ECONOMIC COMMUNITY OF
WEST AFRICAN STATES

COMMUNAUTE ECONOMIQUE
DES ETATS DE L'AFRIQUE
DE L'OUEST

Sixty fifth Ordinary Session of the Council of Ministers

Abuja, 25 to 26 November 2010

REGULATION C/REG 22/11/10 ESTABLISHING COMMUNITY PROCEDURES FOR MANAGEMENT OF VETERINARY DRUGS OR BIOLOGICS

THE COUNCIL OF MINISTERS,

MINDFUL of Articles 10, 11, and 12, of the ECOWAS Revised Treaty as amended and on the establishment of the Council of Ministers and defining its composition and functions;

MINDFUL of Articles 25 of the ECOWAS Revised Treaty on Agricultural Development and Food Security which prescribes to member states that they pledge to cooperate in the area of protection of plant and animal species control of animal and plant diseases; and the strengthening of existing institutions in the area of natural disaster management

MINDFUL of Decision A/DEC.11/01/05 on the adoption of the Agricultural the ECOWAS Agricultural Policy;

MINDFUL of Decision C/DEC/1/5/81 on the components of control of hunger, extinction of certain plant and animal species, funding programs. research and agricultural projects of production, storage, and treatment of agricultural products;

MINDFUL of Decision A/DEC 5/10/98 of the Conference of Heads of States and Government on transhumance within the ECOWAS region;

MINDFUL of the Supplementary Act A/SA 12/01/07 on the establishment of a Sub-regional Mechanism of Coordination and Prevention and Response against Avian Influenza in West Africa,

MINDFUL of Regulation C/REG.23/11/10 on the establishment, composition, and modalities of operation of the Veterinary Regional Committee within ECOWAS,

MINDFUL of Directive No ... dated 22/11/10 on the Veterinary Pharmacy

CONSIDERING the heterogeneity of national provisions in the area of marketing authorization of veterinary drugs or biologics;

RECALLING the WTO SPS Agreements (Marrakech Accord) on animal and plant health as well as food safety.

WONDERING the risks to human and animal health and the environment that may arise from inadequate monitoring of the flow and use of veterinary drugs or biologics;

CONSCIOUS of the need to harmonize market authorization procedures, through establishment of a community agency in charge of assessing dossiers and through instauration of a centralized market observatory;

TAKING into account the necessity to provide financial arrangements necessary to establish the implementation of the community regulation in the area of veterinary drugs or biologics;

TAKING also into account the necessity to ensure that good quality, effective and safe veterinary drugs or biologicals are marketed in the ECOWAS region;

NOTING that the current inadequacy of available resources does not enable individual ECOWAS member states to have a laboratory specifically assigned the task of quality control of veterinary drugs or biologics;

DETERMINED to organize the networking of laboratories and harmonize their operation in order to maximize their effectiveness and minimize the risks to animal and human health in the ECOWAS region;

ON RECOMMENDATION of the Meeting of Ministers in charge of Agriculture and Animal Resources, held in Abuja on 23rd February 2010

ENACTS

CHAPTER 1: DEFINITIONS AND SCOPE OF APPLICATION

Article one: Definitions

In the terms of this Regulation, the terms below are defined as follows:

1) Veterinary drug

Means those Biologicals, Pesticides and products of bio-technology that safe guard the health and welfare of aquatic and terrestrial animals to enhance their

production and ensure that foods produced from the animals are safe for human consumption and free of potentially harmful residues; and should not cause harm to the environment – plants, insects, non-target animals and wildlife.

Any substance or composition which could be administered to an animal in order to establish a medical diagnosis or restore, correct or modify physiological functions or behaviour.

2) Substance

Any matter or material the source of which could be:

- animal, such as: the micro-organisms, complete animals, organ portions, animal secretions, toxins, substances obtained by extraction, blood by-products,
- plant, such as: the micro-organisms, plants, plant portions, plant secretions, substances obtained by extraction from it,
- Chemical, such as: the elements, natural or synthetic that could be organic or inorganic.

3) Pharmaceutical formulations

Any drug prepared to be put on the market under a special name and particular packaging.

4) Raw material for veterinary drug

Any raw material(s) used for the manufacture of veterinary drug, that is not a pharmaceutical formulation, put on the market in a pharmaceutical form usable in its natural form without any change.

5) Veterinary biologics

Means any of the substances commonly known as vaccines serum, toxin, antitoxin, antibody and antigen used in disease prevention, diagnosis and treatment in animals.

6) Medicinal pre-mixes

Any veterinary drug used for the subsequent manufacture of medicinal feed.

7) Medicinal feed

Any mixture of drug pre-mixes and feeds prepared prior to being put on the market and destined to be administered to animals without transformation, because of the curative or preventive properties or other properties of the premixes such as those listed under item 1

8) Generic drug

Any veterinary drug which has the same active principle or substance in the same pharmaceutical form as the reference drug and whose bioequivalence with the reference drug has been demonstrated by appropriate bioavailability studies.

9) Extemporaneous preparation

Any preparation made upon prescription by a veterinary doctor which at the time of use meets a specific therapeutic need in particular location and time.

10) Withdrawal period (Withdrawal Period)

This is the necessary period between the last administration of a veterinary drug on an animal in normal conditions of use and the time meat or milk are obtained from the same animal, The withdrawal period guarantees that the animal's food products such as meat or milk does not contain any amounts of residues exceeding the maximum established limits for residues in such food commodities.

The maximum limits of residues to be taken into account in order to preserve the consumer's health are as much as possible those established by the Codex Alimentarius pending the establishment by ECOWAS of the maximum limits of residues at the community level.

11) Experimentation

All trials, research or experiments hereinafter designated as trials, which are made in order to obtain marketing authorization or modification. It is an act of testing the efficacy or safety of the drug or biologics.

12) Promoter

Any manufacturer or group of manufacturers who applies for clinical or field trial or authorisation of veterinary drugs or biologics.

13) Experimenter

Any individual who carries out any trial, research or experiment on a veterinary drug or biologic with the purpose of discerning its efficacy and safety.

14) Investigator

Any individual who conducts a clinical trial on a veterinary drug and biologic to determine its efficacy and safety.

15) Veterinary enterprise

Any economic project or entity of an industrial or commercial nature in the area of veterinary drugs or biologics.

A veterinary enterprise can involve several veterinary pharmaceutical establishments.

16) Organisation

An organised public establishment or association carrying out a veterinary pharmaceutical activity

17) Veterinary pharmaceutical establishment

Any structure or institution containing a grouping of human and material resources used for industrial or commercial operations in the area of veterinary drugs veterinary drugs or biologics. It may consist of a portion of a building or one or several buildings in a single geographic area.

18) Manufacturer

Any veterinary pharmaceutical establishment carrying out, for wholesale or free donation or use the manufacture of drugs and biologics .

19) Manufacture of veterinary drugs or biologics

This is any industrial pharmaceutical activity leading to the production of a veterinary drug or biologic as defined under point 1, namely the supply or acquisition of raw materials and packaging materials, putting in galenical form, quality control, release of batches of drugs or biologics as well as corresponding storage operations, as defined by the good practices applicable to this activity.

The manufacturer, or his representative shall carry out monitoring operations on the drugs or biologic to determine the withdrawal period.

20) Operator

Any licensed or authorised enterprise person or body that operates one or several veterinary pharmaceutical establishments involved in the production and sale of veterinary drugs or biologics.

21) Operation

This is the manner of functioning of a veterinary pharmaceutical establishment. It consist of the sale or free donation, publicity, information, pharmaco-vigilance, batch monitoring, drug withdrawal, as well as storage.

The operation is handled either by the holder of the marketing authorization, or for that holder, by another enterprise or body.

22) Agent

Any individual, enterprise or organisation or several veterinary pharmaceutical establishments authorised to carry out, by order and on behalf of one or several holders of marketing authorization (MA) or users, the storage and wholesale distribution of veterinary drugs or biologics.

23) Wholesaler

Any enterprise or organism or person involving one or several pharmaceutical establishments licensed to carry out the purchase, importation or sale and distribution of veterinary drugs or biologics in large quantity other than those submitted to clinical tests.

24) Wholesale distribution of veterinary drugs or biologics

Any pharmaceutical activity of a commercial nature which includes the purchase, sale, distribution, importation or exportation of veterinary drugs or biologics or any other commercial operation dealing with veterinary drugs or biologics, for profit or not, except the provision by a manufacturer of veterinary drugs or biologics manufactured by self, or the retail sale of veterinary drugs or biologics by individuals authorized to conduct such activity in accordance with the national regulation of individual member states.

