MEDICINES CONTROL COUNCIL

GENERAL INFORMATION

This document has been prepared to serve as a recommendation to applicants wishing to submit applications for registration of veterinary medicines. It represents the Medicines Control Council's current thinking on the safety, quality and efficacy of medicines. It is not intended as an exclusive approach. Council reserves the right to request for any additional information to establish the safety, quality and efficacy of a medicine and may make amendments in keeping with the knowledge which is current at the time of consideration of data accompanying applications for registration of medicines. Alternative approaches may be used but these must be scientifically and technically justified. The MCC is committed to ensure that all medicines gaining market approval will be of the required quality, safety and efficacy. It is important for applicants to adhere to the administrative requirements to avoid delays in the processing of applications.

REGISTRAR OF MEDICINES
MS M.P. MATSOSO

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1. INTRODUCTION

Ethical veterinary medicines are registered and controlled , together with human medicines in terms of the Medicines and Related Substances Control Act No. 101 of 1965 [referred to as the Act forthwith] and the Regulations and Guidelines published in terms thereof.

Data submitted for evaluation should substantiate all claims and approval of registration is based on the evaluation of the technical requirements for the medicine, namely quality , safety and efficacy.

In terms of Section 15 of the Act, every application for the registration of a medicine shall be submitted to the registrar in the prescribed form and shall be accompanied by the prescribed particulars and samples of the relevant medicine and by the prescribed registration fee.

Legislation requires that the Medicines Control Council shall register every medicine before it may be sold or marketed .The only exception to this rule is if a Section 21 exemption is granted by Council for an unregistered medicine in terms of the Act for certain purposes.

2.1 APPLICANT / PROPOSED HOLDER OF THE CERTIFICATE OF REGISTRATION (PHCR)

2.1.1 Eligibility to apply for registration of a medicine is governed by Regulation 22 of the Act. An application may be made by any of the following:

a) a person, body corporate/juristic person, company, residing and doing business in South Africa;

b) a closed corporation incorporated in South Africa; or

c) a company in South Africa with at least

- a responsible delegated person residing in South Africa and
- an authorised person residing in South Africa who must be a person with appropriate knowledge of all aspects of the medicine and who shall be responsible for communication with Council.

2.1.2 If the applicant is not a registered pharmacist or pharmacy the application should be co-signed by a Responsible Pharmacist as defined in the Pharmacy Act (Pharmacy Act 53 of 1974 as amended).

2.1.3 An Applicant/Prospective holder of the certificate of registration (PHCR) , should submit a Site Master File (SMF) in accordance with the SMF guideline. For subsequent applications reference to the allocated SMF number will suffice.

A Site mater File is a document prepared by the manufacturer containing specific and factual GMP (Good manufacturing Process) information about the production and / or control of pharmaceutical manufacturing operations carried out at the named site and any closely integrated operations at adjacent and nearby buildings. If only part of a pharmaceutical operation is carried out on the site , a Site Master File need only describe those relevant operations e.g. analysis , packaging , etc.

A Site master File should be succinct and, as far as possible , not exceed 25 A4 pages.

2.2 LANGUAGE

In terms of Regulation 22(4) of the Act, all applications and supporting data submitted to the MCC, should be presented in English (British). Original documents not in English should be accompanied by an English translation **done by an accredited translator**.

2.3 WHERE TO SEND APPLICATIONS

Applications should be posted to Private Bag X 828, Pretoria, 0001 or delivered to Room 204, Hallmark Building, 237 Proes Street, Pretoria, where they will be logged and acknowledged. All correspondence should be addressed to the Registrar of Medicines and should be clearly coded as indicated in section 13 of this guideline.

2.4 WHEN A VETERINARY PRODUCT SHOULD BE REGISTERED

A veterinary product is liable for registration with the Medicines Control Council if any of the following apply.

i) Any of the ingredients of the veterinary product is listed in one of the Schedules to the Act;

ii) The product is a veterinary medicine by virtue of the definition of a veterinary medicine in the Act.

The Act defines a veterinary medicine as:

"any substance or mixture of substances, other than a stock remedy or farm feed to be registered in terms of the Fertilizers Farm Feeds , Agricultural Remedies and Stock Remedies 47 (Act 36 of 1947) , used or purporting to be suitable for use, or manufactured or sold for use in connection with vertebrates , for the treatment, diagnosis, prevention or cure of any disease, infection or other unhealthy condition , or for the maintenance or improvement of health , growth , production or working capacity, or for curing , correcting or modifying any somatic or organ function , or for correcting or modifying behaviour ."

iii) If the product falls under any of the pharmacological classifications as specified in Regulation 25 of the Act.

iv) The intended use of a product and the text/words used in promoting the product, even if no claims are reflected on the label, render the product registerable.

NOTE : All scheduled substances are registerable under Act 101 of 1965, unless they are specifically exempted from the requirements of the schedules in terms of Section 36 of the Act. The Section 36 exemption must be a unanimous decision made by the Medicines Control Council for the scheduled substance in question.

2.5 TYPES OF VETERINARY APPLICATIONS

Medicine applications for registration for animal use are divided into the following types for the determination of fees and allocation to reviewers for evaluation:

2.5.1 New chemical entity applications that include **pre-clinical** and **clinical** information in support of the efficacy and safety of the formulation/dosage form, indication/s per species and dosage regimen.

2.5.2 Multisource/generic applications and innovator product line extension applications that include clinical information in support of efficacy and safety of the formulation/dosage form, or indication/s or dosage regimen.

2.5.3 Multisource/generic applications and innovator line extension applications that include comparative bio-availability/bioequivalence studies as proof of efficacy.

2.5.4 Veterinary biological applications

2.5.5 Post – registration amendments concerning quality control for example change of FPRC or a Pharmaceutical / Analytical Change must be submitted must be submitted on the MRF3A or MRF3B Form as applicable.

2.6 FEES

The following fees are relevant for veterinary medicines as set out in the table below :

TYPE OF APPLICATION / SERVICE	**FEE**
NEW CHEMICAL ENTITY [1ST STRENGTH AND 1ST DOSAGE FORM]	**R 3800**
GENERIC MEDICINES	**R 3800**
HOMEOPATHIC PRODUCTS	**R 3800**
OLD MEDICINE [ACCORDING TO SECTION 14 (3) OF ACT 101]	**R 800**
REGISTRATION	**R 600**
RETENTION OF REGISTRATION	**R 350**
AMENDMENTS	**R 220**
TRANSFERS	**R 400**

2.6.1 A non – refundable pre – screening fee accompanying the screening submission.

2.6.2 An application fee relevant to the type of application accompanying the application for registration.

2..6.3 A registration fee, payable when the application complies with all the requirements for registration, and which is payable before a registration certificate is issued.

