40,000	230	9,200
Blackquarter	100ml	x	70,000	230	16,100
	200ml	x	35,000	300	10,500
Haemorr.Sept.	100ml	x	20,000	230	4,600
	200ml	x	10,000	300	3,000
Brucella	20ml	x	260,000	150	39,000
	20ml	x	260,000	150	39,000
Assorted stoppers and collars			1.0mill.	20	20,000
Cardboard boxes for ca. 750,000 packs aver. 20 packs/box			37,500	1200	45,000
Labels, leaflets			1,000,000	estim.	30,000
TOTAL					230,800

2.5-A Quality Control
(In-process tests, and tests on bulk vaccine and filling lots are included)

Vaccine (No. of batches)	Animal species* (Total nos.)	Keep-days*	TOTAL COST (US $)
Anthrax	Sheep (16)	160	400
(8)	Guinea-pigs (104)	1920	1300
Blackquarter	Calves (28)	204	1600
(14)	Mice (60)	490	280
	Guinea-pigs (220)	7056	4100
Haem.septic.	Cattle (8)	64	1700
(4)	Mice (80)	812	450
Brucella S19	Guinea-pigs (30)	2520	1250
	Mice (75)	300	150
TOTAL			11,300
Media for in-process sterility etc. testing est.			20,000

*Cattle $200: $1/keep day
Calf $ 50: $1/keep day
Sheep $ 20: $0.5/keep day
Guinea-pigs $ 3: $ 0.5/keep day
Mice $ 1:

Annex 6

COMPARATIVE COST OF PRIORITY BACTERIAL VACCINES WITHIN SADCC ACCORDING TO ORIGIN OF SOURCE

1 Actual prices (US cent) of imported priority vaccine 1985/86 in some of the countries within SADCC

Product	Botswana	Zimbabwe	Malawi	Zambia	Tanzania	Avge
Anthrax (Anth)	4.4	3.3	-	13.0	9.0	7.42
Blackquarter (BQ)	9.7	4.7	9.0	12.0	6.0	8.28
Haemorrh.septic (HS)	3.5	-	-	15.0	20.0	12.83
Brucella S19 (S19)	15.0	9.1	30.0	-	30.0	21.02
						$\frac{49.55}{4}$

Average price of four imported bacterial vaccines: 12.38 cents

2 Cost (US cent) of priority bacterial vaccines locally formulated from imported intermediaries

(See Annexes 4 and 5)

Estimated annual running cost of Facility US $: 802,000
Annual output of Facility/Anth., BQ, H.S., doses: 17,000,000

Average cost of three locally formulated priority vaccines 4.17 cent/dose

(See Annexes 4 and 5)

3 Cost (US cent) of priority bacterial vaccines locally produced

Estimated annual running cost of Facility US $: 915,000
Annual output of Facility (Anth., BQ., HS, S19) doses: 20,000,000

Average cost of four locally produced priority vaccine 4.50 cent/dose

Annex 7

THE PRODUCTION OF POULTRY VACCINES IN SADCC

To prepare poultry vaccines to European Pharmacopoeia standards of safety and potency it is necessary to use specific pathogen-free (S.P.F) eggs. S.P.F. eggs can be bought from Lohmann at a cost of US $6.00 (landed cost). An alternative would be to establish a laying flock of S.P.F. birds. It is estimated that to meet the requirements of SADCC, a laying flock of not less than 500 hens would be permanently required.

1. COST OF IMPORTING S.P.F. EGGS FOR LOCAL NEWCASTLE DISEASE VACCINE PRODUCTION

Doses required annually: 10×10^6 of 40% HITCHINER = 40×10^6

40% LA SOTA = 40×10^6

20% KOMAROV = 20×10^6

Estimated yield/egg = 1,000 doses.

