



# DRUGS REGULATORY UNIT

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Application Number: \_\_\_\_\_

## APPLICATION FOR REGISTRATION EXEMPTION

### DRUG OR RELATED SUBSTANCE

Name of the drug or related substance: \_\_\_\_\_  
\_\_\_\_\_

Approved name(s) of active ingredient(s):  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Dosage form: \_\_\_\_\_

Strength(s): \_\_\_\_\_

Name and address of manufacturer: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Country(ies) where registered and registration number(s):  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Motivation for exemption:  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

### SUPPLIER

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**APPLICANT**

Name, address and qualifications  
of the applicant: \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Signature of applicant \_\_\_\_\_ Date: \_\_\_\_\_

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**For Official Use:**

Date request received:  
\_\_\_\_\_

Drug category:  
Investigational \_\_\_\_\_ New \_\_\_\_\_ Old \_\_\_\_\_

Registration Application  
Submitted:

Yes \_\_\_\_\_ NO \_\_\_\_\_

Registration Application Number:  
\_\_\_\_\_

Registration Application

Evaluated:

Yes \_\_\_\_\_ No \_\_\_\_\_

If Yes, state the outcome:

Pending \_\_\_\_\_ Rejected \_\_\_\_\_

If Rejected give reasons:  
\_\_\_\_\_

**Decision:**

Exemption Granted: \_\_\_\_\_

Conditions, if any:  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Exemption Refused \_\_\_\_\_

Reasons  
\_\_\_\_\_  
\_\_\_\_\_

Valid Until: \_\_\_\_\_