



MEDICINES CONTROL AGENCY

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MEDICINES REGISTRATION APPLICATION

Generic Medicine New Chemical Entity (New Active Substance)
Biological Nutritional Supplement Veterinary Medicine
Renewal MCA Product Registration Number

Brand Name
Generic Name
Route of Administration
Dosage form / strength

MANUFACTURER

Name
Premises/Business Address
Tel Email Website

MARKETING AUTHORISATION HOLDER

Name
Premises/Business Address
Tel Email Website

APPLICANT

Name
Address + Full Contact Details
Tel Email Website

STATUS OF APPLICANT

Manufacturer <input type="checkbox"/>	Marketing Authorisation Holder <input type="checkbox"/>	Pharmaceutical Company <input type="checkbox"/>
Importer <input type="checkbox"/>	National Representative <input type="checkbox"/>	Other <input type="checkbox"/> (please specify)

COMPOSITION OF PRODUCT:

(name and quantity of active (pharmaceutical) ingredients & excipients)

INDICATIONS/CLAIMS AND DOSAGES:

PHARMACOLOGICAL CATEGORY/PHARMACOTHERAPEUTIC GROUP/ATC CODE:

REGISTRATION IN OTHER COUNTRIES (Pending or approved):

DISPENSING CATEGORY (mark as X):

Prescription Only Medicines (POM): Over The Counter Medicines (OTC):
Pharmacy Only Medicine (PM) Controlled Drug (CD): Veterinary Medicine

PACKAGE SIZES AND PRESENTATION

MISCELLANEOUS (Special Conditions, etc.)

ENCLOSURES (mark as X)

Container labels <input type="checkbox"/>	Package insert <input type="checkbox"/>	Professional Information/SmPC <input type="checkbox"/>
CTD <input type="checkbox"/>	Other Documents <input type="checkbox"/>	Samples <input type="checkbox"/> #
Registration certificate(s) from country of origin and others, where applicable <input type="checkbox"/>		
Manufacturing License <input type="checkbox"/>	GMP Certificate <input type="checkbox"/>	

DECLARATION:

I, the undersigned certify that the information in the accompanying documentation concerning the application for registration of the medicine indicated herein is true and reflects the total information available.

I also agree that I am obliged to comply with the requirements of the Agency related to the stated products at any time in the future.

Name of Applicant:

Position/Designation:

Address and Contact Details:

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Signature of Applicant: Date:

OFFICIAL USE

Application no:
Comments