For 100×10^6 doses	100,000 eggs are needed
+ 15% hatching loss	15,000
TOTAL	115,000

Price of S.P.F. eggs is US $ 6,00/piece, 115,000 x US46,00 = US $ 690,000

2. COST OF ESTABLISHING AND MAINTAINING LAYING FLOCK OF 500 BIRDS

2.1 CAPITAL

	US $
2.1.1 Building	432,000
2.1.2 Plant and Equipment	70,000
2.1.3 Technology Transfer	100,000
2.1.4 Project Management 2 Man-year	200,000
2.1.5 Project Implementation	100,000
2.1.6 Raw Materials	60,000
2.1.7 Contingency 10%	100,000
GRAND TOTAL	1,062,000

2.2 RUNNING COSTS P.A.

2.2.1 Amortisation Building 1/25	17,280
2.2.2 Amortisation Plant and Equipment 1/10	7,000
2.2.3 Material	45,000
2.2.4 Staff. 1 Overseas Man-year	100,000
2.2.4.1 Staff. 16 Local Man-year	96,000
	196,000
2.2.5 Services	25,000
2.2.6 Transport	12,000
2.2.7 Management Contract	150,000
GRAND TOTAL	452,280

3. COST OF QUALITY CONTROL LABORATORY

3.1 CAPITAL

3.1.1 Building 160m^2 x US $1,200	192,000
3.1.2 Plant and Equipment	50,000
3.1.3 Technology Transfer	100,000
3.1.4 Project Management 2 Man-year	200,000
3.1.5 Project Implementation	100,000
3.1.6 Raw Materials	25,000
3.1.7 Contingency 10%	75,000
GRAND TOTAL	742,000

3.2 RUNNING COSTS P.A.

3.2.1 Amortisation. Building 1/25	8,000
3.2.2 Amortisation. Plant and Equipment 1/10	5,000
3.2.3 Material	15,000
3.2.4 Staff. 1 Overseas Man-year	100,000
3.2.4.1 Staff. 5 Local Man-year	30,000
3.2.5 Services	15,000
3.2.6 Transport	5,000
3.2.7 Management Contract	100,000
GRAND TOTAL	378,000

4. COST OF PRODUCTION LABORATORY

4.1 CAPITAL

4.1.1 Building 440m^2 x US $1,000	440,000
4.1.2 Plant and Equipment	500,000
4.1.2.1 Technology and Transfer 3 x 0.5 Man-year	150,000
4.1.2.2 Training (Overseas)	150,000
4.1.3 Project Management	200,000
4.1.4 Project Implementation (2.5 Man-years)	250,000
Raw Materials	80,000
4.1.6 Contingency 10%	110,000
GRAND TOTAL	1,880,000

* price of 115,000 eggs, ie, US $690,000 excluded.

4.2 RUNNING COSTS P.A.

4.2.1 Amortisation. Building 1/25	17,600
4.2.2 Amortisation. Plant and Equipment 1/10	50,000
4.2.3 Material	25,000
4.2.4 Staff. Overseas. 1 ½ Man-year	250,000
4.2.4.1 Staff. Local 20 Man-year	120,000
	463,000
4.2.5 Services	100,00
4.2.6 Transport	25,000
4.2.7 Management Contract	250,000
4.2.8 Quality Control	25,000
4.2.9 Animal House	12,000
	874,000

5. CONCLUSION

Taking into consideration the production of 100 x 10^6 doses of Newcastle Disease vaccines annually and the prerequisites of the European Pharmacopoiea, S.P.F. flock, laboratory to screen the freedom from pathogens of eggs and a production plant consisting of one common culture medium/preparation section, 3 separated laboratories for the 3 different types of Newcastle virus strains and one common freeze-drying section are needed.

Even if the cost of imported 115,000 eggs - essential for one year production - is disregarded, the running costs of S.P.F. flock, screening, production and auxiliary activities would be US $1,794,880, and the price of one dose of vaccine US $0.0170488. Reputable European Manufacturers will supply Newcastle Disease Vaccine at a landed cost of US $0.001 per dose. Comparing this figure to the price of the recent importation (76million doses for Z$203,000, equivalent approximately to US $135,000) in which one dose of vaccine has a C.I.F. price of US $0.00177631, it seems evident that the local production of the poultry vaccines will not be economic.

