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UNITED NATIONS
INDUSTRIAL DEVELOPMENT ORGANIZATION

PROGRAMME FOR PRODUCTION OF VACCINES IN AFRICA

UC/RAF/83/088

# Technical Report: Programme for Production of Vaccines in Tanzania

Prepared for the Government of the Democratic and People's Republic of Tanzania by the United Nations Industrial Development Organization

Based on the work of L. Hegedüs and N. Lendvai,
experts in production and quality control of vaccines
and S. Szabó, economist

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## 1. LIST OF ABBREVIATIONS

| | |
|---|---|
| UNIDO | United Nations Industrial Development Organization |
| UNICEF | United Nations Childrens Fund |
| WHO | World Health Organization |
| EPI | Expanded Programme on Immunization |
| DPT | Diptheria Pertussis Tetanus Vaccine |
| TT | Tetanus Toxoid Vaccine |
| BCG | Bacillus Calmette Guerin/Vaccine against Tuberculosis |
| PPD | Purified Protein Derivative/Tuberculin/ |
| TAB | Typhoid and Paratyphoid A,B vaccine |
| CSM | Cerebrospinal Meningitis vaccine |
| ATS | Antitetanus Serum |
| ELISA | Enzyme Linked Immunosorbent Assay |
| RIA | Radioimmuno Assay |
| SVS | Central Vaccine Store |
| DANIDA | Danish Industrial Development Aid |

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We are particularly grateful to

Mrs. Hulda Swai /counterpart/
Dr. John F. Shao
Prof. P.M. Sarungi
Mr. S. Henein

for their wholehearted help and hospitality during our mission.

## 2. PERSONS CONTACTED

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Dr. John Fanueli Shao - District Medical Officer

Prof. William Makene - Dean, Faculty of Medicine

Dr. A. Yohani - Head of Paediatrics Department

Dr./Mrs./Fatma Mrisho - Community Health, Fac. of Medicine

Prof. M. Mandara - Head of Community Health

Mr. Smet - Statistician of Dept. of Biotatistics

Mr. E. A. K. Meena - NCT

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K. Valambhia - Keko Pharm. Industries

Theobald B. Mtema - Lab. Technician - Director of Mabibo Vacc. Plant

Felix Allen Mbuye - Adm. Manager

Dr. J.R. L. Mkoma - Senior Veterinary Scientific Officer

## 3. GENERAL INFORMATION

Tanzania is a country with an area of 940.000 sq.km and estimated population of 21 million. The estimated number of newborn per year is 810.000. Between the years 1967-1978 the population of Tanzania grew on average by 3.3 % per year. If growth continues at a rate of around 3 % per year, the population will reach 34 million by the year 2000.

The age group distribution in the country:

| | | | |
|---|---|---|---|
| up to 1 year | 3.6 % | | |
| 1-4 " | 14.5 % | 0-14 | 46.1 % |
| 5-9 " | 15.9 % | | |
| 10-14 " | 12.1 % | | |
| 15-44 " | 39.3 % | | |
| 45-64 " | 10.5 % | | |
| 65- " | 4.1 % | | |

Infant mortality rate /1979/: 150/1000 live births
Life expectancy at birth: 51 years.

90 % of the population lives in rural areas. Most of the childhood diseases found in the country are potentially preventable. The preventive methods include immunization and other public health measures, like provision of safe and adequate water supply and environmental sanitation.

The Government is making great efforts to increase the level of public health care.
The national health policy stems from the Arusha Declaration of 1967. In 1971 the political party directed the Government to place greater emphasis on rural development in order to ensure that the majority of the people living in the rural areas should have the basic needs : water, education and health care.

The strategy, in view of the limited resources, was to reach the maximum number of people in the rural areas with basic health services.

The infrastructure was to be manned by modestly trained auxiliaries, namely Medical Assistants, Rural Medical Aids, Health Assistants, Mother and Child Health Aids. All health services provided by Government Health Institutions were to be free of charge to the people. Each district was to have either a district or designated hospital.

Some data concerning the reported cases of and deaths due to communicable diseases are given in Annex I.

The nation-wide Expanded Program on Immunization was launched in the year 1978. As there is no EPI vaccine production in the country at all, vaccines are imported from abroad or donated by UNICEF and DANIDA to the value of TShs 6 million. The estimated annual vaccine needs are shown in Annex II.

It should be mentioned here, that the waste factor /25-50%/ is very high.

The cost of immunization per child was USD 8.3 in 1983. The amount of imported vaccines and cost are given in Annex III.