25) Medicinal feed manufacturer

Any enterprise or organisation or person including veterinary pharmaceutical establishments authorised to carry out, for the purpose of selling, or donating, or conducting clinical tests on the animal, the manufacture of medicinal feed ; such manufacture involves operations about the purchasing of medicinal premixes, packaging materials, mixing, quality control, corresponding storage operations, corresponding controls notably in the area of homogeneity as well as batch monitoring and if need be, withdrawal of the batches.

For those medicinal feeds subjected to clinical trials, the operations of distribution, monitoring of the said drugs and, if need be, their withdrawal will be carried out by the manufacturer, or his authorised representative..

26) Medicinal feed importer

Any enterprise or organisation or persons including veterinary pharmaceutical establishments authorised to carry out, for purposes of sale, free donation or conduct of clinical trials on the animal, importation, storage, quality control of medicinal feed batches coming from Non-Community Member States. For those medicinal feeds subjected to clinical trials, the operations of distribution,

monitoring, and if need be, withdrawal, are carried out by the importer or his authorised representative.

27) Medicinal feed distributor

Any enterprise or organism or persons including veterinary pharmaceutical establishments authorised to engage in the purchase and storage and distribution of medicinal feed other than those subjected to clinical.

28) Importation

The bringing in or entry into the territory of the Community of batches of veterinary drugs or biologics, from Non-Community Member States or Foreign countries to be sold wholesale, to be donated or to be used in animals..

29) Exportation

The shipping away or sending out from the territory of the Community of batches of veterinary drugs or biologics manufactured within these territorial limits or previously imported for sale or exchange.

30) Intra-community movement

Exchange or shipping or movement of batches of veterinary drugs or biologics between Community Member States, be those drugs manufactured in a Member State or imported from a third country for use or sale..

31) Side-Effects

Any harmful and unwanted reaction, occurring with doses of the drug or biologic normally used with animals for the prophylaxis, diagnosis or treatment of a disease or modification of a physiological function.

32) Human Side-effects

Any harmful and unwanted reaction, occurring with a human being following exposure to a veterinary drug or biologic.

33) Severe side-effects

Any side-effect leading to death, or is likely to endanger life, or provoking a major disability or significant inability or translates into a congenital abnormality/malformation or which causes permanent or extended symptoms in treated animals.

34) Risk related to veterinary drugs or biologics

Any risk related to the use and handling of a veterinary drug and biologics for human or animal health, or the environment.

35) Marketing Authorisation

The approval of certain concentration of chemical and biologic substance(s) in a given pharmaceutical form under a unique trade or generic name for a specific period and conditions for the purpose of use in animal diseases treatment, prevention and control and control or for modification of physiological function(s) or change in behaviour. .

36) Pharmacovigilance of Veterinary Drugs and biologics

This relates to the detection, assessment, understanding, prevention and communication of adverse effects, in particular, short and long term side effects of drugs and biologics.

Article 2 : Scope of Application

1. The present Regulation shall establish community procedures, for the authorization of surveillance and control of veterinary drugs and biological as well as the establishment of a Regional Committee for Veterinary drugs and iological for assessment of drugs.

2. The provision of these regulations shall apply to veterinary drugs and biological intended to be put on the market, in the form of pharmaceutical products, raw material for veterinary drugs and biological as well as medicinal premixes.

3. The present regulation shall not apply to medicinal feed. However, medicinal feed can only be manufactured from medicinal premixes having received an authorization to be put on the market in accordance with Article 10 of this Regulation.

4. The provisions of the current Regulation shall not affect' the competences of member states authorities in the area of control of importation and wholesale distribution establishments, conditions of wholesale distribution and retail sale of veterinary drugs and biological which (for streamlining purposes) will be the subject of a Directive.

5. The setup of the centralized process for the marketing of veterinary drug based on scientific criteria of quality safety, and efficiency aimed at free circulation and movement of veterinary drug in ECOWAS.

CHAPTER 2: ESTABLISHMENT OF THE REGIONAL COMMITTEE OF VETERINARY DRUGS AND BIOLOGICALS AND ITS PERMANENT SECRETARIAT

Article 3 : Establishment and Functions

1. A Regional Committee of Veterinary Drugs and Biologicals (RCVD) called « Regional Committee » is hereby established. The Regional Committee reports to the ECOWAS Commission;

2. A Regional Committee shall be composed by a Chairman and 16 experts all of whom shall be nationals of the ECOWAS Community.

3. The Regional Committee shall, at the request of the ECOWAS Commission, assess the market authorization files and major modifications, from the preparation of proposals to issue, may refuse or ask for additional information, may suspend or withdraw authorisation to put on the market. It also shall advise on all measures related to pharmaco-vigilance. It shall establish a centralized process of marketing veterinary drugs and biologicals, on the basis of scientific criteria of safety and efficacy and shall target the free movement of veterinary drugs and biologicals.

Article 4 : Permanent Secretariat

1. The Regional Committee shall have a permanent secretariat hereinafter called « Regional Committee Secretariat », hosted at the headquarters of the ECOWAS Commission and in charge of managing administrative matters.

2. The Regional Committee Secretariat shall also be tasked with the study of the administrative admissibility of the requests presented following the centralized process for issuance of an authorization to market veterinary products, modification, renewal, transfer to a new bearer, in accordance with the Chapter 6 of this Provisions, as well as management of pharmaco-vigilance.

3. The Regional Committee Secretariat shall prepare regular updates and disseminates the list of authorized veterinary drugs and biologicals.

4. The President of the ECOWAS Commission will decide the composition of the Secretariat

Article 5 : Chairman and Experts of Regional Committee

1. The Regional Committee shall be led by a Chairman who shall be a citizen of the Community and appointed by the ECOWAS Commission for a period of three years, renewable only once.

2. Experts shall be appointed on an individual basis, depending on their skills and scientific experience in the evaluation of veterinary drugs and/or biologicals.
3. The expert selection process shall be managed by the ECOWAS Commission. It shall comprise an application process which is open at the regional level. The ECOWAS Commission may request the World Organization for Animal Health or any other competent body to assist in the selection process. The Regional Veterinary Committee shall also be called on to give an opinion during the expert selection process.

4. The experts must present necessary guarantees of competence and moral integrity and have adequate resources for the accomplishment of the expert work.

Article 6: Operation

1. When the Regional Committee assesses a veterinary drug or biologic, one of its members shall be designated to serve as rapporteur and coordinate the assessment. In this case, one or two additional experts whose names shall be found on the list of experts on veterinary drugs and biologicals (LEMV) mentioned under article 7 of Regulation, shall be appointed to assist rapporteur in his assignment.

2. The Chairman of the Regional Committee shall appoint, after consulting with the members of this Committee, the rapporteur and the expert(s) who shall work with him for development of the assessment report.

3. The Chairman of the Regional Committee and his Secretariat shall ensure that all Committee members in turn to act as rapporteurs.

4. On proposal of the rapporteur, the Regional Committee Secretariat, in consultation with the Chairman of the Regional Committee, shall submit the veterinary drug to a laboratory belonging to the network of laboratories for quality control of veterinary drugs and biologicals for analysis, or should the case arise a laboratory recognized by the World Organization for Animal Health (OIE).

5. The Regional Committee shall meet at a frequency defined according to the number of requests deposited at average of four times a year. An emergency meeting may be convened by its chairman in consultation with the secretariat should the need arise.

6. In the course of its deliberations, the Regional Committee shall ensure that it reaches a scientific consensus agreement. If such consensus cannot be

reached, the accepted opinion shall be that of the absolute majority of members. The committee shall include in its report and at the request of the parties, the different positions with their reasons for differing.

7. The chairman does not vote.

Article 7: Experts List

1. Member States shall transmit to the ECOWAS Commission a list of experts with a proven experience in the areas of drugs assessment, immunology, quality, safety and efficacy of veterinary drugs and biologicals by indicating their qualifications and areas of expertise.

2. Such list of experts shall include the laboratory expert members of the network of quality control laboratories of veterinary drugs and biologics.

4. Such list of experts in veterinary drugs or biologics shall be regularly updated.

4. The experts shall be called on to intervene in the assessment of requests for authorization to put on the market or to participate in specific working groups set up by the Regional Committee in agreement with the ECOWAS Commission or in order to carry out analyses of veterinary drugs and biologicals.

Article 8: Remuneration of Members

The participation of Regional Committee members in proceedings of the said Committee and expert services in a plenary session or specific meetings shall entitle them to a fixed rate honorarium determined by the Chairman of the ECOWAS Commission.

Article 9: Incompatibilities

1. The composition of the Regional Committee of veterinary drugs or biologics shall be officially announced. During the announcement of individual nominations, the professional qualifications and relevant experience of each member are specified.

