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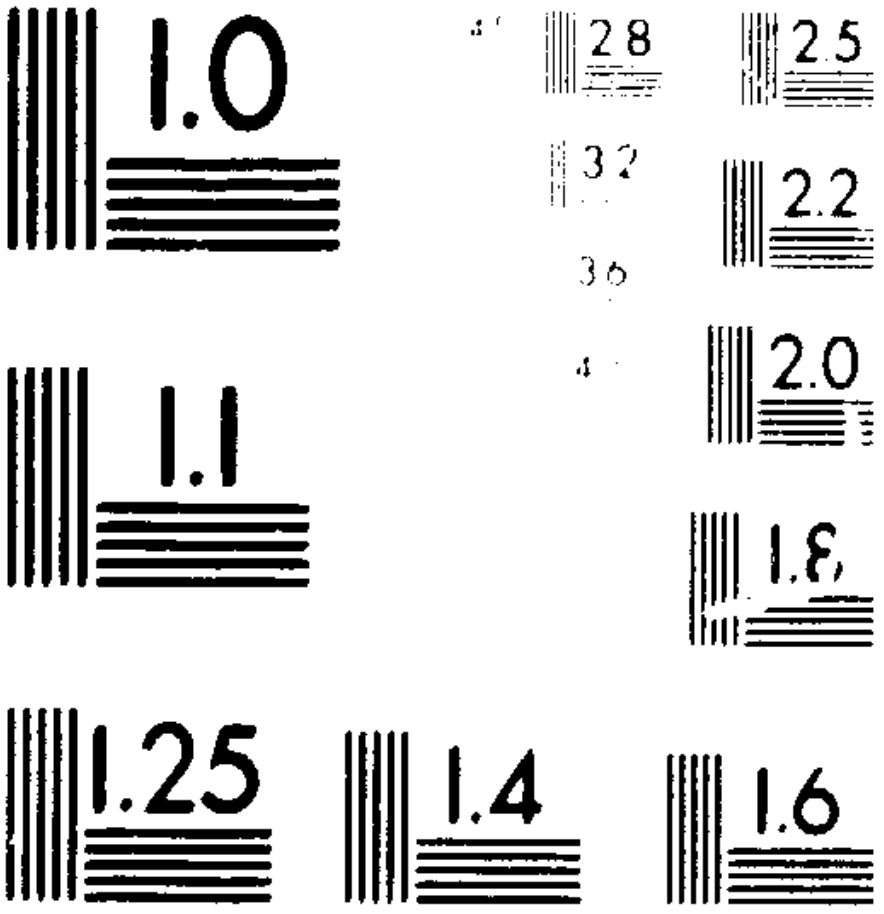

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PROGRAMME FOR PRODUCTION OF VACCINES IN AFRICA

Executive summary

UC/RAF/83/088

Terminal report

Prepared by UNIDO and the Joint UNIDO/Hungary Programmes
for International Co-operation

Based on the work of L. Hegedüs, N. Lendvai and L. Lugosi, experts in production and quality control of vaccines and A. Gál and S. Szaloó, economists

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Explanatory notes

References to dollars ($) are to United States dollars unless otherwise stated.

The following abbreviations have been used:

BCG	Bacille Calmette-Guérin
DANIDA	Danish Industrial Development Aid
DPT	diphtheria-pertussis-tetanus
ECDC	economic co-operation among developing countries
EPI	Expanded Programme on Immunization
FAO	Food and Agriculture Organization of the United Nations
TCDC	technical co-operation among developing countries
TT	tetanus toxoid
UNICEF	United Nations Children's Fund
WAHC	West African Health Community
WHO	World Health Organization

The following symbols have been used in tables:

Two dots (..) indicate that data are not available or are not separately reported.

A dash (-) indicates that the amount is nil or negligible.

