PAN-AFRICAN PROGRAMME FOR THE CONTROL OF EPIZOOTICS (PACE)

Pan African Veterinary Vaccine Center (PANVAC)

Work plan and budget

Period: 15 May 2004 – 31st October 2004

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Annex 1. : Imprest account contractual document
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Acronyms

AC	PACE Advisory Committee
ADB	African Development Bank
AU	African Union
cGMP	Current Good Manufacturing Practices
CIRAD-EMVT	Centre international de recherche agricole pour le développement – Département Elevage et médecine vétérinaire tropicale
EC	European Commission
EDF	European Development Fund
GLP	Good Laboratory Practices
GMP	Good Manufacturing Practices
IBAR	Inter-African Bureau for Animal Resources
FA	Financing Agreement
FAO	Food and Agriculture Organization of the United Nations
IAEA	International Atomic Energy Agency
NVI	National Veterinary Institute of Ethiopia
OAU	Organisation of African Unity
OIE	International Office for Epizootics
PACE	Pan African Control of Epizootic Diseases
PANVAC	Pan African Veterinary Center
PARC	Pan African Rinderpest Campaign
RECs	Regional Economic Commissions
ToR	Terms of Reference
WHO	world health organization
WP	Work Plan

Currency Equivalents

EUR 1.0 = ETB 10.55930 (InforEuro April 2004)

PANVAC

Work plan and budget for the period 15 May 2004 – 31st October 2004

Type of project	Financial and technical cooperation (Art 225 of the 4th Lomé Convention)
Implementing authority	AU/IBAR
Identification	Number REG/5007/005
Sectoral Classification	PUE
Accounting Numbers	7ACPRPR744-9

1. Background and current status of PANVAC

Livestock in Africa's economy: In 1998 the population of livestock in Africa was estimated at 204 million head of cattle, 212 million sheep, 182 million goats, 4 million horses, 3 millions Camel, 22 million pigs, and 1 billion chickens (FAO Quarterly Bulletin of Statistics, vol.11, No3 /4, 1998).

In 1995 Africa, with 12.7% of the world total human population, was producing 5% of the total beef and sheep and goat meat, 3.3% of cow milk, 4% of hen eggs and 8.2% of cattle skins (FAO Production Yearbook, vol. 49, 1995).

Problems to be addressed in the Region:

- **Burden of infectious livestock diseases in Africa:** While rinderpest has been brought under control thanks to the PARC programme, except within some limited areas, the development of African livestock industry is still seriously impeded by the burden of infectious diseases like contagious bovine pleuropneumonia, foot and mouth disease, lumpy skin disease, Rift valley fever, sheep and goat pox, peste des petits ruminants, African swine fever, African horse sickness and Newcastle Disease. These diseases constantly reduce Africa's capacity to achieve self-sufficiency in food proteins, to assure livestock owner welfare (from direct losses through mortality and from indirect losses resulting from depression of growth rate, diminished production, lowered fertility and decreased work capability) and pose significant threat to the world livestock economies. As most of these diseases are highly contagious and transboundary and thus included in the OIE list A, they prevent the majority of African countries to have access to developed world's highly profitable markets due to the imposition of non-tariff trade barriers. In addition some of the diseases are zoonotic and pose a real public health problem, like the 1998 Rift Valley Fever in East Africa that hit 89,000 humans causing 200 fatalities, and affected 70% of small ruminant herds and 20 to 30% of the area's cattle herd (OIE World Animal Health Status Report, Paris, 17-21 May 1999).

- **Veterinary Vaccines in infectious disease control**: Vaccination will remain, for a long time, the most cost-effective and efficient method to control and ultimately eradicate livestock infectious diseases in Africa since animal production systems and economic conditions, do not allow radical implementation of prophylactic sanitary measures such as animal or livestock movements' control, stamping-out and other zoo-sanitary measures. To be successful a vaccination campaign, in addition to sound planning, adequate financial and material resources, needs to be done using GOOD QUALITY VACCINE.

- **Veterinary Vaccines Industry in Africa:** The establishment of Veterinary vaccine production units in many African countries go back to the twenties, under public control by the Veterinary Services to provide vaccines against the most lethal epizootic diseases of livestock (e.g. rinderpest, contagious bovine pleuropneumonia and haemorrhagic septicaemia). This was dictated by the fact that such vaccines were no longer being produced in developed countries which were already clear from the diseases and the lack of interest by private industry whose priorities are set according to fair return on investments.

In the seventies, the deterioration of economic conditions experienced by most African vaccine producing countries prevented them from improving manufacturing processes to meet the **requirements of Quality Assurance system** and to produce vaccines under **conditions which always ensure their safety, potency and efficacy.**

- **Veterinary Immunobiological Regulation**: Although most African countries have, in recent years, adopted veterinary medicinal products legislation, **very few of them offer an effective regulatory system** for licensing such biological products and/or for monitoring their quality to ensure that only those that are pure, safe and potent are used in animal disease control programmes.

Origin and Rationale of PANVAC

In the early 1980's a major resurgence of Rinderpest in Africa led to, according to the FAO, direct losses close to US$ 500 millions, and indirect losses of more than US$ 1 billion. The African Heads of State and Government reacted to this catastrophe and instructed the Organisation of African Unity (OAU) to solicit international support to combat major epizootic diseases.

When OAU/IBAR responded to that instruction, by planning a new regional campaign against this disease, the **availability of GOOD QUALITY VACCINES was not assured** as witnessed by a survey conducted, in 1983 by the FAO Animal Health Service, within 11 African laboratories on rinderpest vaccine produced: quantitative shortage, wide discrepancy on the number and type of quality control tests performed (no regular safety, efficacy and/or identity testing), weaknesses on Good Laboratory Practices.

The FAO Expert Consultation on rinderpest (Rome, October 1984), urged all vaccine producing laboratories to participate in the implementation of an international and independent vaccine quality control scheme. The FAO responded to this recommendation by establishing in 1986, with its Technical Cooperation Programme (TCP/RAF/6767 and 6766), **two Regional Vaccine Quality Control and Training Centres, in Debre Zeit (Ethiopia) and Dakar (Senegal)**, dedicated to improve the quality of the rinderpest vaccine produce in Africa. This initiative was followed, from 1988 to 1993, by an UNDP funding (UNDP/RAF/88/050) of the 2 centres as a single project, which became the **PANVAC** under the responsibility of the OAU/IBAR and with FAO as the executing agency (1989).

In 1993, it became necessary to merge the two units and perform the functions of PANVAC at one site in Debre Zeit (Ethiopia). This was dictated by the lack of immediate funds, but more importantly by the need to pool existing resources within the framework of a sustainable structure after the project phase. Following the end of the UNDP funding, in 1993, and despite of its outstanding achievements and bridging financial supports from FAO (TCP/RAF/2265) and European Commission (GCP/RAF/305/EC), PANVAC had to close temporarily in 1995. This had a serious effect on regional vaccine production activities and on the PARC programmes that could not obtain quality certified vaccines. The European Commission (EC) was sensitised and agreed to support the quality control activity of PANVAC on the basis of cost recovery. Late 1995, before the release of the EC funds, the FAO funded a technical cooperation programme (TCP/RAF/4565) in order to resume PANVAC's vaccine quality control activity and to establish a pilot Cost Recovery scheme.

At resumption of its activities in 1996, PANVAC financial support was secured from the FAO (TCP TCP/RAF/4565 from December 1995 to June 1996), the European Commission, for the quality control component (GCP/RAF/318/EC, from 1996 to 2000), and from Japan for the developmental component (GCP/RAF/337/JPN, from 1997 to 2002). This synergistic financial support and the support of the host country, Ethiopia, which provides laboratories, offices and other logistic resource, permitted the preservation of the integrated functions of PANVAC.

During the PARC programme implementation, PANVACs' immediate objectives were:

- to ensure the quality control of priority vaccines, with particular reference to rinderpest and CBPP vaccines, according to international standards;
- to promote the standardisation and the quality of veterinary vaccines in Africa by providing training and technical support services to African vaccine producers;;
- to promote the transfer of modern vaccine technology appropriate to African conditions;
- to establish a viable laboratory Organisation within OAU/IBAR, by implementing a cost recovery scheme which would support the maintenance of these standards.

These immediate objectives were set to guarantee the quality of vaccines used in PARC Programme and to strengthen the veterinary vaccine production in Africa through the promotion, at the vaccine producers' level, of the concepts and principles of current Good Manufacturing Practices (cGMP) and quality assurance (QA).

Externally, PANVAC has built collaborative partnership with leading institutions in vaccine science. In 1997, a team of OIE experts commissioned by the EC reviewed PANVAC. This review not only evaluated the activities of PANVAC but also provided useful and authoritative guidance on the future direction for PANVAC. It recommended to the EC the funding of a transitional period of 5 years to give time to OAU to achieve its institutionalisation as an OAU Specialized Agency decided by the 67th ordinary session of the OAU Council of Ministers (Addis Abeba, 23 to 27 February 1998). This Council of Ministers request the OAU Secretary General, in collaboration with the FAO, the RECs, the ADB and donors community to explore ways and means to secure financial resources for the launching of the Center.

