MINISTERU GHALL-IZVILUPP SOSTENIBBLI, L-AMBJENT U TIBDIL FIL-KLIMA

SEGRETARJAT PARLAMENTARI GHALL-BIEDJA, SAJD U DRITTIJIET TAL-ANNIMALI

Dipartiment għar-Regolazzjoni Veterinarja u Saħħa tal-Pjanti

MALTA

MINISTRY FOR SUSTAINABLE DEVELOPMENT, THE ENVIRONMENT AND CLIMATE CHANGE

PARLIAMENTARY SECRETARY FOR AGRICULTURE, FISHERIES AND ANIMAL RIGHTS

Veterinary and Phytosanitary Regulation Department

APPLICATION FORM 2D

APPLICATION FOR A MEDICATED FEED MILL

For office use only: **Application Form received on: __ / __ / __**

ABATTOIR STREET, ALBERTOWN, MARSA, MRS 1123 - MALTA
TELEPHONE: (356) 22925375/6

Version 2: 18-04-2013

DEFINITIONS

1. Medicated Feed Stuff

The final medicated feeding stuff means any substance, not being a veterinary medicinal product, which is for use wholly and mainly by being fed to one or more animals for a medicinal purpose, or for purposes that include that purpose, without further processing.

2. Medicated Feed Mill

It is the approved establishment where authorised medicinal premixes are physically mixed with approved feeds to manufacture a final medicated feeding stuff.

3. Medicated Feeding Mill Licence

A Medicated Feed Mill Licence permits the licensee to manufacture Medicated Feeding Stuff in an approved feed business establishments. The licence allows the licensee to distribute the Medicated Feeding Stuff to persons/enterprises authorised to receive them. Persons who are authorised to receive Medicated Feed Stuff are:

(i) Approved and registered animal producers

(ii) Approved owners of registered veterinary pharmacies

Manufacture, distribution and use of the Medicated Feeding Stuff must take place in accordance with Directive 90/167/EEC.

4. Approval and Registration

Regulation requires that certain feed businesses' premises are 'approved', while it requires that certain others are 'registered'.

Approval requires a prior inspection visit by the Veterinary Medicines and Animal Nutrition Section, before the premises are allowed to operate. This is to ensure that the premises are working to the required standards.

Generally, premises subject to approval are those which carryout higher risk activities. These establishments may needs to put in place and operate procedures based on the principles of Hazard Analysis and Critical Control Points (HACCP).

Registration involves the placing of the premises on a list, with subsequent follow-up checks.

A Medicated Feeding Mill requires an approval in order to start operating.

.

SECTION 1: GENERAL INFORMATION

1A. Proposed Medicated Feed Licence Holder Name:

Title/Name/Surname: _____

1B. Proposed Medicated Feed Licence Holder Contact Details:

Name of Enterprise: _____

Telephone Number: _____

Fax Number: _____

E-mail: _____

1C. This application is intended for a:

☐ New Business/Building ☐ Existing Business/Building

1D. Current Feed Business Approval and/or Registration Number/s (*if available):*

_____

1E. Planning permit number as issued by the Malta Environment and Planning Authority's (MEPA) (*if available):*

PA ☐ / ☐

For an Existing Business/Building whose planning permit was not issued by the MEPA quote the name of the Authority that has granted the development, and the permit number or other approval number issued by such Authority

Name of Authority:

Permit or Approval Number:

SECTION 2: OPERATIONAL SITE INFORMATION (Part1)

2A. Will the site where the Medicated Feed is manufactured be used for the manufacture of Medicated Feed only?

YES ☐ NO ☐

2B. If yes, specify the other purposes below:

_____

_____

_____

2C. Will the Medicated Feed line be used to manufacture other type of feed?

YES ☐ NO ☐

2D. If yes, specify the other type/s of feed below:

_____

_____

_____

2E. Facilities available

Provide a description of the facilities/equipment that will be available on the site

_____

_____

_____

_____

_____

_____

SECTION 3: DOCUMENTATION

5A. Record Keeping (*indicate by ticking YES or NO)*

Do records exist to provide for all products (medicated pre-mixes) received and dispatched:

a. the date of receipt and of dispatch

b. the name of the medicated premix

c. the quantity of medicated premix received or dispatched

d. the name and address of the person from whom or to whom the medicated feeds are sold or supplied **(apart from the legally required prescription)**

YES ☐ NO ☐

5B. Dispatch Documentation (*indicate by ticking YES or NO)*

Do all dispatches enclose, with the products, a document which makes it possible to ascertain:

a. the date on which the transaction took place

b. the quantity of products supplied

c. the name and address of the persons to whom the products were supplied

YES ☐ NO ☐

5C. Recalls and Returns Procedure (*indicate by ticking YES or NO)*

Have you prepared an emergency plan for Batch Recalls which will handle to the Veterinary Medicines and Animal Nutrition Section with the application form?

YES ☐ NO ☐

5D. Retainer Agreements with veterinarians (*indicate by ticking YES or NO)*

Do you have a retainer agreement with a veterinarian for the preparation of the prescriptions.

YES ☐ NO ☐

SECTION 4: THE DECLARATION OF THE RESPONSIBLE PERSON

6A The Responsible Person of the Wholesale Dealer Licence Holder

Title/Name/Surname: _____

Year When Graduated as a Pharmacist: _____

Pharmacy Board Registration Number: _____

After office hours contact Number: _____

E-mail: _____

Home address: _____

_____

_____

_____

6B. Declaration from the Responsible Person

I undertake to inform the Veterinary Medicines and Animal Nutrition Section in writing through a signed declaration should my duties with the medicated mill be terminated.

To the best of my knowledge and belief the particulars I have given in this form are correct and complete.

Signed: _____

Capacity in which signed: _____

Date: _____

Name: _____

SECTION 5: DECLARATION OF MEDICATED FEEDING MILL LICENCE HOLDER

I apply for the grant of a Medicated Feeding Licence. I am aware that this will be granted on condition that:

1. The licence to be subject to all the standard provisions applicable to Medicated Feeding Mill Licence under regulations for the time being in force. This is currently Directive 90/167/EEC.

2. The activities will be carried out only in accordance with the information set out in the application or furnished in connection with it.

3. I will immediately inform in writing the Veterinary Medicines and Animal Nutrition Section should I undertake an activity which to date is mentioned in this application form.

4. I will supply the Veterinary Medicines and Animal Nutrition Section the details of the medicated pre-mixes used for the manufacturing of the medicated feeding stuff every six months.

5. I will only procure approved medicated pre-mixes which have been granted a Marketing Authorisation. I will get pre-mixes only from approved sources which are authorised by the Veterinary Medicines and Animal Nutrition Section.

6. I will operate by the principles of HACCP and will update the plan according to the needs. I will inform the Veterinary Medicines and Animal Nutrition Section in case of extensive updates.

7. To the best of my knowledge and belief the particulars I have given in this form are correct and complete.

Signed: _____

Capacity in which signed: _____

Date: _____

Name: _____

ANNEX I – Documents to be attached with Application

1. Site plan (1:250) of area	☐
2. Curriculum Vitae of Responsible Person	☐
3. Standard Operating Procedures	☐
4. Hazard Analysis and Critical Control Points Plan (HACCP).	☐
4. Premises plan (1:100)	☐
5. Proposed layout of Medicated Feed Line	☐
5. Proposed layout of storage areas	☐
6. Security measures	☐
7. Standard Operating Procedures	☐
8. MEPA permit or site Licence	☐
9. Memorandum and Articles of Company (If the applicant is representing a company)	☐