GUIDELINES FOR REGISTRATION OF VETERINARY TEST KITS AND DEVICES IN SRI LANKA

Veterinary Drug Control Authority (VDCA)

Department of Animal Production & Health

Sri Lanka

1.0 INTRODUCTION

1.1 PURPOSE

This document is meant to provide general guidance and assist veterinary test kits and device importers when submitting applications for regulatory approval to the VDCA.

1.2 BACKGROUND

In case of veterinary test kits and device registration, each and every product should be registered separately after evaluating each product for basic parameters (i.e. quality, safety, effectiveness, stability/shelf life) and the applicant will be issued a 'marketing authorization', or license.

For the importation of veterinary test kits and devices, the application should be submitted to the VDCA, through the local agent representing the manufacturer. Regarding manufacturing, the main focus is on the certificate of good manufacturing practices (GMP) issued by the regulatory authority of manufacturing country.

1.3 SCOPE

This document applies for all veterinary test kits and devices. The Veterinary Drug Control Authority of Sri Lanka (VDCA) regulates the importation and/or manufacture, sale of veterinary test kits and devices by requiring that all veterinary test kits and devices to be registered before they are imported/manufactured, supplied, distributed or sold.

1.4 DEFINITION OF A VETERINARY DEVICE INCLUDING VETERINARY TEST KIT

“Veterinary Device” means any article, instrument, apparatus or contrivance, including any component, part of accessory thereof; manufactured or sold for use in,

•the diagnosis, treatment, mitigation or prevention of disease, disorder or abnormal physical state or the symptoms thereof, in animals,

•restoring, correcting or modifying a body function or the body structure of animals,

•the diagnosis of pregnancy in animals, or

•the care of animals during pregnancy and after birth of the off-spring, but does not include a drug

2.0 REGISTERING PROCEEDURE OF VETERINARY TEST KITS AND DEVICES

Persons who import veterinary test kits and devices are responsible for applying to the Veterinary Drug Regulatory Authority (VDCA) to get import free sale approval. The applicant shall be responsible for the product and all information supplied in support of his/her application for registration of the product.

2.1 Responsibilities of an applicant

The applicant/ registration holder or importer must in writing declare that they are responsible for ensuring safety, quality & effectiveness of the registered veterinary test kits and devices and that the product complies with all existing regulations and specifications (standards).

Responsibilities include;

• Responsible for veterinary product and all the information supplied in support of his/her application for registration of product and for updating any information relevant to the product

• Having effective procedure for handling any adverse effects that may occur with the product in use.

• Execute suitable quality control

• Ensuring appropriate packaging material is used to guarantee quality of the product

2.2 The procedure of registration of veterinary test kits and devices is as follows

2.2.1 Submission of application

The application need following requirements on submission

-application should be in a box file

-first page should contain following details

approved name, brand name, manufacturer's details, importer's details.

-application should be numbered inserting polio numbers

(1) Basic requirements

• Index

• Acknowledgement

• Copy of sample import license

I. Name and address of the applicant, manufacturer and importer

II. Name of the veterinary test kit or device, brand name (if any), official or approved name

III. A Certificate from the veterinary authorities of the country in which it is produced confirming that the test kits or device is in use there and the period of use (Free sale certificate) - original or copy of a free sale certificate which is attested by a Sri Lankan embassy is acceptable. If not, reasons for not marketing it in the country of the manufacture.

IV. List of countries with documents to prove registration status in other countries

eg. Foreign country registration certificate

V. Fully packed samples of the veterinary test kits and devices (if requested by the VDCA)

The applicant should be able to submit at least two samples (at any time after registration) from commercial batches. (Eg: For sterile products, Single user products)

Two samples are also be submitted for instruments & apparatus of veterinary use. In case of veterinary machineries & highly expensive veterinary devices the local agent should be in a position to demonstrate description of those machines to VDCA when they require to do so. (The applications without relevant samples are not acceptable)

VI. Sample of the label(s) with inner & outer cartons, product catalogue to aid the identification of the product lot no., manufacture date, expiry date, manufacturer's name, address, country of origin should be indicated on the label

VI. Name, designation, registration number & signature of the applicant consultant.

(2) Other Requirements

The following documents should be submitted in addition to the above mentioned basic documents / details where necessary / if available

1) Own standardization reports

2) Independent standardization reports from Sri Lanka Standard Institution (SLSI) are needed for certain veterinary items

eg. Plasters, gauze, bandages, dressings etc.

3) Following requirements should be fulfilled for absorbable sutures in veterinary use with the application.

- All the samples of absorbable sutures will be kept at the VDCA for six (6) months before sending for evaluation to the committee.
- Details of the raw material sources, purchasing details should be provided.

4) Where necessary certificate of approval from relevant authorities should be provided.

eg: -For radiation emitting devices approval obtained from Atomic Energy Authority of Sri Lanka

- Certification from the relevant veterinary authority of the country of manufacturer that the product is free from BSE (Bovine Spongiform Encephalopathy) should be obtained for animal derived products

eg: Surgical Catgut for veterinary use

5) Instructions for use in three languages- English, Sinhala & Tamil- for relevant products such as Glucometer, Ear and Forehead Thermometers of veterinary use should be submitted whenever necessary.

6) For Borderline veterinary devices with therapeutic claims relevant clinical trial data should be submitted.

7) Labels & Product information leaflets

Labelling requirements

The container of every veterinary test kits or devices imported, processed or packed locally or sold or exposed for sale shall have labels bearing the following information clearly.

1) The approved name (official name) & Brand name (Trade name). Where standards are available labels more should be produced accordingly.

2) The intended purpose of use.

3) Any special storage conditions that may be necessary

4) Any warning and precautions that may be necessary

5) The date of manufacturer and date of expiry where applicable; (An indication of the date until which the veterinary device may safely be used expressed as the year and the month (eg. single –use disposable devices)

6) The batch or lot number assigned by the manufacturer;

7) The name and address of the manufacturer including country of manufacturing;

8) Adequate directions for use of the veterinary test kits or device

9) For imported veterinary test kits and devices, the label to the outer packaging shall have the name and address of the local importer

10) Sufficient details for the user to identify the veterinary test kits or device, or where relevant, the contents of any packing.

11) An indication that the manufacturer for single use has specified the veterinary test kits or device “For single use only”.

12) Date of manufacture & Date of expiry, any special storage and/ or handling conditions on the external packaging condition

13) When a veterinary test kit or device is manufactured by a source other than the principal manufacturer (loan/ contract manufacturer etc.), the label should clearly identify the name and address of such manufacturer as follows. “Manufactured by …… For ……” and the country of origin should be clearly stated in the label.

14) If a particular veterinary test kits or device is distributed by a source other than the principal manufacturer, the label must clearly identify the name and address including the country of origin of the distributor as follows. “Manufactured by ……. Distributed by…….”.

15) In addition to the above, any other requirements for labeling that may be mandated from time to time by the VDCA shall be complied with.

Product information leaflet

1) The performance intended by the manufacturer and undesirable side- effects.

2) The information needed to verify the veterinary test kits or device is properly installed and can operate correctly and safely. Replacement of consumable components, and calibration needed to ensure that the veterinary device operates properly and safely during its intended life.

3) Detail of any further treatment or handling needed before the veterinary test kits or device can be used, where applicable should be indicated. On sterile packaging and, where appropriate, description of methods of re- sterilization /or whether it cannot be re- sterilized /or cannot be re-used by sterilization.

4) If the veterinary test kits or device is to be installed with or connected to other devices or equipment in order to operate as required for its intended purpose.

5) If the veterinary device is implantable, information regarding any particular risk in connection with its implantation.

6) Information regarding the risks of reciprocal interference

(Eg: Electrical interference from electro – surgical devices or magnetic field interference from magnetic resonance imagers).

7) If the veterinary test kits or device is reusable, information on the appropriate processes to allow reuse, including, disinfections, packaging and, where appropriate, the method of re-sterilization and any restriction on the number of re-uses.

8) Where veterinary devices are supplied with the intention that they be sterilized before use, the instruction for cleaning and sterilization should be such that, if correctly followed, the device will “still comply with the essential principles of safety and performance of veterinary devices”.

9) If the veterinary device emits radiation for medical purposes, details of the nature, type, intensity and distribution of this radiation.

10) The instructions for use should also include, where appropriate, details allowing the veterinary staff to brief the patient on any contra indications, warnings and any precautions to be taken. These details should cover in particular:

(a) Precautions to be taken in the event of changes in performance of the veterinary device.

(b) Precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, proximity to other veterinary devices, etc.

12) Adequate information regarding any veterinary product or which the device in question is designed to administer, including any limitations in the choice of substances to be delivered.

13) Precautions to be taken against any special, unusual risks related to the disposal of the veterinary device.

14) Any veterinary substances incorporated into the veterinary device as an integral part of the device.

15) Degree of accuracy claimed for veterinary devices with a measuring function.

16) Any requirement for special facilities, special training or particular qualifications for the use or maintenance of the veterinary device.

2.3 Multiple applications

(1) Separate application to be submitted when a veterinary device consists of different constituents/components. Each and every component of that system is registered separately.

eg: (i) Orthopedic system - separate applications should be produced for bone plates, nails, pins, screws

(ii) Dental appliances

(2) A veterinary device although the manufacturing process is same and share a common intended purpose is registered separately.

eg: (i) Syringes with different volumes

(ii) CV catheters, haemodialysis instruments, blood bags (for single, double and triple)

(3) In vitro diagnostic veterinary devices that consist of reagents or article intended to be used in combination to complete a specific intended purpose is registered as a group

eg: (i) Hematology analyzer with standards, programme and reagents Or as separately

(ii) Blood grouping reagent, blood glucose monitoring system with component

(4) A veterinary device consisting a collection of devices and has a common intended purpose is registered as a group.

eg: (i) Electro surgical unit with standard accessories (electrodes, electrode holders, leads, plates, plug adopter)

(ii) Centrifuge and standard accessories

(iii) Nebulizer system

2.4. File submission procedure

• Application dossier should be submitted to the VDCA & applicant has to make the payments (Rs.3000.00 on submission) to the shroff counter of the Department of Animal Production and Health.

• Completed application should be submitted to the VDCA where the dossier will be cross checked with a checklist by the VDCA & will decide whether the dossier is in order and a serial acceptance number will be issued.

- Upon reception a sample license will be issued in duplicates: one to be annexed to the dossier and the other as a supportive document for requesting sample import. Until the samples are submitted to the VDCA, the dossier will not be considered for further evaluation.

Special Requirements

Special requirements, which apply only to some veterinary devices,

• Chemical, physical and biological properties of the veterinary device

• Minimization of risk of infection and microbial contamination to a patient, user or any other person

• Construction and environmental properties of the device should be safe

• Veterinary devices with a measuring function should provide accurate precise and stable measurements

• Protection against radiation of the patient, user or any other person

• Veterinary devices connected to or equipped with an energy source must be designed and produced in such a way that it ensures the performance, reliability and repeatability of the system and risks associated with a single faulty condition are minimized.

2.5. Processing of evaluation

Applications are subjected to VDCA committee. According to basic evaluation if dossier is unsatisfactory those applications will be rejected.

According to the VDCA committee's recommendation & approval the application will be granted provisional/full registration. If the application is failed with in the process the local agent can appeal for the registration.

2.5.1 Validity of registration

• Full registration

Full registration of veterinary devices will be valid for a period of three (3) years and is specified in the certificate. Renewal of registration is to be done every three yearly.

• Provisional Registration

Under certain circumstances provisional registration will be granted for a period of one year such as ;

- New veterinary device

- New specifications of a veterinary device

- New manufacturer

- In case of agency transfers

- Products which have been suspended due to quality problems

- Applications that do not provide required documentation as outlined above for registration of a veterinary device

These registration certificates will be issued by the VDCA upon payment of certificate fee of LKR 2000.00

2.6 Renewal of import license

• After applicant has obtained a registration, with the copy of registration certificate & request letter the applicant can apply for renewal of import license after 3 years. If there are any changes from the previous submission, they should be indicated clearly with documentary evidence.

• The payment of LKR 2000.00 should be made into shroff counter of the Department of Animal Production and Health when the renewal license is issued.