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ASSISTANCE IN THE PRODUCTION OF
VETERINARY DRUGS IN
SADCC COUNTRIES

DP/RAF/86/012

ZIMBABWE

Technical report: The supply of veterinary drugs and vaccines in Zimbabwe

Prepared for the Government of 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 Dr. Laszlo K. Nagy,
Mr. F. Galencsar, Experts in Production of Veterinary Vaccines,
Mr. F.J.R. Menard, Expert on Marketing of Veterinary Drugs and
Mr. H. Chappel, Expert in Production of Veterinary Drugs

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

United Nations Industrial Development Organization
Vienna

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INTRODUCTION

Zimbabwe is a country of some 390,250sq.km. in south central Africa between the Zambezi and Limpopo rivers. It is bordered by Zambia to the North, South Africa to the South, Mozambique to the East and Botswana to the West.

The human population was estimated at 7.5million in 1982, growing at 2.4%, reaching 11.7million by the end of this century.

1. LIVESTOCK POPULATION AND PRODUCTION TRENDS

Livestock Numbers (000's)

Livestock	Commercial	Communal	Total
Cattle	1,785	3,400	5,185
Sheep	141	270	411
Goats	-	1,000	1,000
Pigs	103	-	103
Poultry - Layers	1,500	-	
Broilers	15,000	-	46,500
Backyard	30,000	-	
Horses	10	-	10
Donkeys	-	180	180

Since independence in 1980 the trend has been for a switch in cattle numbers from the commercial to the communal sector. Compounded by the drought conditions in the early 1980's this has led to a fall in the numbers of animals in the commercial sector of about 1million head. It is now estimated that the commercial sector cattle population will remain roughly static (possibly rising to 2million head by the year 2000) whilst the communal sector will increase by about 50% to about 5million head.

Sheep, goats and pigs are expected to continue their minor role in the livestock industry, but poultry production is expected to increase significantly as the price of red meat goes up and cheaper sources of animal protein are sought. Alone amongst SADCC countries, Zimbabwe has an excess cereal production so can provide poultry rations without direct conflict with human nutritional objectives. The pressure towards higher beef prices is all the more since the recent allocation of the 10,000 ton beef quota by the EEC.

2. NATIONAL DISEASE CONTROL STRATEGIES

2.1 Tick-borne Diseases

Ticks and tick-borne diseases are dominant amongst animal diseases in Zimbabwe, both in terms of the economic losses they cause and the proportion of Animal Health resources devoted to them (in terms of expense and man-power. There is statutory control of dipping (the Cattle Cleansing Act) making cattle dipping compulsory in

defined areas once a week from November to June and twice a month from July to October. There are over 7000 dipping and spraying facilities in the country. Dipping is free in the communal areas and they are well controlled by the Veterinary Department.

As a result of this effective campaign the losses from anaplasmosis, pyroplasmosis, heartwater and theileriosis (T parvo Bovis) are controlled, but these diseases represent a constant threat to livestock production and any reduction in the efficiency of the tick control campaign soon results in the resurgence of tick-borne diseases. Bicond "vaccines" against anaplasmosis, pyroplasmosis and heartwater are issued on a limited scale, but for a variety of reasons (including availability) are not suitable for large scale strategic use.

2.2 Trypanosomiasis and Tsetse Control

The control of tsetse and trypanosomiasis has been a major operation for many years now, interrupted by the war. The control campaign based on several measures such as aerial spraying, ground spraying and the use of targets (both living and artificial) is making excellent progress in clearing the disease from large tracts of Zimbabwe. The main campaign is supported by monitoring and the strategic use of trypanocides.

This campaign is part of a regional strategy funded by EEC which will embrace Malawi, Zambia and Mozambique and which has every chance of success, at least in the first three countries.

2.3 Foot and Mouth Disease

There has been no clinical case in domestic livestock since 1984. Through a policy of fencing off game reserves coupled with rigid vaccination measures in sanitary cordons, backed-up by additional buffer zones and ancillary monitoring and zoosanitary measures, the country is maintained in a Foot and Mouth Disease-free status. It now meets the EEC requirements of FMD-free status to the extent that meat exports to Europe have now been resumed. Within the vaccination zones all bovines are vaccinated every six months with trivalent vaccines (SAT 1, 2, 3)

2.4 Rabies

The mass vaccination of dogs reduced the incidence of rabies dramatically from 1980 to 1984. However there has been an increase in incidence during the last two years, most of it due to the uncontrolled movement of people and dogs into Zimbabwe from neighbouring Mozambique, but some additional cases were associated with Jackals.