The EC decided to fund this transitional period for PANVAC under the PACE programme. The original Financing Agreement of PACE included a sum of EUR 900,000 allocated from the Regional Component in order to:

- provide a technical assistant in veterinary vaccines, for three years, to manage the PANVAC and who should train a counterpart recruited by AU as Director of the Center.
- provide a technical assistant in CBPP diagnostic and vaccine for one year who would train a national counterpart to be recruited by AU;
- provide short-terms consultancies (3 man-month) and training (4 man-month);
- fund PANVAC's operating costs over a 5-year period;
- supply supplementary equipment to enable the Center to fulfil its mandate effectively;
- assist in PANVAC's institutionalisation in developing a sustainable basis for it.

PANVAC technical execution was tendered in July 2000 and awarded to CIRAD-EMVT. The posting of two experts mentioned in the contract could not take place due to the absence of Host country and Host institution agreement between AU/IBAR and Ethiopian authorities so

that the quality control activities of PANVAC were suspended from July 2000 up to now (January 2004). Meanwhile, in October 2002, the FAO handed over all the Centre's equipment, vehicle, consumables and reference material to the National Veterinary Institute (NVI) of Ethiopia.

Currently, the project is re-starting with a 2 x 10-month TA input with support and running costs under a PACE WP until the end of October 2004. Only one TA is in place of now, the other one awaits for finalisation of contractual arrangements.

With regard to PANVAC's status and future the most notable events have been the Decision of the OAU Council of Ministers (Addis Ababa, February 1998) to establish PANVAC as a Specialised Agency of the OAU and the **PANVAC headquarters agreement** (signed on 28th July 2003 in Maputo).

The 8th bi-annual meeting of PACE Advisory Committee (Bamako, November 2003) recommended that:

> *"In view of the important role expected from PANVAC and in order to ensure the cost-effectiveness and sustainability of its activities, the AC recommends that the Director of IBAR nominate one of the senior scientist to be recruited under the new IBAR programme as the Director of PANVAC working directly under his responsibility. This may entail a training period for the selected scientist by a Technical Assistant of the PP. It is stressed that PANVAC will be fully responsible for the* ***independent quality control of veterinary vaccines****. Quality control relating to safety, potency, purity and efficacy of vaccines produced in African laboratories will be* ***extended to imported products****. PANVAC will also be responsible for the* ***maintenance of stocks*** *of disease causing agents, vaccines, bacterial seeds and other reagents.* ***Training*** *of personnel will form an integral component of the on-going activities of PANVAC. The AC stresses that during the* ***resumption of PANVAC activities, measures (including an action plan) must be put in place to ensure the long term financial sustainability of the institution.****"*

2. Beneficiaries

The **immediate beneficiaries** of PANVAC activities are the **vaccine production laboratories** that will benefit from PANVAC's quality certified biologics as well as technical backstopping and thus be able to meet international standards laid down.

The **intermediate beneficiaries** are the **veterinary services and the National Vaccine Quality Control Authorities,** for the guarantee of availability quality certified vaccines for their national vaccination campaigns. This would be a motivating factor for their field staff whose image is associated with the effectiveness of their services.

The **ultimate beneficiaries** are the **livestock owners** of the rural communities of Africa whose livestock, by gaining better health status, through the use of potent, efficacious and safe vaccines, will improve their food security and economic resource base.

3. Financing agreement

The European Development Fund (7th and 8th EDF) decided to support the transitional/interim period of PANVAC in the framework of the Pan African Programme for the control of epizootics (PACE, REG/500/005). The Financing Agreement No 6125/REG for the regional "Pan-African programme for the control of epizootics" (PACE), funded as a grant from the Regional Indicative programme of the 7 and 8th European Development Fund, was signed between the European Commission and the OAU/IBAR on 30 August 1999.

The overall objective of the programme, as mentioned in the financing agreement, is to relieve the poverty of those involved in the livestock-farming sector (producers, service providers and consumers) in Africa by improving animal productivity, trade and food security though effective and efficient animal diseases control programmes.

4. Project implementation and coordination arrangements

The Agency responsible for the implementation of PANVAC is the Inter-African Bureau for Animal Resources of the African Union (**AU/IBAR**) on behalf of AU Member States. The National Veterinary Institute (NVI) of Ethiopia is the hosting institution of PANVAC and the CIRAD-EMVT the provider of technical assistance. The activities carried out under PACE are coordinated by the PACE programme coordinator appointed by the Director of AU/IBAR.

The host country government contribution, through the NVI, would be the provision of laboratory and office spaces, laboratory equipment (handed over equipment) and access to utilities (electricity and water). A Memorandum of understanding, between the AU/IBAR and the Government of the Federal Democratic of Ethiopia represented by the General Manager of NVI should be signed on 12th March 2004 at the launching ceremony of PANVAC.

PANVAC will be managed by the Chief Technical Adviser (CTA- vaccine specialist - recruited and paid under the PACE / CIRAD-EMVT contract)- in close collaboration with : AU/IBAR and the PACE Programme Coordinator.
The CTA will be responsible for the technical coordination and execution of the work plan of PANVAC, and the overall control and administration of the staff, facilities, equipment, supplies and expenditure at the project site.

He will work as an advisor to the Director of the AU/IBAR and work under the supervision of the PACE Programme Coordinator, from whom he may receive directives and to whom he will report (work plans/ programmes, progress reports, technical reports and others as required). These functions should be progressively handed over to the AU/IBAR counterpart who will assume these administrative responsibilities (please see detailed terms of reference in Annex 5).

The financing of the PANVAC Work Programme was foreseen in the PACE Financing Agreement – FA- (see FA: 2.4.2. Paragraph 6 and 3.4. Table : 1) over the funds of the Regional Component.

In order to speed up the implementation of the PANVAC , the PACE Coordinator, AU-IBAR and the Lead Delegation agreed to organize the financing of the WP 1 for PANVAC over the CIRAD-EMVT contract.
As this was not initially foreseen in the CIRAD-EMVT Contract an Addendum 4 , creating the Budget Line: C4- operational Costs PANVAC WP1- to this Contract will be presented for approval to the concerned stakeholders.

Implementation of the WP:

The Programme will be implemented on the basis of a Work programme and cost estimates which will be developed by the CTA in close collaboration with the PACE Coordinator.

The Work Programme and cost estimate will be approved by the PACE Coordinator and endorsed by the RAO and the Lead Delegation in Nairobi .

The RAO will prepare an Administrative order to the endorsed WP ; the Contractor (CIRAD-EMVT) will sign the Administrative Order agreeing to implement the Work Programme .

The operational costs for the implementation of the WP will be met from a provision in the consultants contract : Budget Line : C4 Operational Costs PANVAC WP1-(see higher).

The consultant will only be authorized to incur expenditure on the operational costs within the limits of the provisions of the programme's approved Work Programme and Cost Estimates.

Using the provisions of appropriate budget lines, the consultant will procure essential equipment and materials in accordance with the EDF procedures; the CTA will meet the sub-project's running costs from provisions of the approved Work Programme.

5. Technical Assistance

The cost of the assistance to PANVAC will follow the proposal agreed upon the Technical Assistance Framework Contracts in force between, in one hand, the AU/IBAR and CIRAD-EMVT and, on the other hand, between AU/IBAR and GTZ. Thus PANVAC technical assistance will be provided by CIRAD-EMVT for the expert in veterinary vaccine position and by GTZ for the CBPP diagnostic and vaccine specialist position.

6. Missions of PANVAC

The "Article II: Legal status and juridical personality" of the PANVAC Headquarters agreement is indicating that:

> **"The PANVAC shall be an African Union Regional Centre with the principal objectives of promoting the availability of safe, effective and affordable veterinary vaccines, facilitating the development and the introduction of**

improved or new vaccines and strengthening Africa's capacity building in veterinary vaccine development, production and quality assurance "

Therefore, PANVAC has to be a Regional Technical Resource Centre devoted to the promotion of the Region human and institutional capacity building in veterinary vaccine science and technology. In the line of its sustainability and also to cover the Region needs in diseases laboratory diagnosis, AU/IBAR included into PANVAC's mandate the coordination of the production and distribution of diagnostic reagents and animal diseases diagnostic kits.

7. Objectives, strategies and activities

Development objective

The PANVAC aimed **to promote Africa capabilities to take better advantage of vaccine and biological reagents benefits, for a sustainable livestock production and productivity,** through the region capacity building in veterinary vaccine and veterinary laboratory diagnostic reagents quality assurance.

Specific objectives

The specific objectives of PANVAC, set to have a global and immediate impact on the availability of good quality veterinary vaccines and veterinary diagnostic reagents, are to:

1. Provide international quality control testing services for priority vaccines in Africa;
2. Promote the standardisation of veterinary biologic products and the quality control of veterinary vaccines in Africa;
3. Promote the transfer of appropriate technologies for vaccine production to Africa;
4. Provide training and technical support services to vaccine production laboratories;
5. Establish the regional production and standardisation of diagnostic reagents for animal diseases diagnostic and surveillance;
6. Create optimal conditions to ensure PANVAC viability and sustainability as an African Union Agency.

These specific objectives of PANVAC, which **is not a vaccine production institute (Headquarters Agreement, Article II.6),** do not conflict with those of any other international, regional or national institutions. The Centre offers the following **comparative advantages:**

- PANVAC **belongs to the AU**, the major Regional organisation in Africa;
- PANVAC regional character and scope of activities offer **greater benefits to both vaccine producing and vaccine procuring countries**;

- It is suitably placed to act as a **central point of continental** perspective in Africa for veterinary vaccine quality assurance.

PANVAC, as a regional resource centre for **optimal utilisation of regional resources**, offers an opportunity, for African cooperation and integration as well as for international cooperation in veterinary biologics quality assurance in Africa.

For the current transitional period (February to October 2004), due to time and resources constraints, the immediate objectives will be aim at restoring **PANVAC's vaccine quality control activities, resuming the standardisation of biological products and quality control techniques and assisting the institutionalisation process**. The specific objectives 3, 4 and 5 would have to be addressed with more resources and time period for PANVAC mid and long-term development plans (please see Annex 8).

Immediate objective 1: Provide international quality control testing services for priority vaccines in Africa

Aim: Ensure standardised vaccine quality control service so that beneficiaries are assured that **vaccine batches quality certified** by PANVAC complied with approved international standards.

Output 1.1: PANVAC's vaccine quality control capabilities re-established

Strategy:

- Re-establish and reinforce PANVAC's' vaccine quality control capabilities in using validated techniques.

Activities:

Activity 1.1.1: Assess current (physical and functional) status of PANVAC laboratories and equipment and, if necessary, take corrective actions e.g. repairs, refurbishments, replacements, purchases.

Activity 1.1.2: Supply of complementary equipment, laboratory consumables and reagents.
Although the bulk of the equipments are serviceable, they are old and ideally need replacement. The laboratory consumables and reagents are to be provided as all of them have exceeded their expiry date.

Activity 1.1.3: Revalidate vaccine testing reference material (controls) quality and, if necessary, prepare new ones.

Activity 1.1.4: Re-establish collaborative linkages with previous national and international scientific institutions in relevant areas.

Indicators of achievement:

- Inception report of the CTA
- Purchase order and inventory of equipment and materials

- Nature and number of vaccine quality control reference materials revalidated
- Nature and number of biologics exchanged or cross-checked with relevant international institutions.
- PANVAC's vaccine quality control service capabilities re-established for priority vaccines testing.

Output 1.2: Standardized quality control testing of major veterinary vaccines assured on a cost recovery basis

Strategy:

- Provide standardized quality control services for priority vaccines (just produced or in stock) and sensitise both vaccine producing and importing countries on PANVAC's vaccine certification scheme.

Activities:

- **Activity 1.2.1.:** Inform African laboratories and National Quality Control Authorities of the resumption of the quality control service of PANVAC
  If funding permits, it might be more strategic to hold a 3-day meeting of network laboratory Directors at PANVAC to re-establish working relationships, set up priorities, discuss on vaccine batch quality control fees and PANVAC institutionalisation.

- **Activity 1.2.2.:** Provide independent priority veterinary vaccine batches quality control and certification, according to internationally recognised standards, on a cost recovery basis.

- **Activity 1.2.3.:** Assist African countries and laboratories to revalidate the quality of their priority vaccine stocks.
  For almost 4 years, no independent quality control of vaccine batches produced was available at the continental level.

Indicators of achievement

- PANVAC regains its status of recognised Centre of Excellence in international quality control of priority veterinary vaccines (number of laboratories participating into PANVAC's quality control scheme).
- Number of vaccine batches tested and certified by PANVAC.
- Availability of updated database of certified vaccine batches.
- Income generated from vaccine certification cost recovery scheme.

Immediate objective 2: Promote the standardisation of biological products and quality control of veterinary vaccines in Africa

Aim: Promote standardised/harmonised manufacturing process for veterinary vaccines production in Africa.

Output 2.1: PANVAC's repository of reference materials revalidated and expanded

Strategy:

- Revalidate existing stocks of reference material and, if needed, prepare new ones
- Supply, at cost, certified biologic standards for vaccine production, vaccine quality control and animal diseases diagnosis;
- Maintain links with the relevant reference centres for the supply of biological material and for their external quality control.

Activities:

- **Activity 2.1.1.:** Re-evaluate the quality of master seed banks, master cell stock, reference vaccine preparations and if necessary prepare new ones.

- **Activity 2.1.2.:** Consolidate and expand PANVAC's repository of vaccine strains, cell lines, reference vaccine preparation, reference antiserum and make available at cost.

Indicators of achievement

- Expanded repository of reference biological materials established at PANVAC (inventory of vaccine seed strains, cell lines and reference vaccine preparation) for internal used and for distribution at PANVAC (Nature and number of requests for supply of reference materials);

Output 2.2: Priority vaccine quality control methods harmonised and/or improved

Strategy:

- Disseminate information on internationally recognised vaccine quality control test methods;
- Develop and/or evaluate new or improved vaccine quality testing methods and facilitate their transfer to networked laboratories.

Activities:

- **Activity 2.2.1.:** Produce and distribute widely Standard Operating Procedures (SOPs) and Master Formulae (MF) or instruction manuals on priority vaccines production and quality control.

- **Activity 2.2.2.:** Improve vaccine quality testing methods sensitivity and/or specificity (e.g. application of PCR technology to PPR, RP and CBPP vaccines identity test).

Indicators of achievement:

- Number of SOPs of MF produced
- Number of laboratories referring to PANVAC SOPs and using its reference materials;
- Number of improved testing methods evaluated and/or promoted.

Output 2.3.: Quality Assurance principles and current Good Manufacturing Practices (cGMP) promoted within the Region.

Strategy:

- Improve awareness and help in the implementation and evaluation of Quality Assurance principles in vaccine production and quality control.

Activities:

- **Activity 2.3.1.:** Improve awareness, among directors and key vaccine personnel, on implementation of principles and practices of Quality Assurance to ensure batch to batch consistency and overall vaccine production effectiveness.

  This will be achieved through information and communication activities, including the use of modern communication technologies (i.e. Web site, electronic bulletin, electronic forum), by collecting and disseminating new and/or pertinent information related to veterinary biologics science, technology, supply strategy, licensing and monitoring. Therefore, this broad activity would have to include the:
  - reestablishment of PANVAC's access to the outside world (postal address, email and fax);
  - consolidation of PANVAC's documentation centre and biologic database;
  - collection and timely dissemination of relevant information about veterinary biologics; and the
  - development of PANVAC's web page, launch and animate of electronic discussion group.

- **Activity 2.3.2.:** Assist, though technical advices, the region laboratories and National Quality Control Authorities in implementing and evaluating Quality Assurance principles (assessment of vaccine production or quality control process, drafting of quality manual, documentation of activities and records keeping, quality assurance audit, laboratories evaluation, licensing and monitoring etc...).

Indicators of achievement:

- Number of laboratories operating according to quality assurance principles).
- Number of collaborating Quality Control Authorities or Laboratories.
- PANVAC's' communication links re-established and include a Web page/site and electronic forum launched – Frequency of advices and/or requests and responses given electronically.
- Catalogue of PANVAC's documentation centre.
- Nature and volume of information on veterinary biologics collected and disseminated to networked laboratories and veterinary authorities.

Immediate objective 3: Assist in PANVAC viability and sustainability as an African Union Agency

Overall Aim: Ensure PANVAC viability as an African Union (AU) Regional Specialised Agency in veterinary biologics.

The success of achievement of the objectives aforementioned will depend on the tact, commitment and prudence with which the following issues, influencing directly or indirectly

on PANVAC viability, will be addressed: PANVAC's legal, administrative, technical and financial sustainability; Veterinary vaccine manufacturers' viability in the Region and National Regulatory ability to implement sound vaccine regulations. **Above all the critical factor for the implementation of medium and long-term plans for the PANVAC will be its formal establishment as an AU Agency.**

Phasing strategy for the formal establishment of PANVAC

PANVAC strategic development plan should be developed through a dynamic interaction between vaccine producing laboratories, national control authorities and AU/IBAR to ensure that PANVAC's strategic plan will reflect the rapidly changing nature in vaccine field and responds to the concerns of the African countries. This will inevitably involve for soliciting inputs from a wide spectrum of individuals and institutions (OIE, FAO, WHO and other national and international reference centres etc...). Therefore, ideally, as a part of the developing process of its strategic Plan, and of establishing a regional institutional network, PANVAC should host a consultation bringing together representatives of key institutions and agencies and leading scientists. This consultation should identify key regional concerns and issues, and gives guidelines for future directions for the PANVAC. It will also identify opportunities for mutual cooperation and collaboration in areas of common interest.

PANVAC has now a "juridical personality" through its Headquarters agreement but AU and the Host Country should agree on the institutionalisation timetable for the remaining steps including:

- Drafting of PANVAC's Establishment Agreement and Constitution (by end Year 2004);
- Circulation of the establishment agreement and the Constitution among other AU Member countries;
- Approval/ Ratification of these documents by the majority of the AU Member countries (by end Year 2005);
- Establishment of PANVAC's Governing and/or Advisory bodies and the
- Recruitment of AU staff to run the Center after the transitional period (Year 2006).

The outputs presented below are, in fact, parts of the strategic plans to be achieved in order to ensure PANVAC's mid and long-term sustainability.

Output 3.1.: Drafts of complementary documents for PANVAC institutionalisation submitted to AU/IBAR and AU

Before year 2000, the legal status of PANVAC had never been worked out as it has been operating as a development project with a finite life span according to arrangements between OAU/IBAR, FAO, Governments and donor agencies. The OAU council of ministers decided in 1998 to establish PANVAC as a specialized agency of OAU/IBAR and four years later its Host country agreement has been signed (8th July 2003 in Maputo, Mozambique). This agreement confers to PANVAC the full status of an international organisation in Ethiopia. Nevertheless, there are still additional steps to take so as to achieve its transformation as an Agency by drafting its strategic plan and the approval of its other legal documents by the majority of AU member states.

Strategy:

- Provide AU/IBAR and AU with drafts of PANVAC's strategic plan and other legal instruments.
- To make known the PANVAC.

Activities:

- **Activity 3.1.1.:** Submit a Strategic Plan and phasing (development path) draft to AU/IBAR and AU.

- **Activity 3.1.2.:** Draft a communication plan for PANVAC

- **Activity 3.1.3.:** Submit draft of other Legal instrument documents to AU/IBAR and AU:
  - Agreement of other AU Member States on the Establishment of PANVAC
  - Constitution of the PANVAC (Guiding, supervision and operating principles)

Indicators of achievements:

- Drafts of PANVAC's' strategic plan, communication plan, establishment and constitution produced and submitted to AU/IBAR and AU.
- Information materials about PANVAC.

Output 3.2.: Appropriate governance and management structures established

Appropriate governance and management structures are necessary to gain and reinforce PANVAC's' stakeholders and donor confidence.

Strategy:

- Develop effective, clear and transparent governing and management systems ensuring that the Centre is managed in harmony with the agreed objectives, programs and budgets, and in accordance with the legal and regulatory requirements.
- Establish and maintain a functional Governing body and an Advisory Group(s) (i.e. Scientific and Technical Advisory Committee or Programme Advisory Consultative Group) to ensure the highest level of professional inputs for PANVAC's programme design and implementation;
- Facilitate regular external review and evaluation of PANVAC.

Activities:

- **Activity 3.2.1.:** Assist AU/IBAR and AU to define clear and transparent management system for PANVAC operations.

- **Activity 3.2.2.:** Assist AU/IBAR and AU in establishing functional Governing body and Technical Advisory Group(s) (i.e. Scientific and Technical Advisory Committee or Programme Advisory Consultative Group) to be in charge of monitoring PANVAC's annual work plan, technical reports, policies and procedures for financial, personnel and property management, external review and evaluation.

Indicators of achievements:

- Management system, Governing body and Technical Advisory Group proposed.

Output 3.3.: PANVAC technical sustainability improved

PANVAC can only maintain the confidence of its partners as long as it strives to remain a centre of excellence, as measured by its ability to use sound scientific tools in vaccine science and also by its capacity to facilitate relevant technologies transfer to vaccine production laboratories to significantly upgrade the quality of vaccines within Africa.

Strategy:

- Build and keep a core of highly competent AU staffing capable to implement PANVAC's' programmes and maintain its status of Centre of Excellence.
- Maintain confidence of networked laboratories by developing, evaluating and transferring to them sound scientific tools in veterinary biological science.

Activities:

- **Activity 3.3.1.:** Assist AU and AU/IBAR in establishing attractive staffing/personnel policy to make the PANVAC a highly desirable place for individuals committed to veterinary biologics improvement for developing countries.

- **Activity 3.3.2.:** Assist AU and AU/IBAR to identify and recruit high quality staff and associates who can effectively develop and implement its programmes (eventually establish core units in veterinary biologic production, quality control, standardisation, technology transfer, information dissemination, training and education).

Indicators of achievements:

- Staffing policy and recruitment procedures proposed.

Output 3.4.: PANVAC financial sustainability consolidated

The prime factor in the long term financial sustainability of PANVAC will be the ability to cover its fixed running costs as much as possible using **revenues generated from cost recovery charges**. This in turn is a function of the:

- nature and volume of services rendered;
- rate of invoices settlement;
- diversification of activities to cover all vaccines used in the region;
- institution of mandatory of certification of all vaccines used for national immunization campaigns in all Africa.

The limitations of the past cost recovery system require a more realistic and sustainable resource mobilization policy and procedures, with a strong back-up support by AU/IBAR and other Agencies involved in improvement of animal health activities.

Strategy:

- Secure, through an action plan, stable, sufficient and diversified financial resources that will ensure the long term financial sustainability of PANVAC and allow it to meet its operational and programmatic needs.

Activities:

- **Activity 3.4.1.:** Assist AU in defining clear and realistic resource mobilisation policy.

- **Activity 3.4.2.:** Re-establish and improve PANVAC's cost recovery scheme for services provided by:

    a. diversified range of activities (quality control, vaccine reference and diagnostic materials supply, contracts, training courses, other technical services);
    b. extension of quality certification to all priority vaccines and to diagnostic reagents used against priority animal diseases;
    c. improvement of mechanisms for invoices follow-ups and settlement;
    d. assisting in the formulation of policies that would require that all vaccines to be used in both national and regional immunisation campaigns shall have been quality-certified.

- **Activity 3.4.3.:** Assist AU/IBAR and AU in mobilising contributions from various sources (AU, host country, international agencies, governments, private sector and foundations).

Indicators of achievement:

- resource mobilisation policy proposed;
- level of income from cost recovery improved;

Output 3.5.: Improved viability of PANVAC Networked laboratories

The viability of PANVAC is definitely linked to the viability of the vaccine production units in Africa. In spite of the recent moves toward commercialisation of vaccine production operations, most of these units are still far from meeting the seven viability criteria as set by the WHO:

i. conformity to Good Manufacturing Practices (GMP) and functional quality assurance system;
ii. access to new production technologies;
iii. ability to meet demand and scaling up production when necessary;
iv. management structure that can ensure efficient operation in the long term;
v. a legal status allowing sufficient autonomy to operate efficiently;
vi. economies of scale for a given volume product portfolio; and
vii. supervision/monitoring of the vaccine production activity by an effective National Quality Control Authority.

This state (inability to meet the set viability criteria) created one of the "raison d'être" of PANVAC, and explains the rationale found in PANVAC initial project document to be a Centre dedicated to assist African laboratories to meet the viability criteria. PANVAC quality control programme has been focused on the first criteria (conformity to GMP), but it is **worthy to consider its involvement in the improvement of the potential and viability of the Region's manufacturers in order to guarantee its own viability**.

Strategy:

- Provide to the Region laboratories with adequate technical and managerial supports to upgrade both their level of how-know and the standard of their products.

Activities:

- **Activity 3.5.1.:** Participate in the build up of functional quality assurance system into networked laboratories (taken in charge by activities 2.3.1. and 2.3.2.).

- **Activity 3.5.2.:** Assist the networked laboratories to access new production technologies.

Indicators of achievement:

- Region laboratories capacity building and sustainability improved (number of laboratories operating according to QA principles; nature and volume of vaccines batches certified by PANVAC; vaccine production *versus* demand)
- Relations with networked laboratories.

Output 3.6.: National Quality Control or regulatory authorities' effectiveness in veterinary biologics evaluation, licensing and monitoring improved

In spite of the recent demonstration by PARC of the benefit of certified vaccine batches in Rinderpest control programme, implementation of effective veterinary biologic regulation is still the exception in African countries. The demand in quality certified vaccine heavily depends on the effectiveness of biological licensing and monitoring system by the respective National Quality Control Authorities in the Region. This situation calls for **more information/communication inputs** from PANVAC towards the vaccine and other biologic National Quality Control Authorities.

Strategy:

Inform and assist National Quality Control or regulatory authorities into veterinary biologics evaluation, licensing and monitoring.

Activities:

- **Activity 3.6.1.:** Facilitate the access of National Quality Control or other regulatory authorities to: training, technical support and information about vaccines and other biologics evaluation, licensing and monitoring.

Indicators of achievement:

- Number of collaborating National Quality Control Authorities;
- National Quality Control Authorities more effective;
- Increased demand in quality certified vaccine.

8. Assumptions and risks

Assumptions

- The Donors funding will be available for a 3-year bridging period to allow AU to be ready to fully take over PANVAC.
- PANVAC intrinsic factors for its sustainability are worked out.
- The viability of veterinary vaccine producing laboratories is improved.
- The veterinary biologic National Quality Control Authorities are overseeing properly the manufacturers and their product.

Risks

PANVAC sustainability factors (legal, administrative, technical and financial sustainability) are not properly addressed due to failure to:

- progress with its institutionalisation as an AU specialised Agency by lack of appropriate governance and management systems;
- ensure its technical sustainability: failure to post to PANVAC technically competent AU staffing;
- ensure its financial sustainability: low income from cost recovery, poor resource mobilisation/ funding scheme.

The viability of veterinary biologic producing laboratories in the Region is not assured or impeded by a:

- poor quality assurance systems;
- poor management systems;
- low level vaccine batches submitted to PANVAC;
- inadequate resources (personnel, financial, material), and/or
- low level of generated incomes (market size, demand exceeding the offer).

The majority of the veterinary biologic National Quality Control Authorities are ineffective and fail to enforce requirements for PANVAC's certification by:

- absence of effective veterinary biological products regulation;
- poor resources (financial, personnel, material) and power to assure products quality licensing and monitoring;
- inefficient National Quality Control laboratories to back up National Quality Control Authorities.

9. Project Reporting, Review and Evaluation

1. Reports

Quarterly Progress Reports

Progress reports will be prepared every three months by the CTA who will be provided with inputs from the project team. Each report shall contain:

- actual implementation of activities compared to those planned in the work plan
- identification of problems and constraints (technical, human, financial and others) in implementation
- recommendations for corrective measures and
- detailed and quantified work plan for the following reporting period.

Progress reports will be submitted by the project management to the Director of CIRAD-EMVT for review, finalisation and submission to the Director of AU/IBAR and to EC the Delegate.

Technical reports

The CTA will be expected to submit yearly two technical reports. The frequency of such reports may be increased upon request from CIRAD-EMVT or AU/IBAR.

Technical reports will be submitted by the project management to the Director of CIRAD-EMVT for review, finalisation and submission to the Director of AU/IBAR and to the EC Delegate.

Financial reports

Financial reports will be prepared according to the periodicity and the procedures set out in the technical assistance agreement and then forwarded by CIRAD-EMVT and GTZ to AU/IBAR and the EC Delegation in Nairobi.

Terminal Report

Towards the end of the project the CTA, in close collaboration with the project team, will prepare and send to CIRAD-EMVT Headquarters a draft Terminal Report for technical clearance, finalisation and submission to the Director of AU/IBAR and the EC Delegate.

The report will assess in a concise manner, the extent to which the project's scheduled activities have been carried out, its outputs produced and progress towards achievement of immediate objectives and related development objective. It will also present recommendations for any future follow up action arising out of the project, specifically addressing implications for continuing transboundary animal disease control. The report should contain as an annex a copy of any project proposal for continuing activities or assistance after the current phase.

2. Review

The progress of the project will be bi-annually examined by the PACE Advisory Committee (AC) whose meetings are organised by the Director of AU/IBAR.

3. Evaluation

The need for and timing of a possible terminal evaluation mission will be identified by the Director of AU/IBAR or by the Advisory Committee in consultation with the EC Delegation. The terms of reference, exact timing and places to visit will be decided in consultation among all concerned parties (AU/IBAR, EC Delegation, CIRAD-EMVT). Any party may call for evaluation at any stage of the project if deemed necessary

10. Project budget – Plan of expenditures

The Annex 4 indicates the operating cost of PANVAC (except for TA cost) for the time period 15 may 04 to October 2004. All this operating cost will be funded by the EC through the PACE programme.

The host country, through the National Veterinary Institute, is providing office and laboratory spaces, utilities (electricity and water) and facility guards and all imported goods by PANVAC will be free of custom and other tax charges.

11. Gender, social and environmental issues

PANVAC promotes and encourages whenever and wherever possible the active participation and implication of women in all its activities and grants equal opportunities and access to projects benefits (training, access to information etc..).

PANVAC would ensure that all its activities and all its proposals to decision makers have no negative impact on the environment and are compatible with the region social and cultural contexts.

ANNEXES

Annex 1: Laboratory and office equipment made available to the PANVAC by the National Veterinary Institute (NVI) of Ethiopia

Location	Description	Serviceable	Remark
Laboratory 1: Normal cell culture			
	Electronic balance Sartorius	Yes	
	Water purifier Elgastat	Yes	Cartridge needed
	Liquid nitrogen container Taylor 35HC	Yes	
	Liquid nitrogen container Taylor 35HC	Yes	
	Liquid nitrogen container Taylor 35HC	Yes	
	Inverted microscope	Yes	
	Regular Incubator	**No**	Unusable
	Water bath Grant 28L	Yes	
	Laminar flow hood	Yes	
	Micro centrifuge	Yes	
	Magnetic stirrer	Yes	
	Refrigerator Whirlpool 215L	Yes	
	Refrigerator Whirlpool 487L	Yes	
Laboratory 2: Infected cell culture			
	Air conditioner National CS-1800KH	Yes	
	CO2 Incubator	Yes	
	Regular incubator	Yes	
	Refrigerator Whirlpool 215L	Yes	
	Laminar flow cabinet MDH	Yes	
	Micro centrifuge	Yes	
	Inverted microscope Zeiss ID02	Yes	
	Water bath Grant 28L	Yes	
	Micro centrifuge	Yes	
	Magnetic stirrer	Yes	
	Shaker	Yes	
Laboratory 3: Bacteriology			
	Air conditioner National CS-1800KH	Yes	
	Laminar flow cabinet MDH	Yes	
	Water bath Grant 28L	Yes	
	Normal incubator B6200	Yes	
	Vertical freezer -20°C	Yes	
	Horizontal freezer -20°C	Yes	
	Table centrifuge	Yes	
	Micro centrifuge	Yes	
	Magnetic stirrer	Yes	
	Dark field and UV microscope	Yes	
	Elisa reader	Yes	
	Vacuum tester Edwards	**No**	Unusable
Laboratory 4: Freeze drying and incubation room			
	Freeze dryer	Yes	
	Eggs incubator	Yes	
	Roller flasks incubator	Yes	
	Vertical freezer -20°C	Yes	
	Ultra deep freezer -80°C	**No**	Unusable
	Precision balance 0.0001g	Yes	

Location	Description	Serviceable	Remark
	Vacuum pump	Yes	
	Water bath	Yes	
	Ice maker	Yes	
	Water bi-distiller	**No**	Unusable
Laboratory 5: Washing and sterilization room			
	Oven	Yes	
	Autoclave	Yes	
	Test tube washing machine	Yes	
	Ultra deep freezer -80°C	**No**	Unusable
Laboratory 6: Biotech laboratory			
	Refrigerator Sharp	Yes	
	Polaroid Camera system Sigma MP4	Yes	
	Transilluminator Sigma	Yes	
	Power supply 500V	Yes	
	Micro centrifuge	Yes	
	Microwave oven	Yes	
	Thermocycler Perkins	Yes	
	Electrophoresis unit	Yes	
	Water bath	Yes	
	Balance	Yes	
	Horizontal laminar flow cabinet	Yes	
	Multipipette 12 channel	Yes	
	Multipipetters	Yes	
	Moisture analyser Sartorius	**No**	To repair
Chief Technical Adviser Office			
	Telephone	Yes	
	Uninterruptible power supply APC	**No**	Unusable
Expert Office			
	Air conditioner split Sanyo SAP-KC72G5	Yes	
	Computer Compaq Deskpro 166 with monitor	Yes	
	Computer Compaq Deskpro P132 with monitor	**No**	
	Printer HP LaserJet 6L	**No**	Unusable
	Printer HP LaserJet 5L	**No**	Unusable
	Uninterruptible power supply APC	**No**	Unusable
	TV Sharp 29"	Yes	
	Video cassette recorder Sharp VC-7	**No**	Unusable
Secretary Office			
	Telephone	Yes	
	Computer Compaq Deskpro 166 with monitor	Yes	
	Printer HP LaserJet 6L	**No**	To repair
	Telephone Fax machine Canon B100	Yes	
	Typewriter Olympia 2000	Yes	
	Calculator Canon P1252	Yes	
	Uninterruptible power supply APC	**No**	Out of order
Library			
	Photocopier canon NP6612	Yes	
	Photocopier canon NP4835i	**No**	Unusable
Kitchen			
	Refrigerator Sharp	Yes	

Annex 2: Indicative list and costs of laboratory and office equipment

	Description	Destination(s)	Quantity	Unit cost	Amount
				(Euro)	(Euro)
	Laboratory equipment				
1	Refrigerated bench centrifuge & accessories	Lab1	1	8 000	8 000
2	Regular Incubator 200L with accessories	Lab1	1	4 000	4 000
3	pH meter and accessories	Lab1 & Lab3	2	800	1 600
4	Water purifier 4l/h	Lab4	1	5 000	5 000
5	Water distiller 4l/h	Lab4	1	4 000	4 000
6	Single Channel Digital Pipette 1-5ml with tip ejector	Lab2 & Lab3	4	300	1 200
7	Eppendorf maxipettor	Lab2 & Lab4	2	500	1 000
8	Vacuum tester Edwards	Lab3	1	500	500
					25 300
	Office equipment				
1	Computer Desktop Pentium IV with CD RW & DVD	CTA & Secretariat	2	1 900	3 800
2	Laser printer	CTA & Secretariat	2	400	800
3	Color printer	Library & training	1	350	350
4	Uninterruptible power supply UPS 620VA	CTA & Secretariat	2	250	500
5	Scanner	Secretariat	1	550	550
6	Label printer	Laboratories	1	2 000	2 000
					8 000
				TOTAL	**33 300**

Annex 3: Indicative list and estimated cost for laboratory biological, chemical and consumables