The quantity of vaccines distributed from Central Vaccine Store in the year 1983 and in the first months of 1984 are shown in Annex IV.

The number of immunizations carried out in the country from 1975-1982 is given in Annex V.

## 4. FINDINGS

MABIBO Vaccine Plant, Dar es Salaam

There is no vaccine production for human use in Tanzania at all. In the year 1969, in line with the WHO global smallpox eradication program, the Tanzanian Government decided to reduce dependence on foreign supplies by establishing a vaccine production plant with aid from the People's Republic of China. The capacity of the plant was to produce 1.5 million doses of smallpox and 250,000 doses of BCG vaccine.
The quality of the freeze-dried smallpox vaccine manufactured here, met the WHO requirements.

In 1979, WHO declared the eradication of smallpox and subsequently the Plant stopped the production of this vaccine.

At the same time, 50 persons from the total of 70 left the Plant. The production of BCG vaccine still continued, but after the Chinese experts left , the quality of the freeze-dried vaccine no longer met the WHO requirements as far as viable counts were concerned.

In 1980, the Plant was transferred to the National Chemical Industries /NCI/ through the Ministry of Industries. Due to this move, the Plant had to stop even the production of BCG vaccine, since the latter was found to be below WHO standards for human use.

The remaining personnel left, and since that time the Plant has been totally out of use.

To start the operation of the Plant will require both trained and untrained personnel. Untrained staff can be obtained easily. For trained manpower, some agreement could be reached upon whereby the following trained personnel could be released/seconded by their employers for this project:

1. Administrative Staff

1. Project Co-ordinator - Mrs. H. Swai
2. Personnel Officer - Mr. Mbuke

2. Specialist:

Dr. John Shao - Clinical Microbiologist Muhimbili Vaccine Unit

3. Technical Staff:

1. Mr. Mtema - Officer in Charge - Mabibo Vaccine Unit
2. Mr. Koshuma - Muhimbili Medical Centre Dep. Bacteriology
3. Mr. Msangi - Muhimbili Medical Centre Dep. Bacteriology
4. Mr. S. Seif - " " " " "
5. Mr. Cheyo - " " " " "
6. Mr. Mweri - " " " " "
7. Mrs. Kunte - " " " " "

It will be necessary for these personnel to visit other vaccine producing centres elsewhere to familiarise themselves with principles of vaccine production during the initial stages of the project.

Description of Mabibo Vaccine Plant

The Plant is situated in a well isolated place along the port access road at a distance of about 10 km from the city-center. The compound is big enough /about 12 hectares/ fenced and protected from easy reach of the public.

The buildings are solid, permanent structures, well constructed with several pavements adjoining individual units.

The plant is divided into the following sections /Scheme is given in Annex VI./

A/ Quality Control Department /Main building/

Facilities in this section include cooling systems, running tap water, electricity.

1. Room for microbiological examinations, sterility testing
   Equipment: Sterile cabinet
   Balance /Sartorius/
   Refrigerator /Bosch/
   Thermostat /Memmert/
   Microscope /Zeiss/
2. Room for chemical analysis
3. Room for washing and sterilization
   Equipment: Hot air ovens /2/
   Autoclaves /2/ Chinese
   Waterbath /Chinese/ etc.
4. Water distillation
   Equipment: water distillation apparatus /Chinese/
   SIMAX glass distillation apparatus, 20 l/hour capacity
5. Media preparation room
   Equipment: Deep freezer Philips
   Deep freezer IGLIS for vaccine storage
6. Halfsized room with thermostat Memmert and hot air oven /Chinese/

There are changing rooms and toilets as well.

B/ Former Smallpox Production Department /Main building/

1. Big area with separated places for washing, inoculating, killing, harvesting and autopsy of calves /100 calves/year/.

2. Laboratory for Smallpox vaccine production
   Equipment: Sterile cabinet /2/
   Thermostat /Chinese/
   Refrigerator /General Motors/
   Incubator
   Freeze-Dryer /Fisher-Paykel New Zealand/

3. Media sterilization room

4. Dark room for the potency testing of smallpox vaccines on the chorioallantoic membranes of eggs.

5. Changing room.

This part of the main building seems to be suitable for DPT and TT vaccine production from bulk

C/ Former BCG vaccine producing Department

There are 5 rooms in a separate building. /Staff room, changing room, laboratory for chemical analysis, air conditioned room for vaccine production equipped with 4 balances, Autovest mixer, refrigerator, incubators, room for sterilization etc./

The building and equipment seems to be suitable for BCG vaccine production.