2. The members of the Regional Committee and experts mentioned under Article 7, shall not have vested financial interests or other in the pharmaceutical industry, which might call into question their impartiality. Any indirect interest related to this industry shall be reported in a register held by the Secretariat of the Regional Committee and can be accessed by the public.

CHAPTER 3: MARKETING

No veterinary drug shall be given free of charge, or for a fee or administered by a veterinarian to an animal if a marketing authorization has not been issued), except in the case of clinical trials of veterinary drugs and/or biologicals, approved by the Commission under conditions described by Article 23 of this Regulation.

Article 10: Marketing authorization

1. Except for medicinal feed, no veterinary drug and/or biological shall be put on the market of a member state for or without charge without marketing authorization issued by the ECOWAS Commission.

2. The medicinal feeds shall be prepared only from medicinal premixes having received marketing authorization in accordance with the this Regulation.

3. The authorization to put on the market shall be issued to a natural person or legal entity designated hereinafter as "the holder of the marketing authorization" for a veterinary drug or biologic corresponding to a pharmaceutical product or a raw material for veterinary drug or biologic as defined under Article 1, for a qualitative and quantitative composition and a given pharmaceutical form as well as for use on one or several animal species.

4. The authorization to put on the market shall be issued to a holder residing in one of the Member States of the Community. If the latter is not residing in one of the States of the Community, he shall appoint a local representative in charge of following up on the marketing authorization request and after obtaining it, to follow up on pharmaco-vigilance, management claims, batch monitoring and withdrawal if necessary.

5. It shall only be granted if the holder shows evidence of best practice as follows:

    i) He has a manufacturing method and control procedures guaranteeing the quality of the drug at the level of the serial production,

    He has carried out verification of the pharmaceutical properties and that of safety to animals, humans, and the environment,

    ii) For those drugs for use in animals producing commodities for human consumption, the maximum amount of residues depending on the active substances that they contain and potentially harmful residues for humans in commodities derived from such animals is determined, as well as the withdrawal period necessary for

obtaining them is justified and that he has a method to detect such residues.

iii) That he has proceeded to the verification of the effectiveness of the drug in the light of the claimed therapeutic indications.

6. The authorization to put on the market shall be issued for a period of five (5) years, and renewable on the terms found under Article 33.

Article 11: Waiver

1. Any drug which shall be authorized on the market shall be subjected to special monitoring given the state of progress of veterinary scientific knowledge. In this case, the marketing authorization is reviewed annually.

2. If, because of the rarity of indications planned or because of the state of advancement of scientific knowledge, the demand is not coupled with the set of planned justifications, a marketing authorization can be granted, under reserve that the veterinary drug shall be obtained on prescription by a veterinary doctor and administered by the latter.

Article 12: Mandatory Labellings

The marketing authorization shall be coupled with:

a. A mandatory labelling on the primary packaging, the external packaging as well as on the directions for use, special mentions for the security or for the protection of health, notably the particular precautions of use and other warnings resulting from clinical and pharmacological tests planned under article 22, paragraph 3, and under article 23, paragraph 1, or which, after the commercialization, result from the experience acquired during the use of the veterinary drugs and/or biologicals ;

b. Issuance of particular prescription rules and restricted conditions necessary for animal and human protection;

c. Technical conditions which shall be observed by the manufacturer of corresponding medicinal feeds, as well as the modalities of use of such medicinal feeds, which is written on a medicinal pre-mix.

Article 13: Rejection or refusal

The marketing authorization shall be refused if it appears:

a. that the application and accompanying file are not in line with the contents set under articles 22 or 23.,

b. that the veterinary drug or Biologic does not have the qualitative or quantitative composition claimed,

c. that it is harmful under the conditions of use indicated in the application file,

d. that the therapeutic effect announced is lacking on the intended animal species,

e. that putting on the market of the veterinary drug or Biologic is likely to seriously jeopardize human or animal health;

f. that, for drugs intended for use on commodity producing animals intended for human consumption, the withdrawal period indicated in the dossier is inadequate to ensure that food commodities derived from the treated animals would not contain residues at levels likely to be dangerous for consumers, or that it is inadequately justified.,

g. that the veterinary drug or biologic presented for use is prohibited on ECOWAS territory.

Article 14: Suspension: conditions, motives

1. The marketing authorization shall be suspended for maximum period of one month by the Chairman of the ECOWAS Commission when it appears that:

a. It does not have the required qualitative or quantitative composition,

b. The controls provided for in the file have not been carried out,

c. The veterinary drug or biologic is harmful in the conditions of use indicated in the dossier of request for authorization to put on the market based on the pharmaco-vigilance data collected after the marketing on ECOWAS territory or coming from a third party,

d. The drug present a risk for human or animal health,

e. For, those drugs intended to be used on animals producing commodities intended for human consumption, the withdrawal period indicated is inadequate to ensure that the food commodities derived from the treated animal would not contain residues which could present dangers for the health of the consumer,

f. The therapeutic effect claimed is not seen on the intended animal.

g. The use for which the veterinary drug is presented is subject to a ban by virtue of other community provisions,

h. The documentation and information provided in the application dossier turn out to be erroneous,

i. The documentation and information provided in the application dossier have not been modified according to article 31, paragraphs 1 and 2 of this regulation,

j. The holder of the marketing authorization has not advised the Regional Committee about any new information in accordance with article 31, paragraph 3 of this regulation.

k. The labels or instructions are not in line with the labelling requirements or specifications under articles 36 through 39 of this regulation.

2. The President of the ECOWAS Commission shall withdraw the marketing authorization if the reasons for suspension are not addressed on the expiration of the deadline .

Article 15: Modification of the marketing authorization

The President of the ECOWAS Commission, upon the advice of the Regional Committee shall modify the marketing authorization, of a veterinary drug and/or biological in order to limit its contra-indications, the conditions of issuance, modify its dosage, add a contra-indication or any other preventive measure when it appears, subsequent to the assessment of pharmaco-vigilance data, that the veterinary drug does not meet the conditions stipulated under Article 22 of this Regulation.

Article 16: Modification and information

1. When the decisions reached on modification, suspension or withdrawal are justified, the channels and appeals deadlines are indicated. Except in case of emergency, the decision is upheld only after the holder of the marketing authorization has been invited to present his remarks. Such decisions are reported to the holder of the marketing authorization and relevant authorities in the Member States.

2. When the authorization is suspended, withdrawn or formally modified, the holder shall immediately notify the stock holders so that the latter take all necessary steps to end to the distribution of the veterinary drug or biologic concerned. If such steps are not taken within reasonable period compatible with the public health interest as defined in the decision, the Chairman of the ECOWAS Commission shall ensure that in conjunction with the relevant authorities of Members States, all appropriate measures are taken.

Article 17: Recall of authorized batches

Independent of the suspension, formal modification and recall decisions as mentioned above and as a protective measure, the President of the ECOWAS Commission may prohibit the issuance of certain batches of drugs authorized which are the subject of a dispute and request that the holder of the marketing authorization recall those batches.

Article 18: Exceptions : provisional import authorization

1. Not withstanding the provisions of Article 10 (1), in the event of a severe epizootic disease outbreak, a member state can temporarily authorize :

   a. the importation by a veterinary pharmaceutical establishment:

   b. The use by one or several veterinary doctors, of veterinary drugs on its national territory, without the marketing authorization under article 10, in the absence of adequate drugs and after having informed the Commission on the detailed conditions of use.

2. Within a period of six months, the ECOWAS Commission, after consulting with the Regional Committee, shall take a position on the use of the drug by issuing if necessary a special provisional authorization.

3. In case of need, the ECOWAS Commission may extend such authorization to other member states.

4. The member states shall prepare a quarterly bulletin of the epidemiological situation and the use of the drug to the ECOWAS Commission.

Article 19: Modes of special administration of veterinary drugs

1. When there are no veterinary drugs authorized for a given condition, a veterinary doctor can, in exceptional cases, administer to one or more animals on a farm:

   a. A veterinary drug which has been authorized by virtue of this Regulation for animals of another species or animals of the same species, but for a different disease, or

   b. b) if the drug referred to under item (a) does not exist, a human drug authorized in the Member State concerned by virtue of the national regulation;

   c. c) if the drugs referred to under items a) and b) do not exist, a veterinary drug authorized in a third party state. In this case, the veterinary doctor requests a special authorization for importation and use, limited to his client, from his country's veterinary authority. The veterinary authority of each member state shall address the list of drugs imported through this process every year to ECOWAS.

2. The provisions under paragraph 1 above shall apply only on condition that the drug, when administered to commodity producing animals intended for human consumption, contain only substances already present in a veterinary drug authorized in such animals in the Community and that the veterinary doctor in charge of administering the drug sets an appropriate withdrawal period.

