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Quality control of PPR vaccines in Africa: the role of AU-PANVAC

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1. Introduction

Peste des Petits ruminants (PPR), also called rinderpest of small ruminants, is an acute contagious disease of sheep and goats which causes a devastating plague with morbidity and mortality rates as high as 100% and 90% respectively. PPR is an OIE listed disease because of the morbidity and mortality it causes and of its economic importance as a transboundary viral disease that constitutes a threat to livestock production in many developing countries, particularly in West Africa, East Africa, the Arabian Peninsula and South-East Asia. The control of PPR is considered a priority for poverty alleviation as it is a major constraint in augmenting the productivity of small ruminants in developing countries and particularly severely affects poor farmers' economy.

Following the rinderpest eradication celebrations of the OIE in May 2011 and the FAO[1] in June 2011, attention suddenly turned to other transboundary animal diseases. The OIE and FAO have recognised PPR as one of the most economically important animal diseases and also its huge impact on production; and, given its many similarities with cattle rinderpest, have considered it a strong candidate for eradication.

Several technical factors were taken into consideration to work towards achieving global eradication of the PPR virus. In addition to the fact that the causal agents of both diseases are closely related and belong to the *Morbillivirus* genus [2], these include: availability of low-cost safe attenuated vaccines [1, 5] conferring life-long immunity with a single shot; availability of diagnostic tests for sero-monitoring vaccination programmes and virus detection; effective sero-conversion achieved with sub-minimal doses of the vaccine ($10^{0.8}$ $TCID_{50}$) [5].

On the basis of this knowledge, the international community consensually selected PPR as one of the next animal diseases to be eradicated and this gave rise to the development of a global strategy for the control and eradication of the disease by the OIE and the FAO.

Drawing on the lessons learned from the role played by the African Union (AU) Pan African Veterinary Vaccine Centre (PANVAC) in ensuring the quality of the vaccines used in the rinderpest eradication campaign, the quality of PPR vaccines to be used was considered a key element especially given the enormous challenges faced by the majority of developing countries in producing and distributing PPR vaccine.

2. Role of AU-PANVAC

AU-PANVAC is the only organisation mandated by the AU Member States to provide the quality assurance of all veterinary vaccines either produced or imported into Africa. The subsequent Institutionalisation of PANVAC under the AU as an AU Technical Centre of Excellence was made in recognition of PANVAC's contribution to the success of the Pan African Rinderpest Campaign (PARC). It was also based

1 FAO: Food and Agriculture Organization of the United Nations


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on that recognition that the AU-PANVAC mandate was eventually expanded to include the quality control of all veterinary vaccines and the production of basic diagnostic reagents. Thus AU-PANVAC was founded on the belief that livestock health in Africa, especially with regards to major infectious vaccine-preventable diseases, can be substantially improved by the use of good quality vaccines and good laboratory diagnostic support.

The AU-PANVAC mandates include:

– provision of international independent quality control of veterinary vaccines produced in Africa and imported to Africa;
– production and distribution of essential biological reagents for animal disease diagnosis and surveillance;
– facilitating the standardisation of veterinary vaccines production and harmonisation of their quality control techniques in Africa;
– promoting the transfer of appropriate vaccine production technologies in Africa; and
– providing training and technical support services to veterinary vaccine production and quality control laboratories.

2.1. Certification of veterinary vaccines on the continent

AU-PANVAC continues to ensure that laboratory networks throughout Africa are supported to achieve high performance standard by promoting the adoption of improved methods for the production and quality control of priority vaccines. Providing International Independent quality of all veterinary vaccines used in Africa has been a major activity of the AU-PANVAC since its inception in 1986. This has resulted in significant improvements in the quality of vaccines produced and used on the African continent, which is a clear demonstration of the importance of an independent and secondary level quality testing [3]. Roll-out of this service was most extensive in Africa between 1988 and 1993, when PANVAC tested a total of 694 batches of rinderpest vaccine used in PARC [4]. In the last five years alone, AU-PANVAC has tested more than four times the number of batches and the quality improvement rate of vaccines from African laboratories has now exceeds 90% compared to about 30% in the early days. The responsibilities of AU-PANVAC continue to increase with regards to animal disease control, along with stakeholders' appreciation and recognition of its performance. A number of evaluation and review teams reported that PANVAC's activities in the rinderpest eradication campaign have resulted in a significant improvement in the quality of rinderpest vaccine produced in Africa, thereby contributing to the success of the PARC. One review team noted that '*The success of the PARC and the Pan African Programme for the Control of Epizootics (PACE) clearly demonstrated that no amount of vehicles, syringes, trained personnel, communication materials, would have eliminated rinderpest if the vaccine batches used had been of poor quality. The secondary and independent level of quality control assessment assured by PANVAC played a major role for this success and at the same time led to sustained improvement in the quality of vaccines against rinderpest and contagious bovine pleuropneumonia produced in Africa*'. The then OAU Council of Ministers decided to elevate PANVAC to the level of an OAU Specialised Agency in 1998 and eventually institutionalised it under the African Union as AU-PANVAC in 2003 with a view to sustaining this achievement in the interests of Africa.