Therefore the best way to meet the regional requirements is the importation of these products.

Annex 8

SADCC Countries - Veterinary Drugs

Market Information and Projections

1. Sources of Information

1. Livestock population statistics.
2. Official reports from each of the countries.
3. Detailed discussions with Livestock Development Authorities and Veterinarians in each of the countries.
4. Outside official sources (e.g. FAO).
5. Private market research information.
6. Official statistical data in some countries.

2. Drug and Vaccine Requirement

1. Forecast drug and vaccine requirements from the Government Authorities.
2. Historical data from the Livestock Department.
3. Historical data and trends from State Importing Companies (where they exist).
4. Historical information and trends from private Importing Companies.
5. Forecast drug and vaccine requirements from private companies.
6. Private market research data.
7. Consultations with the private sector where appropriate.

Animal Health Markets in SADCC Countries

1. Acaricides (Ectoparasiticides)

Ectoparasites, notably ticks are controlled predominantly by immersion dipping.

Four groups of compounds are used to a significant* extent

Organo-chlorine compounds
Organo-phosphorous compounds
Amidines
Synthetics pyrethroids

There is a transition from the organo-chlorine compounds (now only widely used in Tanzania) to organophosphorous which itself is rapidly giving way in some markets to amidines, in particular, and synthetic pyrethroids.

The markets in Botswana, Swaziland and Zimbabwe are dominated by amidines and, with parasite resistance emerging and more awareness of the environment this trend is likely to continue, elsewhere.

It is estimated that by the year 2000 approximately 50% of acaricides in the SADCC region will be based on amidine the remainder divided between organo-phosphorous (especially dichlofenvinphos) and synthetic pyrethroids, with the phasing-out of organo-chlorine compounds.

No estimates of tonnage of these compounds has been given as the dilution rate in the dip wash varies more than 10-fold depending on the compound and the formulation.

Order-of-magnitude estimates can easily be made for specific products (many still covered by patent protection) on the basis that a bovine on average removes 2.5 litres of dip wash per immersion and that immersions vary from 10-40 per year, depending on many factors, amongst them parasite challenge, the climate and the efficiency of the veterinary services in the country concerned.

*Arsenic is still used, notably in Malawi.

Principal Acaricides used in the SADCC Countries

Arsenic
Toxaphene
Chlorvenvinphos
Diazinon (Lesotho only)
Dioxathion
Amitraz
Decamethrin

2. Antibacterials

The market in SADCC is dominated by injectable dosage forms. Of these approximately 50% is made up of tetracyclines, the rest being penicillin and penicillin combinations (e.g Pen/Streptomycin) making up about another 30%, the remainder being mainly sulphonamides and combinations with a small proportion of semi-synthetic penicillin, chloramphenicol, furazolidone etc.

There is no information on number of animals dosed.

Principal Antibaterials utilised in SADCC Countries

Oxytetracylcine
Tetracycline Rydrochloride
Penicillin
Streptomycin
Tylosin
Amoxycillin
Ampicillin
Trimethoprim
Suphamethamezathine
Sulphathiazole
Sulphaquinoxaline
Nitrofurazone

3. Anthelmintics

The market is fragmented.

Benzimidazoles dominate round-worm treatment. and rafoxonide the treatment of fluke, but many older drugs such as levamisole, piperazine and morantel are still important locally.

The combination of anti-nematode activity with action against liver fluke means that the benzimidazoles will probably continue to grow in importance to the end of the century. Many of these are still covered by patent protection.

Principal Anthelmintics used in SADCC Countries

Albendazole
Fenbendazole
Oxfendazole
Morantel
Rafoxanide
Levamisole
Piperazine

Requirements for Veterinary Drugs and Acaricides, SADCC Countries

Because of the number of drugs being used within the main Product Groups and the variety of dosage forms and the different rate of dosage in different species and different diseases it is not possible to give a detailed requirement country by country.