2.6.4 An annual retention fee to maintain registration .

2.6.5 A fee to pay for amendments to the dossier or certificate .

2.6.6 A fee to cover any inspection of any manufacturing site.

Cheques should be made out to "Medicines Control Council ".

2.7 SAME OR SEPARATE APPLICATIONS

For the purpose of registration the following products will be regarded as either being the same product or separate product applications:

TYPE OF APPLICATIONS	Application	
	Same	**Separate**
2.7.1 Each individual dosage form of a particular medicine		X
2.7.2 Variations of the active ingredient of a product		X
2.7.3Tablets Capsules/Suppositories/ Lozenges		
a) Different pack-sizes of exactly the same strength and formulation.	X	
b) Different strengths and formulations.		X
c) Uncoated and coated tablets of the same strength and formulation.		X
2.7.4 Syrups/Liquids/Solutions (excluding parenterals) /Creams/Ointments		
a) Different container sizes of the same strength and formulation.	X	
b) The same container size of different strengths and formulations.		X
2.7.5**Ampoules and Vials and Large Volume Parenterals**	**Same**	**Separate**
a) Ampoules containing identical solutions of the same strength (provided the dose remains constant) but of different volumes.		X
b) Ampoules containing solutions of different strengths.		X
c) Ampoules and single dose vials containing e.g. dry powder, crystals of different mass.		X
d) Ampoules and single dose vials containing the same respective masses of e.g. dry powder, crystals.	X	
e) Ampoules, single dose vials, as well as pre-filled disposable syringes and cartridges containing identical solutions of the same strength and same volume of liquid.	X	
f) Dental cartridges containing different volumes of fluids of the same strength (provided the dose remains constant).	X	
g) Ampoules containing "water for injection", but of different volumes.	X	
h) Special ampoules of dry powder and "water for injections" contained in the same unit, but intended for mixing at the time of injection if water for injections is fully described in dossier.	X	
i) Ampoules containing identical solutions of different volumes used only as diluent in the reconstitution of a preparation for parenteral use.	X	
j) Multidose vials containing different volumes of the same strength and formulation with the same dosage schedule.	X	
k) Multidose vials and a single dose ampoule of the same formulation if the single-dose ampoule corresponds to the dose indicated for the multi-dose vial.	X	

l) Multidose vials containing dry powder of different mass of the same formulation, and the same concentration when reconstituted.	X	
m) An ampoule of diluent packed together with any preparation including biological medicines if diluent is fully described in dossier.	X	
n) Infusion solutions of the different volumes and of the same formulation which are packed in containers of exactly the same type of material depending on the relevant information submitted.	X	
o) Infusion solutions of the same formulation and of the same or different volume which are packed in containers made of different types of materials.	X	
p) A preparation, packed in plastic containers, intended to be marketed in glass containers containing the same volume and the same formulation.	X	
q) Products with the same strength and formulation but with different colours and/or flavours.		X
r) Applications containing the same active ingredient(s) applying for additional indications which render the product in a different scheduling status, or different pharmacological classification, or have any other restrictions imposed other than the original application.		X
2.7.6 Same formulation with different proprietary names whether of the same or different applicants		X

2.8 CANCELLATION OR WITHDRAWAL OF APPLICATIONS

HCRs of medicines and applicants should, before applying to the Registrar, carefully consider any decision to cancel or withdraw, as the case may be, a registration or application for registration, as Council after consideration of all issues involved has resolved the following with immediate effect.

2.8.1 Any medicine

- of which the registration has been cancelled, or any "old medicine" of which the application for registration has been withdrawn by notice in the Government Gazette, and
- for which a written application or request to the Registrar of Medicines has been submitted by the holder of a certificate of registration or by the applicant,

will under no circumstances be re-instated.

2.8.2 Should the HCR or the applicant desire to re-register such medicine, a new application for registration of a medicine must be submitted in accordance with the requirements of the Act and the relevant Regulations.

2.8.3 An application for registration of a medicine may at whatever stage of processing be withdrawn by written application to the Registrar of Medicines. The withdrawal shall under no circumstances be reversed once such an application is approved and the approval confirmed in writing. A new application for registration must be submitted should the applicant wish to proceed with registration thereafter.

3 REQUIREMENTS AND PREPARATION OF AN APPLICATION

3.1 REQUIREMENTS

3.1.1 PART 1A Administrative Data

The details as per the application form [Veterinary Medicines Registration Form (VMRF1] should be completed.

a) applicant/prospective holder of the certificate of registration (refer to Section 2.1).

b) "Business address" in relation to a business that is carried on in the Republic of South Africa, means the full physical address of the premises where such business is conducted.

c) Person authorised to communicate with Council. Refer to Regulation 22(2) of the Act.

d) Category. Stipulate that this is a veterinary medicine . Refer to Regulation 25 of the Act.

e) "Proprietary name" means the name that is unique to a particular medicine and by which it is generally identified and which, in the case of a registered medicine, is the name approved in terms of Section 24 (8) of the Act in respect of such medicine. (Refer to Section 7).

Medicines which are not identical in composition or strength are not regarded as the same medicine and should be submitted separately. (Refer to Section 2.7).

f) Pharmacological classification. Refer to Regulation 25 of the Act.

g) Dosage form: Select the most appropriate dosage form from this list, when completing the administrative data. This dosage form will also be reflected on the medicine registration certificate. For the purpose of the package insert, application may be made to give a more detailed description of the dosage form, e.g. chewable tablet, slow release tablet.

Blood bag	Gel	Pellet
Bone cement	Globule	Pessary
Beads	Granules	Plaster
Caplets	Gum	Pods
Capsules	Implant	Powder
Cleansing bar	Infusion (parenteral)	Shampoo
Combination of dosage forms	Inhaler	Soap
Condom	Injection	Solution
Cone	Insert	Sponge
Cord	Intra-uterine device	Spray
Cream	Jam	Stick
Cardioplegic solution	Leaves	Suppository
Chip (dental)	Liquid	Suspension
Decoction	Lotion	Swab
Dialysate	Lozenge	Syrup
Diluent for injection	Lump	Tablet
Dental material	Medical device	Tampon
Dressing	Mouthwash	Test kit
Drops	Nasal inhaler	Tincture
Elixir	Nasal spray	Toothpaste
Emulsion	Oil	Towelette
Enema	Ointment	Transdermal therapeutic system
Foam	Ovule	Vaginal ring
Gas	Paste	Wafer

h) 'Approved name' in relation to a medicine means the internationally recognised name of such medicine, or such other name as the Council may determine, not being a brand name or trade name registered in terms of the Trade Marks Act, 1963 (Act 62 of 1963). (Defined in Section 1 of the Act.)

i) The Active Pharmaceutical Ingredient [API] and strength per dosage unit applies only in the case of a dosage form with a single active ingredient.

j) The descriptive name of the veterinary biological medicine, e.g. viral vaccine, viral antiserum, bacterial vaccine, bacterial antiserum, allergen, immunoglobulin or blood product, as given in a recognised pharmacopoeia or where such name does not exist, a name determined by the Council.

k) The country of origin, i.e. the country where the original development was done. If development took place in more than one country all the countries should be specified.

l) The name and complete physical address including the country, of all the manufacturing and packer facilities/sites for the veterinary medicine should be given. The site performing each stage of manufacturing and packaging where these do not all occur at the same site, should be clearly indicated. The various stages of manufacturing and packing reflected should correspond with those submitted in PART 3E.