2.2. Transfer of new vaccine production technologies

In addition to ensuring the quality of vaccines produced, and providing training to technicians from National

Vaccine Production Laboratories in Africa, PANVAC has also been involved with the transfer of new vaccine production technologies to Africa and the improvement of existing technologies. Accordingly, PANVAC pioneered the development of an alternative method for preparing thermo-tolerant vaccines known as the Xerovac process which demonstrated that the vaccine was capable of withstanding 45 °C for a period of 14 days with minimal loss of potency and with the distinct advantage of a shorter, cheaper and simpler process compared to other 'thermostable' vaccines [11].

This technology ensures that the vaccine will maintain the minimum titre required when it reaches the field. The minimum requirement for attenuated PPR vaccine dose is $10^{2.5}$ $TCID_{50}$ per ml. The recommended value for the field efficacy should be 1 to 2 log higher than the minimum protective dose. This technology has been transferred to several vaccine-producing laboratories in Africa.

2.3. Recognition of AU-PANVAC by the OIE

AU-PANVAC has collaborated with the OIE and has participated actively in its activities since inception. AU-PANVAC has taken part in the OIE Working Group on Veterinary Drug Registration and the FAO/AU-IBAR[2]/OIE/IAEA[3] Consultative Group on Contagious Bovine Pleuropneumonia (CBPP) for several years. It has also been invited annually to attend the General Session of the OIE which takes place in May. In recognition of the key role AU-PANVAC has played in animal disease control by providing quality control of vaccines produced in Africa, and the expertise it has gained through the years, AU-PANVAC was officially designated as an OIE Collaborating Centre for Quality Control of Veterinary Vaccines by the OIE World Assembly of Delegates in May 2013.

2.4. Maintaining Africa free from rinderpest

During the 'Declaration of global eradication of rinderpest and the follow-up measures to maintain the world free of rinderpest', the OIE World Assembly of Delegates through Resolution No. 18 of its 79th General Session in 2011 [7], requested the Director of the OIE to approve facilities where material containing the rinderpest virus can be held, and to conduct regular site visits of those facilities to verify whether their biosafety/biosecurity conditions are adequate. Furthermore, the Assembly urged Member States to 'destroy, under the supervision of the Veterinary Authority, rinderpest virus-containing materials or assure the storage or use of these materials in a biosecure facility in their country or, where applicable, assure the safe transfer to an approved laboratory in another country in agreement with the Veterinary Authority of the receiving country and complying with the standards of the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (the *Terrestrial Manual*) [10] and the Guidelines elaborated by the Joint FAO/OIE Committee on Global Rinderpest Eradication'. It is in compliance with the general framework of the global eradication of rinderpest and specifically in order to maintain Africa free of the disease, that the Ministers responsible for Animal Resources in Africa during their 8th Conference held in Entebbe, Uganda, in May 2010 recommended Member States of the AU to destroy all rinderpest virus strains held in Africa and to hand over what is deemed necessary to AU-PANVAC for safe storage. This Recommendation was subsequently endorsed by all the Heads of State of the AU during their January Summit of 2011.

In Resolution No. 23 of the 82nd General Session of the World Assembly of Delegates in 2014 [9], the OIE established procedures for designating and approving facilities holding material containing rinderpest virus to maintain global freedom from rinderpest, and in

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2 AU-IBAR: African Union – Inter-African Bureau of Animal Resources

3 IAEA: International Atomic Energy Agency

collaboration with FAO to ensure the full implementation of the activities of the Joint Rinderpest Advisory Committee to provide technical advice and oversee post-rinderpest eradication activities.

To pursue its actions, the AU Commission made available adequate resources to AU-PANVAC to acquire bio-safety level 3 required by the international veterinary community for the following:

– safekeeping rinderpest vaccine seed stocks;
– safekeeping of emergency preparedness rinderpest vaccine stock (1.5 million doses); and
– maintain laboratory diagnostic capacity for rinderpest.

In recognition and support of the major role played by AU-PANVAC in maintaining Africa free of rinderpest, the FAO made a grant of 166,800 USD to AU-PANVAC in 2011 through a letter of agreement to strengthen its capacity for the sequestering rinderpest virus in its level 3 bio-safety laboratory. The FAO also jointly organised a workshop with AU-PANVAC on bio-safety, sequestration and risk analysis for laboratories holding rinderpest virus in Debre Zeit, Ethiopia, in July 2011. In view of the need for transparency on information about remaining stocks of virus and the importance of reducing the existing rinderpest virus stocks, the OIE World Assembly of Delegates recommended in its Resolutions nos. 33 (2012) [8] and 23 (2014) [9] that respectively appointed a limited number of OIE Reference Laboratories as 'rinderpest holding facilities' and urged Member Countries to ensure that the remaining stocks of all material containing rinderpest virus to be safely transferred to one of the designated rinderpest holding facilities.

On the basis of these recommendations and those of the Ministers responsible for animal resources in Africa, the OIE/FAO Joint Advisory Committee on Rinderpest indicated and assessed AU-PANVAC for rinderpest holding capacity. The Committee recommended that AU-PANVAC facility should be considered for holding rinderpest virus material subject to the implementation of a number of corrective actions that AU-PANVAC has subsequently implemented. AU-PANVAC will ensure full compliance with the corrective actions recommended by the Committee within the stipulated time.

3. The OIE Sub-grant and the Pan African Quality Control Strategy for PPR vaccines

3.1. OIE Sub-grant to AU-PANVAC

After the eradication of rinderpest, scientists' attention turned to PPR which has been devastating small ruminant production in Africa and some parts of Asia. On account of the role played by AU-PANVAC in the eradication of rinderpest, it was considered to strengthen AU-PANVAC to ensure the use of good quality vaccines during the PPR eradication campaign. In line with this, a sub-grant of USD 1 million was given by the OIE to AU-PANVAC for three years to establish capacity for AU-PANVAC [6]. This project was awarded within the framework of a Bill & Melinda Gates Foundation funded grant to the OIE 'Vaccine Standards and Pilot Approach to PPR Control in Africa' (VSPA).

The sub-grant project aimed to build capacity for PPR quality control at AU-PANVAC, develop the capacity of PPR vaccine-producing laboratories to produce good quality PPR vaccine, develop a quality control strategy for ensuring the use of good quality PPR vaccines in Africa and contribute to the definition of a sound scientific PPR reduction programme in Africa. Under the terms of this project, which was implemented in collaboration with and under the responsibility of the OIE, AU-PANVAC monitored the PPR vaccine cold chain in the field and the quality of the vaccines used in a pilot PPR reduction programme implemented by the OIE in West Africa. A Pan African quality control strategy was developed in collaboration with all the major stakeholders and capacities for quality control and good manufacturing practices were built in all PPR vaccine-producing laboratories. Finally, the PANVAC role and the continental strategy for quality control of PPR vaccines produced and used in Africa were used to support the regional and continental initiatives for the control/eradication of PPR in Africa.


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3.2. The Pan African Quality Control Strategy

As part of the implementation of activity 8 of the OIE Sub-grant, AU-PANVAC and the OIE in collaboration with consultants/experts defined a PPR vaccine quality control strategy, to ensure the production of good quality PPR vaccines in Africa. Activity 8 of OIE Sub-grant to AU-PANVAC – 'Define a quality control strategy for PPR vaccines produced in Africa' – was one of the 11 activities relating to VSPA. The two consultants recruited by AU-PANVAC to develop the Pan African Quality Control Strategy in collaboration with the OIE were Geneviève Libeau, Head of the OIE Reference Laboratory for PPR, CIRAD, and Pierrette Mefomdjo, an expert with several years' experience as head of vaccine quality control in Africa. During the implementation phase of this activity, several meetings were organised by the OIE and AU-PANVAC in collaboration with the consultants, including one which was held at the OIE Headquarters in Paris. The strategy developed and provided a general framework for PPR vaccine quality control with a view to promoting the use of good quality PPR vaccines in Africa. The strategy also determined the roles and responsibilities of PPR vaccine-producing laboratories, PPR vaccine importers, National Veterinary Services and AU-IBAR, National Veterinary Institute of Ethiopia (AU-PANVAC Host Institute) and AU-PANVAC in a PPR eradication campaign. This strategy will enable AU-PANVAC to perform its core mandate of international independent quality control and also support other PPR disease control activities in full.

The key elements of the strategy include:

– general considerations for vaccine quality certification;
– defining the procedures to be followed by PPR vaccine producers for vaccine shipments to AU-PANVAC;
– defining the role of National Veterinary Services and AU-IBAR in ensuring the exclusive use of quality-certified PPR vaccine in the field;
– defining the procedures to be followed by PPR vaccine importers for requesting AU-PANVAC to undertake quality control on imports of PPR vaccine batches;
– defining the role of National Veterinary Institute of Ethiopia for the purpose of facilitating the rapid clearance of PPR vaccine samples from Ethiopian Customs; and
– defining the tests to be undertaken by AU-PANVAC for PPR vaccine quality certification and developing their standard operating procedures.

The major issues considered necessary within the strategy for enhanced and efficient implementation of quality control of vaccines in Africa include:

– ensuring that there is adequate expertise to implement the independent quality control of all PPR vaccines produced and delivered in a sustainable manner;
– promoting the harmonisation of quality assurance for veterinary vaccine manufacture;
– AU-PANVAC playing a leading role in facilitating the harmonisation of veterinary vaccine registration on the African continent;
– strengthening vaccine manufacturing capacity in Africa to meet national and regional vaccine supply needs;
– AU-PANVAC support of the vaccine delivery network by ensuring that transportation, storage and distribution are implemented through an appropriate cold-chain, at national and regional levels; and
– support for the implementation of post-vaccination monitoring by AU Member States.

3.3. Responsibility of AU-PANVAC in the PPR control strategy

3.3.1. Ensuring that adequate expertise exists to implement the independent quality control of all PPR vaccines produced and delivered sustainably

As an OIE Collaborating Centre for quality control of vaccines, AU-PANVAC will continue to ensure that all methods implemented for ensuring PPR vaccine Quality certification are consistent with OIE requirements and standards. The OIE is the world organisation responsible for the development

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and promotion of international animal health standards, guidelines, and recommendations affecting trade in live animals and animal products. The OIE provides a normative framework for laboratory diagnosis and for production and control of vaccines and other biological products through the *Terrestrial Manual* that comprises internationally-agreed methods.

The methods currently used by AU-PANVAC for vaccine testing include:

– test of vaccine identity
– freedom from contamination test
– vaccine efficacy test
– vaccine safety and stability tests.

The relevant *Terrestrial Manual* 2014 chapters that outline the requirements for the production of conventional vaccines before authorisation for use are included in the following chapters:

– Chapter 1.1.7. Tests for sterility and freedom from contamination of biological materials
– Chapter 1.1.8. Minimum requirements for vaccine production facilities
– Chapter 1.1.9. Quality control of vaccines (revision of the chapter is in progress)
– Chapter 1.1.10. International standards for vaccine banks.

The specific chapter dedicated to PPR is Chapter 2.7.11.: Peste des Petits Ruminants.

3.3.2. Promoting the harmonisation of quality assurance for veterinary vaccine manufacture

AU-PANVAC will support AU Member States' (AUMS) laboratories to ensure that all vaccine production procedures and techniques comply with standards and that the vaccines produced meet accepted international standards. AU-PANVAC will continue to support participation of vaccine production laboratories in both internal and external assessments to ensure the harmonisation of Quality Assurance for veterinary vaccine manufacture; and will ensure that they are accredited under ISO 9005 for production and ISO 17025 for internal quality control which covers sterility, safety, potency, identity and stability tests. AU-PANVAC will play a greater role in facilitating/negotiating a regional contract with certified calibration organisations on behalf of the AUMS laboratories for the maintenance and calibration of their laboratory equipment.

3.3.3. AU-PANVAC to play a leading role in facilitating the harmonisation of veterinary vaccine registration on the African continent

Several African countries have in recent years, adopted veterinary medicinal products legislation, but only a few possess an effective regulatory system for licensing of biological products such as vaccines to ensure that that they are pure, safe and potent. In the few countries where regulations relating to vaccine quality standards and registration exist, these regulations vary from one country to the next. In third countries, veterinary medicinal products are licensed on the basis of the application submitted by the suppliers. These tend to be unreliable and do not comply with laboratory or field data from assessment by the National Authorities responsible for vaccine approval.

To remedy this situation, AU-PANVAC was mandated by the Seminar for OIE National Focal Points on Veterinary Products held in Johannesburg in November 2010 to coordinate the harmonisation of veterinary vaccine registration in the Regional Economic Communities (RECs) with the support of Global Alliance for Livestock Veterinary medicine (GALVmed) and the OIE. Since then, several meetings and workshops have been organised by AU-PANVAC and GALVmed in support of this initiative. The harmonised dossier for the registration of veterinary vaccines and biological products in the East African Community (EAC) is already at the stage of implementation. Workshops on harmonising veterinary vaccine registrations have also been organised in the Economic Community of West Africa States

(ECOWAS) and the West Africa Economic and Monetary Union (WAEMU). AU-PANVAC will continue with this initiative within the scope of the Pan African Quality Control Strategy to ensure that registration procedures are harmonised between the RECs and gradually spread throughout the African continent.

3.3.4. Strengthening vaccine manufacturing capacity in Africa to meet national and regional vaccine supply needs

By implementing its mandate, AU-PANVAC has provided technical expertise to vaccine-producing laboratories to strengthen vaccine manufacturing capacity and improve their productivity to meet national and regional vaccine needs. Accordingly, AU-PANVAC recently organised training on PPR vaccine production and quality control within the framework of the OIE Sub-grant for Member States vaccine production laboratories. Furthermore, AU-PANVAC recently assessed the performance of PPR vaccine production laboratories using questionnaires and visits to all vaccine manufacturers in Africa with a view to improving the capacity and quality of the PPR vaccines produced. These crucial activities by AU-PANVAC will enable it to continue to play a leading role in supporting vaccine-producing laboratories in Africa through its laboratories network at continental level to ensure the production of good quality vaccines in Africa. This network will provide a forum for sharing expertise and make for the harmonisation of techniques, training and development of scientific and technical exchanges to resolve major vaccine production-related problems.

3.3.5. AU-PANVAC to support vaccine delivery network by ensuring that transportation, storage and distribution are implemented through appropriate cold-chain, at national and regional levels

Vaccines must be stored properly from the time they are manufactured until they are administered to ensure that vaccines meet the requirements for quality assessment at AU-PANVAC or that they are delivered in good condition in the field. AU-PANVAC will provide support through its laboratory network to ensure that distribution of vaccine is made with minimal adverse impact on vaccine potency. All vaccine shipments from manufacturers to AU-PANVAC for quality control and

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to the field for use will be made in accordance with IATA[4] regulations. AU-PANVAC has produced guidelines describing the procedure to be followed for vaccine handling and shipment from the manufacturer to the field to contribute to ensuring the appropriate shipment of the vaccine from the manufacturer to the country or region, while the national veterinary authorities can proceed with vaccine delivery after shipment. These Guidelines provide the necessary facilities and procedures used in the transport, storage and handling of vaccines through a proper cold chain. AU-PANVAC will also encourage the use of data loggers for cold chain monitoring to be included in the vaccine parcels to ensure cold chain integrity.

3.3.6. Support for the implementation of post-vaccination monitoring by African Union Member States

AU-PANVAC will support vaccination campaigns by implementing vaccine quality control by random sampling in the field during vaccination campaigns. This will be performed as audit missions to monitor the quality of PPR vaccines used during vaccination campaigns in Africa.

The audit will comprise:

a) evaluating the vaccine quality in terms of potency by titration to ensure that vaccine potency is maintained at the time of administration;

b) supporting the sero-monitoring process at national level throughout Africa by ensuring that the relevant laboratory techniques for sero-monitoring are transferred (in collaboration with IAEA) and that data obtained from the field can be used for monitoring the vaccination campaign;

c) making the link between a) and b) to monitor vaccine performance;

d) making the information obtained from the random sampling of vaccines from the field available to the different target groups, especially the vaccine manufacturers and the Veterinary Services.

4 IATA: International Air Transport Association

All these activities will be implemented in support of and in close cooperation with the National Laboratories and Veterinary Services to ensure that effective sero-monitoring is undertaken and the results obtained are processed on completion of the vaccination campaign.

4. Conclusion

The heavy economic and social losses caused by PPR, necessitated international intervention and the conclusion that global eradication was not only the viable option available to overcome the continuing spread and impact of the disease on food security and livelihoods of poor livestock farmers. Just like rinderpest, total eradication of PPR infection from the world is justified and technically feasible. Now, all conditions are in place for ensuring the availability of good quality PPR vaccines produced or imported to Africa. AU-PANVAC will support all global initiatives to control and eradicate PPR incorporating the lessons learned from the global rinderpest eradication campaign. Consequently, the overall objectives of the OIE Sub-grant Project which was to ensure the production and use of good quality PPR vaccines in Africa as a major tool of PPR control and eradication strategies and programmes, has been achieved and is ready for implementation at AU-PANVAC.

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