ABSTRACT

The project "Programme for production of vaccines in Africa" (UC/RAF/83/088), which encompassed 10 African countries, became operational in March 1984 and ended in May 1984. It was implemented by the Joint UNIDO/Hungary Programmes for International Co-operation. The following are the main recommendations for the countries visited:

1. Algeria. Manpower training and transfer of technology for the new vaccine production centre.

2. Chad. Priority project would be the establishment of a production unit for infusion solutions.

3. Ethiopia. Strengthening the quality control in the existing production units for bacterial and viral vaccines.

4. Ghana. Filling, packaging and quality control of diphtheria-pertussis-tetanus (DPT) and tetanus toxoid (TT) for the West African Health Community (WAHC).

5. Kenya. Production of viral vaccines (polio, measles) for East Africa.

6. Madagascar. Improving the existing facilities: training in the maintenance of new equipment.

7. Nigeria. Bacille Calmette-Guérin (BCG) production for West African Health Community (WAHC). The establishment of a new vaccine production centre for WAHC in Abuja.

8. Senegal. Extension of the production programme (measles). Training courses. DPT production.

9. Tunisia. The establishment of a centre for scientific and technological exchange and training in vaccine production for African countries.

10. United Republic of Tanzania. Production of bacterial vaccines (DPT, TT, BCG) for East Africa.

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INTRODUCTION

A. Historical background

Although immunization is one of the most effective and least expensive ways of preventing disease, it is still not used enough.

Reports on immunization are available in only one third of the African countries and it is estimated that only 34 per cent of children under the age of one year receive Bacille Calmette-Guérin (bCG) immunization, that 42 per cent receive immunization against measles, that 21 per cent receive a third dose of diphtheria-pertussis-tetanus (DTP) vaccine and that 21 per cent receive a third dose of poliomyelitis vaccine.

In Africa more than 15 million children are born each year and at least 1 million die from diseases that could be prevented by the Expanded Programme on Immunization (EPI), such as diphtheria, pertussis, tetanus, tuberculosis, poliomyelitis and measles. (See annexes I and II.) It is therefore urgent to intensify the efforts to control these communicable diseases.

The vaccines against the above diseases are manufactured mainly by the pharmaceutical industry of developed countries. The demand for these vaccines in the developing countries does, however, far exceed their purchasing power.

Since the market for these products is stagnating or even shrinking in the developed countries and the purchasing power in the developing countries is limited, many manufactures have completely withdrawn from vaccine production.

According to a World Health Organization (WHO) study in 1980 the number of manufacturing facilities in developed and developing countries were 72 and 32 respectively. Recent information shows that, at least in developed countries, the number of the active manufacturers is lower than that of the registered ones. In several cases, the manufacturers either do not produce vaccines any more or their products are not being marketed.

This is particularly true of Africa, where not even half of the existing manufacturers are active. According to the same WHO study, nine African countries had such facilities in 1980: 5 institutes were producing BCG vaccines, but only one unit is manufacturing DPT vaccines, that is those vaccines that are included in the Expanded Programme on Immunization (EPI). (See annex III.) In 1974, WHO had launched the EPI with the goal of ensuring that by 1990 all children should receive their age-dependent vaccinations against the above six diseases. These vaccines are also included in the list of essential drugs drawn up by WHO in 1977.

The above vaccine facilities can with minimal investment be used for the production of most essential vaccines against many childhood diseases.

The vaccines recommended for use in the EPI are also supplied by the United Nations Children's Fund (UNICEF) and other organizations as donation to developing countries.

Donations must not, however, be relied upon as the sole source for the future. It is namely estimated that $US 290 million was invested in the programme in 1983. At an estimated cost of $5 to 15 per fully immunized

child, direct costs of vaccines are only approximately $0.50. However about $500 to 1,500 million will be required each year by the end of the decade to reach the target coverage in the developing world. Thus, while much has been done, much more is required.

On the basis of the above principles and facts and recognizing the interests of several African countries, a programme is proposed for implementation in Africa. This programme takes into account the importance of the Industrial Development Decade for Africa and seeks to contribute to it.

The fundamental objective of the Lagos Plan of Action is to promote self-reliant and self-sustaining integrated economic and social development at country and regional levels in order to satisfy the basic needs of the peoples of Africa.

UNIDO received the first suggestion in this field from an African country in 1975. On-going projects (TS/GHA/78/002, and DP/CMR/77/029) clearly show the need for technical assistance requested by some African Governments.