D/ Freeze-drying department

Equipment: 2 freeze-dryers from China. Capacity: 16 boxes, each containing 144 ampoules.
Aseptic room for filling and sealing.

E/ Animal houses and food stores

On the grounds of the Institute there are separate buildings for animal breeding and for the infected animals.
The buildings are in an acceptable condition, except one part of the infected animal house, which was damaged during last year. Before renewed use, modification and modernization of these facilities will be necessary.

F/ Cold room and stores

G/ Building for Administration

Summarizing our findings, Mabibo Vaccine Plant seems to be a suitable facility for the production and quality control of bacterial vaccines /DPT, TT, BCG/ at regional or subregional level.

It is to mention here, that the Plant is suitable for the production and quality control of livestock vaccines and other pharmaceutical products as well, according to the decision of local authorities.

Animal Diseases Research Institute, Dar es Salaam

Buildings and facilities are of mediocre level, without any possibility to harmonize them with human vaccine production.

Activities:

Production of 250,000 doses of Anthrax and Blackquarter vaccines.
Research work is carried out on Brucella S 19 and Haemorrhagic Septicaemia vaccines.

## 5. RECOMMENDATIONS

1. The rehabilitation of MABIBO Vaccine Plant is highly recommended with the aim of becoming a regional or subregional center for bacterial vaccine production and quality control. (For both human or animal vaccines)

2. It is recommended to restart production of BCG vaccine. The existing facilities are after some renovation suitable for this purpose.

3. The introduction of the production of DPT and TT vaccines from bulk concentrates as a first step. The rooms and laboratories of the former Smallpox vaccine production area, after remodelling seem to be suitable for this purpose.

4. The main facilities for quality control are available. Purchase and installation of some equipment is necessary. /Laminar air flow box for sterility tests, photometer for opacity test, pH meter/.

5. Training for at least 4 persons is recommended in the following topics:
   BCG vaccine production
   BCG vaccine quality control
   DPT vaccine production
   DPT vaccine quality control.

6. When the production of vaccine will begin two outside experts should be present for about 3 months in an advisory capacity, one for BCG vaccine production and quality control, the other one for DPT vaccine production and quality control.

## PROPOSED TIME SCHEDULE

| | |
|---|---|
| /a/ Construction/remodelling works | up to 6th month |
| /b/ Purchasing equipment | 3th - 9th month |
| /c/ Training course | 3th - 9th month |
| /d/ Installation of equipment | 9th - 12th month |
| /e/ Trial runs | 12th - 18th month |
| /f/ Starting routine production | from 18th month |

## COST ESTIMATE

| | | |
|---|---|---|
| /a/ Remodelling and reconstruction | | 50,000 USD |
| /b/ Equipment | | 350,000 USD |
| /c/ Experts | 2 m/3 months | 48,000 USD |
| /d/ Training | 3 m/6 months | 36,000 USD |
| Total investment | | 484,000 USD |

# 6. ANNEXES

ANNEX I

MORBIDITY AND MORTALITY DATA REPORTED 1977-1982

| | 1977 | 1978 | 1979 | 1980 | 1981 | 1982 |
|---|---|---|---|---|---|---|
| Tuberculosis | 324 | 318 | 1,594 | 5,103 | 6,964 | 2,125 |
| Tetanus | NR | NR | 908 | 652 | 421 | NR |
| Diphtheria | 136 | 43 | 8 | 4 | 160 | 5 |
| Measles | 7,511 | 34,956 | 66,062 | 56,182 | 79,764 | 102,127 |
| Whooping Cough | 364 | 1,509 | 1,991 | 2,788 | 2,604 | 2,125 |
| Poliomyelitis | NR | 111 | 196 | 91 | 69 | 26 |

NR = Not reported

Source: EPI Review Report: 1983

## Outpatient Attendance/Admissions and Causes of Death

| Diseases | Outpatient % | Cause of Death % |
|---|---|---|
| Pneumonia | 8.4 | 14.4 |
| Gastroenteritis | 8.7 | 6.6 |
| Malaria | 9.0 | 3.8 |
| Tuberculosis | 1.4 | 4.7 |
| Measles | 4.9 | 14.6 |
| Defective nutrition | 2.3 | 7.2 |
| Anaemia /all forms/ | - | 5.7 |
| Tetanus | - | 3.9 |
| | 35.2 | 60.9 |

Source: Tanzania Food and Nutrition Journal Vol.No.4.3,1983

## Diseases Associated with Measles

| Disease as recorded on Death Certificate | Finally assigned to Measles No. | % |
|---|---|---|
| Measles | 915 | 51.5 |
| Pneumonia, influenza and other U.R.T.I. | 339 | 19.2 |
| Diarrhoea | 288 | 16.1 |
| Other infections and parasitic diseases | 77 | 4.3 |
| Nutritional deficiencies | 79 | 4.4 |
| All other causes | 79 | 4.5 |
| Total: | 1.777 | 100 |

Source: Tanzania Food and Nutrition Journal Vol. No. 4.3, 1983

## Death cases in 1980

| Disease | Deaths in hospitals /%/ |
|---|---|
| Measles | 15 |
| Pneumonia, bronchitis | 15 |
| Malnutrition + iron deficiency | 13 |
| Malaria, diarrhoea | 11 |
| Tetanus, meningitis | 6 |
| Prematures | 5 |
| T B C | 5 |
| Heart diseases | 4 |
| Tumours | 1 |
| Brain haemorrage | 1 |
| Other | 24 |
| | 100 |

ANNEX II

ESTIMATED ANNUAL VACCINE NEEDS 1984

| | | Estimated needs | Waste factor |
|---|---|---|---|
| EPI vaccines | BCG | 1,488,000 | 50 % |
| | D P T | 2,526,000 | 25 % |
| | Polio | 2,526,000 | 25 % |
| | Measles | 1,440,000 | 50 % |
| | D T | - | - |
| | T T | 1,728,000 | 25 % |
| Others | Cholera | 100,000 | 20 % |
| | Rabies | 50,000 | 5 % |
| | Yellow fever | 100,000 | 30 % |
| | TAB | 100,000 | 30 % |

ANNEX III

## COST OF IMMUNIZATION IN 1983

| | | |
|---|---|---|
| Cost per child | TShs | 103.6 |
| Cost per child | USD | 8.3 |

## IMPORTED VACCINES IN 1983

| Vaccines | Doses | Cost/TShs |
|---|---|---|
| Measles | 1,411,000 | 1,859,000 |
| DPT | 1,827,800 | 1,267,500 |
| TT | 1,347,000 | 585,000 |
| Polio | 2,011,700 | 1,170,000 |
| BCG | 1,295,300 | 1,222,000 |
| | Total: | 6,103,500 |

Donated by UNICEF /50 %/ and DANIDA /50%/

ANNEX IV

DISTRIBUTION FROM CVS /Central Vaccine Stores/

YEAR: 1983

| REGION | BCG | DPT | MEASLES | POLIO | TT |
|---|---|---|---|---|---|
| Arusha | 53,400 | 67,100 | 56,600 | 68,200 | 43,800 |
| Pwani | 62,200 | 84,600 | 51,500 | 75,500 | 59,000 |
| Dar es Salaam | 73,400 | 126,300 | 50,000 | 140,000 | 103,600 |
| Dodoma | 32,000 | 63,000 | 62,000 | 70,000 | 47,000 |
| Iringa | 83,800 | 123,000 | 66,500 | 141,500 | 78,600 |
| Kigoma | 61,400 | 95,500 | 86,500 | 108,000 | 79,700 |
| Kilimanjaro | 71,800 | 109,100 | 106,000 | 115,000 | 92,600 |
| Lindi | 2,000 | 1,000 | 4,000 | NR | 2,000 |
| Mara | 44,600 | 53,200 | 33,500 | 64,000 | 53,000 |
| Mbeya | 100,800 | 188,200 | 162,500 | 196,500 | 95,500 |
| Morogoro | 58,000 | 116,900 | 52,000 | 135,000 | 78,300 |
| Mtwara | 108,800 | 68,300 | 81,500 | 76,000 | 41,700 |
| Mwanza | 139,400 | 116,200 | 244,500 | 193,000 | 154,700 |
| Ruhwa | 31,000 | 63,700 | 35,500 | 67,500 | 22,000 |
| Ruvuma | 52,100 | 59,000 | 42,500 | 78,000 | 46,000 |
| Shinyanga | 91,200 | 96,900 | 92,500 | 123,000 | 90,900 |
| Singida | 39,200 | 73,000 | 25,000 | 44,000 | 42,000 |
| Tabora | 85,200 | 100,000 | 69,000 | 125,000 | 85,000 |
| Tanga | 56,000 | 109,900 | 55,000 | 107,000 | 72,000 |
| Kagera | 41,200 | 85,400 | 28,500 | 58,500 | 43,500 |
| Zanzibar | 7,800 | 27,500 | 6,000 | 26,000 | 16,100 |
| Total: | 1,295,300 | 1,827,800 | 1,411,100 | 2,011,700 | 1,347,000 |

