

# HARMONISATION OF THE REGISTRATION AND CONTROL OF VETERINARY MEDICINAL PRODUCTS IN AFRICA

## The model of the West African Economic and Monetary Union (WAEMU)

### I. Dare

Director for Animal Resources, WAEMU Commission<sup>1</sup>

Original: French

**Summary:** *The main consequences for the veterinary medicinal product sector of the recent wave of liberalisation in Africa's livestock sector have been a proliferation of operators, a diversification of product origin and a general decline in product quality. In this context, all the stakeholders involved agree that legislation on veterinary medicinal products needs to be harmonised among the African countries. Despite this consensus, however, the situation has not changed much in the countries themselves.*

*In order to explore operational guidelines for harmonising national legislation in Africa, with particular reference to the registration and quality control of veterinary medicinal products, the OIE (World Organisation for Animal Health) drew up a status report on the member countries of the OIE Regional Commission for Africa based on the answers to a questionnaire. The report revealed that, even though a number of countries had developed legislative texts on medicinal products, these texts vary widely from one country to another and in only a few cases are they specific to veterinary medicinal products. In most cases, the implementing regulations are not properly enforced. As regards the registration of medicinal products, marketing authorisation (MA) applications receive only cursory examination because approval systems do not have sufficient capabilities. The situation is even more disturbing when it comes to quality control of medicinal products, as most countries do not have effective control systems (laboratories, pharmacovigilance system, etc.). Existing laboratories are facing equipment, human resource and budget problems.*

*In view of all this and of the poor capabilities of individual member countries, a regional approach appears to be the best option for undertaking the necessary reforms.*

*The West African Economic and Monetary Union (WAEMU) could serve as a model for building a system for harmonising national legislation on registration and quality control in Africa. The Regional Economic Communities offer the most appropriate institutional framework for promoting these reforms. The WAEMU reform relies on three complementary mechanisms, governed by a set of regulatory texts:*

- (i) A centralised MA mechanism, structured around the Regional Committee for Veterinary Medicinal Products, which is responsible for examining MA applications.*
- (ii) A single quality control mechanism, by setting up a network of efficient laboratories in the WAEMU member countries.*
- (iii) A regulatory mechanism, represented by the WAEMU Veterinary Committee, an advisory body responsible for coordinating regulatory actions.*

*In the light of the WAEMU experience, two approaches could be used to harmonise MA procedures within a community of nations:*

- (i) A centralised procedure (adopted by WAEMU), which leads to the delivery of a regional MA recognised by all member countries. This procedure could be governed by either an agency for veterinary medicinal products, or a regional committee (a more streamlined structure that would be cheaper to run but would have less extensive tasks than an agency).*

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<sup>1</sup> Dr Issoufou Daré, Directeur des Ressources Animales, Commission de l'UEMOA, 380 rue Agostino Neto, B.P. 543, Ouagadougou 01, Burkina Faso

- (ii) *A decentralised procedure, based on mutual recognition of the national MAs delivered by the competent bodies of the countries concerned.*

*The choice of procedure must be based on an in-depth analysis to assess the feasibility of each system, taking into account the specific characteristics of the Regional Economic Community or of the groups of countries wishing to take part (including institutional framework, budget resources, and so on).*

*With regard to the quality control of veterinary medicinal products, the most efficient way for African countries with insufficient resources to support the MA procedure and to guarantee pharmacovigilance is to form a network of quality control laboratories.*

**Key words:** Africa – West African Economic and Monetary Union (WAEMU) – veterinary medicinal product – marketing authorisation – quality control – regional harmonisation of legislation on veterinary medicinal products

## Introduction

The liberalisation of the veterinary medicinal product sector that began in Africa around ten years ago has resulted in a substantial increase in trade in the veterinary medicinal products, a proliferation of operators and a diversification of products and product sources. One of the effects of liberalisation has been a decline in quality. Increasing numbers of basic products, for which the active ingredients are in the public domain, now come from countries where there is little control over commercial practices. Moreover, the guarantees required for the domestic markets of the countries producing the medicinal products are not generally imposed on exported products. Products prohibited for use in the producer countries in the Northern hemisphere are sometimes used in formulations 'reserved' for the Southern hemisphere. A counterfeiting industry has developed in some countries, including African countries.

