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

DIRECTIVE C/DIR.1/11/10 ON ECOWAS VETERINARY PHARMACY

THE COUNCIL OF MINISTERS,

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

MINDFUL of Article 25 of the Revised ECOWAS Treaty on Agricultural Development and Food Security and prescribing that member states pledge to cooperate in the area of the protection of plant and animal species, controlling animal and plant diseases and the strengthening of existing institutions in the management of natural disasters;

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

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

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

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

Recalling the WTO SPS Agreements (Marrakech Accord) on animal and plant health as well as food safety items;

Considering that transhumance is a livestock production system which affects pastoral resources and increased cattle production within the ECOWAS Region; but it constitutes, however, a source of numerous health related problems;

Noting that the handling of the issue of veterinary drugs and biologicals in the ECOWAS region is not homogenous;

Convinced on the need to harmonize legislations and regulations in the areas of plant, animal and aquatic health as well as their well-being, animal feed and food safety, veterinary pharmacy, zoo noses and the veterinary profession, in order to meet the livestock goals of the Community;

Determined to create and set rules on Veterinary Pharmacy within the ECOWAS region in order to address all veterinary drug use and supply issues as it relates to animal health and institute cooperation among member states;

On the Recommendation of the Meeting of the ECOWAS Ministers of Agriculture and Livestock, held in Abuja on 3rd February 2010.

PRESCRIBES

CHAPTER I: DEFINITIONS AND SCOPE OF APPLICATION

Article 1: Definitions

1. The definitions in Article 1 of the Regulation C/REG.22/11/10 on community Procedures for the Management of Veterinary Drugs and Biologicals are applicable to these Guidelines.

2. For the enforcement of these Guidelines, the veterinary authority is that which is defined by the Terrestrial Animals Code of the World Organization for Animal Health (OIE).

Article 2: Scope of application

1. The provisions of these guidelines describe and prescribe the procedures and rules that Member States shall enforce in the areas of control of imports and exports, movement and marketing, the opening and operation of manufacturing establishments, marketing and distribution of veterinary drugs and biological, retail and wholesale within the ECOWAS region.

2. The provisions of these guidelines shall also apply to veterinary drugs and

biologicals for testing, sales, donations or presented as raw materials for veterinary drugs and biologicals and medicinal premixes.

3. The medicinal feeds are governed by special provisions in these Guidelines.

CHAPTER 2: AUTHORIZATION TO MARKET, IMPORT AND INTRA-COMMUNITY MOVEMENT

Article 3: Requirement of a marketing authorization

1 Except for medicinal feeds, no veterinary drugs and/or biologicals shall be distributed on the Community's market without prior market authorization issued by the Commission in the conditions mentioned in Regulation C/REG.22/11/10 relating to the Community Procedures on Management of Veterinary drugs and biological;.

2. However, a veterinary drug and/or biological shall:

a be subjected to a pre-clinical and/or clinical trials after authorization by the ECOWAS Commission under conditions stipulated in Regulation C/REG.22/11/10 on community procedures of management of veterinary drugs and biologicals;

b be used in a member state with special authorization issued according to conditions stipulated under articles 19 and 20 of Regulation C/REG.22/11/10 on Community Procedures of Management of Veterinary Drugs and Biologicals.

Article 4: Requirements for Imports of veterinary drugs and biologics

1. Imports of veterinary drugs and/or biologicals shall be subject to authorization by the veterinary authority of the importing member state. The modalities for issuance of the authorization shall be set by member states.

2. Authorization to import shall be requested:

a. By the officer of an establishment which has the administrative authorization referred to under article 10 of the Regulation C/REG. 22/11/10 on Community Procedures of Management of Veterinary drugs and biologics as agent acting on behalf of the holder of a Marketing Authorization or by the official of an authorized wholesale distributor;

b. For research purposes, by the officer of an establishment having received administrative authorization, as per Article 8 of these directives, and acting on behalf of the promoter of the research or by investigators or researchers themselves upon proving their qualification.

3. The request for authorization to import authorized veterinary drugs and biologics shall include at least the following items :

a. The name of the drug and the holder of the Market Authorizations (MA),

b. The number and references of the batches involved,

c. The origin of the drugs and their destination,

d. The composition of drug, strength, dosage, form and quantities requested,

e. A copy of the marketing authorization.

f. Address of manufacturer

4. The request for authorization to import batches of drugs for clinical trials and/ or research shall specify the name of the trial, investigator or promoter, the quantity to be imported, the destination of the product and the reference at experimentation or authorization to experiment. This authorization to import is only valid for a single experiment or trial.

5. Special authorizations of use provided for under articles 19 and 20 of Regulation C/REG.22/11/10 on community procedures of Management of Veterinary Drugs and Biologicals shall be valid as import authorization. The imported drugs, in that respect, shall move only within the Community in transit to the State which has provided the authorization.

Article 5: Conditions for circulation of veterinary drugs and biologicals

1. Any drug authorized by the centralized procedure and imported shall be circulated freely in the Community territory, provided it shall be accompanied with the marketing authorization and the authorization to import issued by the Member State for entry into the Community.

2. Any drug authorized by the centralized procedure and manufactured by one of the Member States of the Community shall circulate freely within the Community accompanied with the marketing authorization and the certificate of the manufacturer.

CHAPTER 3: MANUFACTURE, WHOLESALE DISTRIBUTION, IMPORTS AND EXPORTS

Article 6: Representation requirement or authorized branch

The member states shall take the legal and administrative measures to ensure that the manufacture, importation, wholesale distribution and exportation of veterinary drugs and biologicals are subject to clinical trials to be carried out only by businesses or agencies having one or several certified veterinary pharmaceutical establishments and operating under conditions governed by these guidelines.

Article 7: Procedures for opening or changing ownership of Veterinary Pharmaceutical Establishment

1. The opening, modification, or change of ownership of a veterinary pharmaceutical establishment shall be the subject of prior authorization issued by the relevant veterinary authority without prejudice to the other necessary conditions for the exercise of the corresponding industrial or commercial activity.

2. Anyone who requests opening, change in ownership or modification to a pharmaceutical establishment shall submit a request to the relevant veterinary authority.

3. The opening authorization of a veterinary pharmaceutical establishment shall be issued to the business or agency by the veterinary authority, after relevant investigation, inspection and consultation with the Veterinary council that the pharmaceutical officer reports to.

   a. When a business or agency has several veterinary pharmaceutical establishments, each one of them shall have a separate authorization.

   b. For establishments where veterinary drugs and biologics are manufactured or imported, the authorization shall specify the nature of the drugs concerned, namely chemical, immunological, or medicinal plant based.

   c. The authorization to open shall specify the activity for which it is certified. For a single establishment, the authorization may mention several activities.

   d. The duration of the process of authorization shall not exceed a period of ninety (90) days from the date of receipt of a duly completed application form. .

   e. The veterinary authority shall request the applicant to provide any additional information necessary for the processing of the application. The deadline

scheduled above shall in this case be suspended until such information is provided.

f. Any positive or negative decision shall be communicated to the applicant.

g: If, in a period of two (2) years following the notification of opening authorization, the establishment is still not operational, its authorization loses its validity. However, upon justification given before expiry of the said deadline, this authorization shall be extended by the veterinary authority.

4. Prior authorization shall be necessary for any modification concerning the premises and technical equipment as described in the file taken into account for the issuance of the initial authorization.

5. For establishments which manufacture or import drugs, such prior authorization shall also be necessary for an extension of activity to new pharmaceutical forms or, veterinary drugs and biologicals of another nature than those listed in the initial authorization.

6. The duration of the procedure shall be ninety (90) days from the date of receipt of the complete application.

7. The relevant authority shall request from the applicant any additional information necessary for processing the application. The period scheduled above shall in this case be suspended until provision of the information.

8. In case of change of ownership of a veterinary pharmaceutical establishment, a request for transfer of the opening authorization to the new business or new agency shall be addressed to the veterinary authority.

9. The administrative authorization shall be, after formal notice, suspended, or withdrawn by the veterinary authority in case of violation of the provisions of this Section. The suspension which shall not exceed one (1) year, and the withdrawal of the opening authorization, shall be pronounced by the veterinary authority. Except in a case of an emergency, these decisions shall be implemented after the individual has been invited to present his/her comments.

Article 8: Veterinary Pharmaceutical Establishments: Administration and Operation

1. Any enterprise which includes at least one veterinary pharmaceutical establishment as indicated in Article 7 above, shall be owned either by a veterinary pharmacist, or a veterinary doctor, or a holding company with

participation of a veterinary pharmacist or a veterinary doctor according to the provision of corporate law in force in the member state.

2. Any agency which includes at least one veterinary pharmaceutical establishment as indicated Article 7 above shall have within its executive management either a veterinary pharmacist or a veterinary doctor.

3. The veterinary pharmacists or veterinary doctors referred to under the previous paragraphs are called "Pharmaceutical Officers". They shall be responsible for the implementation of the provisions on veterinary pharmacy in the company, without prejudice to the corporate accountability of the company in case of failure to implement the provisions of these Guidelines on veterinary pharmacy.

4. In every veterinary pharmaceutical establishment of the enterprise or the agency, where veterinary drugs and biologicals are wholly or partially a component of its production, there shall be in its employ a veterinary doctor or veterinary pharmacist who shall be responsible for the implementation of these guidelines on veterinary pharmacy. When the pharmaceutical officer exercises his activities in one of the pharmaceutical establishments of the enterprise or the agency, the designation of veterinary pharmacist or veterinary doctor shall not be mandatory in this establishment;

5. The pharmaceutical officer(s) shall have relevant practical experience:

   a. Exercising authority in one or several establishments for manufacture or marketing of veterinary drugs and biologicals in a Community Member State or a third country where similar provisions are in force. All or part of this experience may have been acquired in one or several establishments authorized to manufacture human drugs in a Community member state or in a third country where similar provisions are in force. The pharmaceutical officer(s) shall justify that such practical experience, which shall be at least one (1) year, involves activities in the qualitative analysis of drugs, the quantitative analysis of active ingredients as well as trials and verifications necessary to ensure the good quality of drugs;

   b. In those enterprises or agencies and their wholesale distribution pharmaceutical establishments (wholesale distributor or agent), the pharmaceutical officer shall have practical experience of at least six (6) months in a pharmaceutical establishment dealing with human drugs or a veterinary pharmaceutical establishment.

Article 9: Control of compliance of veterinary drugs and biologicals

The member states shall take legal and administrative measures to ensure that the manufacture, importation, and wholesale distribution of veterinary drugs and biologicals shall comply with principles of best practices as defined by decision of the veterinary authority.

Article 10: Modalities of distribution or commercialization of veterinary drugs and biologicals

1. The member states shall ensure that the veterinary drugs and biologicals are commercialized by animal health professionals authorized under the following conditions:

   a) Either the manufacturer shall carry out his/her own activity, i.e., sells wholesale, or gives free of charge those drugs that he/she has manufactured; Or

   b) The manufacturer or holder of the marketing authorization shall resort to an operator who may be the authorised representative.

2. The operators and holder of marketing authorization of veterinary drugs and biologics shall distribute drugs only to other enterprises authorized to distribute them wholesale or to individuals or entities entitled to retail them.

3. The distributors of drugs submitted for clinical trials shall distribute these drugs only to other distributors, investigators, individuals or entities entitled to exercise similar activities outside the national territory.

4. The enterprises or agencies that have marketing Authorizations shall export out of the Community territory, veterinary drugs and biologicals that they manufacture or sell, or give free of charge or distribute.

5. The concessions undertaken by these enterprises or agencies towards other Community Member States shall only be intended for individuals or entities authorized to retail these drugs, or in the case of medicinal feeds, to use them in these States.

6. All these stakeholders involved in the distribution channel shall store veterinary drugs and biologicals in a conducive environment, either as wholesale or for distribution free of charge.

Article 11: Prohibition for Sale to the Public

1. The veterinary pharmaceutical establishment shall not be allowed to sale to the public:

2. However, for medicinal feeds, veterinary pharmaceutical establishments shall not be authorized to sell or distribute veterinary drugs and biologicals to the public, unless prescribed by a veterinary doctor.

3. The Ministry of Livestock/Agriculture of a member state or the public or semi-public establishments under such ministry can acquire veterinary drugs and biologicals directly from- veterinary pharmaceutical establishments, through authorized agents for the realization of missions that they must conduct in terms of prophylaxes or sanitary control measures.

Article 12: Pharmaceutical Officers and the Veterinary Pharmaceutical establishment

1. The member states shall ensure that veterinary pharmaceutical establishments operate under the effective responsibility of a pharmaceutical officer in accordance with the rules defined in Article 8 of these Directives.

2. Any act contributing to veterinary pharmaceutical activities shall be carried out under the effective control of a pharmaceutical officer who shall fulfill, depending on the case, the conditions of professional practice in the member state. The pharmaceutical officer of an enterprise or agency shall exercise his activities in a permanent and continuing manner. Any pharmaceutical officer in the employ of a pharmaceutical company shall not while in that employment maintain either a human or veterinary pharmacy for dispensing of veterinary drugs to farmers groups or individual in the case of pharmacists except where such functions are part of his employment.

3. The qualification of a pharmaceutical officer shall be recorded for only one enterprise.

4. In case of absence of the pharmaceutical officer as a result of his being called for another business, there shall be a replacement officer who shall hold and act in that capacity for a maximum period of one year.

5. Deputies shall be appointed to assist the pharmaceutical officers in case of need. For application of these guidelines, these deputies are individuals, who, fulfill the conditions of practice of pharmacy or veterinary medicine in the member state, or practice their activity in a pharmaceutical establishment, with the pharmaceutical officers or his deputy who is in charge or who is acting.

6. In case of absence or impediment to the functions of the pharmaceutical officer or his deputy, he shall be replaced without delay by a new pharmaceutical officer by the competent bodies of the firm or company.

7 The veterinary doctors or veterinary pharmacists employed in veterinary pharmaceutical establishments as pharmaceutical officers, or deputies shall be registered with the competent legal professional body and shall be subject to the ethical rules and to the discipline of their profession.

Article 13: Functions of the pharmaceutical establishment officer

For the application of rules prescribed in public health interest, the Member States shall ensure that the pharmaceutical officer fulfils the following functions to the extent that they correspond to the activities of the firm in which he practices and are defined under Article 1 of Regulation on Community Procedures in the Management of Veterinary drugs and biologicals:

1. He shall organize and monitor the entire pharmaceutical operations of the firm, or the organization, in the area of manufacturing, advertizing, information, pharmacovigilance, monitoring and withdrawal of batches, distribution, importation and exportation of veterinary drugs or biologicals as well as corresponding storage operations ;

2. He shall ensure that transport conditions guarantee the quality preservation, integrity, quality and safety of these veterinary drugs or biologicals;

3. He shall sign, after reading and agreeing with the report file, any administrative authorization request related to activities that he organizes and supervises;

4. In the absence of, or incapacity of the pharmaceutical officer or his deputies, the Authority shall approve their replacement.

5. He shall inform the management of the firm or organization about any obstacles affecting the performance of his duties.

Article 14: APPLICATION OF BEST PRACTICES

The member states shall undertake the legal and administrative measures to ensure that:

1. The veterinary pharmaceutical establishments operate in accordance with best practices applicable to them and that they shall possess notably:

   a) Premises which are prepared, structured and maintained depending on the pharmaceutical operations carried out there;

   b) Necessary human and material resources needed to carry out these activities;

2. Establishments take all the necessary measures to ensure that transport and delivery of veterinary drugs or biologicals are handled in conditions guaranteeing their good conservation, integrity, quality, efficacy and safety.

Article 15: Procedures for Compliance with Best Practices and Veterinary Safety

In addition to the general obligations in Article 14 above, the manufacturers of veterinary drugs and/or biologicals:

1. Shall justify, at any moment, that the products that they used to manufacture and distribute are in conformity with the agreed procedures and that the necessary control operations have been complied with ;

2. Shall ensure that all operations of manufacturing of veterinary drugs and biologicals which are the object of marketing authorization shall be conducted in accordance with the data file of this authorization accepted by the ECOWAS Commission. They shall re-assess, and if necessary, shall modify their methods of manufacture according to the scientific and technical progress made. Should the case arise, the manufacturer shall advice the holder of the marketing authorization and the operator of the veterinary drugs and/or biologicals of these modifications;

3. Shall ensure that each batch of veterinary drugs and biologicals which is authorized on the market is subject to a finished product check as detailed in the authorization file prior to the release of the batch. When batches of veterinary drugs or biologicals being authorized on the market are imported from another Member State of the Community, the accounts of the control corresponding to such batches shall be held by the manufacturing establishment located in this Member State as indicated in Article 7 of this Guideline. The holder of the authorization shall inform the veterinary authority of the identity of the holder of these accounts;

4. Shall ensure that the veterinary drugs and/or biologicals that are subcontracted shall be manufactured by duly authorised manufacturers under the legislation or regulations of the Member State concerned and shall be subjected to the best practices equivalent to those in force in the Community;

5. Shall have a quality control laboratory which shall be placed under the authority of a person with necessary qualifications required to manage the laboratory and shall be independent of the other officials, namely those of production. The control laboratory shall be well equipped with the necessary personnel and materials to undertake the necessary controls and tests on the raw materials and packaging articles as well as the controls of intermediate level and finished products.

6 Shall have a documentation system which includes the specifications, the manufacturing formulas, the procedures and statements, reports and recordings, covering the various operations that they shall undertake. The documents on each batch shall be kept by the veterinary pharmaceutical establishment () for at least one year after the expiry date of the batch concerned and for at least five years after its retail;

7. Shall register and immediately declare to the veterinary authority when they become aware of it, after the marketing of a batch of veterinary drugs and/or biologicals, any incident or accident that may occur during the manufacturing or the distribution of this batch and can likely cause a public health hazard.

Article 16: Obligations of Pharmaceutical Establishments

Without prejudice to the general obligations stipulated under Article 14 of this Directives;

1. Any veterinary wholesale distribution pharmaceutical establishment shall keep records of each input and output transaction as follows:

   a) the transaction date,

   b) the designation of the veterinary medicine,

   c) the date and number of the manufacturing batch and the expiration date,

   d) the quantity received or supplied,

   e) the names and addresses of the supplier and of the recipient.

   This information shall be recorded by all appropriate systems allowing an immediate publication on the request of the control authorities and no data modification shall be allowed after validation of their recording. The information thus recorded shall be held for a period of five years, at the disposal of the relevant veterinary authorities and the ECOWAS Commission.

2. Shall ensure that the individuals and legal entities for whom it is intended shall be legally entitled to distribute and retail the veterinary drugs and biologicals, in accordance with the legislation of the Member State where they are installed.

3. Shall register with the veterinary authority, the area on which he conducts his activity of wholesale distribution. This registration shall be undertaken at the opening of the establishment; it can be modified following a change of the initially registered distribution territory. In the registered area of

distribution, each veterinary pharmaceutical establishment shall be able to satisfy at any moment the needs of its usual clients.

4. Any veterinary pharmaceutical establishment conducting wholesale trading, giving free of charge or undertaking wholesale distribution of veterinary drugs and biologicals shall have an emergency plan which guarantees the effective implementation of any withdrawal of batches of these drugs and biologicals whenever necessary. This obligation applies also to the establishments selling wholesale, making free transfers or conducting the wholesale distribution of veterinary drugs and biologicals submitted for clinical trials or medicinal feed distribution that are withdrawn by the manufacturer.

5. The sales agents shall carry out their activities under conditions stipulated in a written contract which shall comply with the best practices applicable to these activities. The respective obligations of selling agent apply and operator for whom he is working. They shall only distribute those batches of veterinary drugs or biologics that have been subject to release by the pharmaceutical officer of the firm or company which shall ensure the manufacturing or the importation.

Article 17: Advertising drugs

The member States shall provide rules on advertising regarding veterinary profession, veterinary drugs, biologicals and production establishments. These rules are without prejudice to the rules of the veterinary profession. .

CHAPTER 4: MEDICINAL FEED

Article 18: Rules of compatibility

The member States shall provide for the special provisions for the establishment of firms manufacturing, importing, or distributing medicinal feed. These special provisions will be compatible with the community arrangements on animal feed.

Article 19: Responsibilities of the pharmaceutical officers of the Medicinal Feed Manufacturing Firms

1 The leaders in these firms mentioned in article 18, shall engage a veterinary pharmacist or a veterinary doctor who discharges at least the following functions:

a. He shall be responsible for the quality of medicinal feeds manufactured, imported or distributed by the concerned establishments,

b. He shall organise and control the manufacturing, importation or distribution activities in conformity with the best practices applicable to these activities and ensure collaboration with the person in charge of the pharmaco-vigilance control within the Company selling the medicinal premixes being used, as well as with the pharmaceutical officer responsible for advertisement for these companies,

c. He shall control the registers or recordings planned and described below: (list with roman numerals)

d. He shall monitor the compliance to the retail conditions specified by the national regulation.

e. He shall implement any emergency plan for the withdrawal of medicinal feed batches.

f. He shall propose all improvement measures that he deems useful to ensure the implementation of best practices.

g. In addition, the pharmaceutical officer shall make regular visits to veterinary medicinal feeds establishments to get them to comply with best practices. The frequency of such visits shall depend on the nature and significance of operations relative to medicinal feed applicable to this activity.

h. The pharmaceutical officer shall record the dates of visits as well as his observations by any appropriate system allowing an immediate publication upon the request of the control authorities and not authorizing any modification of data after validation of their recording. He puts such information at the disposal of the relevant authority in case of request.

2 The provisions on the full time practice and replacement appearing under Article 12 are not applicable to the pharmaceutical officers mentioned in this article. However, in case of absence or unavailability, the company shall find a replacement to the pharmaceutical officer duly contracted by the company.

4. In case of death or after the company ceases trading or in case of ban of the pharmaceutical officer, the company proceeds immediately to appoint a new pharmaceutical officer.

Article 20: Obligations of Medicinal Feed Manufacturers

Without prejudice to the general obligations mentioned in article 15 of these directives, the manufacturer for medicinal feeds shall ensure that:

1. Only medicinal premixes authorized to be on the market and issued by the ECOWAS Commission in compliance with the conditions defined by this authorization shall be used.

2 The ingredients and premixes used in the manufacture of medicinal feed shall not contain the same antibiotic or the same coccidiostat as additive used as active principle in the medicinal premixes and to only feeds or combinations of those to be used in compliance the requirements of the national or community rules on animals' feeds.

3. The medicinal feed shall be:

a) subject to regular controls to ensure homogeneity, stability and good storage,
b) kept during the period covered by the prescription;

4. The composition of medicinal feed shall be compatible with the daily feed ration of the animals treated; when the medicinal feeds are manufactured with a view of undertaken for a clinical trial, this manufacturing shall be conducted according to the dictates of the promoter. The manufacturer shall ensure that the medicinal feeds thus manufactured are used exclusively in the framework of the clinical trial undertaken.

5. All necessary provisions shall be adhered to in order to avoid any contamination by the medicinal feed of the other categories of feed, as well as any contamination of medicinal feed during manufacturing, importation, distribution or transportation operations.

6. The medicinal premixes and the medicinal feed shall be stocked in premises locked up or in hermetically sealed containers or airtight containers separated by category and specially designed for the keeping of these products.

7. The packages, bags and containers for medicinal feed shall not be reusable, modes of closing of these packages or containers shall not allow for reuse after opening

Article 21: Requirement for prior import authorization

Any importation of medicinal feed shall require a prior importation authorization issued by the national competent authorities, subject to medicinal premixes used, have benefited from Marketing Authorization issued by the ECOWAS Commission as defined under Article 20 above.

Article 22: Mandatorily consigned information

1. Without prejudice to the provisions of Article 4 Paragraph 2, of these directives, the following information shall be recorded:

a. In the case of establishments authorized to manufacture and import medicinal feeds:

i. The date of manufacture, importation, transfer or issuance, depending on the case,

ii. the denomination, quantity and the number of the batch or used medicinal premixes

iii. the nature and quantity of ingredients used and their proportions;

iv. the commercial denomination or, failing that, the nature as well as the quantity of manufactured, imported, medicinal feeds held and transferred;

v. the number of medicinal feed batch and the expiry date;

vi. according to the case, the name and address of the veterinary doctor who made the prescription as well as the name and address of the livestock breeder or owner of animals recipient of the medicinal feed or the name and address of the distributor of the medicinal feed to which it was transferred.

b. In the case of establishments authorized to distribute medicinal feeds:

i. the date of acquisition, transfer or issuance;

ii. the trade designation or, failing that, the nature as well as the quantity of medicinal feed or, failing that, the nature and the quantity of medical feeds acquired and transferred;

iii. the batch number of the medicinal feed and the expiry date;

iv. the name and address of the manufacturer, supplier or distributor of medicinal feeds;

v. the name and the address of the veterinary doctor wrote the prescription;

vi. the name and address of the livestock-breeder or the holder of animals or the recipient distributor of medicinal feeds.

2. The information mentioned under Article 22(1) sub-Paragraphs (a and b) shall be right after each operation, recorded by any appropriate system allowing an immediate publication on the request by control authorities and authorising no modification in the data after validation of their recordings. The registers, the recordings as well as the paper publications of these recordings by maximum periods of one month shall be kept for a period of five years and shall be held at the disposal of control authorities during that period.

Article 23: Restrictions

The member states shall ensure that:

1. The marketing of Medicinal feeds remains in a circuit of legally entitled individuals or authorised establishments.

2. The retail delivery shall be subject to the presentation of a veterinary doctor's prescription established in compliance with national regulation.

CHAPTER 5: EXTEMPORANEOUS PREPARATION, RETAIL SALE AND DISTRIBUTION

Article 24: Entitlement to retail sale and distribution

1. The Member States shall take all the necessary legal measures for compliance with the acquisition, distribution and retailing whether freely or subject to payment to the users of veterinary drugs and biologicals shall be reserved to legally entitled persons and under conditions defined by each Member State.

2. These legally entitled persons in the framework of a full exercise shall be:

   a. veterinary doctors who own a veterinary pharmacy,

   b. the veterinary pharmacist who owns a pharmacy,

   c. The Clinicians in veterinary schools, for the treatment of animals admitted in consultation or hospitalized,

   d. The persons in charge of animal health in Community as appointed in compliance with National rules.

3. As a waiver, for limited categories of veterinary drugs and/or biologicals to be defined by each Member State, the legally entitled persons shall be:

a veterinary doctors registered in the order for an activity within livestock breeders' groupings or agricultural professionals submitted to an approval procedure in the Member State as regards commonly used veterinary drugs and biologics as defined below and for the exclusive use of their members,

b. The persons in charge of State Veterinary Services drugs and/or biologicals required for the implementation of mandatory prophylaxis where there are no practising veterinary doctor or paramedical grouping found in the area.

Article 25: Prescription and Labelling guidelines for Veterinary Drugs and/or Biologicals

1. The Member States shall undertake the necessary legal measures for compliance with prescription and labelling guidelines for the retail distribution of veterinary drugs and biologicals based on the following categories:

a. the veterinary drugs and biologicals containing one or several active ingredients that may either present toxicity for the animal or dangerous for the user of the medicines or the consumer of products of animal origin through harmful residues:

i) Virulent matters and products of microbial origin intended for diagnosis, prevention and the treatment of animal diseases.

ii) Substances of organic origin intended for the same purposes except those which contain only the ingredients known chemically.

iii) Hormonal substances,

iv) Products likely to remain in the state of toxic or dangerous residues in the foodstuffs of animal origin,

v) Products which violate legislations on fraud at the point of origin,

vi) Products which may hamper the safety of foods coming from animals to which they were administered;

b. the veterinary drugs and biologicals with no toxicity for the animal, no danger for the user of the drug or the consumer of animal products through harmful residues.

2. the retail distribution, whether free or charged for, of veterinary drugs and biologicals (referred to in Article 25(1 a) above) shall be prescribed, in writing, by a veterinary doctor, before it can be delivered to the user;

3. The substances referred to in Article 25(1) (a) above shall not be distributed in the state to stockbreeders or certified breeders' groupings, or purchased by these stockbreeders or groupings, except if they are authorised or under the prescription of a veterinary doctor.

4. The substances referred to in Article 25(1) (b) can be accessed by stockbreeders or groupings without prescription

Article 26: **Records of veterinary drugs and biologicals**

1. The Member States shall make legal arrangements so that: any person legally entitled to engage in retail distribution shall hold detailed documentation for each input and output of prescription drugs as follows:

   a. the date of the operation,

   b. the identification of the medicine(name, pharmaceutical form, dosage, target species),

   c. the manufacturing batch number,

   d. the quantity received or delivered,

   e. the name and the address of the supplier or recipient,

   f. The name and address of the prescribing officer.

   g. Date of manufacture and expiry

   h. Manufacturer's full location and address

2. These records shall be held at the disposal of competent authorities and their control staff.

Article 27: **Prescribing appropriate veterinary drugs and biologicals**

The member states shall take all the legal steps to allow the prescription of appropriate drugs and biologicals in accordance with the provisions of Regulation C/Reg.22/11/10 on Community Procedures of Management of Veterinary drugs and biologicals.

Article 28: **Registration of acquisitions and administration of veterinary medicine**

The Member States shall encourage the owners of animals producing commodities intended for human consumption to keep a register giving details of the drug and its administration on animals.

Article 29 : Extemporaneous preparation.

1. The Member States shall ensure that extemporaneous preparation of veterinary drugs and biologics shall be limited to:

a. veterinary doctors owning a veterinary pharmacy,

b. veterinary pharmacists holding a veterinary doctor's prescription,

c. authorised persons by veterinary authorities under the conditions provided in Article 24 of the these Directives

2. The Member States shall ensure that:

a) the extemporaneous preparation of pharmaceutical medicine is only developed from an authorised or approved raw material by the Commission having obtained an authorisation of sale in the market;

b) The extemporaneous preparation of medicinal feeds is made by a person designated by Article 29(1) above through installations at the disposal of the user;

c) The preparation complies with best practices and shall be subjected to inspection by competent veterinary authorities and basic laboratory analysis of the raw material and the finished product.

Chapter 6: CONTROL AND INSPECTION

Article 30: Inspection procedures

1. The Veterinary Authority shall ensure through repeated inspections, unannounced if necessary, that the national and community, legal, administrative and technical guidelines concerning veterinary drugs and biologicals as well as veterinary pharmaceutical establishments are respected.

2. The inspections shall be carried out by the agents of the veterinary authorities, who shall have integrity, independence warranties and sufficient competence and shall legally be entitled to:

a. carry out inspections in the establishments or manufacturing firm, import, wholesale and retail distribution of veterinary medicines;

b. take samples,

c. access to all documents concerning their field of competence.

3. These agents shall submit a report at the end of each inspection on the compliance of these establishments or firms with respect to the provisions of these Guidelines to the veterinary authority officials.

4. The veterinary authority can suspend or withdraw the administrative authorization of manufacturing and wholesale or retail distribution when the functioning requirements are not fulfilled. This decision shall be justified only after the officials have had the possibility to submit their observations.

5. The veterinary authorities can ban or forbid the importation of a veterinary drugs and biologics batch coming from a third country if there is suspicion on the quality or pharmaco-vigilance problems. This decision shall be referred to the ECOWAS Commission. In emergencies, the ban can be decided without advice from the Commission.

6. The veterinary authority shall proceed with samplings and forward the analysis to the network of quality control laboratories of veterinary drugs and biologicals instituted by Regulation C/REG.22/11/10.

7. For the destruction of veterinary drugs and biologicals by the competent authorities and considering their potentially hazardous nature to health, as well as for the environment, the Member States shall take appropriate measures to limit possible harm.

Article 31 Mutual recognition of Inspections

1. Veterinary authorities shall recognize the inspections carried out by other Member States and mutually communicate any useful information on the various establishments.

2. Upon, the veterinary authority can demand for an inspection report or the results of control carried out by the laboratory of another Member state.

Article 32: Pharmaco-vigilance

1. Member States shall encourage the Veterinary Doctors and other health professionals to declare to the veterinary authority all side-effects occurring to man or animal and which are likely to be traced back to a veterinary drug.
2. The information shall be transmitted without delay to the ECOWAS Commission in case of side- effects on man or animal.
3. Member States shall be encouraged to exchange and share pharmaco-vigilance information between each other.

CHAPTER 7: PROVISIONAL AND FINAL ARRANGEMENTS

Article 33: Annual implementation report

1. The veterinary authority of each Member state shall prepare and transmit annually to the ECOWAS Commission, a synthesis report on the implementation of the these Guidelines. The ECOWAS Commission shall specify from time to time the nature of information required.

2. The circulation of already authorized drugs and biologics at the national level at the time of publication of these guidelines is only allowed within that State until the ECOWAS Commission rules on the authorization requests for putting on the market in accordance with Article 49 of the Regulation on establishing Community Procedures for Management of Veterinary Drugs and Biologicals.

3. The Member States shall make legislative, regulatory and administrative arrangements necessary for the implementation of these Directives.

4. In events of emergency, before the implementation of these Guides, protective measures shall be taken by the Member States and immediately notify the Commission.

5. The adopted legal acts taken to this effect shall contain a reference or shall be accompanied by such a reference during the publication

Article 34: Publication

These Directives shall be published by the ECOWAS Commission in the Official Journal of the Community within thirty (30) days upon signature by the Chairman of the Council of Ministers. It shall also be published by each Member State in its National Gazette 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