B. Scope of the mission

Within the framework of the project "Programme for production of vaccines in Africa" (UC/RAF/83/088), which became operational in March 1984 and ended in May 1984, two teams of experts were sent to 10 African countries. The project was implemented by the Joint UNIDO/Hungary Programmes for International Co-operation. The UNIDO input was $81,699; the input of the counterpart agent was 960,000 forints in kind.

For each of the countries visited (Algeria, Chad, Ethiopia, Ghana, Kenya, Madagascar, Nigeria, Senegal, Tunisia and the United Republic of Tanzania) a separate report has been prepared. The present report is a summary of the 10 country reports.

As a result of the mission, the Government of Madagascar officially requested, through the UNDP office, a project for the rehabilitation and strengthening of the existing BCG vaccine production unit.

I. RECOMMENDATIONS

A. Recommendations for the countries visited

The summary of recommendations and the cost estimates are given in annex VI. The following recommendations were made for individual countries:

1. Algeria. Manpower training and transfer of technology for the new vaccine production centre.

2. Chad. Priority project would be the establishment of a production unit for infusion solutions.

3. Ethiopia. Strengthening the quality control in the existing production units for bacterial and viral vaccines. A joint project with WHO might be foreseen.

4. Ghana. Filling, packaging and quality control of DPT and tetanus toxoid (TT) for the West African Health Community (WAHC).

5. Kenya. Production of viral vaccines (polio, measles) for East Africa. A quality control system is already available.

6. Madagascar. Improving the existing facilities: training in the maintenance of new equipment. Extension of existing facilities: joint project with UNICEF might be foreseen.

7. Nigeria. BCG production for West African Health Community (WAHC). The establishment of a new vaccine production centre for WAHC in Abuja. Feasibility study and architectural drawings are available.

8. Senegal. Extension of the production programme (measles). Postgraduate training courses for francophone least developed countries. DT production.

9. Tunisia. The establishment of a centre for scientific and technological exchange and training in vaccine production for African countries.

10. United Republic of Tanzania. Production of bacterial vaccines (DPT, TT, BCG) for East Africa.

B. Recommendations for meetings

1. A high-level meeting is recommended, with the participation of representatives of UNIDO, WHO, UNICEF, the Government of France and the francophone African countries concerned, to discuss marketing problems of vaccines manufactured by francophone African countries, which could be used within the framework of the EPI in Africa.

This meeting might be organized by the Joint UNIDO/Hungary Programmes for International Co-operation. The purpose of the meeting would be to find a solution for the problem that on the one hand African Governments are prepared to enter vaccine production and on the other hand manufacturers with high quality products are facing marketing difficulties.

Creating this specific subsector of the pharmaceutical industry can be successfully carried out if the required skilled manpower and infrastructure are available from the donor of the technology along with a long-term support programme, lasting for about 2-10 years.

The main obstacle to overcome is the reluctance to accept the products. This should be discussed at the Third Consultation on the Pharmaceutical Industry.

2. A meeting on technical co-operation among developing countries (TCDC) and on economic co-operation among developing countries (ECDC) might be organized in Hungary by the Joint UNIDO/Hungary Programmes for International Co-operation.

The present report with the recommendations of the meeting should be discussed at the meeting. There should also be a discussion of how the capabilities of selected francophone and anglophone African countries could be utilized for establishing facilities in other African countries. A stage-by-stage approach should be followed. The quality control capability is imperative since without it even the quality of imported vaccines cannot be tested.

3. A meeting for African countries at the ministerial level will be organized by the Joint UNIDO/Hungary Programmes for International Co-operation, at which the recommendations of the above two technical meetings should be presented for final decision to be taken by the Ministers of Health and Industry of African countries.

II. OBJECTIVES OF THE PROJECT

The immediate objectives of the project are:

(a) To define which of the most needed vaccines, not yet manufactured, could be manufactured in the existing facilities;

(b) To define follow-up action for introducing the manufacture of vaccines at a later stage.

The development objective is to increase the manufacturing capabilities of African countries to produce vaccines against a number of critical but preventable diseases, which affect large parts of the population.

The report assesses the existing manufacturing facilities for vaccines and makes recommendations country by country on how to strengthen, and on how to extend the above facilities.

