

# **Registration Guidelines of the Veterinary Drug Control Authority, Department of Animal Production and Health, Sri Lanka.**

## **INTRODUCTION**

With the rapid growth of animal production as an industry, the "Industry of Veterinary Drugs" also has been significantly expanded. As a result, control of import, export, manufacture, re-packing, sales and use of veterinary drugs has become a statutory requirement. Therefore, in order to establish an effective system to undertake such regulatory activities the "Veterinary Drug Control Authority" was established according to the Section 32 of the Animal Diseases Act No 59 of 1992 with the following objectives.

### **1. Powers, Duties and Functions of the Veterinary Drug Control Authority (VDCA)**

- (a) Exercise control over the manufacture, import, export, re-packing, sale and use of veterinary pharmaceuticals and veterinary biological products;
- (b) Ensure efficient and safe use of veterinary pharmaceuticals and veterinary biological products on animals ;
- (c) Determine whether licenses shall be granted for the manufacture or importation of veterinary pharmaceuticals, biological products and other products (Eg: Shampoos, deodorants, toothpastes etc) ;
- (d) Advise the Minister on any matter he may refer to the Authority for advice or any other matter which it considers necessary to bring to the notice of the Minister;
- (e) Promote research which the Authority considers necessary to test or improve veterinary pharmaceuticals ,biological products and other products (Eg: Shampoos, deodorants, toothpastes etc) ;
- (f) Disseminate information relating to the safe and prudent use of veterinary pharmaceuticals and veterinary biological products ; and
- (g) Carry out or cause to be carried out, tests on veterinary pharmaceuticals and veterinary biological products already licensed or pending issue of a license whenever necessary in the opinion of the Authority.

These guidelines are published to assist those who are involved in the veterinary pharmaceutical industry and to familiarize with the legal backup, which regulate the whole process.

### **2. ANIMAL DISEASES ACT NO. 59 OF 1992 (RELEVANT SECTIONS 17, 18, 21, 31, 32, 34).**

17. (1) No person shall manufacture any veterinary drug or veterinary biological product in Sri Lanka except under the authority of a license issued in that behalf by the Director General, Department of Animal Production and Health (DAPH). *Manufacture of veterinary drugs and veterinary biological products and issue of license thereof.*
- (2) Every person desirous of obtaining such license shall make an application to the Director General in that behalf in the prescribed form which shall be accompanied by such fees as may be prescribed.
- (3) Every application under sub section (2) shall be made separately in respect of each veterinary drug or veterinary biological product, as the case may be.

(4) Upon receipt of an application under sub section (2) the Director General shall –

(a) Issue a license, if he is satisfied that –

(i) the application has been made in compliance with the provisions of sub section (2) and that the particulars contained in such application are true and accurate.

(ii) the premises and the equipment therein used for such manufacture conform to the prescribed standards; and

(iii) the person in charge of such manufacture has obtained the prescribed training and experience; or

(b) Reject such application if he is not so satisfied.

18. (1) A license issued under section 17 shall be valid for a period of one year from the date of issue unless earlier cancelled or suspended.

(2) The Director General may cancel or suspend any license issued by him if he is satisfied that the manufacturer has contravened any provision of the Act or Regulations made thereunder.

*Validity of  
the License*

(3) No order under subsection (2) shall be made against the license except after notice issued to him to show cause within such period as may be specified in the notice as to why such order should not be made and except on his failure to show cause within such period or on his not showing sufficient cause.

(4) Any person aggrieved by the rejection of an application under subsection (4) of section 17 or the cancellation or suspension of a license under subsection (2) may prefer an appeal in writing to the Secretary to the Ministry of the Minister against such rejection, cancellation or suspension, as the case may be, within fourteen days after such decision is communicated to such person and the Secretary may, in dealing with an appeal preferred to him, affirm, vary or amend the order against which the appeal has been preferred.

(5) The decision of the Secretary upon such appeal shall be final and conclusive.

21. (1) No person shall import any animal, animal product, veterinary drugs or veterinary biological product, animal semen or embryo except under the authority of a permit issued under this Act by Controller of Imports and Exports on the recommendations of the Director General.

*Prohibition  
on import  
without  
permit*

(2) Where such import is recommended, the Director General shall specify the port of entry.

31. (1) The Director General shall not recommend the issue of a permit to any person for the import of any veterinary drug or veterinary biological product unless such person produces to the Director General a certificate from the Chief Veterinary Surgeon or a veterinary surgeon authorized by him in the country of origin of the product, certifying the safety of such drug or veterinary biological product.

*Import of  
Veterinary  
Drugs and  
Veterinary  
Biological  
Products*

(2) The certificate under sub section (1) shall be substantially in the form set out in the second schedule hereto.

32. (1) There shall be a Veterinary Drug Control Authority (herein after referred to as the "Authority) consisting of the following:

- (a) The person for the time being holding the office of Director General who shall be the chairman of the Authority;
- (b) One member appointed by the Director General from among veterinary surgeons employed in the Department who shall be Registrar of the Authority;
- (c) Six members nominated by the Minister from among persons who appear to the Minister to have wide knowledge and experience, in the following subjects:-
  - (i) Veterinary clinical practice in both state and private sectors;
  - (ii) Veterinary microbiology and immunology;
  - (iii) Veterinary parasitology;
  - (iv) Veterinary pharmacology;
  - (v) Veterinary clinical nutrition;
  - (vi) Veterinary reproductive physiology and endocrinology;
- (d) One member who shall be a veterinary surgeon appointed by the Minister to represent local manufacturers of veterinary drugs and veterinary biological products;
- (e) Such number of members as may be nominated by the Minister for a specific period of time whenever necessary, for the purpose of obtaining their specialized advice and counsel.

(2) The Registrar appointed under paragraph (b) or any member nominated under paragraph (c) of subsection (1) of Animal Diseases Act shall, unless he vacates office early by death or resignation or removal by the Minister by order published in the Gazette, hold office for a period of three years from the date of such appointment or nomination, as the case may be. Provided that a member appointed or nominated in place of a member who dies, resigns or otherwise vacates office, unless he earlier vacates office, hold office for the unexpired period of the term of office of the member whom he succeeds.

(3) The Minister may, by order published in the Gazette, remove any member other than the Director General from office without assigning any reason thereof.

(4) Any member other than the Director General vacating office by the effluxion of time shall be eligible for reappointment.

(5) Any appointed member may, at any time resign his office by letter to that effect addressed to the Minister and such resignation shall take effect upon it being accepted by the Minister in writing.

(6) If any member is temporarily unable to discharge the duties of his office during any period due to ill health, absence from Sri Lanka or any other causes, another person may be nominated by the Minister to act in his place.

- (7) The Minister may determine the remuneration of the members and the manner of such payment in consultation with the Minister in charge of the subject of Finance.
- (8) The powers, duties and functions of the Authority shall be to -
- (a) exercise control over the manufacture, import, export, re-packing, sales and use of veterinary pharmaceuticals and veterinary biological products;
  - (b) ensure the efficient and safe use of veterinary pharmaceuticals and veterinary biological products on animals;
  - (c) determine whether licenses shall be granted for the manufacture or importation of veterinary pharmaceuticals and veterinary biological products;
  - (d) advise the Minister on any matter he may refer to the Authority for advice or another matter which it considers necessary to bring to the notice of the Minister;
  - (e) promote research which the Authority considers necessary to test or improve veterinary pharmaceuticals and veterinary biological products;
  - (f) disseminate information relating to the prudent use of veterinary pharmaceuticals and veterinary biological products; and
  - (g) carry out or cause to be carried out, tests on veterinary pharmaceuticals and veterinary biological products already licensed or pending issue of a license whenever necessary in the opinion of the Authority.

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- Export. (1) No person shall export any animal, animal product, veterinary drug, veterinary biological product, semen or embryo except under the authority of a permit issued by the Controller of Imports and Exports on the recommendation of the Director General.
- (2) No recommendation shall be made by the Director General for the issue of a permit to export any animal, animal product, veterinary drug, veterinary biological product, semen or embryo unless the exporter produces to the Director General a certificate from an Authorized Officer, before exportation. For the purpose of this section " Authorized Officer " means a veterinary surgeon authorized by the Director General in that behalf.
- (3) The certificate under subsection (2) shall be substantially in the form set out in the Second or Third Schedule hereto, as the case may be.
- (4) Every exporter shall give at least one week's notice to the Director General of any such exportation.

### 3. REGULATIONS TO THE ANIMAL DISEASE ACT NO. 59 OF 1992 (RELEVANT SECTIONS)

The relevant sections of the Regulations to the Animal Diseases Act No 59 of 1992 pertaining to the Veterinary Drug Control Activities are as follows:

17. (1) A person desirous of obtaining a license under Section 17 of the Act shall make an application to the Director General in **Form XXII** as set out in the Schedule I hereto.
  - (2) An applicant for a license shall show the Director General persuasive proof that he has the following qualifications:
    - (a) Availability of adequate and appropriate facilities for quarantine, storing (raw materials and finished products), manufacturing, packing and transport
    - (b) Employment of trained personnel with a degree in Veterinary Science, Pharmacy or Pharmaceutical Science or Science with specialization in Chemistry from a recognized university as minimum qualification for production, quality control, supervision and other technical support service, working full time.
    - (c) Availability of facilities for quality control to ensure that products to be of international standards;  
Eg : GMP certification
    - (d) Possession of adequate and appropriate equipment to serve such purposes as is referred to in paragraph (c);
    - (e) Maintenance of proper records and record keeping system for monitoring the quality of products.
  - (3) The application fee for a license shall be revised by Veterinary Drug Control Authority (VDCA) from time to time.
  - (4) A separate application shall be made in respect of each dosage form of any veterinary product.
  - (5) Every veterinary product manufactured or re-packed under a license shall be registered under Regulation 18(5) for any commercial purpose of such drug.
  - (6) A license issued under Section 17 of the Act shall be valid for a specified period of time from the date of issue of the license unless earlier cancelled or suspended. Application for renewal of a license can be made for products which have not been cancelled or suspended. Application for renewal of a license shall be in **Form XXIII** as set out in the Schedule I hereto. Fee for renewal of a license shall be revised by the VDCA from time to time.

- (7) If the manufacturer of Veterinary Drugs or Veterinary Biological Products violates any of the provisions of the Act or Regulations made thereunder or deviates from the procedure laid down by him in the application, the Director General shall issue a notice to the manufacturer to show cause, within three weeks from receipt of such notice for such violation or deviation. The Director General shall cancel the license issued, if no reason given or the reason given is found to be unsatisfactory.
18. (1) A person may import, subject to paragraph (2) of this Regulation, any veterinary pharmaceutical or veterinary biological product for the purpose of;
- (a) Selling to public;
  - (b) Re-packing or mixing and re-packing for free sales to public; or
  - (c) Using on a specified property owned by such person in limited quantity.
- (2) No person shall be permitted to import any veterinary pharmaceutical or veterinary biological product under subparagraph (a) and (b) of paragraph (1), unless a qualified veterinarian is employed by such person on full time basis or as a consultant.
- (3) In case of an import of a veterinary pharmaceutical or veterinary biological product for commercial purpose, the application shall be in **Form XXVI** as set out in the Schedule II in ten copies (01 hard copy, 09 soft copies), and the recommendation for importation shall be as set out in the Schedule hereto.
- (4) a) A license under Section 21 of the Act shall be permitted only to import veterinary pharmaceuticals or veterinary biological products for free sales, sales after re-packing or mixing and re-packing. An application for registration of such drug shall be in **Form XXVI** as set out in the Schedule hereto. In the case of re-packing, the local company should take proper measures to assure the quality of the product.
- b) Manufacturer should give his consent to the local company to re-pack the product.
  - c) When VDCA decides to get laboratory analysis of re-packed products for quality assurance, the cost of lab analysis should be borne by the company that re-pack the product.
  - d) Dates of manufacture/ re-pack, expiry and “veterinary use only” should be indicated clearly in the label.
- (5) In the case of any drug manufactured for commercial purposes, the free sales application for registration of such drug shall be in **Form XXVI** as set out in the Schedule II hereto.

- (6) In case of importation referred to paragraph (1) (c), the application shall be in **Form XXVII** and the recommendation for importation shall be as set out in the Schedule hereto.
- (7) The Director General may, after giving notice, cancel or suspend any license issued by him under Section 17 or any recommendation issued under Section 21 of the Act, if he is satisfied, that the manufacturer or the importer, as the case may be has contravened any provisions of the Act or any Regulation made thereunder.
- (8) In case where a notice is given by the Director General under paragraph (7), the manufacturer or the importer on whom the notice is served, as the case may be, shall be bound to withdraw all products to which such notice relates, from the market and shall destroy them under supervision of an Authorized Officer as directed by the Director General.
- (9) The Director General may empower an Authorized Officer to take sample of any drug from a manufacturer, retailer, or wholesale dealer for the purpose of ensuring quality control and it shall be the duty of such manufacturer, retailer, or wholesale dealer to provide the Authorized Officer with such sample.
- (10) Where the drugs imported under a license issued under the Act are found, at any time after its import, by the Director General to be of poor quality, the licensed manufacturer or importer shall withdraw such drugs on notice being served on him by the Director General, from the market and shall destroy them under supervision of an Authorized Officer.
- (11) Every license under Section 17 or a permit-holder under Section 21 of the Act to manufacture or import or re-pack veterinary drugs or veterinary biological products, as the case may be, shall submit to the Director General, an annual statement indicating the quantity of individual products manufactured or imported or re-packed, on or before 31st of January of the following year.

#### **4. VETERINARY DRUG REGISTRATION SYSTEM**

This process can be broadly classified into four categories as follows;

- a. Registration of local manufacture of veterinary products
- b. Registration of veterinary pharmaceuticals and biological products for free sales within the country
- c. Registration of veterinary pharmaceuticals and biological products for export purpose
- d. Importation of veterinary products under user permits

### **a. Registration of local manufacture/re - packing of veterinary products**

According to the section 17 of the Animal Diseases Act No 59 of 1992, anyone who wishes to manufacture/re-pack any veterinary pharmaceutical or a biological product shall obtain approval from the Director General (DG) of Department of Animal Production & Health (DAPH) prior to functioning.

Application should be submitted according to the section 17(1) of Regulation in Form **XXII** (Annexure 01 of this guideline) to the DG with a specified fee per product. On such a request DG will appoint a team of Inspectors to inspect the facility. Depending on the observations of the Inspection Team, DG may grant approval to commence the activities.

The approval granted for manufacturing is valid only for a period of one (01) year and it should be renewed annually thereafter. Such a request for renewal should be made according to the Section 17(6) of the Regulation in Form **XXIII** (Annexure-01 in this guideline) with a specified fee per each product, 03 months prior to the expiration of the approval.

Once a product is approved for manufacture, the company should submit relevant information and obtain free sales license to market the product in the country.

### **b. Registration of veterinary pharmaceuticals and biological products for free sales within the country**

Any person who wishes to manufacture or import veterinary pharmaceuticals or biological products for the purpose of free sales within the country should register and obtain particular approval prior to make the product available in the open market.

Applications should be submitted according to the Section 18 (3, 4 & 5) of Regulations and the Section 31 of the Act , prepared conforming to the **Form XXVI** (Annexure - 02 of this guideline) in the form of one hard copy and nine soft copies. The application should be essentially authorized with the signature of the applicant who submits the document on behalf of the manufacturer. Such an application should be submitted to the Registrar of the Veterinary Drug Control Authority with a specified fee per each dosage form. These applications are evaluated at the meetings of the Veterinary Drug Control Authority (VDCA) and decision on whether or not to grant approval for free sales are made there. Depending on the decisions made at the meeting the Registrar will issue a registration certificate.

The approval granted for free sales is valid only for a specified period and it should be renewed thereafter. Such a request for renewal should be made in **Form XXVII** (Annexure-02 in this guideline) with a specified fee per each product, 03 months prior to the expiration of the approval.



### **c. Registration of manufacture of veterinary pharmaceuticals and biological products for export purpose**

According to the section 34 of the Animal Diseases Act No 59 of 1992, anyone who wishes to manufacture any veterinary pharmaceutical or a biological product export shall obtain approval from the Director General (DG) of Department of Animal Production & Health (DAPH) prior to functioning.

Application should be submitted according to the Section 17(1) of Regulation in **Form XXII** (Annexure 01 of this guideline) to the DG with a specified fee per product.

Recommendation to export these products should be obtained from VDCA prior to export with the fee specified by the VDCA.

### **d. Importation of veterinary products under user permits**

This category of approval allows importation of a limited quantity of a particular product for a specified period to be used exclusively on animals owned by the applicant. User permits are issued under very special circumstances such as disease outbreaks, research & testing purposes.

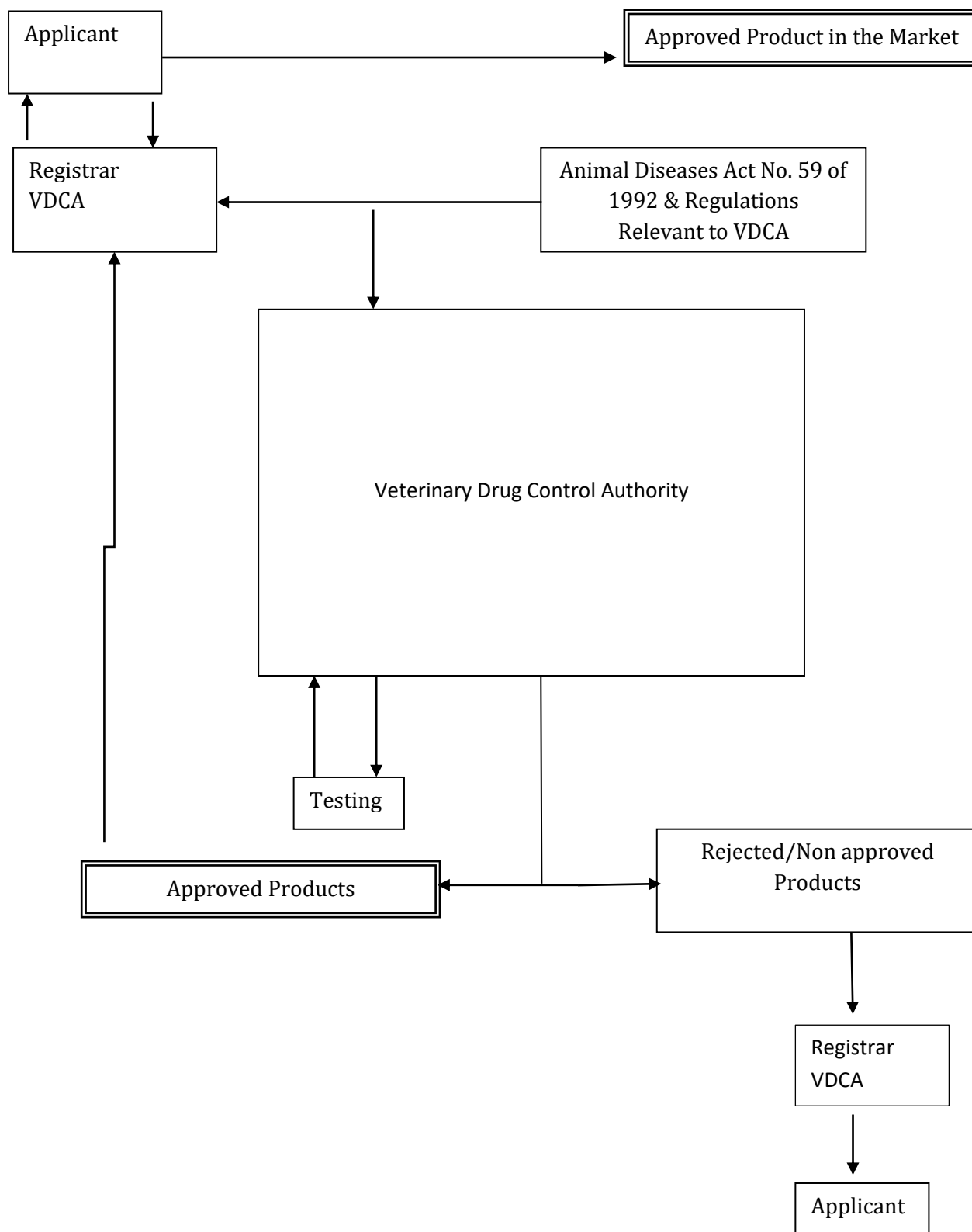
Eg-products such as some live poultry vaccines that are allowed only to be used on breeder animals, but not allowed for free sales

Special User Permits are granted for veterinary practitioners who are registered in the Veterinary Council of Sri Lanka for the use in the own clinical practice under the strict supervision of the applicant, for products that are critically important but not registered for free sales in Sri Lanka.

Applications should be prepared in the relevant **Form XXVIII/XXIX** as the case may be (Annexure -03 of this guideline) and should be submitted to the Registrar of the Veterinary Drug Control Authority with a specified fee per each application. Following the evaluation, the Registrar will issue a User Permit. This approval is valid only for 06 months for the stated quantity and it is prohibited to sell such products that are imported under User Permits.

Applications that do not comply with the VDCA guidelines will not be accepted.

## 5. VETERINARY DRUG REGISTRATION FLOW-CHART



## **6. IMPORTANT FACTORS TO BE CONSIDERED IN REGISTRATION OF VETERINARY PHARMACEUTICALS**

Registration of the following products for food producing animals is not granted (Gazette No. 1,292, 06.06.2003)

- Nitrofurans
- Dapsone
- Ronidazole
- Chloramphenicol -not under any veterinary label
- Aminoglycosides - parenteral preparations - streptomycin, dihydrostreptomycin, neomycin, framycetin, gentamycin, spectinomycin.
- Anabolic steroids as growth promoters
- Antibiotics as growth promoters
- Therapeutic antibiotics indicated for disease prevention.
- Combination of antibiotics, vitamins, minerals, ions, amino acids, and similar products
- Carbadox
- Olaquinox

VDCA may ban the use of any other pharmaceuticals for animals when necessary.

## **7. IMPORTANT FACTORS TO BE CONSIDERED IN REGISTRATION OF VACCINES**

### **a. Killed vaccines**

- Presence of the causative agent in the country must be established
- Safety/potency should be within the acceptable limits
- No adverse effects
- Duration of immunity should allow for a possible immunization program
- Acceptable Adjuvants
- Mode of inactivation - agent and concentration used for inactivation
- Details of the master seed (origin, concentration, manufacturing process)
- Vaccination protocol (when necessary )
- Details of the vector organism
- Dosage
- Shelf life

### **b. Live vaccines**

Here, exceptional care should be taken to prevent the entry of novel organisms into the country.

- Presence of the causative agent in the country must be established
- Stability of the vaccine seed

- Level of attenuation
- Lateral spread and persistence of the organism
- Safety/potency should be within the acceptable limits
- No adverse effects.
- Duration of immunity should allow for a possible immunization program
- Details of the master seed (origin, concentration, manufacturing process)
- Dosage
- Shelf life

**c. Vector vaccines/Recombinant vaccines**

- Presence of the causative agent in the island
- Safety/potency should be within the acceptable limits
- No adverse effects
- Duration of immunity should allow for a possible immunization program
- Acceptable Adjuvants
- Mode of inactivation - agent and concentration used for inactivation
- Details of the master seed (origin, concentration, manufacturing process)
- Dosage
- Shelf life
- Details of the vector organism
- Vaccination protocol when necessary

**8. DOCUMENTS OF IMPORTANCE IN REGISTRATION OF VETERINARY PRODUCTS**

The following documents should be submitted with the applications for registration of products for free sales. English translation should be submitted if the original document is in a different language.

• **Manufacture and Free Sales Licenses in country of origin.**

Certified copies (from Sri Lankan Embassy/High Commission of the country of manufacture) of manufacture license and a copy of free sales license issued by the relevant authorities of the country of origin which allows the particular party to manufacture and free sale the said product in the manufacturing country should be submitted unless the disease is not reported in the country of manufacture. In such cases justification should be submitted.

• **GMP Certificate of the manufacturing plant**

Authenticated GMP (by Sri Lankan Embassy/High Commission of the country of manufacture) certificate should be submitted with the application.

• **Analytical report**

Certificates obtained from a state recognized independent laboratory (does not belong to the manufacturer) and own laboratory should be submitted in order to prove the claims that have been made regarding the properties of the product (chemical, physical, biological).

Verification will be done by VDCA when necessary. Cost of laboratory tests should be borne by the manufacturer/importer. Method of analysis should be submitted by the manufacturers.

- **Registration in other countries**

Evidence of registration in other countries should be submitted with the application (Eg: registration certificate) when applicable.

Products that are not registered for free sales in any other country will not be accepted unless research articles are published in peer reviewed journals.

- **Clinical evaluation/Efficacy trial report**

When application for free sales registration for a new combination or formulations is submitted, articles published in refereed journals or presented in international symposia within last 05 years are preferred.

Clinical evaluation of the particular product conducted by the manufacturer should be submitted for the registration.

- **Toxicity trial reports**

Adequate data on toxicity trials of the particular product should be submitted.

- **Stability test reports**

Stability test reports should be submitted to prove the stated shelf life.

- **Labels and empty cartons**

- ❖ Imported products

Final label/s and carton/s, which would be available in the open market, should be submitted. Once the label and carton get approved it is illegal to make any alterations or changes of such materials without prior approval obtained in writing from the VDCA.

- ❖ Locally manufactured products

Drafts of labels and cartons should be submitted with the application. As in previous case once the label and the carton get approved, any alterations or changes made to that label or to the carton is illegal, if the applicant has not obtained approval in writing from the VDCA prior to such alteration.

- **Company Profiles – Local Company and the Manufacturer**

A document duly authenticated by a Notary Public on the staff profile and infrastructural facilities should be submitted.

- **Distributors**

Detail of local the distributors (name, address, Tele. no. s, email and facilities to store veterinary pharmaceuticals) should be submitted with the applications.

## 9. LABELLING REQUIREMENTS

The following are the essential points that should be included in the label, which will be made available in the open market.

- Signal heading(s)/Keep out of reach of children
- The statement "For veterinary use only" or "For animal treatment only"
- Proprietary name of the product
- Name(s), amount(s) of active constituent(s) and excipients
- Withdrawal periods
- Name & Address of the manufacturer (postal address)
- Batch number
- Date of manufacture
- Date of expiry
  - ❖ Date of repacking if necessary
- Registration number of the VDCA
- Storage instructions
- Any other statement identified by the VDCA where required

Pack insert (if available) should contain additional information such as drug interactions, adverse reactions etc.

- Statement of claims (indications and special claims recommended by the VDCA also should be mentioned).
- Directions for use - dose rate, indicated species, route of administration, duration.
- Safety precautions and contra-indications (when required)
- First - aid instructions (when required)
- Precautionary environmental statement/ special methods of disposal (where required)

### **Additional requirements on registration of ectoparasiticides /disinfectant**

- Outer immediate label - has to be prepared in all three languages (Sinhala/Tamil/English)
- Precautions - should be highlighted by using bold letters
- Safety instructions and directions for use should be clearly indicated
- Antidote, first - aid instructions in case of accidental exposure
- Transport conditions
- Storage instructions
- Method of disposal of empty containers
- Any other requirements specified by the Registrar of Pesticides

**10. FORMAT FOR STANDARD SUBMISSION IN VETERINARY DRUG REGISTRATION FOR FREE SALES.**

Cover page

Proprietary Name  
Generic Name

Strength & Presentation  
Pack sizes

Name and Address of the Manufacturer

Name & Address of the Local agent

**Animal Diseases Act No. 59 of 1992 & Regulations  
Schedule 0I**

**APPLICATION FOR MANUFACTURE / RE-PACKING OF A VETERINARY PRODUCT IN  
SRI LANKA**

**FORM XXII**

1. Name of the product
2. Name, Address, Tele. No. and Email of the applicant
3. Name, Address, Tele. No. and Email of the manufacturing company
  - a) for manufacturing –manufacturer/s of the raw materials expected to be used
  - b) for re-packing – details of manufacturer of the product with the letter of consent for re-packing of the product
4. VDCA import registration No.–annex a copy of the import and free sales license (if applying for re-packing)
5. Name, Address, Tele. No. and Email of the Consultant (trained personnel with a degree in Veterinary Science, Pharmacy or Pharmaceutical Science or Science with specialization in Chemistry from a recognized university)- Include employment details
6. Analysis reports of the raw materials/product

Part- I

**Manufacturing / Re-packing Process**

1. The description of the place to be utilized for manufacturing/re-packing: (should be supported by a sketch of the buildings)  
Describe in detail, arrangements for storage (quarantine, storage of ingredients and finished products), manufacture, mixing, packing, hygienic and aseptic measures adopted.
2. Details of equipment:
  - a. Already available at the site
  - b. Expected to be brought in before the commencement of manufacture



### 3.Details of trained personnel available.

|                 | Name | Qualification | Special training | Nature of employment |
|-----------------|------|---------------|------------------|----------------------|
| Manufacture     |      |               |                  |                      |
| Quality control |      |               |                  |                      |
| Supervisory     |      |               |                  |                      |
| Technical       |      |               |                  |                      |
| Other (Specify) |      |               |                  |                      |

### 4. Quality control.

Detail description of quality control procedure:

- for raw materials/imported product
- for the finished product for each batch

### Part II

#### Product information

1. Generic name(s)/Active ingredient(s)/Composition
2. Pharmacological category
3. ATC vet Code/ATC Code
4. Dosage form
5. Pack size
6. Method, route, species of administration
7. Storage condition and stability
8. Shelf life
9. Label instructions/carton instructions (annex sample label, empty carton)

10. Specimen drug insert (should be annexed)

Note Licensing for sale of this locally manufactured/re-packed veterinary drug or veterinary biological product should comply with the regulations as in Section 18(5).

Signature of the consultant

Name and the Official stamp of the consultant

Date

Signature of the applicant

Name &Designation of the applicant

Date



**Animal Diseases Act No 59 of 1992 & Regulations  
Schedule II**

**FORM XXVI**

**APPLICATION FOR FREE SALES REGISTRATION OF A VETERINARY PRODUCT  
IN SRI LANKA**

1. Name of the product
  - Proprietary name
  - Generic name
2. Dosage form & strength(s) of the product (separate applications should be submitted for different dosage form of the same product)
  - Dosage form
  - Strength
  - Pack sizes
3. Name, Address, Tele. No. and Email of the Local Agent
4. Name and address of the Consultant (trained personnel with a degree in Veterinary Science, Pharmacy or Pharmaceutical Science or Science with specialization in Chemistry from a recognized university) - Include employment details
5. Name, Address, Tele. No., website and Email of the manufacturer
6. Name, Address, Tele. No. and Email of the supplier
7. Is the product registered in the country of origin?  
If so attestation by the authority concern from the country of origin:
8. Certified copies (from Sri Lankan Embassy/High Commission) of Free Sales License, Manufacturing Certificate , Export License and GMP certificate  
Original documents (excluding GMP Certificate of the manufacturing site) need to be produced to the VDCA if the copies are annexed – Annex. No., Page No. s
9. Other places / countries where the product is made, tested and distributed - Annex. No., Page No.s
10. Other countries where the product is registered (provide evidence)- Annex. No., Page No.s
11. Following product information should be supplied with this application- Annex. No.,
  - a. Generic name/active ingredient(s)/composition
  - b. ATCvet/ATC code
  - c. Pharmacological category
  - d. Method, route & dosage for administration
  - e. Animal Species for which the product is indicated
12. Report on laboratory analysis – Raw materials and the finished product - Annex. No.,

- a. From a state recognized independent laboratory- Page No.s
  - b. Own Certificate of Analysis- Page No.s
13. Manufacturing process- Annex. No., Page No.s
  14. Records of clinical evaluation/efficacy trials (published articles in refereed journals or presented in an international meeting are preferred) of the particular product preferably for all the indicated species- Annex. No., Page No.s
  15. Storage conditions and shelf life- Annex. No., Page No.s  
(Proven by stability test reports)
  16. Indications & contraindications- Annex. No., Page No.s
  17. Drug interactions- Annex. No., Page No.s
  18. Withdrawal periods - Annex. No., Page No.s
  19. Information on toxicity trials (for the particular product) - Annex. No., Page No.s
  20. Specimen of empty carton, label and pack insert- Annex. No., Page No.s
  21. Pack size and the number of samples submitted (annex a copy of the invoice approval, recommending the import of samples)- Annex. No., Page No.s
  22. Method of disposal of unused/expired products- Annex. No., Page No.s
  23. In case of a "New Drug" additional information is required on pharmacology, methods of quantitative and qualitative analysis, adverse effects, human toxicity, safety to environment and relevant publications (New Drug is defined as one, which has not been used to a great extent or for a considerable period of time/New combinations or formulations).
  24. Details of payment.  
(A fee of Rs .....would be levied for registration of a veterinary pharmaceutical/biological product/disinfectant in a single dosage form of any given strength(s)).
  25. Deceleration by the applicant.
- I make this application for registration of a veterinary product conscientiously believing the above to be true.

**Suspension or withdrawal of an approval may be decided upon;**

- a. defective therapeutic effects or the product does not provide anticipated therapeutic results.
- b. holder of the license is unable to supply the product for sale.
- c. on request of the manufacturer or importer.
- d. violation of any condition specified in the registration certificate/VDCA from time to time.

Signature

Name and the Official stamp of the consultant

Date

Signature

Name & Designation of the applicant

Date

**Animal Diseases Act No. 59 of 1992 & Regulations**  
**Schedule II**

**FORM XXVII**

**APPLICATION FOR RENEWAL OF FREE SALES REGISTRATION OF A VETERINARY PRODUCT IN SRI LANKA**

1. Name of the product.  
     Proprietary name  
     Generic name
2. Date of the first VDCA registration and the VDCA code
3. Copies of the previous registration certificates
4. Name and address of the Consultant (trained personnel with a degree in Veterinary Science, Pharmacy or Pharmaceutical Science or Science with specialization in Chemistry from a recognized university)- Include employment details
5. Name, Address, Tele. No. and E.mail of the manufacturer
6. Name, Address, Tele. No. and E.mail of the supplier
7. Is the product registered in the country of origin?  
     If so attestation by the authority concern from the country of origin:
8. Certified copies (Sri Lankan Embassy/High Commission) of free sales certificate, manufacturing certificate and GMP certificate –Original documents (excluding GMP Certificate) should be produced to the VDCA – Page No.s
9. Other places / countries where the product is made, tested and distributed- Page No.s
10. Other countries where the product is registered- Page No.s
11. Report on laboratory analysis – Raw materials and the finished product
  - a. From a state recognised independent laboratory- Page No.s
  - b. Own Certificate of Analysis - Page No.s
12. New records of clinical evaluation (recently published articles in refereed journals or presented in an international meeting) of the particular product - Page No.s
13. Storage conditions and shelf life- Page No.s
14. Quantities imported during last 3 years (pack size, quantity)
15. Information of sales during last 03 years (district, quantity)
- 16 Any changes of the product submitted for the previous registration
17. Label/Carton/Pack insert
18. Details of payment.  
     (A fee of Rs ..... would be levied for registration of a veterinary pharmaceutical/biological product/disinfectant in a single dosage form of any given strength(s)).

19. Deceleration by the applicant.

I make this application for registration of a veterinary product conscientiously believing the above to be true.

**Suspension or withdrawal of an approval may be decided upon;**

- a. defective therapeutic effects or the product does not provide anticipated therapeutic results.
- b. holder of the License is unable to supply the product for sale.
- c. on request of the manufacturer or importer.
- d. violation of any condition specified in the registration certificate/VDCA from time to time.

Signature of the consultant

Date

Name and the Official stamp of the consultant

Signature

Date

Name & Address of the applicant.

**Animal Diseases Act No. 59 of 1992 & Regulations**

**VETERINARY DRUGS CONTROL AUTHORITY  
DEPARTMENT OF ANIMAL PRODUCTION & HEALTH**

**THIS APPLICATION IS ISSUED BY VDCA AS PER THE DECISION BY DAPH, PERADENIYA  
SCHEDULE NO.02**

**APPLICATION FOR A USER PERMIT TO IMPORT VETERINARY PHARMACEUTICALS OR  
VETERINARY BIOLOGICAL PRODUCTS TO SRI LANKA**

පශු ඖෂධ හෝ ජෛව නිෂ්පාදන ශ්‍රී ලංකාව තුළට ආනයනය කර භාවිතය සඳහා බලපත්‍රයක් ලබා ගැනීමේ අයදුම්පත්‍රයයි

**Form XXVIII**

**\* To be filled by the User/Farm Owner**

ඖෂධ භාවිතා කරන්නන් /ගොවිපල හිමියන් විසින් පිරවිය යුතුය.

01. Name of the User / Farm Owner:ඖෂධ භාවිතා කරන්නාගේ/ගොවිපල හිමියාගේ නම:

.....

02. Postal Address and the telephone number of the User/Farm Owner :ගොවිපල හිමියාගේ තැපැල් ලිපිනය හා දුරකථන අංකය:

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03. Name and DAPH registration number of the Farm:ගොවිපලේ නම හා ස.නි.සෞ.දෙ.ලියාපදිංචි අංකය:

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04. Location of the Farm (detailed address):ගොවිපලේ ලිපිනය:

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.....

05.Veterinary Range; පශු වෛද්‍ය කොට්ඨාශය:.....

06.Veterinary Investigation Center;පශු විමර්ශන මධ්‍යස්ථානය:.....

07.Species; සත්ත්ව විශේෂය: .....

a. Poultry (Breeder/Layer/Broiler): කුකුළන් වර්ගය(බිත්තර දමන/අභිජනන/මස් පිණිස):

.....

b. Cattle /Goats/Swine/Other (specify):හරකුන්/එළවන්/ඌරන්/වෙනත්(සඳහන් කරන්න):

.....

08. a. Details of the present flock:දැනට සිටින සතුන් පිළිබඳ විස්තර:

| Flock No.<br>කාණ්ඩ අංකය | Age to Date<br>අදාළ දිනට<br>වයස | Strain<br>මාදිලිය<br>Breed<br>ප්‍රභේදය | Source of Day<br>Old Chicks &<br>එක් දිනක් වයස<br>ඇති කුකුල්<br>පැටවුන්ගේ<br>විභවය | No. of Birds at<br>Beginning<br>ආරම්භයේ ඇති<br>සතුන් ගණන | No. of Birds<br>to Date<br>අදාළ දිනට ඇති<br>සතුන් ගණන |
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|                         |                                 |  |  |  |   |

b. If not intended for Poultry, give relevant details of the animal species concerned:

කුකුළන් නොවේ නම් අනෙකුත් සතුන්ට අදාළ විස්තර:

| Species<br>සත්ව විශේෂය | Age<br>වයස | No. of Animals<br>සතුන් ගණන |
|------------------------|------------|-----------------------------|
|                        |            |                             |
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09. Required type & the quantity of the vaccine/ pharmaceutical product (Annex product information; අවශ්‍ය එන්නත්/ ඖෂධ වර්ගය හා ප්‍රමාණය (අවශ්‍ය එන්නත්/ ඖෂධ වර්ගය පිළිබඳ විස්තර අමුණන්න):

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10. Specific purposes or the problems related to the importation of vaccines/pharmaceutical products:එන්නත්/ඖෂධ ආනයනය කිරීමට ඇති විශේෂ හේතුව:

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11. Treatment protocol/ප්‍රතිකාර කිරීමේ සැලැස්ම)

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11. Details of the vaccinations/treatments:එන්නත් / ඖෂධ භාවිතය පිළිබඳ විස්තර:

| Date of vaccination/treatment<br>එන්නත්/ඖෂධ භාවිතා කිරීමේ දිනය | Flock size/Herd Size<br>සතුන් ප්‍රමාණය | Requirement of quantity of vaccine/<br>pharmaceutical product<br>එන්නත්/ඖෂධ ප්‍රමාණය |
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12. Details of the previous consignment:අදාළ ඖෂධ /එන්නත ආසන්නතම ආනයනය පිළිබඳ විස්තර:

| Date/දිනය | Quantity/ප්‍රමාණය |
|-----------|-------------------|
|           |                   |
|           |                   |

13. Name and address Signature & Official Stamp of the Veterinarian recommending this vaccine/ pharmaceutical product;

I. Name:.....

II. Address:

.....  
.....  
.....

III. Recommendations:

.....  
.....  
.....

Signature & Official Stamp ..... Date:.....

Declaration by the applicant:

I certify that the above mentioned statement is true and correct. Furthermore if approved I declare that the above mentioned doses of the above mentioned vaccines/drugs will be used absolutely in my farm under my personnel supervision. If I violate this procedure I agree that I will not be eligible for any future user permit approvals. ඉහත සඳහන් තොරතුරු නිවරදි හා සත්‍ය බව මෙයින් ප්‍රකාශ කරන අතර, තව දුරටත් මා ප්‍රකාශ කර සිටින්නේ ඉහත සඳහන් එන්නත්/ඖෂධ වඩි ප්‍රමාණය අනුමත වුවහොත්, නියමිත වශයෙන් හා එය මාගේ ගොවිපලේ පමණක් මාගේ අධීක්ෂණය යටතේ භාවිතා කරන බවයි. මෙම පිළිවෙලට හානිකර පරිදි මා එන්නත්/ඖෂධ භාවිතා කළහොත් ඉදිරියේ දී අයදුම්පත් ඉදිරිපත් කිරීමට මා නුසුදුස්සකු වන බවට එකඟ වෙමි.

13. Name& Signature ;නම/අත්සන Date: දිනය

14. Name and Address of the Importer: ; එන්නත්/ඖෂධ ආනයනකරුගේ නම හා ලිපිනය:

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.....  
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15. Name and Address of the Manufacturer: ; එන්නත්/ඖෂධ නිෂ්පාදනය කරන ආයතනයේ නම හා ලිපිනය:

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16. Name& Address of the Supplier: ; එන්නත්/ඖෂධ සැපයුම්කරුගේ නම හා ලිපිනය:

.....  
.....  
.....

**Attestation by Range Veterinary Surgeon**

01. Number of years of poultry farming in the above location/relevant details in case of other species:

.....

02. Total population of the farm/location (type and age to be mentioned):

.....

a) Poultry:- no. of chicks:

-no. of growers

-no. of layers

b) Other animals: -no. of species and/or animals: .....

c) Any other details (annex if necessary):.....

03. Observation on type of housing and biosecurity:

.....

.....

.....

04. History of diseases outbreak during the current year and previous year separately:

Current year:

Previous year:

05. Current Situation: Recent Clinical Cases, Mortality and Vaccination/treatment Schedules with type of vaccines/pharmaceutical products used (annex):

.....

.....

06. Recommendation regarding the need to import and usage of special vaccine/pharmaceutical product for any special problems:

1) Recommended/Not Recommended:

2) If recommended, Quantity:

3) If not reasons: .....

.....

.....

.....

Name/Signature&Official Stamp of Range Veterinary Surgeon:

Date:

**Observations and Comments by Veterinary Investigation Officer of the Area**

01. Name of the Farm/ Institution:

.....

02. Address of the Farm/Institution:

.....

03. Name of the Veterinary Range:

.....

04. Observations ( Type of housing and biosecurity measures):

.....  
.....  
.....  
.....

05. Details of the laboratory confirmed diseases in the current year (annex if necessary):

.....  
.....  
.....

06. Comments about the above requirement for this farm (including population of animals);  
\*\* (please specify the type and the quantity of the pharmaceutical/biological product and the disease/clinical situation);

.....  
.....

Name/Signature/Seal of Veterinary Investigation Officer:

Date:

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For Office Use only by VDCA/DAPH

Approved / Not approved

Approval Number

**Animal Diseases Act No. 59 of 1992 & Regulations**

***VETERINARY DRUGS CONTROL AUTHORITY  
DEPARTMENT OF ANIMAL PRODUCTION & HEALTH***

**THIS APPLICATION IS ISSUED BY VDCA AS PER THE DECISION BY DAPH, PERADENIYA  
SCHEDULE NO.02  
APPLICATION FOR A SPECIAL USER PERMIT TO IMPORT VETERINARY PHARMACEUTICALS OR  
VETERINARY BIOLOGICAL PRODUCTS TO SRI LANKA**

**Form XXIX**

**To be filled by the applicant (Veterinarian registered in Veterinary Council of Sri Lanka)**

01.Name:.....

02.Address:  
.....  
.....  
.....

03. Telephone No:.....

04. E.mail :.....

05. Name , address and the DAPH registration number of the veterinary practice:  
.....  
.....  
.....

06. Information of the product (Detailed product information should be annexed)

Brand name:.....

Generic name:.....

ACTvet/ACTcode:.....

Indicated species:.....

07. Required quantity:  
.....

08. Specific purposes or the problems related to the importation of vaccines/pharmaceutical products:

.....  
.....  
.....

09. Name and address Signature & Official Stamp of the Veterinarian recommending this vaccine/  
pharmaceutical product;

I. Name:

.....

Veterinary Council Registration No:.....

Address:.....

.....

Telephone No.: .....

E.mail:.....

II. Recommendation:

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Signature & Official Stamp .....

Date.....

10. Name and Address of the Importer:

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11. Name and Address of the Manufacturer:

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12. Name & Address of the Supplier:

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.....

13. Declaration by the applicant:

I certify that the above mentioned statement is true and correct. Furthermore if approved I declare that the above mentioned product will be used only in my veterinary practice under my supervision and I will submit information of the usage of the product to the VDCA. If I violate any condition, I understand that I will not be eligible for any future Special User Permit approvals.

Name & Signature ;

Date:

---

For Office Use only by VDCA/DAPH

Approved / Not approved

Approval Number