# GUIDELINE ON APPLICATION FOR REGISTRATION OF UNREGISTERED VETERINARY MEDICINES ALREADY ON THE ZAMBIAN MARKET

## ABBREVIATIONS

**µg** Microgram

**API** Active Pharmaceutical Ingredient

**ATC** Anatomic Therapeutic Chemical classification

**BP** British Pharmacopoeia

**cGMP** current Good Manufacturing Practices

**e.c** Enteric coated

**f.c Film** coated

**FDC** Fixed dose combination

**FP** Finished Product

**GMP** Good Manufacturing Practice

**GS** General Sale

**i.m** Intramuscular

**i.v** Intravenous

**INN** International Non-proprietary Name

**IP** International Pharmacopoeia

**IU** International Unit

**JP** Japanese Pharmacopoeia

**M.R** Modified Release

**mg** Milligram

**ml** Millilitre

**OIE** Office International des Epizooties

**P** Pharmacy

**Ph. Eur** European Pharmacopoeia

**POM** Prescription Only Medicines

**PRA** Pharmaceutical Regulatory Authority

**s.c** Sugar coated

**SPC** Summary of Product Characteristics

**SR** Sustained release

**USP** United States Pharmacopoeia

**VM** Veterinary medicines

**VMP** Veterinary Medicinal Product.

**WHO** World Health Organization

## DEFINITIONS OF TERMS

For the purposes of these guidelines, the following definitions shall apply:

***Active pharmaceutical ingredient (API)*** means a substance or compound that is intended to be used in the manufacture of a pharmaceutical product as a therapeutically active compound (ingredient).

***Authority*** means the Pharmaceutical Regulatory Authority established under Section 4 of the Pharmaceutical Act No 14 of 2004.

***ATC Classification*** means the Anatomical Therapeutic Chemical Classification system as per description given on www.whocc.no/atcvet

***Composition*** composition in relation to a medicinal product means the ingredients of which it consists, proportions, degree of strength, quality and purity in which those ingredients are contained.

***Container*** means a bottle, jar, box, packet, sachet or other receptacle which contains or is to contain in it, not being a capsule or other article in which the product is or is to be administered or consumed, and where any such receptacle is or is to be contained in another receptacle, includes the former but does not include the latter receptacle.

***Container labeling*** Means all information that appears on any part of a container, including that on any outer packaging such as a carton.

***Veterinary Medicines, Medicinal or Pharmaceutical product***

Means any substance or mixture of substances manufactured sold or represented for use in:

(a) The diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical or mental state, or the symptoms thereof, in an animal;
(b) Restoring, correcting or beneficial modification of organic or mental functions in an animal;
(c) Disinfections of premises in which Medicines are manufactured, prepared or kept, animal hospitals or clinics and equipment;
(d) Articles intended for use as a component of any articles specified in clause (a), (b) or (c); but does not include medical devices or their components, parts or accessories.

***Excipient*** means any component of a finished dosage form which has no therapeutic value

***Finished product*** means a product that has undergone all stages of production, including packaging in its final container and labelling

***Formulation*** means the composition of a dosage form, including the characteristics of its raw materials and the operations required to process it.

***General sale Medicines (GS)*** means any medicines whose use does not need the direction or prescription by a Veterinary surgeon or dentist.

***Generic products*** means products that are pharmaceutical equivalents or alternatives to innovator or reference products and which are intended to be therapeutically equivalent and can therefore be used interchangeably with the innovator or reference product.

***Immediate release dosage form*** means a dosage form that is intended to release the entire active ingredient on administration with no enhanced, delayed or extended release effect.

***Impurities*** include by-product of synthesis arising from side reactions products in starting materials etc., residual solvents and reagents, trace elements arising from other sources and products of degradation

***Innovator (or pioneer) pharmaceutical product*** means a pharmaceutical product which was first authorized for marketing (normally as a patented product) on the basis of documentation of quality, safety and efficacy.

***Label*** means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed or impressed on or attached to a container of any Medicines

***Manufacture*** means production, quality control, release and packaging of a product.

***Manufacturer*** means a firm that is engaged in the manufacture of products

***Pharmacopoeia*** includes but not limited current edition of the British Pharmacopoeia, European Pharmacopoeia, United States Pharmacopoeia, International Pharmacopoeia and Japanese Pharmacopoeia.

***Shelf Life*** means the combination of physical, chemical, biological and microbiological test requirements that determine whether a Medicines product is suitable for release at the time of its manufacture

***WHO-type certificate*** means a certificate of pharmaceutical product of the type defined in the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce

***OIE*** means the World Organisation for Animal Health.

***Meat*** means animal tissue used as food.

***Proprietary name*** means the (trade or brand) name, which is unique to a particular medicine and by which it is generally identified (and by which it is registered in the country of manufacture).

***Approved/ INN / generic name*** in relation to a medicine mean the internationally recognized non-proprietary name of such a Medicines.

***Dosage form*** means the form in which the medicine is presented, e.g. solution, suspension, eye drops, emulsion, ointment, suppository, tablet, capsule, etc. For injections, the type of presentation (e.g. vial, ampoule, dental cartridge, etc), and the type of content (e.g. powder for reconstitution, solution, suspension, oily solution, etc.) shall also be stated.

***Description of the product*** means a full visual description of the medicine including colour, size, shape and other relevant features, e.g. 'black and red gelatin capsule with marks "Ampro", 'Green uncoated bolus with word "ALBENDAZOL" embossed on one side' etc.

***Commercial Presentation*** means the final product pack as it will be presented in the market (e.g. 10 ampoules of 2ml each, 10 blister packs of 10capsules each, etc.)

## 1. Introduction:

The Pharmaceutical Act (No. 14) of 2004 requires that veterinary medicinal products intended to be marketed in Zambia meet acceptable standards of quality, safety and efficacy and at the same time be assessed to have been manufactured in facilities which comply with current Good Manufacturing Practices (cGMP).

One of the means for ensuring that a veterinary medicinal product meets the required standards of quality, safety and efficacy is by conducting product specific pre-marketing assessments to determine whether the product should be registered.

These guidelines have been prepared to provide information to applicants who intend to register veterinary medicinal products which are already on the Zambian Market.

This document is intended to provide guidance to applicants on how to complete each part of the application form and the procedure for submitting the application.

## 2.0 Submitting Applications

A separate application is required for each product. Products differing in active ingredient(s), strength, dosage forms, package size (preparations for injection only) or manufactured at different sites are considered to be different products and hence require separate applications.

Applications shall be made by submitting a duly completed application form in a prescribed format. The application shall be made both in hard and electronic copies (word format) and this application should be accompanied by:

i). A non-refundable registration fee;
ii). Proof of registration of the product in the country of origin (such as; WHO-type Certificate of a Pharmaceutical Product specifically addressed to Zambia, Registration Certificate, Free Sale Certificate or an equivalent document);
iii). Package insert, if information is not part of the label;
iv). Two (2) samples of the smallest commercial pack(s) with the respective batch certificate of analysis.

All documents shall be addressed to the Director General, Pharmaceutical Regulatory Authority, Tuleteka Road, Off Makishi Plot No.6903 Rhodes Park, P.O. Box 31890, LUSAKA.

## 3.0 Completing the Application Form

The application form should be completed in a legible font in English. Where the space may not be enough extra pages can be attached.

### 3.1 Details of Applicant

The Application maybe made by:

- A manufacturer;
- Patent holder/Owner of the formulation;
- Person responsible for placing the product on the market with power of Attorney from or contract with the manufacturer or owner of the formulation

All the details required in this section should be provided and where the applicant has power of attorney or contract with manufacturer or owner of formulations the relevant documentation should be submitted with the application.

Type of applicant should be indicated by way of ticking in the appropriate box on the application form.

### 3.2 Details of the Distributor

Every applicant should have a local distributor who is resident in Zambia.

A Distributor is a person(s) registered to conduct business in Zambia with legal authorization to take full responsibility for the product on behalf of the applicant. Letter of appointment as distributor from the applicant should be submitted.

The name, physical and postal address, telephone number, fax number and e- mail address should be provided.

### 3.3 Manufacturer(s), Site(s) for the Finished Veterinary Medicinal Product

The following information relating to the manufacturer shall be provided by the applicant:

The name, physical address, telephone number, fax number, and e- mail address of the manufacturer shall be provided. Where different activities of manufacture of a given product are carried out at different manufacturing sites, the above particulars shall be provided for each site and the activity carried out at the particular site shall be stated.

### 3.4 Name of Product and Dosage Form

The following details of the veterinary medicine shall be submitted:

- Proprietary name
- Approved INN / generic name
- Dosage form

### 3.5 Description of the Veterinary Medicinal Product

A full description of the product including; physical characteristics, consistency of the product, shape, size, colour, odour, taste, type of tablet (i.e. s.c, f.c, e.c, SR etc). Liquids should be clearly stated if it is emulsion, elixir, suspension etc. (e.g. Green uncoated bolus with word "ALBENDAZOL" embossed on one side)

### 3.6 Active Pharmaceutical Ingredient(s)

The following details of the active pharmaceutical ingredient(s) shall be submitted:

- Name
- Strength
- Anatomic-therapeutic classification system (ATC) code. Refer to WHO collaborating centre for drug methodology statistics for current codes (www.whocc.no/atcvet/)

### 3.7 Therapeutic indications

A full description of all indications the product is intended for, including target species should be provided.

### 3.8 Directions for Use

A full description of method of use should be provided and should include dosage, route of administration, dilution rates, frequency and duration of treatment for each indication and species.

### 3.9 Contraindications/ Drug interactions

A full description of situations, species and breeds in which the product is contraindicated should be provided. A full description of all possible drug interactions should be provided

### 3.10 Warnings/Precautions/Overdosage

A full description of all warnings or precautions including those that need to be taken by persons administering/handling the product should be given. Concise symptoms of overdosage and possible management should be provided.

### 3.11 Side effects

A full description of common side effects should be given.

### 3.12 Withdrawal Periods

Details of withdrawal periods should be provided in all food producing animals clearly indicating the time for each type of animal product (i.e. eggs, meat, milk etc).

### 3.13 Storage Conditions

Clear instructions on the storage of the product should be provided and should include specific storage temperature and those related to light and humidity.

### 3.14 Container- Closure System and Administration Devices

A full description of the nature of material construction of the container- closure system should be provided. The details should include; size, shape, colour and details of desiccant, rubber stoppers, seal, devoid filler when present. Specification and full description of administrative devices should be provided where applicable.

### 3.15 Package Sizes/ Presentation

Details of all packages sizes intended for the market should be provided (e.g. 100ml vial, 2 x 10 boluses).

### 3.16 Shelf Life

Shelf life should be provided in months.

### 3.17 Method of sale/ Category of Distribution

The method of distribution should be stated as one of the following:

- Prescription only medicine (POM)
- Pharmacy (P)
- General sale Medicine (GS)

### 3.18 Composition

The approved INN /generic name (s) and the chemical name (s) of the substances (active and inactive) shall be given, and in the absence of a chemical name, the chemical nature of the substance shall be described. Trade names shall not be used. Quantities shall be given in terms of the dosage unit, e.g. mg/ tablet, g/mL, etc. Specifications or reference text shall be precisely stated, e.g. BP (Vet) 2006 page 200.

The reason for inclusion of each inactive ingredient (excipient) in the formulation shall be stated. Any raw materials used, although not present in final dosage form, shall also be stated.

### 3.19 Any Other Information

Details of the product not described above that might be useful in the registration of the product should be provided. This could include any safety updates, status of registration in other countries etc.

### 3.20 Declaration by an Applicant

Each application form shall be duly signed by an authorised person who should be a regulatory affairs person, company pharmacist or quality control manager. The name, qualification, position in the company, signature and date on which that person signed should be submitted.