EPI Review Report: 1983

DISTRIBUTION FROM CVS 1984 /PER MONTHS/

| REGION | BCG | DPT | MEASLES | POLIO | TT |
|---|---|---|---|---|---|
| Arusha | 5,500 | 12,500 | 6,000 | 12,500 | 9,000 |
| Pwani | 5,000 | 2,000 | 4,000 | 8,000 | 6,000 |
| Dar es Salaam | 6,500 | 12,000 | 4,500 | 12,000 | 9,000 |
| Dodoma | 6,000 | 11,000 | 6,000 | 11,000 | 8,500 |
| Iringa | 7,000 | 12,000 | 6,000 | 12,000 | 8,000 |
| Kigoma | 5,000 | 9,000 | 7,500 | 9,000 | 7,000 |
| Kilimanjaro | 7,000 | 12,000 | 9,000 | 12,000 | 7,000 |
| Lindi | 3,500 | 6,000 | 3,000 | 6,000 | 4,000 |
| Mara | 5,000 | 8,000 | 4,000 | 8,000 | 5,000 |
| Mbeya | 8,500 | 16,000 | 14,000 | 16,000 | 9,000 |
| Morogoro | 7,000 | 12,000 | 5,000 | 12,000 | 7,500 |
| Mtwara | 6,500 | 10,000 | 5,000 | 10,000 | 8,000 |
| Mwanza | 12,000 | 15,000 | 10,000 | 15,000 | 13,000 |
| Ruhwa | 3,000 | 6,000 | 3,000 | 6,000 | 3,000 |
| Shinyanga | 8,000 | 12,000 | 8,000 | 12,000 | 9,000 |
| Singida | 3,500 | 7,000 | 3,000 | 7,000 | 4,000 |
| Tabora | 7,500 | 10,000 | 6,000 | 10,000 | 8,000 |
| Tanga | 7,000 | 11,000 | 6,000 | 11,000 | 7,000 |
| Kagera | 4,500 | 10,000 | 4,000 | 10,000 | 5,000 |
| Zanzibar | 1,500 | 4,000 | 2,000 | 4,000 | 2,000 |
| TOTAL/MONTH | 124,000 | 210,500 | 120,000 | 210,500 | 144,000 |
| YEARLY: | 1,488,000 | 2,526,000 | 1,440,000 | 2,526,000 | 1,728,000 |

## PRESENT STOCK OF VACCINES /APRIL 1984/

| | Vaccine | Number of doses | Comply with WHO standard |
|---|---|---|---|
| EPI vaccines | BCG | 430,400 | yes |
| | DPT | 725,000 | yes |
| | Polio | 547,000 | yes |
| | Measles | 423,000 | yes |
| | T T | 533,000 | yes |
| Others | | | |
| | Rabies | 26,780 | yes |
| | Cholera | 96,260 | yes |
| | Yellow fever | 8,200 | yes |