The name and complete *physical* address including the country, of the final product testing laboratory/ies (FPRC) and final product release responsibility (FPRR) should be given. If applicable the details of both the pre- and post- importation FPRC and FPRR should be given.

This information may be submitted on the next page as a separate appendix if necessary.

m) The following are required for all the manufacturing, packaging, FPRC and FPRR sites:

i) Site (Plant) Master File (SMF)

ii) - Confirmation of a Technical agreement between the parties, and
- a schedule of the limits of responsibilities accepted by each of the parties as specified in a Technical agreement or addendum to the contract should be included

iii) From the country of manufacture, if not South Africa:

- A copy of manufacturing licence or a statement by the competent medicine regulatory authority that the manufacturing facility complies with GMP and
- A copy of the Certificate of GMP compliance in terms of the WHO Certification Scheme.
- Confirmation that the manufacturing site is inspected at regular intervals and a copy of the latest written inspection report (not older than 3 years), from a Medicine Regulatory Authority of the country of origin is available for inspection.
- A copy of the registration or marketing authorisation certificate.
- A Certificate of a Pharmaceutical Product in terms of the WHO certification scheme (Free Sales Certificate)

n) FPRR should be vested in a person who has appropriate knowledge of the relevant aspects of the medicine and who is either the holder of the certificate of registration or is in the employment of the holder of such a certificate.

o) For subsequent post registration amendments to the dossier PART 1A (c) Amendment history, of the VMRF1 should be completed in accordance with the Post-registration amendment guideline.

3.1.2 PART 1B Comprehensive table of contents

A comprehensive Table of Contents of the dossier including the SUB-PARTs of the different PARTs should be included.

Each heading and sub-heading of the VMRF1 should be identified by a page number or tab and should be tabbed accordingly. Should the heading not apply an explanation as to why the heading does not apply should be supplied on the relevant numbered page or cover page of the relevant tab.

3.1.3 PART 1C Labelling

a) PART 1 (a)Package inserts for Veterinary medicines (Regulation 40 of the Act)

This guideline serves to help applicants with the correct way of presenting a veterinary package insert for evaluation. Applicants are requested to follow the format stipulated in the guideline in conjunction with the provisions set out under Regulation 40 of the Act.

The package insert is regarded as the document that ensures the safe and effective use of the veterinary medicine under most circumstances. It presents a scientific, objective account of the veterinary medicines' uses and limitations as established by the supporting evidence. All statements should be adequately cross-referenced and referenced. No promotional material may be included. Promotional statements and comparisons to other agents, suggestive of any potential advantage over competitors, will not be allowed.

After registration, the veterinary package insert may not be altered without the approval of the MCC. In the case of safety-related matters the Council should be informed immediately. The approved package insert, a proposed amended package insert and the evidence/motivation for the change should be submitted together with the notification in the MRF4 Package insert amendment form.

Package inserts should be typed in double-spaced text and should be in English (British) and at least one other official language. The spelling and grammar in the package insert text should be checked thoroughly before submission of the application.

The printing quality of the package insert should be clear to enable duplication, for inclusion into various documents, during the evaluation and registration process.

References for each statement should be included in a broad margin on the right hand side of each page of the package insert. Alternatively the reference numbers may be included in the text as in scientific publications. Every statement should be verified by a reference. The exact page/s should be stated and if possible, the column and line number. If an entire section is quoted from one source, the reference may be listed at the end of the relevant section. No references should however be included in the finalised printed package insert.

An electronic copy (Word document) on diskette or CD of the package insert should be included.

b) Headings and particulars in a package insert (Regulation 40 of the Act)

Multisource medicine (MSM) New Chemical Entity (NCE)

In-house package insert templates **[if available]** , should be used as reference for the compilation of MSM package inserts. The templates will also be used for the subsequent evaluation of therapeutically equivalent, interchangeable, multisource medicines. Reference to the following standard references if applicable, are generally acceptable if templates are not available.

- **Booth and McDonald – Veterinary Pharmacology and Therapeutics Ed. 6**
- **Debuf YM – The Veterinary Formulary (U.K) , Ed . 2**
- **United States Pharmacopoeia Drug Information (USPDI) – Veterinary Information , Ed. 12**
- **Brander , Pugh , Bywater and Jenkins – Veterinary Applied Pharmacology and Textbooks , Ed. 5**
- **FDA Freedom of Information Summaries**

The words "Veterinary medicine" to appear at the top of the package insert

In accordance with Regulation 40 of the Act

Scheduling Status

Applicants to note that the scheduling status of medicines shall be determined from time to time by the Minister and shall be published in the Government Gazette. Medicines are scheduled from S0 to S8.

Proprietary name and dosage form

In accordance with the VMRF1 PART 1A (b).

Composition

In accordance with Regulation 40 of the Act.

Pharmacological classification

In accordance with Regulation 25 of the Act.

Pharmacological action

MSM Should be in line with the relevant package insert template **if available**, or if not available should be referenced to the latest editions of the standard reference books. Any additional information as required by the applicant should be submitted with relevant clinical data.

NCE Source of particulars should be the clinical data and other references submitted.

Indications, Dosage and directions for use

MSM Should be in line with the relevant package insert template **if available**, or if not available in line with the innovator package insert. Any additional information as required by the applicant should be submitted with relevant clinical data.

NCE Source of particulars should be the clinical data and other references submitted.

Contra-Indications, Warnings or withdrawal periods in the case of food – producing animals , Interactions, Pregnancy and lactation

MSM Should be in line with the relevant package insert template **if available**, or if not available referenced to the latest editions of the standard reference books.

Withdrawal times to be substantiated with valid residue depletion data.

Any additional information as required by the applicant should be submitted with relevant clinical data.

NCE Source of particulars should be the clinical data and other references submitted.

Side effects and special precautions for use per species

MSM Should be in line with the relevant package insert template **if available**. Any additional information as required by the applicant should be submitted with relevant clinical data or references and/or references to the latest editions of the standard reference books.

NCE Source of particulars should be extrapolated from the clinical data and other references submitted.

The side effects that belong together should be grouped together, either in one paragraph or under one sub-heading, e.g. gastrointestinal, skin, haematological, as per the Organ Class Classification System .