This problem has been discussed at a number of regional meetings and a consensus has been reached for harmonising veterinary pharmaceutical legislation, with particular reference to the registration and quality control of veterinary medicinal products. International institutions like the OIE (World Organisation for Animal Health), as well as donors, have lent their support to this idea. However, the process has failed to take off in spite of the compelling technical justifications put forward at regional meetings, the efforts that have been deployed and an apparent consensus. There are several possible reasons for this:

- The drawback of entrusting Veterinary Service departments with harmonisation, making them the main contacts on the issue, is that they do not always have the required institutional, human and financial resources, since the implementation of legislative and organisational reform requires substantial resources.
- In some countries, the texts governing medicinal products are not specific to veterinary medicinal products but are more general in scope, focusing mainly on human medicinal products. One of the drawbacks is that it is still problematic for livestock ministries to bring the texts up to the required level, as they are not the sole initiators.
- The lack of a well-structured, joint operational and institutional framework of reference with decision-making powers has long been a handicap in the region.

In order to identify the current status of regulations in the member countries of the OIE Regional Commission for Africa and to draw up guidelines on future harmonised veterinary pharmaceutical legislation, a questionnaire was sent to the member countries. Of the 50 member countries of the Regional Commission<sup>1</sup>, 11 returned the questionnaires duly completed (see [Appendix I](#)).

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<sup>1</sup> The OIE Regional Commission for Africa comprises 50 members, as follows: Algeria, Angola, Benin, Botswana, Burkina Faso, Burundi, Cameroon, Central African Republic, Chad, Comoros, the Republic of the Congo, the Democratic Republic of the Congo, Côte d'Ivoire, Djibouti, Egypt, Equatorial Guinea, Eritrea, Ethiopia, Gabon, Gambia, Ghana, Guinea, Guinea-Bissau, Kenya, Lesotho, Libya, Madagascar, Malawi, Mali, Mauritania, Mauritius, Morocco, Mozambique, Namibia, Niger, Nigeria, Rwanda, São Tomé and Príncipe, Senegal, Sierra Leone, Somalia, South Africa, Sudan, Swaziland, Tanzania, Togo, Tunisia, Uganda, Zambia, Zimbabwe

## 1. Status report on veterinary pharmaceutical legislation, registration procedures and quality control

Even though most of the Regional Commission member countries did not reply to the questionnaire, the analysis of the partial information received still enables us to identify a few key trends.

### 1.1. Pharmaceutical legislation

An analysis of the completed questionnaires shows that all the countries have either adopted pharmaceutical legislation or are in the process of drafting it (1 country). Above all, it highlighted a wide diversity in the type of legislation, the content of texts, the extent to which they are updated and their scope:

- As most countries regulate pharmaceutical products by means of general texts, usually legislative, incorporating aspects such as veterinary practice and human veterinary products, they do not have highly detailed provisions concerning veterinary medicinal products. As a result there are very few legislative texts devoted specifically to veterinary medicinal products. The main consequence of such cross-disciplinary texts (veterinary and human medicinal products) is to make it difficult to undertake reform because the decision does not fall solely to the Livestock Ministry.
- Implementing texts are highly diverse (decree, order, circular, decision, etc.) reflecting their varying levels of implementation.
- The scope of the texts is relatively more uniform, encompassing the entire medicinal product sector (importation, registration, use, etc.), with the exception of manufacturing and pharmacovigilance, which are less well covered.
- For half of the countries, pharmaceutical legislation is relatively recent (implemented or updated less than five years ago).

However, even though the implementing texts have been adopted, in reality the financial and human resources needed for their implementation (updating and revision of texts, dissemination, control, sanctions, etc.) is often lacking. It would be no exaggeration to say that the enforcement of veterinary medicinal product legislation in African countries tends to be highly perfunctory. The legal and technical shortcomings must therefore be addressed in order to improve the effectiveness of legislation.

### 1.2. Marketing authorisation

Marketing authorisation (MA), the process leading to approval by the competent authority for the importation, distribution and use of veterinary medicinal products, is crucial to ensuring the effectiveness of veterinary medicinal product legislation.