The input required for the implementation of the above recommendations in terms of manpower development, technology, equipment and raw materials has been estimated. Particular emphasis has been given to possible training facilities in Africa.

The establishment of new production facilities is recommended, where available skilled manpower and existing infrastructure would make it technically and economically feasible.

III. EXPANDED PROGRAMME ON IMMUNIZATION (EPI) IN AFRICA

The EPI, having been initiated by WHO in 1974, was approved in resolution WHA 30.53, adopted in May 1977. Since then, the EPI has been an essential element of the strategy to achieve "Health for All by the Year 2000".

Since 1977, 38 African countries have joined the EPI and elaborated their programmes of immunization. The countries visited are at different stages of the integration of their EPIs into their general health service. Most of them are still using mobile teams, which are gradually being replaced by fixed centres.

Data on the estimated vaccine requirement calculated on the basis of the crude birth rate and the number of imported vaccine doses are summarized in annex IV. When making the above estimates the total coverage of the target population was assumed and a theoretical schedule of vaccination was used based on the existing different vaccination policies of the ten countries, i.e. per newborn child the following number of vaccinations was assumed:

BCG	1
DPT	4
Polio	4
Measles	1
Tetanus toxoid (for pregnant women)	2
Yellow fever (where included in the EPI of the particular country)	1

The number of doses wasted by administration were not taken into account.

As for the consumption data, those given for Madagascar and Tunisia are the number of vaccinations in 1983; those given for Chad and Senegal are the number of doses delivered to the vaccination teams; those given for Algeria are the number of doses imported in 1983; and those for the five anglophone countries are the estimated needs for 1983-1984.

It should be noted that, in some countries, the number of vaccine doses available for EPI immunization is significantly lower than the theoretical requirement.

In general, the waste factor is very high, up to 25 to 50 per cent. One reason for the waste is the fact that vaccines are available for administration in vials containing 10 to 20 doses only. It would seem practicable to deliver part of the imported vaccines in single dose ampoules.

In spite of the substantial progress of the EPI in the 10 countries and the efforts of the international and national organizations as well as of the personnel involved, there are still enormous difficulties to overcome.

Technical problems, such as cold chain, storage, transportation, manpower, are common in the countries visited.

IV. WAY OF THE FUTURE: VACCINE PRODUCTION IN PREFABRICATED MODULES?

In general, the production of vaccines in the African countries visited has reached only a modest level. Vaccines recommended for use in the EPI are not manufactured at present with the exception of BCG in some countries (Madagascar, Senegal and Tunisia).

Current production includes yellow fever, rabies, cholera, typhoid and typhoid-paratyphoid-A-B combined (TAB) vaccines. It should be mentioned here that any kind of vaccine production even at a moderate scale, must be at present regarded as a valuable asset and as a basic capability for further development in the future.

It should be emphasized that in the years when a world-wide struggle was being waged against smallpox, some African countries, with their good-quality smallpox vaccine production, have contributed to the eradication of this disease.

In some of the countries visited (Ghana, United Republic of Tanzania) there are production facilities formerly used for drugs and vaccines, which are not being used at present. Rehabilitation of them by the introduction of vaccine production from bulk concentrates (diluting, blending, filling and packaging) is highly recommended. No manufacturing facility should be left unused anywhere in Africa.

At the Second Consultation on the Pharmaceutical Industry, held from 21 to 25 November 1983 in Budapest, Hungary, it was suggested that existing manufacturing and quality control facilities should be evaluated and put into operation if needed before setting up new units.

It is recommended to adopt a step-by-step approach for establishing control and production capability of vaccines in two ways:

(a) From filling and packaging towards actual manufacture;

(b) From production of classical vaccines towards modern ones.

From UNIDO experience regarding the implementation of pharmaceutical projects in developing countries, it seems that the longest delays occur during the engineering phase. On the basis of this the use of prefabricated modules is recommended for the construction work instead of conventional techniques. 1/

There are several types of modules: laboratory module for production and control (vaccines, sera etc.), module for animal experimentation, module for medical, surgical, veterinary use etc. The modules can be transported by air, sea or road. They may be set up on their own or integrated with already existing premises or equipment.

According to the same UNIDO study, prefabricated units could save up to 40 per cent of the total investment cost and projects could be completed in six months instead of in three years.

1/ UNIDO Experience in Implementing Pharmaceutical Projects in Developing Countries (UNIDO/IO.570).

The production of vaccines should not, however, be considered from an economic point of view only. Donations from UNICEF and other organizations cannot go on for ever. A relative self-reliance at country, later on at subregional and regional levels should be achieved.

V. QUALITY CONTROL

All vaccine production must be based on a reliable quality control system. Quality control is imperative, i.e. no vaccines without control should ever be used. A quality assurance system has therefore to be introduced and quality control laboratories at the country level should be established simultaneously with the beginning of any vaccine production according to the recommendations of WHO (WHO Technical Report Series 1981. No. 658).

In some vaccine producing institutes control tests are carried out in various laboratories of the vaccine production or clinical diagnostic divisions due to lack of an independent quality control department. As a background to be taken into consideration concerning the quality control of vaccines, the existing possibilities in diagnostic laboratories and medical research institutes were studied in the countries visited (Ghana, Kenya).

A self-sufficient quality control unit is the basis for any further development in the field of vaccine production. The quality control unit with suitable skilled manpower should be acting even in cases of vaccine production from bulk suspensions.

VI. KEEPING IN OPERATION AND EXPANDING THE EXISTING PRODUCTION FACILITIES

A significant finding of the mission is that some vaccine producing laboratories are about to close down or have already done so for various reasons.

A well-known BCG vaccine manufacturing units with products that meet the WHO requirements is facing such economic constraints that it will have to close down in the near future if final solution cannot be found to overcome marketing problems. The production of yellow fever vaccine in the same institute clearly shows that a solution can be found for the above problem. Therefore every possible effort should be made to save and make viable the operation of the existing production facilities with high quality products in Africa. In other words, the existing paradoxical situation should be rectified by projects to develop vaccine production on the one hand, thus increasing self-reliance of the African countries, and by solving administrative problems on the other hand so that laboratories could market their vaccines and consequently continue this production.

The saving of the existing facilities for vaccine production should precede the establishments of new units in Africa. It can be regarded as one of the most economical alternatives for further development of capabilities in this specific subsector of pharmaceutical industry since this approach does not need capital investment.

Before entering into the establishment of new manufacturing units, it is recommended that those existing units should be rehabilitated that have been closed down or ceased their production activity recently.

Suggestions for the rehabilitation of such units, the existing buildings and laboratory rooms, for equipment and the available skilled manpower should be and can be taken into consideration. In most cases there is a nucleus of staff and some equipment, based upon which a new manufacturing unit can be developed after a minimal remodelling of the existing building.

Some of the well-functioning manufacturing units require technical assistance to strengthen and extend their production outputs.

Based on the above findings, recommendations are given in a tabulated form in annex V. It should be noted, however, that the priority of saving and rehabilitation projects is concerned with the production aspects only, consequently the recommendations for the establishment of quality control units always have priority.

Annex I

PRIORITY LIST OF VACCINES FOR HUMAN USE FOR PRODUCTION IN DEVELOPING COUNTRIES*

Conventional vaccines

I. Vaccines recommended for use in the EPI

BCG
DPT
Diphtheria-tetanus vaccine
Live measles vaccine
Oral poliomyelitis vaccine
Tetanus vaccine

II. Vaccines not recommended for use in the EPI

Rabies vaccine produced in cell cultures
Poliomyelitis vaccine for parenteral use
Yellow fever vaccine
Japanese encephalitis vaccine

*Report on Meeting of the Advisory Panel on Preventive Medicine, Vienna, 27-28 February 1984 (UNIDO/IO.583).