Furthermore different presentations of the same drug in the same dosage form can vary many times e.g. injectable oxytetracycline can from 50 to 200 mg/ml. and concentrations of active ingredient in cattle dip formulations can differ 10-fold. As information is available in different units in different countries e.g. bottles, kilos, litres, sometimes doses, it is not possible to give an accurate total by adding the data.

It is possible, however, to give indicative estimates according to current and projected drug usage.

These can be used for planning purposes.

Indicative Requirements for Veterinary Drugs and Acaricides in SADCC Countries by the year 2000

1. Acaricides

Assumptions: Bovine population 30 million
Immersions/year 25
Litres dip-wash/head/immersion 2.5

Acaricides Required	Litres Acaricide required p.a. (000's)
Amidines (12.5% w/v) Dilution 1:500 Percentage of Total Acaricide Requirement 50 Requirement per annum	1,876
Organophosphorous (55% w/v) Dilution 1:2,200 Percentage of Total Acaricide Requirement 2.5 Requirement per annum	213
Pyrethroids (18.75 w/v) Dilution 1:500 Percentage of Total Acaricide Requirement 15 Requirement per annum	562
Others (principally Toxaphene) Dilution 1:200 Percentage of Total Acaricide Requirement 10 Requirement per annum	94
TOTAL	2.745

N.B. These figures must be treated with caution as many other factors are involved such as initial charge rates, exhaustion rates and varying formulations.

Indicative Requirements for Veterinary Drugs and Acaricides in SADCC Countries. 1986

2. Antibacterials

In most SADCC Countries the dominant use of antibacterials is for cattle by the parenteral route. Where intensive pig and poultry industries exist e.g. Zimbabwe and Zambia there is also an in-feed use. but overall this amounts to less than 10% of the total requirement. As in the case of other product groups the cattle sector amounts to over 90% of the market.

Assumptions: Bovine population 30 million
An animal will require a dose on average once every 2.5years.
The market is divided:
Tetracyclines - 50%
Penicillin and combinations - 30%
Sulphonamides and combinations - 20%

Injectable Tetracyclines

Doses per annum 6 million
Dose: 2gm/animal
Dosage form: 10% solution
Volume injectable liquid required per annum 120,000 litres

Injectable Penicillin ± Combinations*

Doses per annum 3.6 million
Active ingredient: 250 mg/ml
Average dose size: 15ml
Volume injectable penicillin + combinations required per annum 54,000 litres

Injectable sulphonamide

Doses per annum: 2.4 million
20 ml/dose of 33% solution
Volume injectable sulphonamide required per annum 48,000 litres

Oral dosage Forms

This can be taken as 10% of the above in terms of active ingredient. They will be mainly powders for mixing with food or water.

* Principal combination is penicillin/streptomycin with streptomycin at 250 mg/ml.

Indicative Requirements for Veterinary Drugs and Acaricides in SADCC Countries. 1986

3 Anthelmintics

Assumptions: Bovine population 30 million
90% of requirement is for use in bovines
50% will be benzimidazoles with an anti-nematode activity. some anti-trematode activity
20% will be anti-trematodes
30% will be a mixture of other products such as levamisole, morantel. oxfendazine etc.
Assume that each young animal is given 2 doses of anthelmintic in its life.

Total doses required p.a.	10,000,000
Assume average body-weight	50kg

Benzimidazoles

Assumptions:
Presentation 5% powder
Dosage rate 10mg/kg active ingredient
Average weight of animal 50kg
Doses/year 2
Animals treated 5 million

Volume of drug required (active ingredient)	2.500 kg
Formulated (5% paste, powder or liquid)	50.000 kg

Flukicides
(Mainly rafoxanide)

5% paste powder or liquid	30.000 kg

Miscellaneous

Levamisole	3% injectable solution	12.500 litres
Others (mainly powders)		20.000 kg

In fact dosage-rates vary greatly e.g. Benzimidazoles vary from 5 to 100 mg/kg in their recommended rate of application therefore the actual capacity required will depend on which drug is to be produced. This could well depend on patent protection.