Apart from one country, all responding countries have a registration procedure for veterinary medicinal products, involving a technical commission which usually comes under the aegis of the Ministry of Health where its scope also includes medicinal products for human use. The technical requirements for granting a marketing authorisation are the same for imported products as for locally made products. A list of authorised medicinal products is drawn up, usually by the Chief Veterinary Officer. According to the questionnaire results, most countries update this list regularly. In all countries, in order to make an MA application, the applicant must submit a technical dossier and an administrative dossier, although the type of documents required varies from one country to another.

From the responses to the questionnaire it transpires that the main constraints that countries face with the registration procedure are weak quality-control mechanisms, inadequate human scientific capacities and financial problems. This of course limits the performance of the technical committees, which are deemed to be mediocre to average depending on the country.

In most countries we find that, even where there is an MA procedure subject to assessment by a technical committee, in reality the investigation of MA application dossiers is still tends to be inadequate, consisting merely of reviewing the data provided by the manufacturer (administrative and non-technical assessment), while the final decision relies largely on the trust placed in the MA from the country of origin.

### 1.3. Quality control

The results of all of the surveys conducted in Africa on the quality of veterinary medicinal products highlight the magnitude of the problem of poor quality, poorly manufactured and counterfeit medicinal products in circulation. A study on trypanocides and anthelmintics in Benin and Togo found that 48% of the controlled products were in fact fake drugs [7]. This illustrates the weakness of control systems in Africa.

An assessment of the questionnaire responses from the countries on control structures confirms this to be true. It reveals an almost universal lack of quality control mechanisms for veterinary medicinal products (out of 11 responding countries, only 4 countries have them). For countries that do not have them, the controls are carried out mainly in neighbouring African countries. In countries that do have quality control mechanisms, they tend to be public organisations responsible mainly for the control of chemicals, with under-exploited capacities (25% to 50% according to the responses received). Their capacities are mainly in the field of physical and chemical, toxicological and bacteriological analysis.

The laboratories in the region are often up against problems such as poor quality financial and human resources and a lack of reagents and proper equipment.

## 2. Proposals for harmonisation

The main goal of harmonisation of veterinary medicinal product regulation is to pool the resources and expertise of a group of countries in the management and evaluation of veterinary medicinal products in order to ensure controlled circulation of such products and their rational use, posing no major risk for animals, humans and the environment.

### 2.1. The WAEMU model

Created on 10 January 1994, the West African Economic and Monetary Union (WAEMU), a grouping of eight countries (Benin, Burkina Faso, Côte d'Ivoire, Guinea-Bissau, Mali, Niger, Senegal and Togo) is one of the most successful models of economic integration in Africa, with a single currency, a customs union and a common construction market (harmonisation of the processes of production, market entry of products, control and surveillance is currently in progress).

The main effect of the free movement of goods in the WAEMU area on veterinary medicinal products since 1 January 2000 is a significant growth in trade in such products. It is estimated that the official market will quadruple from 26 billion FCFA in 2005 (at wholesale prices) to 120 billion over the coming years [5]. By way of comparison, the African market was estimated at 120 billion FCFA in 2001 [1].

However, outdated legislation on veterinary medicinal products in the WAEMU member countries [4], coupled with their poor capability to implement legislation and ensure quality control, has led to plans to harmonise regulations. This was based on granting decision-making powers to the executive arm of the Union (the WAEMU Commission) for regulation, market authorisation and the organisation of product quality control. The member countries retain responsibility for product distribution and for actually carrying out controls.

Using this as a starting point, the WAEMU Commission, with the support of the OIE, conducted a survey [4] to answer the following questions:

- What are the options and methods for harmonising veterinary medicinal product legislation in the WAEMU?
- Which unified framework could be set up, in particular for guiding policies on veterinary medicinal products, and for registration and quality control systems?

#### 2.1.1. Survey analysis

The results of the survey analysis were as follows:

- The legislation governing veterinary medicinal products is old and incomplete in all member countries, legislation varies from country to country and no text has yet been adopted to implement the legislative provisions; enforcement is ineffective.
- National MA systems are weak and unreliable.