Annex II

VACCINATION SCHEDULE

Vaccine	Type of vaccine	Route by which vaccine is administered	Primary vaccination age	Number of stimulants	Interval	First boost	Later boosts
Tuberculosis BCG	Attenuated bacterial	Scarification Intradermal	Birth or 9 months	1		If tuberculin negative	
Diphtheria	Toxoid	Subcutaneous or intramuscular (adsorb.)	3; combined with polio, 4-6 months	3	2-4 weeks	1 year later	Every 5 years
Tetanus	Toxoid						
Whooping cough	Inactivated bacterial	Subcutaneous or intramuscular	3 months; combined with polio, 4-6 months	3	4 weeks	1 year later	After 6 years if necessary
Poliomyelitis	Inactivated viral	Subcutaneous	4-6 months	3	4 weeks	1 year later	Every 5 years
	Attenuated viral	Oral	3 months		4-6 weeks		
Measles	Attenuated viral	Subcutaneous	9 months	1			
Cholera	Inactivated bacterial	Subcutaneous or intradermal	6 months	Child: 3 Adult: 2	5-11 days	6 months	Every 6 months
Yellow fever	Attenuated viral	Subcutaneous	1 year	1		10 years later	Every 10 years
Rabies	Inactivated viral	Treatment: subcutaneous and intradermal	Adults: if bite is suspect, any age	7 subcutaneous 2 intradermal	1 per day 11th and 15th day	If+serum: 25th, 35th and 90th If not: 30th and 90th day	
		Prevention: intradermal			3 weeks	1 year later	Every year

Annex III

VACCINE PRODUCTION FACILITIES IN AFRICA

Name and address	Vaccine and sera manufactured	
Institut Pasteur d'Algérie Rue du Docteur Laveran, Alger, Algeria	Smallpox	
Egyptian Organization for Biological and Vaccine Production 51 sh. Wezaret El Zeraa Agouza, Egypt	BCG, cholera, diphtheria, DPT pertussis, rabies	Smallpox, antivenin, tetanus, typhoid, albumin, gammaglobulin
National Public Health Laboratory Service P.O. Box 20750, Nairobi, Kenya	Cholera, smallpox, typhoid	
Institut Pasteur BCG, rabies, B.P. 1274, Antanarivo, Madagascar	smallpox	
Vaccine Production Laboratory Lagos/Yaba, Nigeria	yellow fever	Rabies,
Laboratoire Universitaire (Laboratoire de Médecine Humaine et Vetérinaire) B.P. 221, Butara, Rwanda		Typhoid
Institut Pasteur 36, Avenue Pasteur, B.P. 220, Dakar, Senegal	BCG, Rabies, yellow fever	
Vaccine Institute, Ministry of Health P.O. Box 9473, Dar es Salaam, United Republic of Tanzania	BCG, smallpox	
Institut Pasteur 13, place Pasteur, Tunis, Tunisia	BCG, cholera, rabies, smallpox, antivenin, typhoid	

Source: International list of availability of vaccines (WHO/BLG/80.1).

Annex IV

ESTIMATED VACCINE DEMAND IN DOSES CALCULATED BY BIRTH RATE AND THE NUMBER OF DOSES DELIVERED

Country	Algeria		Chad		Ethiopia		Ghana		Kenya		Other WAHC countries
Number of live birth	900 000		300 000		1 400 000		400 000		1 000 000		..
Vaccine	By birth rate	Doses delivered	By birth rate	Doses delivered	By birth rate	Doses delivered	By birth rate	Doses delivered	By birth rate	Doses delivered	Doses delivered
BCG 1	900 000	3 000 000	200 000	160 000	1 400 000	250 000	400 000	560 000	1 000 000	2 200 000	460 000
DPT 4	3 600 000	4 000 000	800 000	25 000	5 600 000	500 000	1 600 000	1 470 000	4 000 000	3 000 000	230 000
Polio 4	3 600 000	6 000 000	800 000	16 000	5 600 000	500 000	1 600 000	1 470 000	4 000 000	3 600 000	430 000
Measles 1	900 000	3 030 000	200 000	155 000	1 400 000	200 000	400 000	700 000	1 000 000	1 600 000	240 000
TT 2	1 800 000	..	400 000	..	2 800 000	400 000	800 000	490 000	2 000 000	3 000 000	300 000
Yellow fever	..	..	-	77 000	..	..	..	..	..	..	..

continued

Annex IV (continued)

