Medicines Control Authority of Zimbabwe

LEF 40

LICENSING AND ENFORCEMENT DIVISION

APPLICATION FOR AUTHORITY TO IMPORT CATEGORY III UNREGISTERED VETERINARY MEDICINES

Section 75 of the Medicines and Allied Substances Control Act [Chapter 15:03]

Part A (To be completed by the Applicant (Wholesale Dealer)

1. Applicant:

   ……..

2. Physical address:

   ...……

3. Phone/cell number:

   ……

4. Email address:

   ……...

5. Table 1: Unregistered Veterinary Medicines to be imported under the Section 75 of the MASCA, [CAP 15:03]

Generic name	Trade name	Strength & Form	Quantity (x pack size)	Manufacturer	Source (Country)	Port of Entry*

*Medicines should be imported through approved ports of entry see Annex I of the guidelines

6. Intended Use:

   ……

7. I declare that, the medicine acquired under the provisions of Section 75 of the MASCA, [CAP 15:03] shall not be distributed for resale or use by unauthorized individuals,
8. Name:

   ……
9. Position / Rank (if in a company):

   ……
10. Signature:

    ……..
11. Date:

    …….....

Part B (To be completed by the Company Veterinarian)

12. Table 2: Clinical Condition and the Medicinal requirements of the herd/flock

Clinical Condition	Medicine (Strength & Dosage form)	Dose/animal/day

13. I declare that:

13.1 I shall monitor usage of the products

13.2 I shall report all adverse events to MCAZ

13.3 I am aware that any misrepresentation, submission of misleading or false information constitutes a professional misconduct which can be reported to the Council of Veterinary Surgeons and may result in disciplinary action and criminal proceedings

14. Name &Company of Veterinarian (who will monitor use of drugs):

    ……

    ……

15. Physical address:

    ……...

16. Phone/cell number:

    ……

17. Email address:

    ……..…….

18. Qualifications:

    ……...

19. Signature:

    ……..…….

20. Date:

    ……..

NOTE: A COMPLETE APPLICATION COMPRISES

1. A completed form
2. A Proforma Invoice/ Invoice from the supplier
3. A cGMP certificate of the manufacturer
4. A registration certificate from country of origin or from other countries to which the product is exported (preferably SRA countries)
5. Package inserts
6. Labels for the product information.
7. In cases of biologicals and vaccines the applicant is required to attach a letter/import permit from DVS confirming the prevalence of the disease/clinical condition(s) to be alleviated.
8. The requisite annual authorisation fee and consignment application fee per product (for first time application) or just the consignment application fee per product for all subsequent consignments in that particular year period.