- Quality control is generally deficient: for medicinal products only one national laboratory is really operational; for vaccines, the three control laboratories are production-linked and therefore not independent.
- The organisation of prescription and distribution is in a transitional phase: a more or less organised reduction in the role of public services, progressing at different rates depending on the country; growing power of the private sector (not only veterinarians but also technicians and auxiliaries and even wholesalers). The definition of the prerogatives for these interventions is still unclear.

### 2.1.2. Study proposals

The main proposals of the study are to:

- a) Create a Regional Agency for Veterinary Medicinal Products (ARMV<sup>1</sup>) to:
- examine the administrative and scientific aspects of all authorisation applications for the manufacture, importation, marketing and wholesale distribution of veterinary medicinal products;
  - submit to the WAEMU Commission draft decisions to be taken on the applications;
  - examine authorisation applications for pharmaceutical establishments;
  - help provide information and training on veterinary medicinal products;
  - define technical standards, maximum residue limits and veterinary pharmacovigilance;
  - support control laboratories and organise networking among them.

MA administrative decisions would be taken by the WAEMU Commission, based on proposals from the Agency, and would be binding on all countries of the Union.

Two options are proposed for organising and financing the Agency:

- minimum option: a staff of 23 employees and a budget of 300 million FCFA.
  - advanced option: a staff of 40 employees and a budget of 500 million FCFA.
- b) Set up a network of existing laboratories that are recognised to be effective, specialising them, at least to begin with, for:
- chemicals: the Niamey, Dakar, and later Bamako, laboratories.
  - vaccines: the Bamako, Dakar, and later Niamey, laboratories.

The laboratories' activities would be coordinated by the Agency, which would determine how complementary their areas of expertise are and would conduct a technical audit to assess their equipment and staffing needs.

- c) Set up a veterinary committee comprising representatives of the competent administrations of each of the member countries. This committee would give its opinion on draft community texts concerning veterinary medicinal products.

### 2.1.3. Comments on the study proposals

The member countries have recognised a centralised MA procedure at regional level to be the only really effective and relevant option in a single market. However, the Union rejected the proposal to create in the short term an Agency to manage the centralised procedure because its long-term survival and effectiveness would require more human and financial resources than the Union could provide.

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<sup>1</sup> ARMV: Agence régionale du médicament vétérinaire

#### 2.1.4. Alternatives to the study proposals

- a) The alternative scenarios proposed mainly involve the organisation of the MA mechanism, and in particular the creation of a regional agency for veterinary medicinal products.

Owing to budgetary constraints on setting up an agency and the resulting recurring expenditure, the 'Agency' option is not thought to be vital in the short term. The proposed alternative is a less onerous institutional mechanism with a more flexible organisation which is less costly to operate, hinging on a body called the Regional Committee for Veterinary Medicinal Products (CRMV<sup>1</sup>). This committee would carry out the key technical evaluation missions of MA applications, and would be composed of scientists from member countries with recognised expertise. The CRMV would meet at least four times a year to examine MA applications and to prepare the draft decisions to submit to the WAEMU Commission. The CRMV would have a Permanent Secretariat housed at the WAEMU Commission. The Secretariat would be responsible for:

- receiving all MA applications;
- verifying the administrative admissibility of application dossiers;
- preparing CRMV meetings;
- preparing the draft administrative decisions after the CRMV has assessed the application dossiers, for submission to the WAEMU Commission.

Under this scenario, the creation of the Agency would be a long-term objective, after assessing several years of operation of the proposed mechanism.

- b) The missions of the Veterinary Committee have been extended beyond veterinary medicinal products to include all matters of community interest in the field of livestock production, especially the safety of animal foodstuffs, animal health, veterinary practice and animal welfare. The Committee would give its opinion on all these matters, prior to the Union bodies taking any decisions. It would propose reforms to the regulatory framework for these matters.
- c) The other study proposals were approved, in particular setting up a network of quality control laboratories in the member countries (under the responsibility of the ministries for livestock and health) and conducting an in-depth technical audit of their technical and scientific capabilities in order to select the laboratories that should be included.

In brief, the reform of legislation on veterinary medicinal products in the WAEMU member countries is based on three mechanisms:

- 1) A centralised MA mechanism, structured around the Regional Committee for Veterinary Medicinal Products which would issue a regional MA recognised by all WAEMU member countries.
- 2) A single quality control mechanism for veterinary medicinal products, by setting up a network of existing laboratories responsible for the control of veterinary medicinal products.

A technical audit of laboratories for the quality control of veterinary medicinal products led to the selection of nine laboratories (for veterinary and human medicinal products), some for the control of chemicals and others for the control of immunological products. All laboratories that agree to form part of the network must meet the specifications [3] concerning the maintenance of their expertise at an optimum level, regular updating of the analytical methods used, the establishment and implementation of a continuing training plan for their staff, contribution to the development of cooperation with the other laboratories in the network, quality assurance measures for their control activities, etc.

- 3) A regulatory mechanism, represented by the WAEMU Veterinary Committee, the Union's advisory body on matters of common interest concerning livestock production which is responsible for coordinating regulatory actions.

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1 CRMV: *Comité régional du médicament vétérinaire*

To refine thinking on veterinary medicinal products and ensure the effectiveness of the three mechanisms, four working themes are under study:

- A real survey on the quality of veterinary medicinal products in the WAEMU area and a few neighbouring countries.
- The feasibility of a regional system to combat fraud in the veterinary medicinal products sector.
- The functioning (malfunctioning) of the market for veterinary medicinal products in the WAEMU area.
- Veterinary practice in the WAEMU area.

The study on the veterinary medicinal products market is available [5]. The terms and conditions for veterinary practice have been debated in the Union on several occasions: the conclusions and proposals resulting from these discussions will be presented to the Union's decision-making bodies in 2007 in the form of community implementing texts.

Community texts on veterinary medicinal product legislation:

With a view to establishing the regulatory framework for the reform and to specify in detail the operation of the institutional mechanisms, five community texts have been drafted laying the foundation for veterinary medicinal product legislation [6]. They were all adopted by the Union's decision-making bodies on 23 March 2006.

❖ **Regulation no. 01/2006/CM/UEMOA on the creation and procedures for the operation of a veterinary committee within WAEMU**

This text creates the WAEMU veterinary committee and lays down the key provisions concerning its composition, scope and operation.

❖ **Regulation no. 02/2006/CM/UEMOA establishing community procedures for the marketing authorisation and monitoring of veterinary medicinal products and establishing a regional committee for veterinary medicinal products**

This community text is the basis of the veterinary pharmaceutical legislation of the WAEMU member countries. It defines the regulatory framework, the institutional procedures and systems required for operating the centralised marketing authorisation system for veterinary medicinal products, for organising the control of veterinary medicinal products and for and monitoring of the veterinary medicinal product market.

❖ **Directive no. 07/2006/CM/UEMOA on veterinary medicinal products**

This text details how Regulation 02/2006/CM/UEMOA should be implemented in the field. Its purpose is to describe the provisions that the member countries must implement for controlling imports of veterinary medicinal products, their movement within the Union, placing them on the market, controls for opening and operating manufacturing facilities, holding them for commercial purposes, importing them and their wholesale distribution.

❖ **Regulation no. 03/2006/CM/UEMOA establishing fees for veterinary medicinal products within WAEMU**

This text establishes the fees and specifies the different types of authorisation and service for which fees are paid, as well as the respective amounts of such fees.

❖ **Regulation no. 04/2006/CM/UEMOA establishing a network of laboratories responsible for the quality control of veterinary medicinal products in the WAEMU area**

This text establishes the network and defines its objectives and its operating and organisation procedures.

## 2.2. Proposals for other countries

### 2.2.1. Registration of veterinary medicinal products

In the light of the WAEMU experience in the matter, two approaches could be used to harmonise MA procedures, a prerequisite for the free (controlled) movement of veterinary medicinal products within a community of countries.

#### *a. The centralised procedure*

This is the system adopted by WAEMU. It is based on setting up a unified regional mechanism that issues a regional MA recognised by all WAEMU member countries. The mechanism is administered by the WAEMU Commission, which has legislative and regulatory powers. This system allows pooling of available resources in the countries (expertise as well as institutional, regulatory, financial and material capacities, and so on), and the fast and effective and delivery of a regional MA.

Most of the countries that replied to the questionnaire opted for this procedure.

The centralised procedure could be used as a model for building a future harmonisation system common to a community of countries. However, this would require:

- A very strong political will by the countries involved to undertake such an approach, which implies a loss of sovereignty on key issues of regulatory powers and transparency in the organisation and administration of the mechanisms to be set up.
- The existence of an institutional framework (e.g. Regional Economic Community – REC) which would act as a regulatory authority for veterinary medicinal products, coordinating registration activities and receiving from members the supranational prerogatives and budgetary resources required to achieve the objectives assigned to it.

For the centralised procedure there are two options:

- The option of a ‘Regional Agency for Veterinary Medicinal Products’ responsible for managing all MA administrative and technical procedures, and in general all matters relating to veterinary medicinal products (training, information, monitoring of veterinary pharmaceutical establishments, etc.). This is the European Union model.

Owing to its budgetary requirements for investment and operation, this option is only possible and viable for RECs with substantial financial resources and a large enough veterinary medicinal product market to warrant its introduction.

- The ‘Regional Committee for Veterinary Medicinal Products’ option, with less extensive duties than the Agency, limited to examining MA applications.

This option requires a lighter system, lower operating costs and can progress towards the optimum desirable organisation (i.e. it is a first step towards the ‘Agency’ option).

The centralised system would be financed from fees charged for examining application dossiers, as well as from REC resources.

A feasibility study could be used to enable each REC wishing to follow this path to determine the option most appropriate to its institutional framework and budgetary capacity.

#### *b. The decentralised procedure*

This system is based on setting up a decentralised mutual recognition procedure for national MAs delivered by the competent bodies that decide to pool their efforts. The countries then legislate to define the scope of pharmaceutical legislation, and in particular the scope of registration and quality control, based on a mutually-agreed reference framework for harmonisation.

However, to be effective and operational, this system calls for:

- Proven institutional and human skills in drawing up and implementing on veterinary pharmaceutical legislation to be available in each country (e.g., national pharmaceutical regulatory authority).

- The existence of a technical structure with qualified human resources (Technical Commission) in each of the countries, capable of delivering an MA recognised by the countries involved which is trusted by the third countries asked to recognise these national MAs (technical requirements, independence and transparency).
- The provision of adequate financial resources for the effective and sustainable operation of all these mechanisms.
- The institution of regular meetings between the national pharmaceutical regulatory authorities.
- The establishment of an effective communication network between these countries.

It has to be admitted that in most African countries these conditions are rarely met.

In fact the WAEMU member countries did not choose the option of mutual recognition of national MAs because most of them do not have (and will not have for a long time) the capacity to manage the mechanisms to be introduced (regulatory authority, technical commission, quality control laboratories).

The decentralised procedure could be operated by a restricted group of countries at regional level (REC) or at continental level.

### **2.2.2. Quality control of veterinary medicinal products**

Investment in the harmonisation of legislation on veterinary medicinal products, in particular registration, would be ineffective unless accompanied by a quality control mechanism for medicinal products which are manufactured locally, imported or authorised to circulate within a given area. This highlights the importance of the evaluation-control-inspection triangle, the triple foundation for ensuring the quality of medicinal products [2].

This means that, whatever the geographical scale, networking of laboratories appears to be the most realistic option, especially in countries that lack control structures. The advantage of integrating laboratories in an African context is to create the critical mass required for expertise and cost recovery, whilst harmonising techniques and training/retraining and developing scientific and technical exchanges, as well as the complementarity of the structures in the network.

Almost all countries that replied to the questionnaires welcomed the prospect of creating a network of quality control laboratories.

In the network context, control must be repositioned within a global strategy that incorporates effective procedures in the various fields of granting MAs, import controls, inspections of the implementation of good manufacturing practices for veterinary medicinal products and the proper operation of pharmaceutical wholesalers selling these medicinal products [3].

However, the limited resources of most African countries suggest that the network should be gradually brought into operation. The strategy should therefore define the priority objectives for each successive phase of network implementation.