Country	Madagascar		Nigeria		Senegal		Tunisia		United Republic of Tanzania	
Number of live birth	360 000		4 200 000		240 000		240 000		800 000	
Vaccine	By birth rate	Doses delivered	By birth rate	Doses delivered	By birth rate	Doses delivered	By birth rate	Doses delivered	By birth rate	Doses delivered
BCG-1	360 000	416 000	4 200 000	3 000 000	240 000	167 000	240 000	no data available	800 000	1 500 000
DPT-4	1 440 000	610 000	16 800 000	3 000 000	960 000	260 000	960 000	1 400 000	3 200 000	2 500 000
Polio-4	1 440 000	346 000	16 800 000	3 000 000	960 000	260 000	960 000	2 000 000	3 200 000	2 500 000
Measles-1	360 000	vacc. started in 1982 only	4 200 000	2 300 000	240 000	186 000	240 000	650 000	800 000	1 500 000
TT-2	720 000	vacc. started in 1982 only	8 400 000	3 000 000	480 000	50 000	480 000	300 000	1 600 000	1 700 000
Yellow fever	-	-	-	-	240 000	184 000	-	-	-	-

Annex V

RECOMMENDATIONS FOR KEEPING IN OPERATION AND EXPANDING THE EXISTING PRODUCTION FACILITIES IN THE VISITED COUNTRIES

Country	Present production	Saving	Rehabilitation	Strengthening	Extension	Creation of new units
Algeria	Rabies					Quality control (institute under construction)
Chad	Veterinary vaccines			Veterinary vaccines		Quality control
Ethiopia	Veterinary vaccines Rabies, Cholera TAB			TAB Cholera		Quality control (bacterial vaccine)
Ghana	Veterinary vaccines					Bacterial vaccine production from bulk (DPT, TT, CSM) Quality control (animal colony)
Kenya	Veterinary vaccines Cholera Thyphoid			Cholera Thyphoid Quality control		Viral vaccine production from bulk (polio, measles)
Madagascar	BCG Rabies		BCG Rabies	BCG		Quality control (DPT)
Nigeria	Yellow fever Rabies		Rabies	Quality control		BCG, viral vaccine bulk (polio, measles)
Senegal	BCG Yellow fever Rabies	BCG		BCG		Measles Quality control DPT
United Republic of Tanzania	Veterinary vaccine		BCG Quality control			Bacterial vaccine from bulk (DPT, TT)
Tunisia	BCG Rabies				BCG	Measles or DPT

Annex VI

SUMMARY OF COUNTRY BY COUNTRY RECOMMENDATIONS
AND COST ESTIMATES

Project	Cost (dollars)	Timing
Algeria		
Introduction of vaccine production and quality control in the new Institute Pasteur of Algeria:		
(a) Transfer of technology for the production of viral vaccines	..	Being implemented
(b) Training for vaccine production and quality control 4 m/6 months	48 000	After approval
(c) Experts 2 m/6 months (vaccine production and quality control)	96 000	At the beginning of vaccine production and control
Chad		
(a) Establishment of National Control Laboratory	60 000	After approval
Training 2 m/6 months (quality control of vaccines)	24 000	After approval
Expert 1 m/3 months	24 000	When control work starts
(b) Increasing the vaccine production for veterinary use	..	As soon as possible
(c) Introduction of the production for infusion solutions	..	After approval
Ethiopia		
Increase vaccine production and reinforce quality control:		

continued

Annex VI (continued)

Project	Cost (dollars)	Timing
(a) Modernization of rabies vaccine production by transfer of technology (using suckling mouse brain or human diploid cells)		Up to the twelfth month
(b) Equipping of the existing quality control laboratories, introduction of quality control potency tests (cholera, typhoid, DPT vaccines)	50 000	Up to the tenth month
(c) Training 1 m/3 months	6 000	Urgent
(d) Expert 1 m/1 month	8 000	When potency tests are introduced
Ghana		
Bacterial vaccine production and quality control at the regional level		
Phase I. Production from bulk		
Remodelling and reconstruction	50 000	Up to the twelfth month
Equipment	350 000	Up to the twelfth month
Training 3 m/6 months	36 000	After approval
Experts 2 m/3 months	48 000	At the beginning of the production
Total	484 000	
Phase II. Production from raw materials		
Remodelling and reconstruction	50 000	After
Equipment	400 000	
Training 2 m/6 months	24 000	
Experts 2 m/3 months	48 000	Phase I has been completed
Total	522 000	

continued

Annex VI (continued)

Project	Cost (dollars)	Timing
Kenya		
Viral vaccine production from bulk (polio, measles) and quality control at the regional level		
Building	80 000	Up to the eighteenth month
Equipment	350 000	Up to the eighteenth month
Training 2 m/6 months	24 000	As soon as possible
Expert 2 m/3 months	48 000	At the beginning of production and quality control
Madagascar		
Rehabilitation of the BCG laboratory*		
(a) Revision of equipment		Immediately after approval
Specialist to be sent for 15 days	2 500	
Spare parts	5 000 to 7 500	
Training of two local local maintenance experts	5 000	
(b) Change of certain pieces of equipment to limit the risk of contamination	25 000	Immediately after approval
(c) Installation of new equipment to increase production	100 000 to 125 000	1985-1986
Establishment of a production unit for DPT		
(a) Establishment of the national quality control system and laboratory	60 000	1985-1986
(b) Production unit for DPT	800 000	1989

continued

*Official request already sent to UNIDO.

Annex VI (continued)

Project	Cost (dollars)	Timing
Training		
(a) Experts in quality control 2 m/6 months	48 000	1985-1986
(b) Experts in production of DPT	..	1988-1989
Nigeria		
Development of vaccine production and quality control:		
(a) BCG vaccine production (building ready)		
Equipment	100 000	Up to the sixth month
Training 1 m/3 month	6 000	As soon as possible
Expert 1 m/3 month	24 000	At the beginning of production
(b) Modernization of rabies vaccine production		
Remodelling of building	50 000	Up to the sixth month
Equipment	25 000	Up to the sixth month
Training 1 m/3 month	6 000	At the beginning of the production
Transfer of technology		
(c) Viral vaccine production (polio, measles) in prefabricated module		
Module unit and equipment	500 000	Up to the twenty-fourth month
Training 3 m/6 months	36 000	Up to the twenty-fourth month
Experts 2 m/6 months	96 000	After approval
(d) Bacterial and viral vaccine production and quality control in Abuja (Feasibility study ready)	20 000 000	..

continued

Annex VI (continued)

Project	Cost (dollars)	Timing
Senegal		
(a) Establishment of a laboratory for the production of measles vaccine in the "Institute Pasteur"		
Equipment	120 000	1986-1989
Technology transfer	..	
International co-ordination on marketing	..	
(b) Establishment of a production unit of DPT		
(i) Establishment of the national control laboratory	60 000	1985 (starting)
Training of two persons in control 2 m/m	24 000	1985
(ii) Training of two persons in DPT production 2 m/m	24 000	1988
(iii) Establishment of the DPT production unit		1989
(c) Study of possibilities for post-graduate training at the University of Dakar		
(d) "Save the BCG Laboratory" of Institute Pasteur. Find solution for the marketing problems		Urgent
Tunisia		
(a) Increase of BCG vaccine production Precondition: possibilities of marketing		Up to the twelfth month
(b) Production of DPT or measles vaccines depending on marketing possibilities		Up to the twenty-fourth month
(c) Possibilities concerning training in vaccine production and quality control at the regional level		After approval

continued

Annex VI (continued)

Project	Cost (dollars)	Timing
(d) Training 2 m/6 months (DPT and measles vaccine production and quality control)	24 000	After approval
(e) Experts, 2 m/3 months	48 000	At the beginning of production and quality control
United Republic of Tanzania		
Bacterial vaccine production and quality control at the regional level		
(a) Rehabilitation of Mabibo vaccine plant BCG vaccine production and quality control	50 000	Up to the twelfth month
(b) Introduction of bacterial vaccine production from bulk, quality control	350 000	Up to the eighteenth month
(c) Training 3 m/6 months	36 000	Urgent
(d) Experts 2 m/3 months	48 000	At the beginning of the vaccine production and quality control