The control policy is mass vaccination and identification of dogs. There is scope for increased usage of rabies vaccine. 187 cases were reported during 1985.

2.5 Nutritional Diseases Although this is less significant than in the case of other SADCC countries it is still of major importance in areas of overgrazing and of widespread importance during drought years.

2.6 Newcastle Disease The disease is controlled by free vaccination where outbreaks have occurred in the East of the country. Commercial hatcheries use prophylactic vaccine routinely.

2.7 Anthrax The extensive epidemic in 1979-80 was followed by country-wide vaccination, up to 4 million doses of vaccine being used per annum. Only 6 outbreaks were reported in domestic livestock in 1985.

2.8 Other diseases including Rift Valley Fever, Blue Tongue, African Horse Sickness and Tuberculosis are recognised.

2.9 Brucellosis Brucellosis occurs and between 5-10% of tested animals are sero-positive. Female calves in dairy herds and some improved herds are vaccinated between 4 and 8 months of age.

3. THE ORGANISATION OF VETERINARY SERVICES

The Veterinary Services are among the best in Africa and a good infrastructure and extension service has been maintained. Although much ground was lost in the late 1970's the infrastructure is being built up again with particular emphasis being placed on the training of livestock managers whose main job will be to educate farmers in the growing communal sector and supervise the implementation of disease control policies and the correct use of medicines.

The veterinary services are divided into:

- Research
- Tsetse and Trypanosomiasis Control
- Meat Hygiene
- Field

Each is headed by an Assistant Director.

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

4.1 The Market Alone amongst SADC countries the great majority of Veterinary Drugs and acaricides are formulated locally, probably over 90%. Exceptions are patented and highly specialised products such as trypanocides and other anti-protozoan drugs, sophisticated anti-bacterial compounds or products with a low demand which do not justify local manufacture. Included in the product groups of locally-manufactured materials in particular are acaricides, (the great majority), anthelmintics and antibiotics.

Biological products, however, are all imported.

The Animal Health Industry is tightly controlled by the allocation system, but generally speaking sufficient funds are available to meet requirements, although there are some exceptions (e.g. anthelmintics).

There is a strong private sector market with well-known international companies operating, including Coopers, Ciba-Geigy, Shell, Pfizer, Hoechst, May and Baker, Agricura, Bayer and also CAPS. There is a Drug Control Council which controls registration and licensing of animal health products in Zimbabwe.

There is price control but the system is working in an acceptable manner.

Drugs and acaricides produced by the government for use in official campaigns are being bought on a tender basis, usually annually. These include acaricides, Foot and Mouth Disease vaccine, Anthrax vaccine, rabies vaccine, Brucella vaccine etc. However the government may still use private sector distribution and sales outlets even in the case of materials supplied under tender e.g. acaricides.

The approximate market breakdown in value terms is approximately 50/50 between the government and private sectors, but the government sector is dominant in volume terms.

Estimated value of the Zimbabwean Animal Health Market is about US \$ 10.5million in 1986 broken down as follows:

Acaricides	46%
Anthelmintics	14%
Foot and Mouth Disease Vaccine	12%
Feed Additives	11%
Antibiotics	6%
Anti-protozoan Drugs	1.5%
Poultry Drugs	1.6%

The rest is made up of other vaccines such as anthrax, rabies, blackquarter, etc.

4.2 Estimated drug and vaccine requirements (These are detailed in Annex 1)

Significant increases can be realistically predicted in line with the government livestock strategy to build up the communal sector, control the major debilitating diseases, (Trypanosomiasis, Foot and Mouth disease and tick-borne disease) and concentrate on increasing livestock production. In particular the use of anthelmintics and antibiotics should increase.

5. CONSTRAINTS ON DRUGS AND VACCINE USAGE

The livestock policies in Zimbabwe are such that there is a reasonable balance between resource allocation and objectives. Although foreign exchange is always short, enough is made available to enable the Veterinary Department to adopt progressive strategies to animal disease control, greater productivity and up-grade markets. So, with caution, one is able to be optimistic about future growth prospects of the animal health market.

As advances are made in the control of major diseases such as Foot and Mouth Diseases and Trypanosomiasis the resources can be switched to the control of disease associated with intensification and new management systems.

6. CONSIDERATIONS FOR LOCAL MANUFACTURING

6.1 Pharmaceuticals

6.1.1 DATLABS BULAWAYO

Officially designated No. 2 to CAPS in the country Datlabs own two buildings in the Industrial area of Bulawayo. One is for the production of high class sterile products, the other for the production of tablets, liquids, suppositories and vitamins. The buildings are adjacent.

6.1.1.1 The company produces its own products and is a sub-contract manufacturer for ROCHE, MSD, SKF, BEECHAMS, ORGANON and GLAXO. The standards of manufacture are monitored yearly by the above but are monitored quarterly by BAXTER TRAVENCOL, for whom the Company produces intravenous liquids in a Bioglex container in Class 1000 sterile conditions.

6.1.1.2 The site is provided with all basic facilities and has limited space available for expansion. All service plant was renewed in 1985 and is in good workable condition. The plant could provide extra output for limited

expansion. Whilst the sterile building is an example of excellence in design, flow, logistics and operation, its counterpart for producing the normal pharmaceutical range is badly in need of refurbishing and redesign. It is planned to start the refurbishment shortly, area by area, which will be a difficult operation as the objective is to continue production during the refurbishing.

6.1.1.3 Products include tablets, liquids, vitamins, suspensions, creams, granules, capsules, ointments, sterile products and ampoules/vials for injection. Products are segregated at 80% ethical and 20% OTC. Product specification is as per the requirement of the product owner.

6.1.1.4 Technology and manufacturing processes are as supplied by the product owners' product operating instructions and validated by regular technical audits.

6.1.1.5 Equipment in the sterile building is two years old, the best available and all in good order. Except for tanks, which are to a high standard and produced in Zimbabwe, all other equipment has been imported. Equipment in the basic pharmaceutical building, although functional, is not of such a high standard and consideration must be given to the replacement or complete overhaul at the time of building refurbishment.

6.1.1.6 The company has its own transport system, has telephone and telex and has a distribution branch in Harare.

6.1.1.7 The company is efficiently and strongly led by the General Manager who is also in charge of general administration. The production department has 315 operatives controlled by 12 pharmacists. The control operation, said to be No. 1 in the country, has a staff of 20. The company has a well equipped engineering unit. Key staff members are sent to Baxter Travenol and Beecham yearly.

6.1.1.8 Discussion

The company has the best sterile production facilities in the country and also the best QC facilities in the country. Currently, plant is only running at 30% capacity and although it has a full order book it is constrained for purchase of raw materials by a shortage of foreign currency which is common to other companies. As a guide, it is still managing to produce 378,000,000 tablets annually and 260,000 litres of liquids. It has no plans for the production of bacterial vaccines or acaricides in the foreseeable future. It is however considering production of Anthelmintics now under discussion for Glaxo.

6.1.1.9 Recommendations

The US \$ 1,000,000 sterile area must be used to its maximum to provide sterile products for SADCC countries and new products to maximise on the investment should be considered. The basic pharmaceutical plant should be upgraded as soon as possible to conform to GMP international standards. This recommendation applies to human pharmaceutical products.

6.1.2 Ian Wilson PTY LTD Bulawayo

6.1.2.1 Manufacturing standards are to EP, GMP and other international standards. Production is monitored by in-house QC and return-of-batch samples to the parent company in UK, the Wellcome Foundation Ltd, for assay.

6.1.2.2 The site, situated on the outskirts of Bulawayo, is fed with electricity, water, drainage and has its own steam generator. The buildings were refurbished as new in 1984, are in very good condition, clean, air conditioned and conform to GMP standards. All service equipment is new.

6.1.2.3 The products are varied, ranging from expectorants to antibacterials for the Wellcome Foundation and some products for Ciba Geigy. Mentholated balms are produced for Vick International. A baby-care range of creams and ointments is also being produced. Specifications of products are as per the respective product owners requirements. Aerosols for cosmetic use are produced, suppositories and an experimental range of capsules for Parke Davis.

Production capacity is as follows:

- (a) Tablets. 20,000,000 per annum
- (b) Liquids. 252, 000L per annum
- (c) Aerosols. 500,000 per annum
- (d) Suppositories. 500,000 per annum.
- (e) Creams and balms - not yet itemised.
- (f) Capsules - still experimental.

6.1.2.4 Technology and Manufacturing processes are as supplied in Process Operating Instructions from the Wellcome Foundation Ltd and others.

6.1.2.5 Apart from local tanks for liquid production all other equipment is imported from either UK or European sources. The equipment is new and is in good condition.

6.1.2.6 The company has its own distribution system and transport. This is supported by telex, telephone and a branch in Harare.

6.1.2.7 There are 57 staff in production guided by 2 pharmacists. The Control Laboratory, well equipped, is staffed by 2 chemists, 5 technicians, and 3 in-process control inspectors. Training of operatives is in "in-house". A visit to Europe has recently been undertaken by the Head of Production for product familiarisation.

6.1.2.8 Discussion

Production in an area of 300sq. metres are efficiently carried out with first class equipment and discipline. A project to expand facilities in an area of 1250sq. metres is under discussion to increase production of ethical products. There are no plans to move into the biological field, the sterile products field or the Acaricides field.

6.1.2.9 Recommendations

As the bulk of products are ethical and the facilities are only 60% utilised the proposed expansion should be studied and consideration given to diversification of products in line with SADCC requirements in the human pharmaceutical field.

6.1.3 Central African Pharmaceuticals (CAPS - HARARE, ZIMBABWE) (Visit on 16th October 1986)

6.1.3.1 Manufacturing Standards

International standard and to GMP with a strong input of Quality Assurance.

6.1.3.2 The site situated on the outskirts of Harare is 3.5 acres on which has been constructed facilities for manufacture of 18 500sq. metres. Part of the facilities were constructed in 1969 the remainder as late as 1984. All buildings are in good condition, clean and well preserved. There are adequate supplies of steam, water, electricity and compressed air for the present and also for some expansion. There is good segregation of operations in the buildings but although a class 1000 sterile area has been built on the one hand cross contamination of air flow is still possible between tablet compressing cubicles. Safety standards are high and so is discipline. Adequate storage areas are available.

6.1.3.3 Products produced are either to the company's own specifications or to acquired specification from other companies. A full QC operation is in being.

The following types of products are produced:-

- (a) Tablets - 1,200,000,000 per annum.
- (b) Liquids - 500,000 per annum
- (c) Capsules - 96,000,000 per annum
- (d) Antibiotic powders - 20,000,000 bottles per annum.
- (e) Antibiotic liquids - 20,000,000 bottles per annum
(The antibiotics are produced in a totally separate building erected in 1984)
- (f) Sterile products, suspension powders and liquids:
As injections - numbers not divulged,
Eye and ear drops - numbers not divulged.

The product range is multi from analgesics up to sterile products through vitamins, diuretics, laxatives, tranquilisers, cough and cold preparations and various ointments and cosmetic creams. As stated previously various amounts of antibiotics are produced. A small operation on filling aerosols exists using ARCTON as a propellant but this line is likely to be dropped in the future.

6.1.3.4 The technology used is the standard method to be found in any large national or multi national company well backed up by Quality Control, supported by good Store Control and rigid quarantine of unpassed raw materials. There is good control over product segregation especially in the packing hall where one product at a time per line is packed. The department is exceptionally good and it was noted that although double distillation of water for injections was used all water for liquids was also tested for pyrogens in rabbits.

6.1.3.5 The process plant and equipment is exceptionally good and it was apparent from experience that the most costly International suppliers had been used although some local stainless steel tanks had been purchased. The equipment in the new antibiotics area and the sterile area can all produce much more if required as the capacity to fulfil orders at present is only 60% utilised.

6.1.3.6 The company which is 42% state owned has a network of sister companies in Zambia, Malawi and Botswana. It has its own distribution system and sales force plus a product recall system.

6.1.3.7 There are 700 employees in the company including 14 pharmacists; there is on the job training continuously and the operation is well administered.

6.1.3.8 Discussion

The company is outstanding in Southern Africa for its production standards and facilities and its prime objective is to expand business to enable a three shift system to be worked.

6.1.4 PFIZER - ZIMBABWE
(Visit on 17th October 1986)

6.1.4.1 Except for Tetracycline products which are produced elsewhere at another factory there is no production which is included in the terms of reference of the mission. Interest was expressed in the production of bacterial and viral vaccines. There are, however, no facilities and no expertise available.

6.1.5 ZIMBABWE - ZIMPHOS

Zimphos are engaged in the production of bulk chemicals for use in the Veterinary, mining insecticides and fertilizer fields. Of particular interest are the products in the Veterinary field which include processing of the following:

Sulphuric Acid) part of the products
Phosphoric Acid) of phosphates family.

User products are formulated as concentrates for cattle dips namely

DELNAV, SUPONA & AMITRAZ

which are of the Organic Phosphate family.

Arsenic based dips are also produced.

The total capacity of the plant is as follows,

Arsenical Dips - 142,500L per annum

Organo Phosphates - 333,000L per annum

The plant for Arsenical dips is only operating at 25% of capacity whilst the plant for Organo Phosphates is operating at 55% capacity based on a single shift. Total capacity would increase by 2-2.5 times on 3 shift working.

Other products of the company are Super Phosphates, aluminium sulphate, lead nitrate, odium, chemically pure sulphuric acid and bulk breaking of hydrochloric acid and nitric acid. Some sodium silicate solutions, gum resin and turpentine are also produced. In a separate area Insecticides are produced at the rate of 90,000L and 200,000Kgs of powder per annum.

The plant for insecticides is operating at 60% capacity, also on a single shift system.

Specifications of veterinary products is supplied by the distributor who is the Zimbabwean representative of a Multi National Company.

6.1.5.1 The site of 50 acres is East of Harare some 16km from the city. Although the company has been in existence for 60 years the first 25 years were concerned only with fertilisers. The remainder of the facilities were built starting in 1950. The manufacturing complex is large, in well kept buildings and the site is supplied with all basic services. There is room for expansion on the site. In house engineering facilities are available and other buildings on site included two housing schemes, a clinic and occupational therapy together with social areas and a club. The company has a modern Control Laboratory for assay of products and a Technical Department.

6.1.5.2 The manufacturing process of veterinary products is as supplied by the distributor via his parent company.

6.1.5.3 Process equipment is consistent in standard with the Heavy Chemical Industry standards.

6.1.5.4 All products are delivered to the distributor who is responsible for delivery to clients. He has his own distribution system and depots in Harare and other towns and cities in Zimbabwe.

6.1.5.5 Administration is under the wing of Chemplex Ltd. which is part of a group known as African Explosives Corporation Ltd. The complex is staffed by 720 people all of whom are Zimbabweans. There are no expatriate staff. Training is an ongoing in-house commitment.

6.1.5.6 Discussion

Veterinary products are only being supplied to a Zimbabwean distributor for sale mainly in Zimbabwe. The company itself is not in the export market for either veterinary or insecticide products. Clearly from the unused plant capacity being on a single shift basis there are facilities available to supply acaricides to the remainder of the SADCC countries. Production of Anthelmintics was discussed and interest was shown.

As for the comparative cost of pharmaceutical production in Zimbabwe it was established during the survey of four companies in Bulawayo and Harare that to produce locally from imported raw materials the cost was between 15-20% higher than the importation of finished goods direct. The basic reason for importing raw materials instead of finished goods was to provide local employment in line with Government policy. Production in all four companies could be increased but the over-riding constraint is the allocation of foreign exchange to purchase raw materials. This constraint applies equally to parastatal or privately owned companies.

6.2 Biologicals

There is no production of biologicals in the country at the present time. However, Central African Pharmaceuticals (CAPS) Harare has been considering expansion into the field of human and veterinary biologicals. Steps have already been taken on this by holding discussions with an Eastern European company.

7. RECOMMENDATIONS

7.1 Zimphos, Harare, is the only company producing Acaricides in the SADCC region. With its under-utilised facilities it should be considered as a source of Acaricides for the SADCC region.

7.2 Zimphos should be also encouraged to formulate Anthelmintics for the region.

7.3 Central African Pharmaceuticals (CAPS, Harare), because of its very high production standards which is not fully utilised, should be encouraged to expand its range of veterinary pharmaceutical products and increase output for export in the SADCC region.

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

DRUG/BIOLOGICAL	1986		YEAR 1990		2000	
	UNITS Treatments millions	VALUE US\$000's	UNITS Treatments millions	VALUE US\$000's	UNITS Treatments millions	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
Pastuerella	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