ANNEX V

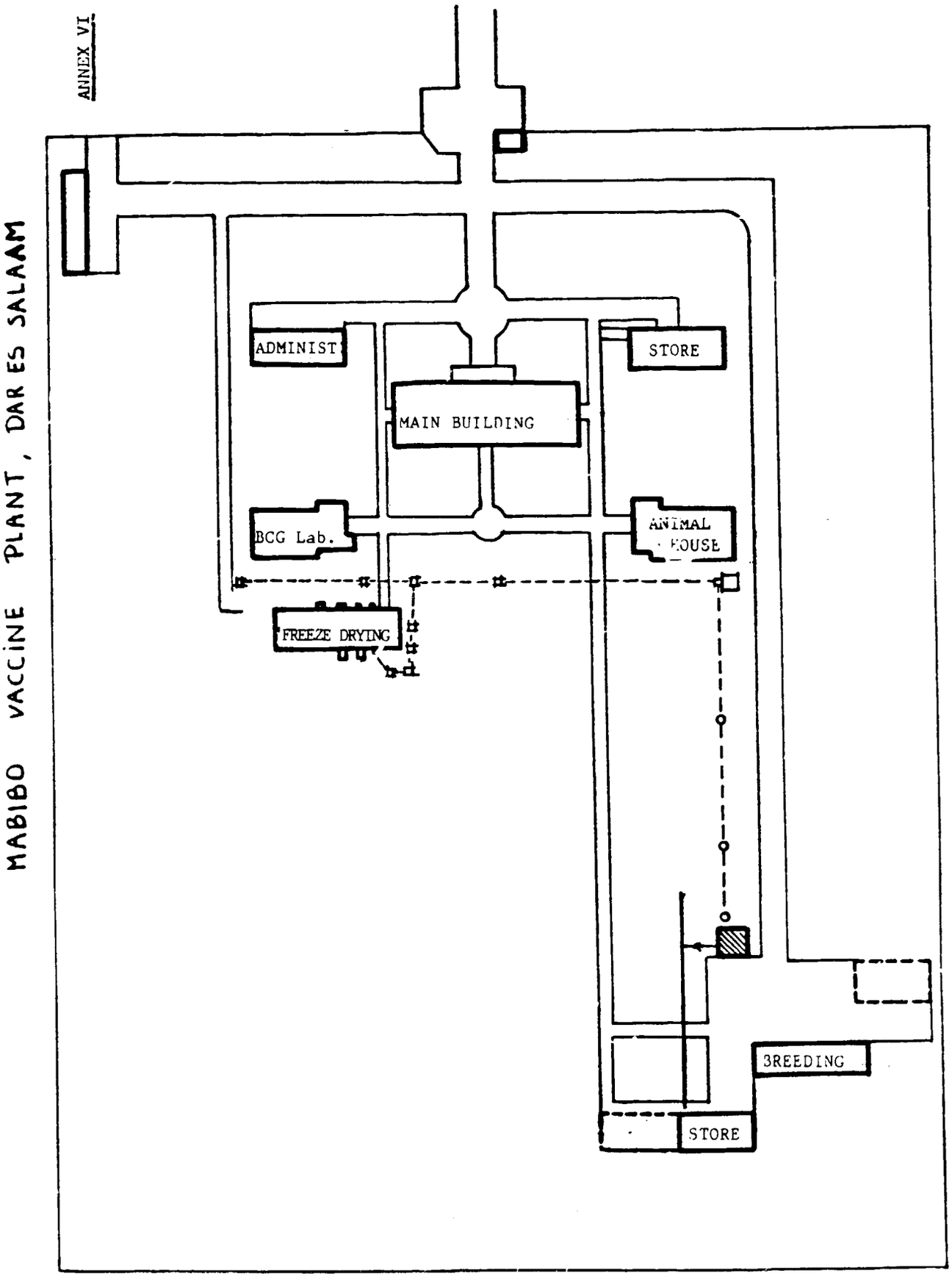
IMMUNIZATION PER YEAR 1975-1982

| | 1975 | 1976 | 1977 | 1978 | 1979 | 1980 | 1981 | 1982 |
|---|---|---|---|---|---|---|---|---|
| BCG | 64.447 | 301.027 | 191.756 | 522.736 | 605.266 | 619.130 | 589,672 | 515,531 |
| DPT I | 59.400 | 263.550 | 215.146 | 547.351 | 545.370 | 575.729 | 556,050 | 567,555 |
| DPT 2 | 41.107 | 182.465 | 150.810 | 421.277 | 428.639 | 467.422 | 460,078 | 432,259 |
| DPT 3 | 37.134 | 142.765 | 125.420 | 351.648 | 375.275 | 429.709 | 437,912 | 401,576 |
| Polio 1 | 59.620 | 254.514 | 226.634 | 543.100 | 529.333 | 560.716 | 492,233 | 502,309 |
| Polio 2 | 50.081 | 161.551 | 143.261 | 411.352 | 410.239 | 450.683 | 399,912 | 406,105 |
| Polio 3 | 39.953 | 124.350 | 105.479 | 356.252 | 371.486 | 414.336 | 370,704 | 386,109 |
| Measles | 48.620 | 275.173 | 238.390 | 587.012 | 562.019 | 604.195 | 572,831 | 495,123 |
| T T | 12.551 | 310.702 | 219.108 | NR | 820.257 | 941.362 | 892,188 | 775,517 |
| Smallpox | 63.520 | 365.458 | 494.527 | 560.597 | 411.193 | 20.470 | 0 | 0 |

Source: EPI Review Report: 1983

NR = not reported

ANNEX VI


MABIBO VACCINE PLANT, DAR ES SALAAM
ADMINIST
STORE
MAIN BUILDING
BCG Lab.
ANIMAL
HOUSE
FREEZE DRYING
BREEDING
STORE