3. If no withdrawal period for the animals concerned is indicated for the drug utilised, the withdrawal period specified must not be less than:

   a. 7 days for milk;

   b. 14 days for poultry meat;

   c. 28 days for the meat of mammals. including fats and giblets;

   d. 500 degrees - day for fish.

Article 20 : Information register

In the course of implementation of the provisions of Article 20 by a veterinary doctor, the latter shall hold a register of all appropriate information, namely:

   a. The date of visit of the animals,

   b. Owner identification,

   c. Number of animals treated,

   d. Diagnosis,

   e. Drugs prescribed,

   f. Doses administered,

   g. Duration of treatment as well as recommended withdrawal period.

He shall make such documentation available to the relevant authorities, for inspection purposes, over a period of at least three years.

Article 21: Waiver of presentation of trial results

1. By waiver as per article 25, and without prejudice to the rights on the protection of industrial and commercial property, the applicant shall not be bound to provide the results of toxicological, pharmacological and clinical trials, if he can demonstrate:

a) That the veterinary drug or biologic is essentially similar to a drug authorized in the Community and that the holder of the marketing authorization of the original veterinary drug or biologic has agreed that the toxicological, pharmacological and/or clinical documentation found in the dossier of the original veterinary drug or biologic be used for processing the application in question;

b) That the component(s) of the veterinary drug or biologic have a well established medical use and present a proven efficacy as well as an acceptable level of safety, using a detailed scientific bibliography;

c) That the veterinary drug or biologic is a generic of an authorized drug in the Community according to community arrangements in force or in a third country, for at least ten years, and commercialized in the Community.

2. The President of ECOWAS Commission shall by an implementation regulation apply by analogy in the course of the presentation of a detailed scientific bibliography as per paragraph 1, item b above.

Article 22: **Trial report : validity**

1. The documents on the trials referred to under article 21 of this Regulation are produced and signed by experimenters or investigators and endorsed by the authorised person or ethical committee.

2. Any trial undertaken should generate a report produced by the experimenter or investigator who has carried it out. Such report must include:

   a. The identity of the experimenter(s) or investigator(s), title(s), experience(s) and functions;

   b. The dates and places of the trials;

   c. Information on the drug subjected to the trial;

   d. Information on the control drug or to the placebo;

   e. Presentation of the results of trials conducted;

   f. The trials shall observe, depending on the case, best practices involving the principles of Good Laboratory Practices (GLP) or Good Clinical Practices (GCP) set at the international level.

3. The documents referred to under article 21 and 25 of this Regulation, shall be produced and signed by experts having the technical or professional qualifications required, before being presented to the ECOWAS Commission.

a) The qualifications and experience required for the aforementioned experts are the following:

i) For the expert working on the documentation on clinical trials: according to the case, a veterinary degree or pharmacy degree or a degree in chemistry, biology, micro-biology or bio-technology and a practical experience of no less than five years, either in the field of research and development, or in production, or in the control of drugs;

ii) For the expert working on the documentation on safety trials : a veterinary degree or a doctorate in clinical pharmacy or a degree in general or special toxicology and a practical experience of at least five (5) years in this discipline;

iii) For the expert preparing the documentation on residue studies: a degree certifying a general or special qualification in the area of pharmacology, toxicology, biology, or chemistry, and a practical experience of at least five (5) years;

iv) For the expert preparing the documentation on preclinical trials: a degree, certifying qualification in pharmacology, toxicology, or biology and a practical experience of no less than five (5) years;

v) For the expert working on the documentation on clinical trials: a veterinary doctor degree and a practical experience of no less than five (5) years.

b) According to their qualification, the experts' role shall be as follows:

i) Carry out the activities in their discipline (analysis, pharmacology and related experimental sciences, clinical) and objectively describe the results obtained (quantitative and qualitative);

ii) describe the findings that they made according to the Standards and Analytical Protocols, of safety, preclinical and clinical trial of veterinary drugs or biologics referred to under paragraphs 3 of article 22 and notably:

- For the analyst, to make a decision about the conformity of the drug to the declared composition, and justify control methods which will be used by the manufacturer;

- For the pharmacologist as well as the specialist with adequate skills in toxicology to make a decision on the safety or possible toxicity of the drug, its pharmacological properties, degree of tolerance of the drug and the validity of the withdrawal period;

- For the clinician, validate the data dealing with the effectiveness of the drug on the animals treated, at the recommended dose, on the tolerance of the drug and on the possible contra-indications and side-effects.

iii) When there is a reference to the published scientific literature, experts shall justify resorting to this bibliographic documentation and shall demonstrate that it meets the requirements of protocols found in Annex II, on account notably of the pharmaceutical form and the components of the excipient.

c) The experts shall present the criteria of competence and guarantees of integrity of honorability necessary to have adequate resources for conducting the expert works. A brief curriculum vitae of the expert is found in the annex of every report. Should the case arise, the professional links with the promoter shall be reported.

Article 23: Characteristics of Veterinary Products

The summary characteristics of the product include the following information in the order indicated:

a. name of the veterinary drug;

b. qualitative and quantitative composition in active substances and components of the excipient??? which must be known for a good administration of the drug. International generic names recommended by the World Health Organization (WHO) are used whenever such names exist or, if not the common generic names or chemical names are used;

c. pharmaceutical form;

d. pharmacological properties and, to the extent that such information is useful for therapeutic use, pharmaco-kinetic elements;

e. Clinical information:

i. Target species,

ii. indications of use, by specifying the target species,

iii. contr a-indications,

iv. side effects (frequency and seriousness),

v. special precautions of use,

vi. usage in case of pregnancy and lactation,

vii. medicinal interactions and others,

viii. dosage and mode of administration,

ix. over-dosage (symptoms, emergencies, antidotes should the case arise),

x. warnings special to each target species.

xi. withdrawal period,

xii. particular precautions to be taken by people administering the drug to animals ;

f. Pharmaceutical information:

i. major incompatibilities,

ii. limited duration of use, if necessary after the drug has been reconstituted or when the container is opened for the first time,

iii. speci al storage precautions,

iv. nature and content of container,

v. especial measures to take during elimination of unused medication or wastes, should the need arise;

g. name or corporate name and permanent address or head office of the holder of marketing authorization and those of the local representative as per article 13, paragraph 2 of this Regulation

Article 24 : Clinical trials

1. The promoter who wants to make a trial shall forward to the ECOWAS Commission within three (3) months a dossier including the following information:

a. Promoter's identification;

b. the trial context:

i. title and goal of the trial,

ii. place or places of the trial,

iii. ide ntity of investigator(s), their titles, experiences, and functions,

iv. if the latter is distinct from the promoter, identification of the manufacturer of the drug subject to trial and of the placebo or control drug,

v. identification of the importer for imported drugs,

vi. references for market authorizations obtained in a third country for the drug under trial as well as those of possible decisions to refuse, suspend or withdraw such authorizations.

vii. the date when it is planned to begin trial and the possible duration of the trial;

c) The trial protocol specifying in particular:

i. the type of trial and design,

ii. the therapeutic indication object of the trial,

iii. the dosage of the experimental drug and, if necessary, that of the control drug,

iv. the length of the treatment,

v. the number of animals that should eventually be included in the trial and the principal inclusion criteria;

d. For the veterinary drug experimented:

I. its name as defined under article 25, paragraph 2 or its code name,

II. its pharmaceutical form,

III. its qualitative and quantitative composition by using, if necessary, international designations if any or by default, the designations of European or French pharmacopoeia,

IV. the possible presence of a new active principle,

V. the indication, if known, of chemical classes, pharmacological and clinical that the active principle belongs to,

VI. manufacturers' full location address,

VII. the method of administration,

VIII. the intended animals,

IX. the proposed withdrawal period, if necessary

X. manufacturing and expiry dates

XI. the batch number;

e. For a reference drug:

I. its name,

II. its pharmaceutical form,

III. its qualitative and quantitative composition in active principles,

IV. the withdrawal period, if necessary

V. batch number

VI. manufacturing and expiry dates;

VII. manufacturer's full location address

f. For a placebo:

I. its pharmaceutical form,

II. manufacturer's full location address,

III. its qualitative and quantitative composition

IV. batch number

V. manufacturing and expiry dates;

g) The synthesis of the other trials conducted previously and referred to under Article 22, together with references of the major works used for this synthesis.

2. The President of the ECOWAS Commission after consulting with the Regional Committee, may oppose, within a period of three months after reception of the information above, the implementation of this trial by well-founded decision. He advises the promoter about his decision and informs the relevant authority of the member state where the trial must take place.

CHAPTER 4: Procedure on Authorization for Marketing

Article 25: Marketing Authorization : procedures and, formalities

1. To obtain a marketing authorization for a veterinary drug and biologicals, a request shall be made to the ECOWAS Commission together with payment of a fee as per Chapter 8 of this Regulation.

2. Such request shall include information indicated under paragraph 3 and 4 below as well as the summary of product characteristics (RCP) planned under article 24 of this Regulation.

3. The request, the RCP proposals, branding and instructions are written in at least two working languages of ECOWAS.

4. In addition, the applicant shall submit to the Commission samples of the drug and shall make available samples of raw materials, reference standards and other components, in adequate quantities to proceed on to controls planned under paragraph 2 of article 31 of this Regulation.

5. Any request for marketing authorization of a veterinary drug or biologic shall include the following information:

a) The name of the drug (trade name, generic name, coupled or not with reference pharmacopoeia and chemical formula.

b) The qualitative and quantitative composition of all components of the veterinary drug or biologic in common terms and with the international generic name recommended by the World Health Organization, if such a name exists,

c) The pharmaceutical form, the dosage and the presentations,

d) The modes and methods of administration,

e) The intended species and the dosage for each of the different animal species for which the veterinary drug or biologic is intended.

f) Therapeutic indications, contra-indications, and side-effects

g) Maximum duration of use,

h) The withdrawal period shall be indicated for animal species producing commodities intended for human consumption; the applicant shall propose and justify a level of residues acceptable in food commodities without any risks for the consumer.

i) The name or the company name and address of the applicant, and that of the local representative for imported veterinary drug or biologic,

j) The name or company name and address of manufacturer(s),

k) The designation of the places of manufacture, including packaging and quality control,

l) Should the need arise, the list of third countries which have granted a marketing authorization for this drug or in which an application is being processed.

m) The number and title of volumes of documents presented in support of the application including license to manufacture, free sale certificate, certificate of analysis of the drug and/or biologicals etc).

6. The application shall also be prepared along with the following information and documents, presented according to the Standards and Analytical Protocols on quality and safety of veterinary drugs or biologics.

a) Description of the manufacturing method,

b) Description of the control methods used by the manufacturer (quantitative and qualitative analysis of the components and of the finished product, particular trials, for example sterility and pyrogenic tests, research analysis for heavy metals, stability studies, biological and toxicity tests, control on intermediate products in the manufacturing process.

c) The routine analytic methods that can be used by the relevant authorities for testing residues,

d) If need be, the explanations on the precautionary and safety measures during the storage of the drug, its administration to animals and the elimination of waste, as well as indication of potential risks that the drug could present for the environment, human and animal health, and for plants,

e) The results of trials, namely analytical trials, safety tests, residue studies, preclinical and clinical trials or effectiveness tests,

f) Expert reports about these documents and essays, samples of the veterinary drug or biologics as well as instructions of use,

g) The copy of administrative authorization decisions of manufacturing establishments issued to the manufacturer of the drug in question, in enforcement of the national legislation of the establishment, and should the need arise a document proving that the manufacturer has been inspected by the relevant authorities and has been operating in accordance with the principles of Best Manufacturing Practices in force at the international level,

h) A copy of any marketing authorization secured for this veterinary drug or biologic in a third country, as well as a copy of the instructions proposed in that country, the deadlines for any decision to refuse authorization and the reasons for such decision.

Article 26: Procedure for granting Marketing Authorization

1. ANY INDIVIDUAL OR ENTITY REQUESTING A MARKETING AUTHORIZATION FOR A VETERINARY DRUG SHALL SUBMIT A FILE TO THE REGIONAL COMMITTEE.

2. THE SECRETARIAT OF THE REGIONAL COMMITTEE SHALL RECEIVE, RECORD THE DOSSIER AND EVALUATE IT, IN CONJUNCTION WITH THE CHAIRMAN OF THE REGIONAL COMMITTEE. FOR PURPOSES OF EXAMINATION OF THE SAID DOSSIER, THE CHAIRMAN OF THE REGIONAL VETERINARY COMMITTEE DESIGNATES A RAPPORTEUR.

3. THE DURATION OF THE PROCEDURE FOR GRANTING THE MARKETING AUTHORIZATION OF A VETERINARY DRUG AND/OR BIOLOGICAL SHALL NOT EXCEED TWO HUNDRED AND FORTY (240) DAYS FROM THE SUBMISSION OF A NORMAL APPLICATION.

4. AFTER EXAMINATION OF THE FILE AND THE DOSSIER, THE REGIONAL COMMITTEE SHALL TAKE THE FOLLOWING MEASURES AS APPROPRIATE:

   i. DECLARES IT RECEIVABLE WHEN THE CONDITIONS UNDER ARTICLE 22 AND ARTICLE 23, PARAG.1 ARE MET. COMMITTEE THEN NOTIFIES THE

APPLICANT FOR THE AUTHORIZATION OF THE TWO HUNDRED AND FORTY (240) DAYS PERIOD NECESSARY FOR THE PROCESSING OF THE FILE;

ii. IF THE FILE IS DEEMED INCOMPLETE, THE APPLICANT SHALL BE INVITED TO COMPLETE IT;

iii. IF THE FILE DOES NOT MEET THE LEGAL CONDITIONS REQUIRED, IT SHALL BE CLASSIFIED AS NO RESPONSE TO THE APPLICATION AND THE APPLICANT SHALL BE ADVISED OF THE DECISION.

5. ALL THESE MEASURES SHALL BE CONTAINED IN THE EXPERT REPORT.

Article 27: Processing of the Application for marketing authorization

1. To process the marketing authorization application, the rapporteur and the Regional Committee experts:

1. Shall verify the conformity to Article 26 of the file presented, and examine, based on reports produced by experts, in accordance with Article 27, if the conditions of issuance of the marketing authorization have been fulfilled;

2. Shall subject the veterinary drug, its raw materials, and if necessary, its intermediate products or other components and especially those drugs which have no marketing authorization and control by a laboratory belonging to the network of quality control laboratories of veterinary drugs and/or biologicals or a Laboratory recognised by the World Animal Health Organization, and shall ensure that the control methods used by the manufacturer and described in the application file are satisfactory should the need arise, the control of the analytical method proposed by the applicant for testing residues;

3. SHALL REQUIRE THAT THE APPLICANT PROVIDE SUBSTANCES IN ADEQUATE QUANTITIES TO CONTROL THE METHOD OF ANALYTICAL DETECTION PROPOSED BY THE APPLICANT, IN ACCORDANCE WITH ARTICLE 24 AND FOR THE IMPLEMENTATION, UNDER ROUTINE CONTROLS AIMED AT DETECTING THE PRESENCE OF RESIDUES OF THE VETERINARY DRUGS AND/OR BIOLOGICALS CONCERNED;

4. SHALL REQUIRE, SHOULD THE NEED ARISE, THAT THE APPLICANT COMPLETE THE FILE AS AFAR AS THE ELEMENTS REFERRED TO UNDER ARTICLE 24 AND ARTICLE 25, PARAGRAPH 1, ARE CONCERNED. WHEN THE REGIONAL COMMITTEE OF VETERINARY DRUGS OR BIOLOGICS TAKES ON THIS PREROGATIVE, THE DEADLINE STIPULATED UNDER ARTICLE 29 IS SUSPENDED UNTIL THE ADDITIONAL DATA REQUIRED IS SUBMITTED. LIKEWISE, THIS DEADLINE IS SUSPENDED OVER THE TIME LEFT, SHOULD THE NEED ARISE, TO THE APPLICANT TO EXPLAIN HIS CASE ORALLY OR IN WRITING.

Article 28: Verification and control

At the request of the Regional Committee, the ECOWAS Commission shall ensure from the relevant authorities of Member States or third countries that the

manufacturers of veterinary drugs or biologics submitted for marketing authorization are capable of achieving manufacturing and carrying out controls in observance of indications provided in implementation of Article 21 and in accordance with best manufacturing practices. It can also request that the relevant authorities allow for an on-the-spot inspection or study of the conditions of manufacture and control.

Article 29: Evaluation report

1. The Regional Committee shall deliberate on the evaluation report prepared by the rapporteur, the summary of product characteristics, the instructions and the labeling. This finalized report and the attached documents aforementioned shall be submitted with a draft proposal to the President of the ECOWAS Commission, not later than sixty days before the deadline provided at Article 26. This sixty (60) day period includes the consultation of the Veterinary Committee.

2. The Regional Committee shall keep this evaluation updated.

3. The President of the ECOWAS Commission makes a decision within two hundred and forty (240) days from the date of presentation of a complete and regular application which may be extended should the need arise with periods necessary for the submission of additional elements provided under article 27, paragraph 4. Failure to respond by the Chairman of the ECOWAS Commission is synonymous with refusal to authorize at the expiration of the aforementioned deadline until notification of the justified decision, which shall be made not later than four (4) months following the said deadline.

4. THE DECISION SHALL BE REPORTED TO THE APPLICANT, THE VETERINARY AUTHORITIES AND THE AUTHORITIES IN CHARGE OF LIVESTOCK, COMMERCE, AND CUSTOMS IN THE MEMBER STATES. THE DECISION TO ISSUE A MARKETING AUTHORIZATION SHALL BE COUPLED WITH THE SUMMARY OF THE CHARACTERISTICS OF THE PRODUCT REFERRED TO UNDER ARTICLE 25, AS APPROVED BY THE REGIONAL COMMITTEE AND THE DRAFT INSTRUCTIONS AND VALIDATED LABELING BY THE SAID COMMITTEE.

5. DECISIONS ON MARKETING AUTHORIZATIONS SHALL BE PUBLISHED IN THE OFFICIAL BULLETIN OF THE COMMUNITY.

Article 30: Change of conditions of manufacture and control of veterinary drugs and/or biologicals

1. After issuance of a marketing authorization, the holder shall take into account scientific and technical progress made and shall introduce all necessary changes into the methods of manufacture referred to under Article 285 of this Regulation. so that the veterinary drug or biologic shall be manufactured and controlled according to generally accepted scientific methods.

Such modifications are submitted to the ECOWAS Commission for approval.

2. At the request of the ECOWAS Commission, the holder of the marketing authorization shall also examine all methods of analytical detection of residues provided for under Article 22 and shall propose any modification potentially necessary to take into account scientific and technical progress.

3. The holder of the marketing authorization shall immediately forward to the Regional Committee any new element which could cause a modification of information and documents provided for under Article 23 and Article 24, of this Regulation, or of the approved summary of product characteristics. He shall advise the Regional Committee about any prohibition or restriction imposed by the relevant authority of the countries where the veterinary drug or biologic is commercialized and of any side-effect on human beings or any serious side-effect on treated animals.

Article 31: Information of the Regional Committee

1. The holder of the marketing authorization shall automatically inform the Regional Committee of any modification provided for under Article 33 that he has proposed to bring information and documents provided for under Article 24, paragraph 3, and Article 25, paragraph 1.

2. The modifications shall be classified into the following two categories:

a. MINOR MODIFICATIONS: ADMINISTRATIVE MODIFICATIONS AND TECHNICAL MODIFICATIONS NOT AFFECTING THE QUALITY, SAFETY, OR EFFICACY OF THE VETERINARY DRUG OR BIOLOGIC AND NOT REQUIRING ANY SCIENTIFIC ASSESSMENT;

b. Major modifications: technical modifications affecting the quality, safety or effectiveness of the veterinary drug and requiring a scientific assessment.

3. A decision of the ECOWAS Commission specifies the list of minor and major modifications.

4. Modifications concerning information and documents provided for under paragraph 1 shall be authorized beforehand by the ECOWAS Commission. Any request for modification shall be presented and processed as per the provision under Article 31 of this Regulation:

5. Applications for minor modifications shall be directly processed by the Regional Committee Secretariat. No later than fifteen (15) days before the deadline, the Secretariat shall address a notice and a draft decision to the ECOWAS Commission.

6. An aggrieved applicant may request for a review before the authorities

7. An aggrieved applicant can appeal before the ECOWAS Court of Justice

8. For major modifications, when the file is deemed valid, the chairman of the Regional Committee in liaison with the Secretariat shall designate one of the members of the Regional Committee to act as rapporteur and shall ensure or coordinate the evaluation. Should the need arise, additional experts belonging to the group of experts referred to under article 7 may be called on. They shall assist the rapporteur in developing the evaluation report.

9. The Secretariat may request from the applicant any additional information that the Regional Committee deems necessary, in light of information or items in the file, in order to rule on the application, by making known the reasons for his decision. The time planned under paragraph 2 above shall therefore be suspended until reception of the items requested. The Regional Committee shall make a decision on the evaluation report produced by the rapporteur, and the modifications to be made should the need arise on the summary of product characteristics, instructions and labeling. This finalized report and the attached documents shall be forwarded with a draft decision to the President of the ECOWAS Commission, no later than sixty (60) days prior than the deadline as per paragraph 3.

10. The President of the ECOWAS Commission shall take a decision in a period of sixty (60) days for the minor modifications and one hundred and fifty (150) days for the major modifications, from the date of the presentation of a complete and regular modification application file.

11. Failure by the President of the Commission to reply shall be synonymous with refusal to authorize modification at the expiration of the aforementioned deadlines.

12. The requests for modification shall be rejected on the same grounds as those planned for under article 13.

13. The President of the ECOWAS Commission shall inform the applicant and the relevant authorities of member states of his decision.

14. Any other change shall be subjected to a new request presented under conditions provided for under article 24 and article 25 in paragraph 1 of this Regulation and processed in accordance with articles 29 and 30 of this Regulation.

Article 32: Renewal of marketing authorization of veterinary drugs or biologics

1. THE APPLICATION FOR RENEWAL SHALL BE INTRODUCED BY THE HOLDER OF THE MARKETING AUTHORIZATION AT LEAST THREE (3) MONTHS PRIOR TO THE DATE OF EXPIRATION OF THE AUTHORIZATION TO PUT ON THE MARKET. THE APPLICATION FOR RENEWAL SHALL BE SENT TOGETHER WITH A SUMMARY OF MODIFICATIONS AUTHORIZED SINCE OBTAINING THE INITIAL AUTHORIZATION OR THE LAST RENEWAL OR OF A DOCUMENT CERTIFYING THAT NO MODIFICATION HAS EVER

BEEN MADE IN THE ELEMENTS PRODUCED TO SUPPORT THE INITIAL AUTHORIZATION REQUEST OR THE LAST REQUEST FOR RENEWAL.

2. The request shall be addressed to the ECOWAS Commission, together with the fee provided for as per Chapter 8 of this Regulation. Processing of the file is provided for under article 26 of this Regulation and the period for notification of the justified request shall be three months. In a maximum period of fifteen (15) days prior to the end of this period, the Secretariat of the Regional Veterinary Committee shall forward a notification and a draft decision to the ECOWAS Commission.

3. The President of the ECOWAS Commission shall advise the applicant and the relevant authorities of Member States about his decision. If no decision is notified or if no additional justification request is forwarded to the applicant in a period of three (3) months following reception of his complete and regular request, the authorization shall be considered as renewed at the expiration of this deadline.

Article 33: Change of holder by transfer of marketing authorization

1. Any transfer of the authorization to put on the market to another holder shall be subjected to a decision of the President of the ECOWAS Commission.

2. The request shall include the name or company name, and full location address of the applicant, and should the need arise, those of his local representative, the designation of places of manufacture, including packaging, proposed label of the product and control and the external and primary packaging materials and, if necessary, of instructions It shall also include:

   a) The agreement of the holder of the marketing authorization,

   b) The commitment of the pharmaceutical officer of the beneficiary enterprise of the transfer or the manufacturing establishment to submit to the entire set of requirements for the marketing authorization, and notably, to observe the methods of manufacturing and control.

3. The request shall be addressed to the Regional Committee Secretariat, together with payment of the fee provided for under Chapter 8 of this Regulation. No later than fifteen (15) days prior to the end of the deadline, the Secretariat shall forward a notice and a draft decision to the ECOWAS Commission.

4. The President of the ECOWAS Commission shall inform the applicant and the veterinary administration of member states about his decision.

5. Failure to reply by the President shall be deemed to as being authorized at the expiration of a three (3) month period with effect from the date of the application.

Article 34: Manufacturers' Liability

The marketing authorization shall not violate the common law liability of the manufacturer and, should the need arise, of the holder of the marketing authorization.

CHAPTER 5: Labels and instructions on veterinary drugs and biologicals

Article 35: Labelling Requirements

1. The labels or printings on containers and external packagings of veterinary drugs or biologics shall carry in legible characters the following information, in line with the information and documents provided by virtue of Article 23 and article 25, paragraph 1 and shall be approved by the ECOWAS Commission:

   a. The name of the drug or biologic, which shall bear a trade name or a generic name, together with a brand or the name of the holder or a scientific designation or formula, together with a brand or the name of the holder.

   b. If the particular name of a drug or biologic containing only one active substance is a trade name, such name shall be associated with, in legible characters, the international generic name recommended by the World Health Organization, when it exists or, by default, the common generic name.,

   c. The qualitative and quantitative composition in active and inactive substances per unit or according to the method of administration for a given size and weight, using generic names recommended by the World Health Organization, if they exist or by default, the common generic name,

   d. The number of the manufacture batch,

   e. The number of the marketing authorization,

   f. The name or the company name and the permanent address or the head office of the holder of the marketing authorization and, should the need arise, of the local representative,

   g. The animal species for which the veterinary drug or biologic is intended, the mode and the method of administration.

h. The withdrawal period, even if it is equal to zero, for those veterinary drugs or biologics administered to animals producing animal commodities intended for human consumption,

i. The dates of manufacture and expiration clearly specified,

j. The particular storage precautions, if necessary,

k. The particular precautions for disposal of unused drugs or drug derived wastes, if necessary,

l. Information on conditions of prescription and issuance, if necessary,

m. The mention « for veterinary use ».

n. Dosage

o. Dilution

p. Address of the Manufacturer.

2. The information provided for under Paragraph 1 shall be written on the external packaging and on the container of the drugs at least in English, French and Portuguese languages and eventually in the language or languages of the country where the drug is put on the market. Should the need arise, pictograms corresponding to essential information about administration and safe use shall be added.

Article 36: Labelling Veterinary Vials

1. When there are vials, the information under article 36, paragraph 1, shall be written on the outside packaging. On the other hand, only the following information shall be necessary on containers:

   a. The designation of the veterinary drug,

   b. The quantity of active substances,

   c. The method of administration,

   d. The number of the manufacture batch,

   e. The dates of manufacture and expiration clearly specified,

   f. The mention « for veterinary use ».

2. As regards small containers other than vials which contain only a single dose and on which it is impossible to place information provided for under Paragraph 1, the prescriptions of Article 36, Paragraph 1 and 2, are applicable to only the external packaging.

Article 37: Container characteristics

Short of external packaging, all information which, by virtue of articles 36 and 37, shall be found on the container.

Article 38: Notice of packaging

1. A notice shall be attached to the packaging of the veterinary drug or biologic, unless all necessary information by virtue of the present article can be found on the container and the external packaging. The notice shall be only on the veterinary drug or biologic to which it is attached.

2. The notice shall be written at least in French or in English and in the official language(s) of Member States. Should the need arise, pictograms corresponding to essential information in the area of administration and safe use can be added.

3. The notice shall include at least the following information, in accordance with information and documents provided by virtue of article 24 and article 25 and approved by the ECOWAS Commission :

   a. Name or company name and permanent address or head office of holder of marketing authorization and, should the need arise, the local representative.

   b. Designation and qualitative and quantitative composition of veterinary drug and biologicals in active substances. The international generic names recommended by the World Health Organization (WHO) must be employed whenever such names exist,

   c. Therapeutic indications,

   d. contra-indications, side-effects and if any, antidotes, to the extent that such information is necessary for the use of veterinary drugs or biologics,

   e. animal species for which the veterinary drug and biologicals is intended, dosage depending on individual species, mode and method of administration, indications for a sound administration, if necessary.

   f. Withdrawal period, even if equal to zero, for veterinary drugs or biologics administered to animals producing commodities intended for human consumption;

   g. Special storage precautions, if necessary,

   h. Information on conditions of prescription and delivery, if necessary,

   i. Special precautions for disposal of unused drugs or wastes derived from veterinary drugs or biologics, if necessary.

4. The other information must be clearly separated from information as per paragraph 2.

CHAPTER 6 : MARKET MONITORING AND SURVEILLANCE

Article 39: Pharmaco-vigilance

1. The ECOWAS Commission and Member States shall take all appropriate steps to encourage notification about presumed side-effects or any other concerns of veterinary drugs or biologics to ECOWAS by health professionals.

2. The reports of side-effects or other concerns shall be addressed to veterinary authorities who shall forward them to the ECOWAS Commission which, depending on the urgency of the situation and the gravity of side-effects, shall take appropriate measures after consultation with the Chairman of the Regional Committee. The reports of side-effects shall be submitted to the Regional Committee.

3. The holder of the marketing authorization shall have in a permanent and continuing manner at his disposal an individual having the appropriate qualifications, in charge of pharmaco-vigilance. This latter individual is either the local representative or a person linked by convention to the latter and resides in one of the Member States.

4. This qualified individual shall hold a degree that permits exercise of the veterinary profession in one of the Member States.

5. This qualified individual shall be in charge of:

   a) Establishing and managing a system that would ensure that information about all presumed side-effects or other concerns are reported to him or are reported to importers, shall be collected and processed so as to be accessible upon demand by the ECOWAS Commission;

   b) Guaranteeing that any request stemming from the ECOWAS Commission and aimed at obtaining necessary additional information for assessment of risks and benefits of a veterinary drug or biologic, shall find a complete and rapid response, including the volume of sales for the veterinary drug or biologic involved;

   c) Providing the ECOWAS Commission with any other information of interest for assessing the risks and benefits of a veterinary drug or biologic.

Article 40: Keeping reports on the side-effects and other concerns of veterinary drugs or biologics

1. The holder of the marketing authorization or his local representative shall keep detailed reports on all presumed side-effects and other concerns which occurred within the Community.

2. The holder of the marketing authorization or his local representative shall record any serious side-effect or side-effect on humans associated with the use of the veterinary drugs or biologics, that he is reasonably supposed to be knowledgeable about or which was brought to his attention, and shall immediately advise veterinary authorities, no later than fifteen (15) calendar days following his/her communication.

3. The books established shall be kept on the territory of the Community, at least five years and shall be made available to the relevant authorities of the Community, on request.

Article 41: Suspension, Withdrawal or Cancellation of Marketing Authorization

1. After the assessment of data on veterinary pharmaco-vigilance, if the Regional Committee considers that the marketing authorization must be suspended, withdrawn or modified to reduce indications or availability, modify dosage, add a contra-indication or a new preventive measure, he shall immediately advice the ECOWAS Commission to that effect.

2. In case of emergency, the ECOWAS Commission shall suspend the marketing authorization of a veterinary drug in accordance with the modalities provided for under Article 17 of this Regulation.

CHAPTER 7: Control of Veterinary Drugs and Biologicals

Article 42: Control of Veterinary Products by the Commission

The ECOWAS Commission shall submit for a formal control by a laboratory of the regional laboratory network of quality control or any other certified laboratory samples of a batch of imported veterinary drugs and biologicals during the first importation after marketing authorization or when he suspects that there is a quality or public health problem on a batch of drugs.

Article 43: Enforcement of Inspection

The ECOWAS Commission shall mandate one or several inspectors of the member states to carry out inspections deemed necessary on or outside Community territory.

CHAPTER 8: FEES

Article 44: Determination of fees

There shall be within the Community, fees to be collected against services provided for obtaining and maintaining marketing authorizations (MA) of veterinary drugs and biologics, as well as for other services provided in that framework.

Article 45: Fees for the marketing authorization of a veterinary drug and biologics

1. Basic fee

a. A basic fee shall be collected for an application for marketing authorization of a drug, together with a complete file. Such fee shall cover both dosage and pharmaceutical form.

b. This fee shall be raised by 10 % for each additional dosage and/or pharmaceutical form when they are presented simultaneously with the complete authorization request. Such increase shall cover any additional dosage and/or pharmaceutical form.

c. This shall be regardless of the number of species and/or each indication.

2. Reduced fee

a. A 50% reduction shall apply to marketing authorization requests for a drug which does not require presentation of a complete file, in accordance with the provisions of Regulation establishing community processes for marketing authorization and observation of veterinary drugs and instituting a Regional Committee of Veterinary Drugs. This fee shall cover both dosage and pharmaceutical form of this drug.

b. This fee shall be raised by 10% for each additional dosage and/or pharmaceutical form when they are presented simultaneously with the reduced authorization request. Such increase shall cover additional dosage and/or pharmaceutical form.

c. This shall be regardless of the number of species and/or each indication.

Article 46 – Fees for modification of a marketing authorization

1. Fees for extension of a marketing authorization

A fee corresponding to 25% of the basic fee shall be collected for each extension of a marketing authorization already granted when the latter covers a new dosage or a new pharmaceutical form or a new species or a new indication or a new mode of administration which do not appear on the initial file.

2. Fees for minor modifications

A fee corresponding to 5% of the basic fee shall be collected in case of minor modification of the marketing authorization.

In case of identical modification concerning several marketing authorizations on a single holder, the fee shall cover all such authorizations.

3. Fees for major modifications

A fee corresponding to 30% of the basic fee shall be collected in case of major modification of the marketing authorization.

In case of identical modification, concerning several marketing authorizations on a single holder, the fee shall cover all such authorizations.

Article 47: Fees for renewal of a marketing authorization

A fee corresponding to 50% of the basic fee shall be collected for the renewal of a marketing authorization of a drug. It shall be collected for examination for renewal of a dossier for 5 years for marketing authorization of a drug and/or biological..

Article 48: Fees for transfer of a marketing authorization

A fee corresponding to 5% of the basic fee shall be collected in the course of the transfer of the marketing authorization to a new holder.

Article 49: Inspection fees

A fixed amount shall be collected for any inspection carried out on community territory or outside the Community. For those inspections carried out outside the Community, travel fees shall be charged in addition to the actual cost.

Article 50: Modalities for assessing fees

a. The respective amounts of the different fees shall be determined in ECOWAS chosen Unit of Account, according to the present Regulation and of which it is part and parcel.

b. The amount of the fees can be modified on decision of the ECOWAS Commission.

Article 51: Modalities of handling fees

a. Fees collected as per the marketing authorization procedure shall fund the operations of the centralized system and support the national structures involved in the control of veterinary drugs and biologicals.

b. The ECOWAS Commission shall define the modalities of collection and management of the fees, in accordance with the ECOWAS financial regulation.

Article 52: Transitional arrangements on Fees

A 50% reduced fee shall be collected on the Marketing Authorization applications filed as per the transitional arrangements of the ECOWAS Regulation setting up community processes for marketing authorization, monitoring of veterinary drugs and establishment of a regional committee of veterinary drugs;

CHAPTER 9 : NETWORK OF LABORATORIES FOR QUALITY CONTROL OF VETERINARY DRUGS AND BIOLOGICALS

Article 53: Establishment of a Network of Laboratories

1 There shall be established a Network of Laboratories charged with the task of quality control of veterinary drugs and biologicals in the ECOWAS territory.

2 The laboratories which are members of the network shall be designated by the ECOWAS Commission, after consulting with the Regional Committee.

Article 54: Goals of the Network

The goal of the network of quality control laboratories of veterinary drugs shall be:

1. To bring to Member States technical support in the area of control of the quality of pharmaceutical products and vaccines;

2. To build capacities of member laboratories by:

    a. Promoting their technical cooperation;

    b. Facilitating their access to new analytical techniques;

    c. Improving the continuing education of their staff;

    d. Speeding- up the quality assurance for their activities;

    e. Providing additional funding as the need arises;

    f. Accord Reference laboratory status where necessary.

Article 55: Modalities of establishment of the network

1. The laboratories identified shall confirm, in writing, their interest in being members of this network. See Daniel

2. The ECOWAS Commission, in consultation with the Member States, shall approve which of the identified laboratory shall be in the network. The identified laboratories shall operate in the following areas:

   a. The goals to be reached in the area of control of the quality of veterinary drugs;
   b. The modalities of such control;
   c. ECOWAS' obligations toward this laboratory in the area of technical and financial support;
   d. The obligations of the line authority of this laboratory in the area of technical and financial support and the financial management conditions which help it fulfill its responsibilities.

Article 56: **Conditions to be fulfilled by the laboratories of the network**

Each laboratory in the network shall comply with the following conditions:

1. Maintain the best possible level of its scientific and technical expertise in the area of quality control of veterinary drugs ;

2. Regularly update the analytical methods used by integrating progress in the knowledge achieved in this area;

3. Implement a continuing education plan for its scientific and technical staff so as to ensure:

   a. Maximization of the use of analytic devices;

   b. The quality of obtained results;

   c. The capacity of the laboratory to integrate achievements in scientific

   d. knowledge into the area of quality control of veterinary drugs;

4. Contribution to the development of the necessary cooperation with other laboratories in the network through its involvement in:

   a. Information exchange over analytical methods;
   b. Harmonization of such methods;
   c. Organisation of training events;
   d. Setting up circular tests if the laboratory is designated reference
   e. laboratory in a particular area ;

5. Development of contacts and technical cooperation with other laboratories working in the same domain;

6. Improvement, particularly thanks to the internet, of access to the relevant bibliography in light of control of the quality of veterinary drugs;

7. Quality assurance of its control activities. Such quality assurance condition and obtaining from an internationally recognized body the accreditation which must ensue, will be programmed based on a timeline adapted to the situation of the laboratory as of the date of its integration in the network;

8. The implementation of the annual work plan decided by the ECOWAS Commission;

9. Observance of the timeline planned for giving test results.

Such conditions will be recorded in a specifications book developed by the ECOWAS Commission.

Article 57: **Modalities of network management**

1. The network shall be placed under the responsibility of the ECOWAS Commission which manages it with the assistance of the Regional Committee on Veterinary Drugs established by Regulation establishing community processes for marketing authorization and monitoring of veterinary drugs.

2. The goals and the annual work plans of the network shall be defined by the ECOWAS Commission on the proposal of the Regional Committee in consultation with the network of the laboratories.

3. The coordination of annual program of the network shall be undertaken by the Regional Committee Secretariat on Veterinary Drugs with the support of reference laboratories.

Article 58: **Organization of network activities**

1. The Commission, on proposal of the Regional Committee, shall develop the annual work plan for the network.

2. It shall define the modalities of the activities in the network with the assistance of the Regional Veterinary Committee and the network laboratories.

THE COMMISSION SHALL DESIGNATE WITHIN THIS NETWORK A REFERENCE LABORATORY FOR EACH GROUP OF DRUGS, WHICH SHALL BE TASKED WITH:

a. Codifying the control methods;
b. Assuring the training of staff from other laboratories on these methods ;

c. Organize inter-comparison tests to ensure adequate control over these methods by the network's laboratories.

Article 59: Collecting samples

1. The samples to be analyzed by the laboratories in the network shall be collected by inspectors designated to that effect by the authorities in charge of veterinary pharmacy in Member States.

2. SUCH SAMPLES, BEING COLLECTED FOR PUBLIC HEALTH PROTECTION PURPOSES, SHALL NOT BE ENTITLED TO PAYMENT OF ALLOCATIONS BY ECOWAS TO ECONOMIC OPERATORS IN WHOSE PLACES SUCH SAMPLES WOULD HAVE BEEN COLLECTED.

Article 60: Technical and financial support

1. The laboratories participating in the activities of quality control of veterinary drugs in the network shall, if need be, and to the extent of available resources, receive ECOWAS support in terms of:

   a. Their scientific and technical equipments;
   b. The training of their staff;
   c. The quality assurance for their activities.

2. The pricing of the quality controls of veterinary drugs shall be streamlined and fixed by Implementing Regulation through the ECOWAS Commission.

CHAPTER 10: TRANSITIONAL ARRANGEMENTS

Article 61: Implimentation

1. The Commission has a period of one year, from entry into force of the Regulation, for setting up the centralized system of putting veterinary drugs and/or biologicals on the market.

2. During this period, the applicable procedures in Community Member States, to requests for marketing authorization of the said drugs and biologicals, remain in force.

3. Likewise, the drugs and/or biologicals which are regularly marketed in one of the Member States of the Community, according to the regulation in force in

that State, shall continue to be put on the market, if the following conditions are met:

a. The holder of a national authorization shall declare within the twelve (12) months following publication of this Regulation that he markets these drugs and shall pledge to turn in a standard file with the ECOWAS Commission no later than two (2) years after the date of entry into application of this Regulation;
b. The national authorization referred to above shall be found on a list provided to the ECOWAS Commission by each member State within a period of three (3) months following publication of this Regulation.

4. The commercialization shall continue in the Member State until the ECOWAS .Commission rules on the request.

5. The processing deadlines provided for under article 30 shall not apply to the processing of those files deposited under the transitional arrangements of this article.

6; At the end of the two (2) year period, referred to under paragraph 2 of this article, failure to submit a file shall lead to cancellation of authorizations and putting an end to commercialization, without prejudice to penalties applicable in the case, in each member state.

Article 62: Miscellaneous

1. One year after the entry into force of this Regulation, the Commission shall submit to the Council of Ministers a report on the state of application of the measures as per article 49 of this Regulation.

2. This report shall specify in particular the details about the processing of requests introduced by the holders of national authorization for obtaining centralized marketing authorization.

3. On proposal of the Commission, the Council of Ministers shall adopt, if the need arose, any community action necessary to complete this Regulation.

Article 63: Final Provision

This Regulation, which goes into effect from the date of signing, shall be published in the Community's Official Bulletin.

Article 64:

This Regulation shall be published by the ECOWAS Commission in the Official Journal of the Economic Community of West African States within thirty (30) days

of its signature by the Chairman of the Council. It shall also be published by each Member State in its National Gazette within thirty (30) days after notification by the Commission.

DONE AT ABUJA, THIS 26TH DAY OF NOVEMBER 2010

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H.E. H. Odein AJUMOGOBIA, SAN

CHAIRMAN

FOR COUNCIL