	Description	Std Unit	Quantity	Unit Price	Amount
				(Euro)	(Euro)
	Biological				
1	GMEM- Glasgow Minimum Essential Medium	10Liter	5	70	350
2	Hanks BSS	10X1L	5	22	110
3	Trypsin 1:250	100g	2	100	200
4	Penicillin G	10million IU	10	15	150
5	Streptomycin Sulphate	5g	2	12	24
6	Tryptic Soy Broth	500g	4	30	120
7	Yeast extract	250g	2	95	190
8	Brain Heart Infusion Broth	250g	5	92	460
9	Tryptose Phosphate Broth	500g	5	32	160
10	Fluid Thioglycollate medium	500g	2	70	140
11	Skimmed Milk Powder	500g	4	10	40
12	Agar, Bacteriological	500g	2	20	40
13	Fœtal calf serum	500ml	2	110	220
14	Newborn calf serum gamma irradiated	500ml	2	122	244
15	Thymic DNA	5X5mg	2	220	440
				Subtotal	**2 888**
	Chemicals				
1	Sodium Chloride	kg	2	35	70
2	Digitonin	5g	2	325	650
3	Pyruvic Acid, sodium salt	100g	2	68	136
4	Ethanol absolute	2.5L	5	70	350
5	PBS	12X1L	2	40	80
6	Dimethylsulfoxide (DMSO)	100ml	2	35	70
7	Ethylene diamine tetra acetic acid (EDTA)	100g	2	32	64
8	Trypan blue	25g	2	30	60
9	Phenol red	25g	2	45	90
10	Glycerol	250ml	2	80	160
11	Phosphate disodique anhydrous	500g	2	60	120
12	Phosphate monopotassique anhydrous	500g	2	60	120
13	D-Glucose	500g	2	30	60
14	Phenolphtalein sodium diphosphate	100g	2	26	52
15	Tetrazolium chloride	25g	2	60	120
				Subtotal	**2 202**
	Consumable & others				
1	Bijoux disposable, 7ml	700/Pkg	10	80	800
2	Universal, plastic, 30ml	400/Pkg	5	60	300
3	Pipette 1ml, disposable, plastic, single wrap	500/Pkg	10	67	670
4	Pipette 5ml, disposable, plastic, single wrap	200/Pkg	3	52	156
5	Pipette 10ml, disposable, plastic, single wrap	500/Pkg	2	190	380
6	Combitips, 2.5ml capacity	1000/Pkg	2	125	250
7	Whatman, Membrane filter, cellulose nitrate 0.2µm, 142mm	25pcs/Pack	6	165	990
8	Propipette caoutchouc	10/pack	5	18	90
9	Anaerobic gas generating kit	Pack of 10	4	150	600
10	Microplate sealer adhesive film, thickness 2mil	Pack of 100	5	95	475
11	Petri dishes, 90 x 12mm triple vent, disposable	Pack of 500	2	130	260

	Description	Std Unit	Quantity	Unit Price	Amount
12	Autoclave tape with color indicator roll of 55mx19mm	Roll	20	8	160
13	Culture flask 75cm2 straight neck	box of 50	10	50	500
14	Tissue culture microplate, 96 well, single wrap	Pack of 50	12	63	756
15	Microplate, U-bottom, 96 well, sterile, single wrap	Pack of 50	12	44	528
16	Ion/organic removal cartridge, LC103 for deioniser Elgastat	Pcs	10	50	500
17	Security propipette	Pcs	5	12	60
18	pH paper 6.0 to 7.7	100 strips/pkg	4	13	52
19	pH paper 7.50 to 9.5	100strips/pkg	4	13	52
20	Reusable filtering funel 250ML	Piece	2	104	208
21	Membrane micronsep 0,22µ	100/Pkg	2	140	280
22	Membrane micronsep 0,45µ	100/Pkg	2	130	260
23	Filtering syringe 0,2µ	50/Pkg	2	109	218
24	Penicillin glass vial 5ml	5000/Pkg	2	400	800
25	Stopper for penicillin vial	5000/Pkg	2	80	160
26	Aluminium cap for penicillin vial	5000/Pkg	2	200	400
				Subtotal	**9 905**
			Total in Euro		**14 995**

Annex 4: PANVAC Global Budget from 15 May to 31st October 2004

	Description	Unit	Quantity	Unit cost	Amount
				(Euro)	(Euro)
	Personnel				
1	Laboratory technicians (GSB5) (X2)	man/month	12	305	3 660
2	Laboratory assistant (GSB3)	man/month	6	140	840
3	Allowance NVI Accountants (X2)	man/month	12	100	1 200
4	Secretary -Administrative Assistant (GSB5)	man/month	6	305	1 830
5	Senior Driver/Clearing agent (GSB4)	man/month	6	200	1 200
6	Cleaner/ messenger (GSB2)	man/month	9	125	1 125
				Subtotal	**9 855**
	Laboratory and Office equipment				
1	Laboratory equipment	Set			25 300
2	Office equipment	Set			8 000
					33 300
	Laboratory and Office supplies				
1	Laboratory consumables & reagents	Set	1		14 995
2	Office supplies	Set			1 505
				Subtotal	**16 500**
	General operating expenses & Services				
1	Operation and maintenance of equipment				8 000
2	Communication services (tel., fax, email, internet, post office parcels)				4 000
3	Web page design (including databases and forum module)				3 000
4	Contract for public awareness communication/ information campaigns				5 000
5	Local staff accident insurance coverage		6	150	900
6	General Office and laboratory costs				5 445
				Subtotal	**26 345**
			Total (Euro)		**86 000**
			Total (ETB)		**908 099,80**

Annex 5: Logical Framework

Immediate objectives, outputs and main activities	Indicators of achievement	Means of verification
Mission: To promote the availability of safe, effective and affordable veterinary vaccines, facilitate the development and the introduction of improved or new vaccines and strengthen Africa's capacity building in veterinary vaccine development, production and quality assurance		
Development objective: To promote Africa capabilities to take better advantage of vaccine benefits, for a sustainable livestock production and productivity, through the region capacity building in veterinary vaccine quality assurance.		
Immediate objective 1: 1. Provide international vaccine quality control testing services for priority vaccines in Africa		
Output 1.1: PANVAC quality control services re-established		
Activity 1.1.1: Assess current (physical and functional) status of PANVAC laboratories and equipment	Updated inventories	Inception report
Activity 1.1.2: Supply of complementary equipment, laboratory consumables and reagents.	Complementary equipment, consumables and reagents supplied	Purchase orders; inventory list
Activity 1.1.3: Revalidate vaccine testing reference material (controls) quality and, if necessary, prepare new ones	Reference material validated	Reference material quality control testing results; inventory
Activity 1.1.4: Re-establish collaborative linkages with previous national and international scientific institutions in relevant areas	Number of centres collaborating with PANVAC	Project report
Output 1.2: Standardized quality control testing of major veterinary vaccines assured on a cost recovery basis		
Activity 1.2.1.: Inform African laboratories and National Quality Control Authorities of the resumption of the quality control service of PANVAC	Distribution list of courier	Project's report
Activity 1.2.2.: Provide independent priority veterinary vaccine batches quality control and certification	Number of vaccine batches tested and certified	Quality control testing results; projects' report
Activity 1.2.3.: Assist African countries and laboratories to revalidate the quality of their priority vaccine stocks	Number of countries or laboratories requesting such service; number of vaccine stocks tested	Quality control testing results; projects' report

Immediate objectives, outputs and main activities	Indicators of achievement	Means of verification
Immediate objective 2: 2. Promote the standardisation of biological products and the quality control of veterinary vaccines in Africa		
Output 2.1: PANVAC reference material repository revalidated and expanded		
Activity 2.1.1.: Re-evaluate the quality of master seed banks, master cell stock, reference vaccine preparations	Nature and quantity of reference material in PANVAC repository	Reference material inventory; projects' report
Activity 2.1.2.: Consolidate and expand PANVAC's repository of vaccine strains, cell lines, reference vaccine preparation, reference antiserum and make available at cost	Nature and quantity of reference material supplied	Reference material inventory; shipping list; projects' report
Output 2.2: Priority vaccine quality control methods harmonised and improved		
Activity 2.2.1.: Produce and distribute Standard Operating Procedures (SOPs) or Master formulae (instruction manuals) on priority vaccines	Number and titles of SOPs and instruction manuals produced	SOPs and instruction manuals produced; projects' reports
Activity 2.2.2.: Improve vaccine quality testing methods sensitivity and/or specificity (e.g. application of PCR technology to PPR, RP and CBPP vaccines identity test)	Number and type of improved testing methods evaluated	Projects' reports
Output 2.3.: Quality Assurance principles and current Good Manufacturing Practices (cGMP) promoted within the Region.		
Activity 2.3.1.: Improve awareness, among directors and key vaccine personnel, on implementation of principles and practices of Quality Assurance	Number of laboratories operating according to quality assurance principles and GMP; Information and communication services of PANVAC	Number of quality manuals produced; projects' reports
Activity 2.3.2.: Assist, though technical advices, the region laboratories and National Quality Control Authorities in implementing and evaluating Quality Assurance principles	Number of laboratories assisted; Number of requests from regulatory authorities	Projects' reports
Immediate objective 3: Create optimal conditions ensuring PANVAC viability and sustainability as an African Union Agency		
Output 3.1.: Drafts of complementary documents for PANVAC institutionalisation submitted to AU/IBAR and AU		
Activity 3.1.1.: Submit a Strategic Plan and phasing (development path) draft to AU/IBAR and AU	Strategic plan proposed	Proposed Draft of strategic plan; Projects' reports
Activity 3.1.2.: Draft a communication plan for PANVAC	Communication plan proposed	Draft of Communication plan; Projects' reports
Activity 3.1.3.: Submit draft of other Legal instrument documents to AU/IBAR and AU	Drafts of PANVAC Establishment and Constitution proposed	Proposed Drafts; projects' reports

Immediate objectives, outputs and main activities	Indicators of achievement	Means of verification
Output 3.2.: Appropriate governance and management structures established		
Activity 3.2.1.: Assist AU/IBAR and AU to define clear and transparent management system for PANVAC operations	Management system and procedure manuals adopted by AU	Proposed Draft of Management system and procedure manuals; projects' reports
Activity 3.2.2.: Assist AU/IBAR and AU in establishing functional Governing body and Advisory Group(s)	Governing board and advisory groups established by AU	Proposed Draft of Governing board and advisory groups
Output 3.3.: PANVAC technical sustainability improved		
Activity 3.3.1.: Assist AU and AU/IBAR in establishing attractive staffing/personnel policy	Staffing policy	Proposed Draft of staffing policy; Projects' reports
Activity 3.3.2.: Assist AU and AU/IBAR to identify and recruit high quality staff and associates	Recruitment procedures; Recruited staff qualifications	Staffing list
Output 3.4.: PANVAC financial sustainability consolidated		
Activity 3.4.1.: Assist AU in defining clear and realistic resource mobilisation policy	Resource mobilisation policy defined	Proposed Draft of resource mobilisation policy
Activity 3.4.2.: Re-establish and improve PANVAC's cost recovery scheme for services provided	Level of generated income for services rendered	Bank statement
Activity 3.4.3.: Assist AU/IBAR and AU in mobilising contributions from various sources	Resources mobilised from other sources	Bank statement
Output 3.5.: PANVAC's networked laboratories viability improved		
Activity 3.5.1.: Participate in the build up of functional quality assurance system into networked laboratories	Number of laboratory engaged into quality assurance system implementation	Projects' reports
Activity 3.5.2.: Assist the networked laboratories to access new production technologies	Number of new technologies or improved methods made available	Projects' reports
Output 3.6.: National Quality Control or regulatory authorities' effectiveness in veterinary biologics evaluation, licensing and monitoring improved		
Activity 3.6.1.: Facilitate the access of National Quality Control or other regulatory authorities to: training, technical support and information	Number of National Quality control authorities assisted	Projects' reports

Annex 6: Main activities timetable

Immediate objectives, outputs and activities	Feb04	Mar	Apr	May	June	July	Aug	Sep	oct-04
Immediate objective 1: 1. Provide international vaccine quality control testing services for priority vaccines in Africa									
Output 1.1: PANVAC quality control services re-established									
Activity 1.1.1: Assess current (physical and functional) status of PANVAC									
Activity 1.1.2: Supply complementary equipment, materials and reagents									
Activity 1.1.3: Revalidate vaccine testing reference material quality									
Activity 1.1.4: Re-establish collaborative linkages with scientific institutions									
Output 1.2: Standardized quality control testing of major veterinary vaccines assured on a cost recovery basis									
Activity 1.2.1.: Inform African laboratories and Quality Control Authorities of the resumption of the quality control service of PANVAC									
Activity 1.2.2.: Provide independent priority veterinary vaccine batches quality control and certification									
Activity 1.2.3.: Assist African countries and laboratories to revalidate the quality of their priority vaccine stocks									
Immediate objective 2: 2. Promote the standardisation of biological products and the quality control of veterinary vaccines in Africa									
Output 2.1: PANVAC reference material repository revalidated and expanded									
Activity 2.1.1.: Evaluate the quality of master seed banks, master cell stock, reference vaccine preparations									
Activity 2.1.2.: Consolidate and expand PANVAC's repository of vaccine strains, cell lines, reference vaccine preparation, reference antiserum and make available at cost									
Output 2.2: Priority vaccine quality control methods harmonised and improved									
Activity 2.2.1.: Produce and distribute Standard Operating Procedures or instruction manuals									
Activity 2.2.2.: Improve vaccine quality testing methods sensitivity and/or specificity									
Output 2.3.: Quality Assurance principles and current Good Manufacturing Practices (cGMP) promoted within the Region.									
Activity 2.3.1.: Improve awareness on implementation of principles & practices of QA									

Immediate objectives, outputs and activities	Feb04	Mar	Apr	May	June	July	Aug	Sep	oct-04
Activity 2.3.2.: Assist the region laboratories and National Quality Control Authorities in implementing and evaluating QA principles									
Immediate objective 3: Create optimal conditions to ensure PANVAC viability and sustainability as an African Union Agency									
Output 3.1.: Drafts of complementary documents for PANVAC institutionalisation submitted to AU/IBAR and AU									
Activity 3.1.1.: Submit a Strategic Plan and phasing (development path) draft to AU/IBAR and AU									
Activity 3.1.2.: Draft a communication plan for PANVAC									
Activity 3.1.3.: Submit draft of other Legal instrument documents to AU/IBAR and AU									
Output 3.2.: Appropriate governance and management structures established									
Activity 3.2.1.: Assist AU/IBAR and AU to define clear and transparent management system for PANVAC operations									
Activity 3.2.2.: Assist AU/IBAR and AU in establishing functional Governing body and Advisory Group(s)									
Output 3.3.: PANVAC technical sustainability improved									
Activity 3.3.1.: Assist AU and AU/IBAR in establishing attractive staffing/personnel policy									
Activity 3.3.2.: Assist AU and AU/IBAR to identify and recruit high quality staff									
Output 3.4.: PANVAC financial sustainability consolidated									
Activity 3.4.1.: Assist AU in defining clear and realistic resource mobilisation policy									
Activity 3.4.2.: Re-establish and improve PANVAC's cost recovery scheme for services provided									
Activity 3.4.3.: Assist AU/IBAR and AU in mobilising contributions from various sources									
Output 3.5.: PANVAC's networked laboratories viability improved									
Activity 3.5.1.: Participate in the build up of functional quality assurance system into networked laboratories									
Activity 3.5.2.: Assist the networked laboratories to access new production technologies									
Output 3.6.: National Quality Control or regulatory authorities' effectiveness in veterinary biologics evaluation, licensing and monitoring improved									
Activity 3.6.1.: Facilitate the access of National Quality Control or other regulatory authorities to training, technical support and information									

Annex 7: Technical Assistant Terms of Reference (as in the original Financing Agreement)

1. Terms of reference of the expert in veterinary vaccine (30m/m)

From the first year of the implantation of the activities, the expert will be responsible for the technical coordination of the work plan of PANVAC, and the overall control and administration of the staff, facilities, equipment, supplies and expenditure at the project site. He/She will work as an advisor to the Director of the AU/IBAR and will work under the supervision of the PACE Programme Coordinator, from whom he may receive directives and to whom he will report (work plans/ programmes, progress reports, technical reports and others as required). These functions should be progressively handed over to the AU/IBAR counterpart who will assume these administrative responsibilities. It should be noted that the expert would conceive an action plan for a sustainable implementation of PACE financial support.

On the technical level, he/she will:

1. be responsible for providing a quality control service for rinderpest, CBPP and other priority vaccines;
2. supervise the standardization of quality control methods for rinderpest, CBPP and other priority vaccines and provide appropriate guidelines to National Authorities on quality control requirements;
3. prepare Standard Operating Procedures and other instruction manuals for vaccines against rinderpest, CBPP and, on request, doer other priority vaccines;
4. prepare and maintain a PANVAC repository of seed material, cell culture, quality control standards and key reference reagents to be used by PANVAC and its network laboratories;
5. carry out appropriate quality control testing and characterization of the materials in the PANVAC repository;
6. co-ordinate the production and distribution of diagnostic reagents and disease diagnostic kits to laboratories in Africa;
7. initiate and oversee the external quality control of the laboratory diagnosis of the main epizootics, starting with rinderpest and CBPP;
8. ensure smooth and efficient collaboration with National laboratories for the production of reagents for the external quality control of diagnostic tests; and
9. supervise research and development partnership with reference laboratories.

On the institutional side, he/she will:

1. be responsible for the overall design and implementation of the PANVAC cost recovery system. Therefore he/she will conceive a comprehensive sustainable plan and strategies;
2. ensure the coordination of the external quality assessment activities, the accreditation of veterinary diagnostic laboratories and the transfer of technology relevant to this process;
3. arrange appropriate linkages with the relevant FAO, IAEA, WHO, International Reference/ Collaborating Centres as the primary sources of vaccine technologies, standards and reference reagents;
4. participate in building up of PANVAC as an AU/IBAR Specialised Agency.

2. Terms of reference of the CBPP diagnostic and vaccine specialist (10m/m)

The expert will be responsible for the technical activities relating to the diagnosis of CBPP and the quality control of CBPP vaccine. He/She will work as advisor to the Director of the AU/IBAR under the supervision of the PANVAC expert in veterinary vaccines to who he will report.

The CBPP diagnostic and vaccine specialist will:

1. implement the laboratory activities for quality control testing of CBPP vaccine according to international standards;
2. participate in the preparation and/or maintenance of a PANVAC repository of seed material, cell cultures, quality control standards and key reference reagents for use in CBPP vaccine quality control;
3. assist in the preparation of Standard Operating Procedures and other instruction manuals for use in the production and quality control of CBPP vaccine (and other priority vaccines for Africa);
4. assist in the implementation and operation of the cost recovery system for PANVAC's CBPP quality control service;
5. assist the PANVAC vaccine specialist as necessary, in quality control testing of other priority vaccines, and in the introduction of new techniques in accordance with PANVAC standard operating procedures;
6. participate in the implementation of Good Laboratory Practices (GLP), Laboratory Safety Codes for the PANVAC laboratory as well as Training and supervising the work of counterpart personnel and trainees in veterinary vaccines quality control.

Annex 8: Mid and long term specific objectives

(Specific objectives listed 3, 4 and 5 in Page 7)

Specific objective 3: Promote the transfer of appropriate technologies for vaccine production to Africa

Aim: Promote technical and financial efficiency in vaccines production by taking better advantage of advances in veterinary biologic science and technology.

Output 3.1.: New and/or improved veterinary vaccines production technology transferred into the Region laboratories

Strategy:

- Identify and facilitate the technology transfer of new and/or improved veterinary biologics of particular concern to Africa in order to achieve significant upgrade of products quality.

Activities:

- **Activity 3.1.1.:** Undertake bench scale evaluation of new and/or improved veterinary vaccines production.
- **Activity 3.1.2.:** Evaluate new techniques (and their cost effectiveness) aimed at improving vaccine safety, efficacy, potency or stability and transfer validated technologies to networked laboratories.
- **Activity 3.1.3.:** Undertake collaborative work, with recognised investigators, on new and/or improved vaccine technologies.

Indicators of achievements:

- Number of new and/or improved vaccine production techniques evaluated
- Nature and volume of work with collaborative institutions.

Specific objective 4: Provide training and technical support services to vaccine production laboratories

Aim: Provide technical support to and participate in the capacity building of vaccine production laboratories, diagnostic laboratories and national quality control authorities. This will be achieved by organizing customized training programmes (e.g. workshops, bench training, quality assurance audits) and communication (dissemination of information on vaccine and diagnostic technologies).

Output 4.1: Scientific personnel of veterinary laboratories well trained in vaccine production and quality control procedures

Strategy:

- Create, at PANVAC, opportunities for continuing educational training in veterinary biologic production, quality control and regulation.

Activities: At request and on a cost recovery basis, organize and/or conduct:

:

- **Activity 4.1.1.:** Bench training for technicians and/or technologists
- **Activity 4.1.2.:** Fellowship arrangements for laboratories technical staff to undertake at PANVAC developmental work
- **Activity 4.1.3.:** Study tours for senior staff members from manufacturing laboratories (in veterinary biologic production, quality control and management).
- **Activity 4.1.4.:** Study tours for regulatory agencies (National Quality control Authorities, National Quality Control laboratories) for proper foresight on vaccine production, quality control of vaccines and other biologics, laboratory inspection and licensing.
- **Activity 4.1.5.:** Workshops on veterinary biologics quality control and quality assurance.

Indicators of achievements:

- Recognised and sustained training facilities established at PANVAC for veterinary biologic production and quality control.
- Number of bench-trainees, visiting scientists, workshops
- Number of study tours organised for regulatory agencies for the above.

Output 4.2: PANVAC's information services on veterinary biologic expanded

Strategy:

- Collect and disseminate new or pertinent information related to veterinary biologics science, technology, supply strategy, licensing and monitoring and make them available to networked laboratories;

Activities:

- **Activity 4.2.1.:** Resume the consolidation of PANVAC's documentation centre and biologic database.
- **Activity 4.2.2.:** Collect timely and disseminate relevant information about veterinary biologics.

Indicators of achievement:

- Catalogue of PANVAC's documentation centre
- Nature of media used to disseminate information - Volume of updated information on veterinary biologics collected and disseminated to networked laboratories and veterinary authorities.

Specific objective 5: Establish the regional production and standardisation of diagnostic reagents for animal diseases diagnosis and surveillance

Aim: Promote the human and technical capacity building in production and use of good quality veterinary diagnostic reagents in Region.

Output 5.1.: Reagents used for priority diseases diagnosis and surveillance produced locally

Strategy:

- Organise PANVAC's staff training in veterinary diagnostic reagents production
- Produce and distribute cost-effective biological reagents (including ELISA kits) for priority diseases diagnosis and surveillance.

Activities:

- **Activity 5.1.1.:** Training of PANVAC's staff in biological reagents production.

  There is a need for the following training: Senior staff to be trained in reagents production and quality control and Senior Laboratory Technician to be trained in diagnostic kit assembly.

- **Activity 5.1.2.:** Provide PANVAC with the necessary complementary laboratory space, equipment and material for bench production of diagnostic reagents.

- **Activity 5.1.3.:** Produce and distribute at cost biological reagents (including ELISA kit) for priority diseases diagnosis and surveillance.

- **Activity 5.1.4.:** Establish and maintain links with the relevant institutions in animal diseases diagnosis reagents production and/or evaluation.

Indicators of achievements:

- Regional production of Veterinary diagnostic biologics enabled.
- Availability of quality assured and reliable diagnostic reagents improved.
- Number of relevant collaborating Centres in diagnostic reagents production and/or evaluation

Output 5.2.: Facility established for the evaluation of diagnostic reagents produced locally or imported

Strategy:

- Provide external quality control services for diagnostic reagents produced locally or imported.
- Assist the National Veterinary Laboratories in the implementation of quality systems for reagents used in diseases diagnosis and surveillance.
- Assist National Quality Control Authorities in diagnostic laboratories licensing, certification or accreditation process.
- Assist in sustaining quality production of biological reagents through establishment of an effective external quality assurance system.

Activities:

- **Activity 5.2.1.:** Provide external quality control services for diagnostic reagents produced locally.

- **Activity 5.2.2.:** Undertake, on request of National Quality Control Authorities and on cost recovery basis, external quality assurance audit of veterinary diagnostic laboratories.

- **Activity 5.2.3.:** Facilitate the establishment of a laboratories network within the Region diagnostic Centres for reagents inter-laboratory quality control and validation.

Indicators of achievements:

- Number of reagent batches tested
- Number of external audits performed.
- Increased capacity in animal diseases diagnosis and surveillance
- Cost of animal diseases diagnosis/ surveillance decreased

COST ESTIMATE BUDGET DONOR CONTRIBUTION

PAN-AFRICAN PROGRAMME FOR THE CONTROL OF EPIZOOTICS (PACE)

Pan African Veterinary Vaccine Center (PANVAC)

Work plan and budget

Period: 15 May – 31st October 2004

Identification	Number REG/5007/005
Sectoral Classification	PUE
Accounting Numbers	8ACP TPS 032

Approved EDF financed items ..... Euro **86,000.00**
(Euro Eighty seven thousand eight hundred thirty seven Only)

PANVAC BUDGET YEAR 1: COST ESTIMATE BUDGET
DONOR CONTRIBUTION

Table 1: Budget Year 1: Donor Contribution budget breakdown

	Component description	% Budget line	Amount (Euro)
Quality control testing services			
	Personnel		
1	Laboratory personnel	45	2 025,00
2	Support staff	50	2 677,50
	Laboratory and Office equipment		
1	Laboratory equipment	60	15 180,00
2	Office equipment	40	3 200,00
	Laboratory and Office supplies		
1	Laboratory consumables & reagents	60	8 997,00
2	Office supplies	60	903,00
	General operating expenses & Services		
1	Operation and maintenance of equipment	50	4 000,00
2	Communication services	60	2 400,00
3	Web page	40	1 200,00
4	Communication/ information campaigns	40	2 000,00
5	Local staff accident insurance coverage	40	360,00
6	General Office and laboratory costs	45	2 450,25
Standardisation of biological products and quality control			
	Personnel		
1	Laboratory personnel	45	2 025,00
2	Support staff	45	2 409,75
	Laboratory and Office equipment		
1	Laboratory equipment	30	7 590,00
2	Office equipment	40	3 200,00
	Laboratory and Office supplies		
1	Laboratory consumables & reagents	30	4 498,50
2	Office supplies	30	451,50
	General operating expenses & Services		
1	Operation and maintenance of equipment	40	3 200,00
2	Communication services	10	400,00
3	Web page	20	600,00
4	Communication/ information campaigns	20	1 000,00
5	Local staff accident insurance coverage	40	360,00
6	General Office and laboratory costs	45	2 450,25

	Component description	% Budget line	Amount (Euro)
Assistance in PANVAC viability and sustainability			
	Personnel		
1	Laboratory personnel	10	450,00
2	Support staff	5	267,75
	Laboratory and Office equipment		
1	Laboratory equipment	10	2 530,00
2	Office equipment	20	1 600,00
	Laboratory and Office supplies		
1	Laboratory consumables & reagents	10	1 499,50
2	Office supplies	10	150,50
	General operating expenses & Services		
1	Operation and maintenance of equipment	10	800,00
2	Communication services	30	1 200,00
3	Web page	40	1 200,00
4	Communication/ information campaigns	40	2 000,00
5	Local staff accident insurance coverage	20	180,00
6	General Office and laboratory costs	10	544,50

Table 2: Cost estimate with budget Year 1 Donor contribution

	Budget Item	% Budget line	Amount (Euro)
	Personnel		
1	Laboratory personnel	100	4 500
2	Support staff	100	5 355
	Budget for personnel		**9 855**
	Laboratory and Office equipment		
1	Laboratory equipment	100	25 300
2	Office equipment	100	8 000
	Budget for laboratory and Office equipment		**33 300**
	Laboratory and Office supplies		
1	Laboratory consumables & reagents	100	14 995
2	Office supplies	100	1 505
	Budget for laboratory and Office supplies		**16 500**
	General operating expenses & Services		
1	Operation and maintenance of equipment	100	8 000
2	Communication services	100	4 000
3	Web page	100	3 000
4	Communication/ information campaigns	100	5 000
5	Local staff accident insurance coverage	100	900
6	General Office and laboratory costs	100	5 445
	Budget for general operating expenses & services		**26 345**
	Year 1 Budget Grand Total in Euro		**86 000**

APPROVED EDF FINANCED ITEMS: **EURO 86,000.00**
(Euro Eighty seven thousand eight hundred thirty seven Only)

Proposed by the PACE Coordinator: **Dr. Rene BESSIN**

Place and date: 07/05/2004
NAIROBI

Approved by the Regional Authorising Officer (AU/IBAR) for the African Union

Place and date: NAIROBI 10/07/2004

AFRICAN UNION
INTERAFRICAN BUREAU FOR ANIMAL RESOURCES
NAIROBI
AU/IBAR

Endorsed by the Head of the Delegation of the European Commission in Nairobi

Place and date: