Medicines Control Authority of Zimbabwe

LEF 42

LICENSING AND ENFORCEMENT DIVISION

APPLICATION FOR AUTHORITY TO IMPORT CATEGORY II 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]

Application Number	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. Name: ……
8. Position / Rank (if in a company): ……
9. Signature: ……..
10. Date: …….....

Part B (To be completed by the Company Veterinarian)

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

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

12. I declare that:

12.1 I shall monitor usage of the products

12.2 I shall report all adverse events to MCAZ

12.3 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

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

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14. Physical address: ……...

15. Phone/cell number: ……

16. Email address: ……...

17. Qualifications: ……...

18. Signature: ……..

19. 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.