For example, since it would not be possible to effectively control the entire range of veterinary medicinal products, it is necessary to determine which ones should be given priority:

- important veterinary medicinal products for the protection of animal health in the area in question: antibiotics, antiparasitic products, vaccines?
- medicinal products imported from countries with no internationally recognised experience in MA?
- imported medicinal products?
- etc.

During the first phase, it would also be possible to focus on the complementarity and comparative advantages of the laboratories in the network to specialise them (chemicals, immunological products, etc.) in order to improve the quality of controls and to reduce costs.

Since the legitimacy of most of the laboratories to grant approvals and carry out controls is often contested on the grounds of their performance and lack of integration into a certification framework, it would be necessary to gradually commit network laboratories to a quality assurance programme.

Moreover, WHO<sup>1</sup> pre-qualification systems for vaccines, medicinal products and laboratories could be used as a model to facilitate the quality control and registration of veterinary medicinal products. This system facilitates the registration of a product that has been pre-qualified by the WHO or the establishment of a list of pre-qualified laboratories for a given product [2]. This approach should be used under the aegis of the OIE, in association with the most advanced laboratories in the African region.

As one of the major obstacles for the network is financing of investment in human resources and equipment, as well as operating costs, there must be clear indications on the options and on how to finance them.

Lastly, to guarantee the sustainability and relevance of the future networks, the most appropriate solution for financing their activities and for the coordination and effectiveness of their interventions in the process of harmonising veterinary pharmaceutical legislation would appear to be to anchor them in the RECs whilst linking them to MA mechanisms.

The competent REC institutions (jointly with the member countries) should define how the network should be set up and operated (strategy, objectives, plans and annual work programme), as well as the obligations of the laboratories in the network (activities, maintenance of the highest level of scientific and technical expertise, etc.) and the obligations of the REC (additional financing, coordination, etc.). A technical audit would nevertheless be necessary within each REC to assess the laboratories' scientific and technical capabilities and to select those that would form part of the network.

It would also be necessary to examine how the future network could be linked to the African Union's PANVAC laboratory, and the procedure for the pre-qualification of vaccines.

A partnership would need to be forged among the various RECs and between the RECs and non-African countries with a view to cooperation.

## Conclusions

In Africa, the main effect of liberalisation of the veterinary medicinal products sector has been substantial growth in the market and a proliferation of operators, products and product sources. In a context where countries' institutional, material and financial capacities are limited, this presents a real challenge to national authorities responsible for safeguarding human and animal health.

It is therefore urgent to guarantee the controlled movement of veterinary medicinal products by setting up registration and quality control mechanisms. Scant resources in most African countries and the size of their domestic markets for veterinary medicinal products has meant that, despite numerous regional meetings on the matter, it has still not been possible to establish the required legislative and regulatory instruments and institutional and organisational framework to improve the situation.

The current experience of WAEMU in harmonising legislation on veterinary medicinal products (in particular registration and quality control) opens up new perspectives. Founded on a regional approach (REC) to the matter, it offers alternatives ranging from a centralised approach involving regulatory, technical and administrative interventions (Veterinary Committee, Agency, CRMV, etc.) where a regional MA is issued and networks of control laboratories are formed, to options such as mutual recognition of national MAs with or without networking of control laboratories.

Analytical and feasibility studies are required to determine the most appropriate options for the member countries of the OIE Regional Commission for Africa and the RECs, backed by the political will of their leaders and the institutional framework in which they cooperate. These studies should examine in particular the comparative advantages of a national or regional approach to the various aspects of harmonisation.

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1 WHO: World Health Organization

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.../Appendices



Appendix I

**Members of the OIE Regional Commission for Africa having responded to the questionnaire on “Harmonising the registration and control of veterinary medicinal products in Africa”**

1. Algeria
  2. Benin
  3. Burkina Faso
  4. Eritrea
  5. Guinea-Bissau
  6. Malawi
  7. Mauritius
  8. Namibia
  9. Tanzania
  10. Togo
  11. Tunisia
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**Organisation chart for the marketing authorisation (MA) procedure (WAEMU)**