In the case of multicomponent formulations, the side effects should be listed separately for each active ingredient.

Special precautions should be grouped together in a separate sub-section or paragraph. They should also be listed in order of importance.

Known signs of overdosage and particulars of its treatment per species

MSM Should be in line with the relevant package insert template **if available**. Any additional information as required by the applicant should be submitted with relevant clinical data or references and/or references to the latest editions of the standard reference books.

NCE For treatment of overdosage it is usually acceptable to state, "Treatment is symptomatic and supportive". Specific text could however be required.

Identification

In accordance with VMRF1 PART 3F.

Presentation

In accordance with VMRF1 PART 3D.

Storage instructions

In accordance with VMRF1 PART 3G.

Registration number

Allocated by the Registrar in accordance with Section 15 of the Act.

Name and business address of the holder of the certificate

In accordance with VMRF1 PART 1A.

Date of notification of approval of this scientific package insert

This date should be the date of the Medicines Control Council resolution. The date should only change when the package insert is re-evaluated by Council.

d) PART 1C (b) Veterinary Label (Regulation 48)

An example or a facsimile of the label should be included. Requirements, e.g. font size, as stipulated in the Regulation 48 of the Act, should be adhered to.

Note: Any deviation from the requirements described in these guidelines will require approval by Council in terms of Section 18(4) or Section 36 of the Act, prior to implementation.

3.1.4 PART 1D - FOREIGN REGISTRATION

A list of countries, including SADC countries in which an application has been lodged, and the status thereof, should be furnished. Approvals (with indications), deferrals, withdrawals and rejections, should be stated.

The Council aligns itself with

- the following regulatory authorities: USA (FDA), UK (MHRA), Sweden (MPA,) Australia (TGA), Canada (Health Canada), European Union (EMEA) and Japan (MWH).
- members of the Pharamacuetical Inspectorate Corporation [PIC] for quality matters relating to GMP and
- members of the PER scheme for clinical matters.

If the medicine has already been registered in any of the countries mentioned above,

- a copy of the registration certificate and the
- approved package insert (data sheet), as well as
- the conditions of registration, should be provided.
- For rejections or withdrawals relating to safety matters the details for each case should be provided.
- It should be stated whether data packages submitted in these countries, including the proposed indications, are essentially similar to those submitted to Council.

If not registered and/or applied for registration in the country of origin the reason should be given.

3.2 PREPARATION AND SUBMISSION

3.2.1 Applications for registration of a veterinary medicine should be submitted on the VETERINARY MEDICINES REGISTRATION FORM (VMRF1) obtainable from the Registrar of Medicines or from the MCC website www.webmaster@mccza.com.

3.2.2 Each page of the application should

- be numbered and the printing should be clearly legible
- have a header reflecting the HCR, product name, dosage form and strength.

The pages should be numbered according to the MRF1, e.g. 3B.1 (referring to PART 3B, first page). Double-sided copies are allowed except for those of the package insert and patient information leaflet.

3.2.3 The application for registration of a dossier should have clearly labelled tabs to indicate each PART of the dossier.

3.2.4 Each PART or SUB-PART should contain a Table of Contents.

3.2.5 The application for registration should be properly bound on the left side as this allows for easy update/addition of pages. Binding is left to the discretion of the applicant; however, the use of lever-arch files and ring binders is not accepted.

3.2.6 Copies of the covering letter should be bound to the application dossier as indicated in section 4 of this guideline.

3.2.7 Cheques should be submitted in a separate envelope attached to the original covering letter.

3.2.8 The requirements with regard to metrication in accordance with the Trade Metrology Act should be applied.

3.2.9 The boxes in which documentation is submitted to the MCC should be clearly labelled. The following details should appear clearly on each box:

a) Applicant name
b) Name of the veterinary product (at applicant's discretion) or the applicant's product identification code for each application (e.g. NCE-04NOV01)
c) The contents of the box, e.g. File numbers, PARTs, Sample, Covering letter, Cheque.
d) Number of boxes, e.g. 1 of 10
e) Type of application, e.g. routine.
f) Colour stickers indicating screening (red) or post-screening (green).

3.2.10 On receipt at the MCC, all applications for registration will be subject to pre-screening according to the checklist, as per attachment A, also completed by the applicant.

3.2.11 Upon successful pre-screening, the application will be logged onto the system and allocated an application number. A letter acknowledging receipt of the application and receipt of the pre-screening fee will be issued to the Applicant.

3.2.12 If the applicant does not comply with the pre-screening requirements the application will be returned to the Applicant as incomplete.

3.2.13 After successful pre-screening the application will be subjected to screening according to the screening form MRF2.

3.2.14 The screening outcomes i.e. HOLD or RETURN AS INCOMPLETE will be communicated to the applicant together with reasons. Time frames for the applicant to submit outstanding information, or to collect the application, will also be communicated to the applicant. In the event of a dispute regarding outstanding information or time frames, the application will be tabled at the next Council meeting for a formal decision.

3.2.15 The ACCEPTED screening outcome, the required application fee, the number of copies and the time frame for these copies to be submitted, will be communicated to the applicant. The allocated reference number and a copy of the approval letter should be included and also accompany any subsequent correspondence regarding an expedited review application.

3.2.16 The correct number of copies of application and additional documents required for the evaluation of the application, should be submitted in the format detailed in section 4 of this guideline.

4 PRESENTATION OF SCREENING AND POST SCREENING COPIES

Certain PARTs of the application for registration, should be duplicated and submitted as prescribed in the screening approval letter together with the application fee.

No additional documentation, other than that which has been clearly stipulated below, may be bound in any of the sets identified below. Applicants who wish to submit applications in electronic format should make prior arrangements with the Registrar.

4.1 SCREENING SUBMISSION SET 1:

- Covering letter
- Screening fee
- Completed pre-screening checklist (Attachment A)
- Completed MRF2 (screening form)
- One complete application for registration dossier (VMRF1) and the following:
  - Copy of the latest Inspection Report (not older than 3 years) from the Medicines Control Council and/or foreign regulatory body recognised by the Council for the manufacturer of imported medicinal products and medicines
  - GMP/WHO certificate
  - Certificate of analysis for the sample submitted
  - One sample of smallest pack size
  - Batch manufacturing documents for the sample should be submitted or available for inspection
  - Licence for Manufacturer, Packer, Laboratory
  - Proof of registration of the Company and the authorised person.

4.2 FULL SUBMISSION:

Covering letter and application fee, plus the number of copies of the sets requested by MCC post screening.

4.2.1 SET 2 (P + A)

- Covering letter
- Completed MRF2 (screening form)
- PARTs 1A to D, 3A to I

4.2.2 SET 2a (P + A)

- Covering letter
- Completed MRF2 (screening form)
- PARTs 1A to D, 3A to I
- Pharmaceutical Expert Report

4.2.3 SET 3 (NAMES and SCHEDULING)

- Covering letter
- PARTs 1A to D and 3B

4.2.4 SET 4 (MEDICINE REGISTER)

- Covering letter
- PARTs 1A to D, 3B, 3E and 3F

4.2.5 SET 5 (SCHEDULING)

- Covering letter
- PART 3A

4.2.6 SET 6 (SBRAV)

- Covering letter
- PART 1A to D
- SBRAV

4.2.7 SET 7 (CLINICAL)

- Covering letter
- PARTs 1A to D, 2, 3B, 4 and 5.

4.2.8 SET 8 (BIOSTUDY)

- Covering letter
- Completed MRF2 (screening form)
- PARTs 1A to D, 2, 3A to I, 4 and 5.

4.2.9 Summary table of the sets generally required for applications

	Screening	*P+A*	*P+A*	*Names Scheduling*	*Medicine Register*	*Scheduling*	*SBRAV*	*Clinical*	*BA/ BE*	*Extra PART 1C*
SET	**1**	**2**	**2a**	**3**	**4**	**5**	**6**	**7**	**8**	
New Chemical Entity veterinary medicines	1	5	-	4	1	1	3	3	-	1
Veterinary medicines with Pre-clinical & Clinical data	1	5	-	4	1	-	3	3	-	1
Veterinary medicines with biostudy(ies)	1	3	-	4	1	-	-	-	3	1
Veterinary biologicals	1	3	-	4	1	1	3	3	-	1

4.3 Acknowledgement of receipt: An acknowledgement letter will be sent to the applicant and evaluation of the application will proceed on receipt of the additional copies.

4.4 Communication: The applicant will not be permitted to communicate directly with the evaluator. All queries and concerns should be communicated through the Secretariat.

5 SUMMARY BASIS FOR REGISTRATION APPLICATION FOR A VETERINARY MEDICINE (SBRAV)

(i) The primary aim of the SBRAV is to inform applicants of possible shortcomings and prevent substandard applications from blocking the way for others. Secondarily, it is to assist in channeling applications optimally , to be evaluated by the most appropriate expertise available. It therefore assists , albeit roughly , in planning ahead. This is a qualitative application.
The SBRAV is intended to be a very brief and concise document containing the core data on the basis of which the applicant intends to obtain registration for the veterinary product. It is to be presented as a summary only: therefore no articles, reports etc. are to be incorporated into the SBRAV nor should such papers be attached to it either, as these belong with the full submission.

(ii) Applicants must ensure that the general quality of the studies, proper cross-referencing to the data, explanatory notes and the quality of photocopying and binding are of an appropriate standard. The SBRAV must be cross – referenced with the documentation submitted to the Medicines Control Council.

(iii) SBRAV format : as below

1. THIS APPLICATION INVOLVES : a new application

2. DATE OF THIS SBRAV :
- 2.1 Submitted
- 2.2 Discussed(official use)
- 2.3 to applicant (official use)

3. PRODUCT DETAILS

Active ingredient(s) and quantity thereof
Proprietary name
Applicant :
Application / Registration No:
Pharmacological classification
Dosage form

4. NAME(S) of Registration Person and/or Veterinary Adviser responsible for compilation of this application, and telephone number(s) where responsible individual may be contacted during office hours:

Name	Position	Qualifications	Tel. No.	E – mail address

5. PROVEN (ESTABLISHED) PHARMACOLOGICAL ACTION:

(Only information concerning the clinical issues and indications claimed are relevant).
(MAXIMUM 100 WORDS).
(At least two key references in support, preferably published).

6. EVIDENCE OF EFFICACY IN TARGET SPECIES:

(Data should be summarized in tabulated format, preferably under the following headings, as applicable:

- Key trial(s) reference number:
- Trial design : indicate with abbreviations/symbols, e.g.
- 0 = open
- X = cross-over
- P = parallel groups
- R = randomised
- C = controlled
- PC = placebo-controlled
- MC = multi-centre
- LS = Latin square

- Indications/Diagnosis.

- Number of patients treated with each drug.

- Dosage range used.

- Duration of treatment.

- Reference/comparative drug(s).

- Parameters evaluated/findings.

- Statistical data

(Please indicate separately, the total (overall) number of patients treated with the product)

Indicate clearly which trials were done/not done with the formulation and dosage form, for which registration is being applied.

(Free comment, if required, MAXIMUM 200 WORDS, excluding tabulated data).

7. MAIN SAFETY ISSUES AND TOXICOLOGY:

(a) Pre-clinical studies: (Animal and in vitro toxicology data)

(b) Target species studies:

i) (List side effects/adverse reactions/toxicological profile, with incidence figures and key references).

(Free comment, if required: MAXIMUM 200 WORDS, excluding tabulated data).

8. EVIDENCE OF LONG TERM SAFETY/EFFICACY

Tabulate key long-term studies, their duration, indications, findings, tolerability, etc.; with references, where applicable).

(Free comment, if required: MAXIMUM 100 WORDS).

9. EVIDENCE OF BIOAVAILABILITY AND PHARMACOKINETICS OF THE ACTIVE COMPONENT (S):

Methods used and number of subjects studied to be clearly specified, where applicable. Pharmacokinetic data summarized in tabular or graphical form is essential.
(MAXIMUM 100 WORDS).

For medicines containing more than one active component, provide a summary of evidence (with key references), that each contributes materially to the efficacy of the product.
(MAXIMUM 100 WORDS).

10. REGISTRATION STATUS IN OTHER COUNTRIES:

Country	Date of registration	Approved package insert

11. PROPOSED SCHEDULING STATUS:

(Provide reasons briefly, and illustrate structural formula)

12. LIST OF KEY REFERENCES:
(MAXIMUM 25)

(Directly applicable publications in referred scientific journals are preferred. Where suitable published scientific documentation is lacking, selected unpublished key scientific reports or in-house documents may be quoted, provided these are clearly indicated as such.

The "Vancouver Style" of setting out published references, entails the following*:

Author(s), title of article, names of journal (abbreviated according to Index Medicus), journal particulars (year, volume, page no.).

6 EXPERT REPORTS

6.1 *Expert report:* an independent, objective and encompassing report on all the relevant aspects in the specific field of expertise of the reporter who is familiar/acquainted with the development of the product.

6.2 *Expert reviewer's report:* the report of the regulatory reviewer, after evaluation of the data submitted in support of approval for licensing.

6.3 All issues and properties of the product in the submission should be clearly identified and critically discussed in the Expert Reports in light of current scientific knowledge.

6.4 The Expert Report should address all the aspects in the veterinary package insert.

6.5 A list of the key references used in compiling the Expert Report should be attached.

6.6 The *curriculum vitae* of the expert should be included.

7 PROPRIETARY NAME POLICY [Section 15 (3) of the Act]

The term "PROPRIETARY NAME" is defined in the Regulations pertaining to the Act as follows:

> "PROPRIETARY NAME, in relation to a medicine, veterinary or complementary medicine and medical device, means a name:
>
> a) that is unique to a particular medicine, veterinary, or complementary medicine and medical device;
>
> b) that is generally identifiable and approved in respect of that specific medicine, veterinary, or complementary medicine and medical device in terms of the Act. The Act states that a medicine, complementary medicine, veterinary medicine or device should be registered under such name as the Council may approve. "

In evaluating the safety of a medicinal product during the registration process, the Medicines Control Council is obliged to consider whether the proposed proprietary name of such a product could potentially pose public health and safety concerns or if it may be misleading. Mistaking one drug for another because of similar proprietary names can have serious consequences.

Since many medication errors are caused by look-alike and sound-alike medication names, it is evident that public health considerations should be paramount in determining whether a particular proprietary name may be used for a medicinal product.

In order to enable applicants to propose acceptable proprietary names for medicinal products, it is essential that:

a) consistent, non-arbitrary criteria are applied when reviewing the acceptability of proposed proprietary names;

b) a transparent procedure is in place for evaluating the acceptability of proposed names.

The MCC has adopted the WHO naming policy with adaptations.

7.1 SAFETY CONCERNS

In assessing the merits of a proposed proprietary name, the first and foremost issue considered is that of patient safety. Applicants are advised to consider the following guidelines bearing in mind the paramount criterion of "potential safety risk".

7.1.1 The proposed proprietary name should not convey misleading therapeutic or pharmaceutical connotations.

7.1.2 A proprietary name may include a pharmacological/therapeutic connotation, provided that it is in line with the indications in the package insert. Each application, however, will be evaluated on merit.

7.1.3 It is important to bear in mind the claims made in the package insert in relation to the proposed name of the product, when considering the acceptability of names, hence the requirement of submission of package inserts in all instances.

7.1.4 The use of "umbrella/brand types" of names across products in associated therapeutic categories generally may not pose a problem. However, when such names are used for products in different commodity categories, the misrepresentation of non-medicines as medicines and vice versa would be considered unacceptable. It is the responsibility of applicants to include precautionary statements of usage of these brands, simultaneously, so as to inform patients of their correct use.

7.1.5 The proposed proprietary name should not be misleading with respect to the composition of the product.

7.1.6 The proposed proprietary name should not be liable to cause confusion in print, handwriting or speech with the proprietary name of another product.

7.1.7 When the name being applied for is identical/too similar to a name already approved for another product, applicants will be advised that the proposed name is too close to an existing name. Only if the existing product is registered will the name be disclosed. Disputes regarding similarity of names not identified by the Medicines Control Council at the time of registration/change are the responsibility of applicants, not the Medicines Control Council. If however, valid safety concerns are identified, the applicant will be advised accordingly.

7.1.8 Names which are identical to, or which are similar to, the names of products previously marketed will generally not be favourably considered regardless of whether such products are dormant or not.

7.1.9 If an objection is raised on the basis of similarity between the proposed proprietary name and an existing name, or name raising a risk of confusion in print, handwriting or speech, the objection will be evaluated taking into account other potentially distinguishing factors, such as:

- The pharmaceutical form
- The route of administration
- The indication and legal status/condition of supply

After assessing these factors as a whole, a decision on whether the proposed proprietary name poses a potential safety risk will be made.

7.2 INTERNATIONAL NON-PROPRIETARY NAMES' (INN) CONCERNS

The Medicines Control Council subscribes to the WHO guideline in respect of the protection of INN-stems and encourages the pharmaceutical industry to be continually aware of this issue (Document No. "WHO/EDM/QSM/99.6").

7.2.1 A proprietary name should not contain an INN-stem (as published by the WHO). The WHO stresses the importance of the need to protect INN-stems. Using a common stem indicates the relationship of pharmacologically related substances, which in turn forms part of the INN name. The orderly development of generic nomenclature could be hindered if these stems are not protected. The sentiments of the WHO in this regard are shared by the MCC, and are taken into consideration when considering proprietary names.

7.2.2 For example, "-ac" is an INN-stem for anti-inflammatory agents of the ibufenac group, and a proprietary name ending with "ac" would not be acceptable regardless of the active ingredient, which it contains. The reasons are protection of the stem and confusion, which could arise if the product does not contain an anti-inflammatory agent of the ibufenac group.

7.2.3 A proprietary name commencing with, or containing "ac" in another position within the name could, however, be considered.

7.2.4 The derivation of proprietary names from INN names, i.e. generic names is discouraged, as this practice could lead to confusion. For example, the choice of the name "METAPERAMIDE" for a product containing loperamide, could cause confusion if the product contains another loperamide-type compound.

7.2.5 If a proprietary name is derived from a generic name, it should not be similar to the generic name, since it can lead to confusion. For example, the name "TRIMAZOLE" could be interpreted as being an antiprotozoal of the metronidazole group, an antifungal of the miconazole group or a brand of co-trimoxazole, even though the name does not contain an INN-stem for any of these groups.

7.2.6 In the case of single component generic medicines, applicants are encouraged to market their products under the complete generic name followed or preceded by their company name, acronym or other distinguishing feature.

7.2.7 Exceptions may be considered for the anti-retrovirals if these have been previously approved by a recognised Regulatory Authority and are accompanied by a motivation.

7.3 OTHER CONCERNS

7.3.1 The issue of whether a particular proprietary name may constitute an infringement of another entity's intellectual property rights cannot be one of the Medicines Control Council's concerns and is, therefore, not taken into account during consideration of the acceptability of a proposed proprietary name.

7.3.2. The proprietary name should preferably consist of only one word and should avoid qualification by letters or numbers. The use of short qualifications/abbreviations that do not carry an established and relevant meaning is unacceptable. Promotional qualifications/abbreviations/manufacturer's codes are also unacceptable. However, if other qualifications/abbreviations are to be included, appropriate justification should be provided (e.g. for insulin mixtures the proprietary name could be followed by a number or letter representing the fast-acting component of the mixture).

7.3.3. The use of descriptive abbreviations may also be acceptable if there is a need to distinguish different routes of administration for the same medicinal product, e.g. IV: intravenous, IM: intramuscular, SC: subcutaneous.

7.3.4 A proprietary name should not convey any promotional message with respect to the use of the product.

7.3.5 Use of capitals in proprietary names should reflect the proposed/approved trademark registration.

7.3.6 A different proprietary name is required for a medicinal product containing a pro-drug of another product containing the parent active substance. (An umbrella name is not acceptable).

7.3.7 In the case of a switch from "prescription" to "non-prescription" status for limited indications only, a new proprietary name should be chosen for the de-scheduled product.

7.3.8 Any phrase that implies superiority, including use of animal species associated with speed or strength, or implies superiority over other products, is not allowed.

7.3.9 The meaning of abbreviations, symbols, numerals and names, which are in a language other than English, should be explained in the covering letter accompanying an application. With regard to phrases which occur in the proprietary names of products, and which are not English, applicants are requested to submit to the Medicines Control Council, reputable interpretations / translations / explanations of the phrases in question, in relation to the claims made for the product; i.e. the intended use thereof.

7.3.10 Proprietary names will only be evaluated as part of a new application for registration or application for change. Requests for evaluation of acceptability of possible proprietary names prior to submitting a formal application will not be processed.

7.3.11 Proprietary names cannot be reserved for applications that have not yet been submitted.

7.3.12 Current policy will not be applicable to line extensions of older products unless a valid safety aspect has come to the fore, in which case, the applicant will be advised accordingly.

7.3.13 A list of names that are regarded as potentially misleading is available on request. Names, which may lead to self-diagnosis in conditions requiring professional diagnosis, or names implying efficacy that cannot be substantiated for the active ingredient(s), are included on this list.

7.3.14 As stated above, legislation determines that the name under which a medicine is registered shall be unique. The importance of this requirement cannot be over-emphasised, particularly when developing a range of products. Each strength and/or dosage form requires a unique name. Applicants should examine all available resources to establish that names are unique. Motivations should accompany applications where relevant, e.g. to justify the use of an identical or very similar name which appears in Martindale The Complete Drug Reference/other reference book for a product not containing the same ingredient(s) and which may be on the market elsewhere.

7.3.15 As with all registration matters, applicants always have the opportunity to submit comments in the event of a difference in opinion. Such comments will be forwarded to Council for consideration.

8 MANUFACTURING REQUIREMENTS

Only veterinary medicines manufactured, packed and quality controlled at sites compliant with the current principles of Good Manufacturing Practice (GMP) as prescribed by the Medicines Control Council will be considered for registration.

Council's general policy is that the standard to be used to assess compliance with current Good Manufacturing Practice (cGMP), is the South African Guide to Good Manufacturing Practice (SA guide to GMP) (latest edition) as minuted:

> "…that the Guide to Good Pharmaceutical Manufacturing Practice as amended, which was prepared jointly by the Secretariat and the PMA, be considered as the standard determined by Council as referred to in the specific condition for registration of a medicine, namely, that the applicant shall ensure that the medicine is manufactured and controlled in accordance with Good Manufacturing Practice as determined by Council."

Under Section 22C of the Act, all South African manufacturers should be licensed (**effective 2 May 2004**).

The aim of these licensing requirements and standards is to protect public health by ensuring that medicines meet defined standards of quality and are manufactured in conditions that are clean and free of contaminants.

The Act requires that overseas manufacturers of medicine supplied to South Africa should comply with the same or equivalent manufacturing standards as expected of South African manufacturers.

Evidence in relation to compliance with Good Manufacturing Practices of the overseas manufacturer is required for applications for registration of imported medicines. When acceptable evidence of GMP compliance is not available, overseas manufacturers are inspected by the GMP Inspectorate before registration of the medicine is approved.

9 SAMPLES

All medicine applications for registration must include a sample of a unit pack, Section 15(1) of the Act.

10 CODING OF SUBMISSIONS

Coding of applications/submissions/correspondence facilitates distribution, processing and tracking. The coding of uncoded items occurs after receipt at Registry on the second floor, Hallmark Building, Room 214, where documents are logged into the internal mail/post system.

The following codes, placed on the **first page of each cover letter in bold lettering,** should be used for submissions to the MCC to reduce the possibility of misdirection.

Each code consists of three letters. The first letter represents the Section or Unit where the responsibility or function resides. The last two letters indicate the type of application or nature of the request. It should correspond with the specific request(s) stated in the covering letter.

When more than one code is applicable, each should be indicated, for example, VMC/VPC/VLC. A separate application should be submitted per Unit.

10.1 PRE-REGISTRATION (PHARMACEUTICAL AND ANALYTICAL)

The Pre-registration Unit is responsible for pre-registration applications and responses to resolutions and matters pertaining to both human and veterinary medicines during review for registration.

The following codes are recommended for applications and correspondence for the Pre-registration Unit:

CODE	SUBJECT	SUPPORTIVE DOCUMENTATION
PGC	Enquiries that are not technical or are not product-specific	Application letter and supporting information / motivation
PPI	Package insert: involving Composition, Identification, Presentation, and Storage conditions	Annexure 1 PART 1C
PFA	Formulation change: Additions, deletions, reduction or increase in actives or excipients, overages, potency calculations and other formulation changes.	Annexure 2 PART 3B
PRS	Source of active(s), Method of synthesis, Proof of equivalence (physical and chemical), Certificate of Analysis (CoA) for the active ingredient, Drug Master File.	Annexure 3 PART 3A
PRM	Specifications and control procedures for active and inactive pharmaceutical ingredients, release criteria and laboratories including frequency of testing	Annexures 4, 5 and 6 PART 3C
PFP	Specifications and control procedures for the final product	Annexure 7A and 7B PART 3F

PVA	Manufacturing and analytical process validation protocol and report	Annexures 7B and 11 PARTs 3E and 3F
PCA	Specifications and control procedures for Containers.	Annexures 8A and 8B PART 3D
PSE	Stability data, shelf-life confirmation and extension, Preservative efficacy and effect on ageing	Annexure 10 PART 3G
PMP	Manufacturing and packaging process change and in-process control changes	Annexure 11 PART 3E
PFR	Foreign registration, authorisation and package inserts (English translations)	Annexure 12 PART 1D
PEF	Efficacy, Bioavailability, Bioequivalence, Proof of efficacy: acid neutralisation, inhibition zones, skin blanching, and membrane permeability.	Annexure 13 PART 3
PPD	Pharmaceutical development: batch numbers and sizes, source of product and of active, dates of manufacture.	Annexures 16 cross-referenced to Annexures 7, 10, 11 and 13 PART 3H xref to 2, 3E, 3F, + 3G

10.2 POST-REGISTRATION AMENDMENTS (PHARMACEUTICAL AND ANALYTICAL)

The Post-registration Unit is responsible for

a) applicant transfers and applicant name and address changes ;
b) changes of the manufacturer, packer and testing laboratories (FPRC and FPRR);
c) proprietary name changes in consultation with the Names Committee;
d) pharmaceutical changes or amendments to the registration dossier; and
e) cancellations of registered medicines and withdrawal of applications for the registration of medicines

The following codes are recommended for applications and correspondence for the Post-registration Unit: (Refer to the Post-registration amendment guideline for the required documentation)

CODE	**SUBJECT**
VGC	General correspondence involving enquiries on policy issues and changes that are not product-specific
VAC*	Applicant transfer, name and address change of the applicant
VAA	Address only change for the HCR only
VMC*	Change of manufacturer or site of manufacture, name and address change of manufacturer
VPC*	Change of packer, name and address change of packer
VLC*	Change of laboratory, name and address change of laboratory (FPRC or FPRR)
VNC	Updates following a proprietary name change approval
VPI	Package insert changers involving the Composition, Identification, Presentation and Storage conditions only.

Post-registration amendments (pharmaceutical and analytical) continued

VFA	Formulation change: Additions, deletions, quantity reduction or increase in actives or excipients, overages, potency calculations and other formulation changes.
VRS	Change in source of active pharmaceutical ingredient or method of synthesis
VRM	Specifications and control procedures for active and inactive pharmaceutical ingredients, release criteria and laboratories including frequency of testing
VFP	Specifications and control procedures for the final product
VVA	Manufacturing and analytical process validation protocol and report
VCA	Specifications and control procedures for Containers
VSE	Request for shelf-life, shelf-life confirmation; extension and reduction; Preservative efficacy and effect on ageing
VMP	Manufacturing and packaging process changes and in-process control changes
VFR	Foreign registration; notification of foreign submissions, approval or outcome
VEF	Proof of efficacy
VPD	Pharmaceutical development
VUR	Full Update for registered medicines including those with a change in the proprietary name, manufacturer, packer and/or testing laboratories
VUO	Full Update for "Old Medicines" including those with a change in the proprietary name, manufacturer, packer and/or testing laboratories
VCR	Cancellation of registered medicine
VCO	Withdrawal of an application for registration of a medicine
VIA	Applications for exemption from post importation testing of medicines
VSB Urgent	Resubmission of data/information on request by the Unit with a specific deadline. These will be transferred to the Unit immediately after login for finalisation of applications. Failure to supply the required information within the specified period will result in relegation of the application to the end of the queue.

*The applications are first evaluated by the Inspectorate

10.3 INSPECTION AND LAW ENFORCEMENT

The Inspection and Law Enforcement Unit is responsible for

a) inspection and evaluation of sites for the manufacturing, packing, and testing of medicines nationally and internationally, as well as inspection and evaluation of all storage and distribution sites for medicines;

b) investigation of complaints regarding registered and unregistered medicines;

c) monitoring compliance to the Act and prosecution in case of non-compliance;

d) monitoring the importation and exportation of medicines in consultation with customs authorities;

The following codes should be used for applications and correspondence for the Inspection and Law Enforcement Unit: (Any supporting documentation should be included with the cover letter.)

CODE	SUBJECT
BGC	General correspondence involving enquiries on policy and administrative issues
BAI	Advertising enquiries
BCA	Advertising complaints - legal
BCM	Complaints - manufacturing
BCQ	Complaints - quality
BEP	Export permits
BEQ	Exemption - quality
BFG	Site master file
BFP	Inspection follow-up
BFS	WHO free sale certificate
BIP	Import permit/MBR 20 Bill of Entry
BLM	Labelling matters
BLE	Law enforcement – complaints/theft of medicines
BII	Request for inspections
BLA	Applications for licensing of manufacturer, wholesaler or distributor (Section 22C of the Act)
BIR	Response to inspection reports
BSR	Request for scheduling/Scheduled substances
BPP	Request for/inquiry on repackaging

10.4 VETERINARY MEDICINES

The Veterinary Medicines Unit is responsible for

a) submission and amendment of package inserts prior to registration of a veterinary medicine;

b) evaluation of amendments to registered veterinary medicines;

c) evaluation of applications for named patient use of unregistered veterinary medicines (Section 21 of the Act applications).

d) evaluation of applications for the use of unregistered veterinary medicines for clinical trial purposes.

e) evaluation and recording of adverse drug reactions arising from the use of veterinary medicines;

f) co-ordination of SBRAV applications.

The following codes should be used for applications for the Veterinary Medicines Unit: (Any supporting documentation should be included with the cover letter.)

CODE	SUBJECT
RGC	General correspondence
RAD	Report of adverse drug reaction of veterinary medicine
RVI	Amendment of registered package insert for veterinary medicine
RRI	Submission and amendment of package insert prior to registration of a veterinary medicine
RUM	Section 21 of the Act applications (unregistered veterinary medicines)
RCT	Applications for use of unregistered veterinary medicines for clinical trial purposes
RAV	SBRAV applications
RAM	Applications for the amendment of the registration dossier for veterinary medicines

10.5 OPERATIONS AND ADMINISTRATION

The Operations and Administration Directorate is responsible for the following:

a) receiving and acknowledging applications for registration of medicines and for amendment of registration dossiers;
b) receiving correspondence dealing with administrative processes, registration and other application forms, and registration policy information documents and guidelines;
c) receiving fees payable to the Registrar;
d) co-ordination of Council and Committee reports on the evaluation of medicines;
e) preparation and distribution of Council and Committee documents;
f) handling personnel matters; and
g) processing of Council and Committee claims.

The following codes should be used for applications for the Operations and Administration Directorate:

CODE	SUBJECT
AGC	General correspondence: Routine enquiries, Registration policy and Registration queries
AFR	Application for registration fees
AFJ	Retention fees
ACC	Committee and Council claims
ACR	Evaluators and Chairperson reports
ACM	Council Documentation
AHR	Human Resources issues
AIM	Information Management matters
ANA	Submission of new applications and post-screening copies

ATTACHMENT A

PRE-SCREENING CHECK LIST

PRODUCT NAME:

COMPANY:

COMPLIANCE WITH ADMINISTRATIVE CRITERIA	*	OFFICIAL USE	
		YES	NO
Box size (A4 box)			
Number of boxes			
Are the boxes clearly labelled on the side to specify the number and content of each box, e.g. set numbers, PARTs, sample, covering letter, cheque and product identification code? Does a colour sticker indicate the screening phase? (red = screening; green = post-screening)			
Is the dossier correctly bound? (No lever arch files, no ring binders)			
Is each PART of the dossier properly marked with tabs according to the cover letter?			
Does each PART of the dossier have a Table of Contents?			
Is each page of the dossier numbered?			
Is a sample included in an envelope?			
Is the Cheque for the screening fee submitted in a separate envelope?			
Is the type of application indicated? (section 2.7.1 to 2.7.5 of this guideline) Is an approval letter regarding "fast track" status included if relevant?			
Is the completed screening form MRF2 included?			

**** to be completed by the applicant***

Name and signature of applicant: **Date:**

If there is a "NO" answer to any question above, immediately return the dossier to the applicant as incomplete

Outcome:	Accept		Hold		Return as Incomplete	

Name and signature of MCC official:

Date: