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The Medicines Control Council (MCC) is a statutory body that was established in terms of the Medicines and Related Substances Control Act, 101 of 1965, to oversee the regulation of medicines in South Africa. It is appointed by the Minister of Health and its main purpose is to safeguard and protect the public through ensuring that all medicines that are sold and used in South Africa are safe, therapeutically effective and consistently meet acceptable standards of quality.

So far, more than 20,000 medicines have been approved. Since the establishment of the Medicines Control Council, more than 220 meetings have been held to decide on the registration of medicines. Applications for more than 11,800 complementary medicines have been submitted for evaluation by the Complementary Medicines Committee.

The South African Pharmacy Council has licensed 300 wholesalers and distributors. These must still be licensed by the Medicines Control Council in terms of the Medicines Act. The Medicines Control Council approves more than 280 clinical trials annually.

The Medicines Control Council applies standards laid down by the Medicines and Related Substances Control Act, (Act 101 of 1965) which governs the manufacture, distribution, sale, and marketing of medicines.

The prescribing and dispensing of medicines is controlled through the determination of schedules for various medicines and substances.

The MCC operates through external experts who are members of Council Committee structures. Most experts evaluate data sets submitted by the pharmaceutical industry for purposes of registration. These evaluators are from various academic institutions, mainly medical and pharmacy schools.

The office of the Registrar provides administrative and technical support to Council and its activities. The Registrar is also an executive secretary to Council. The Registrar’s office is a Chief Directorate, Medicines Regulatory Affairs, within the Department of Health. There are four Directorates, which are largely responsible for co-ordination and execution of various activities. There is also a Deputy Registrar who performs functions as determined by the Registrar.

The staff complement of Medicines Regulatory Affairs includes doctors, pharmacists, veterinarians, other scientists and administrative staff.

The structure of Council and its committees is described below. The skills of Council and its committees are written into law and include expertise in toxicology and medicine safety, clinical pharmacology, biotechnology,
pharmaceutics, internal medicine, virology, pharmaceutical chemistry, neonatology, paediatrics, immunology, veterinary science, complementary medicines and law.

The Council, in considering whether a medicine is suitable for use for its intended purpose, assesses its relative risk against the benefits.
STRUCTURE OF MRA

Medicines Regulatory Affairs Organogram

Cluster: Medicines Regulatory Affairs
Registrar of Medicines

Directorate
Operations & Administration
Finance
CDCC

Directorate
Inspectorate & Law Enforcement
Inspectorate
Deputy Director
Law Enforcement
Deputy Director

Directorate
Clinical Evaluation & Trials
Clinical Unit
Clinical Trials

Directorate
Medicine Evaluation & Research
Pharmaceutical & Analytical
Pre-Registration
Deputy Director
Pharmaceutical & Analytical
Post-Registration
Deputy Director

DOCUMENTS
1. Acts and Regulations
2. Communications to industry
3. Exemptions in terms of Section 36 of Act 101
4. Fees payable to the Registrar
5. Forms
6. General Documents and Reports
7. Guidelines - Good Manufacturing Practices
8. Guidelines - Human Medicines
9. Guidelines - Licensing
10. Guidelines - Miscellaneous
11. Guidelines - Veterinary Medicines
12. Index to Guidelines and Forms
13. Licenses Issued
14. Notification of Registration of a Medicine
15. Press Statements
16. Workshops & conferences
1) ACTS AND REGULATIONS
A) Medicines and related substances control act 101 of 1965

- To provide the all information related to the registration of medicines and related substances intended for human and for animal use.
- Same like the Drug and Cosmetic Act of INDIA.
- Classified drugs in three categories:
  Category A: Human medicine including biologicals (Ready to use)
  Category B: Human medicine including biologicals (Req. Manipulation)
  Category C: Veterinary medicines, including biologicals.

B) Regulation of Act 101:
- Therapeutic equivalence
- International Tendering Processing
- Particulars to be published in the gazette
- Labelling, Package inserts and Patient information leaflet
- Prescription book
- Advertising of Medicines
- Import and Export
- Licensing
- Registration
- ARD, Price controlling
- Veterinary Medicines

C) Schedules to Act 90

<table>
<thead>
<tr>
<th>Schedules</th>
<th>Term</th>
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<tbody>
<tr>
<td>Any Schedule 0,1 substance</td>
<td>May be sold in an open shop</td>
</tr>
<tr>
<td>Schedule 2, 3 or substance</td>
<td>May be repeated if the person who issued prescription has indicated (NMT 6 times )</td>
</tr>
<tr>
<td>Schedule 5 substance</td>
<td>Shall not be prescribed for longer than six months</td>
</tr>
<tr>
<td>Schedule 6 substance</td>
<td>It shall not be repeated without a new prescription being issued</td>
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</table>

2) COMMUNICATIONS TO INDUSTRY
This section provides certain information to industry which may help them to update the requirements for particular details required for submission. Like this section provides details about :-

ADR Terminology Used In Package Inserts
- According to System Organ Classes
That safety information under ‘SIDE EFFECTS AND SPECIAL PRECAUTIONS’ in package inserts be ordered according to System Organ Classes whenever possible.

<table>
<thead>
<tr>
<th>ADR Terminology Used In Package Inserts</th>
<th>Frequency</th>
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<tbody>
<tr>
<td>Very common</td>
<td>&gt;1/10</td>
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<tr>
<td>Common</td>
<td>&gt;1/100, &lt;1/10</td>
</tr>
<tr>
<td>Uncommon</td>
<td>&gt;1/1000, &lt;1/100</td>
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<tr>
<td>Rare</td>
<td>&gt;1/10000, &lt;1/1000</td>
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<tr>
<td>Very rare</td>
<td>&lt;1/10000</td>
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</table>
**Dear Health Care Professional Letters**

A Dear Health Care Professional (DHCP) letter (also referred to as a Dear Doctor letter) is a letter distributed by an applicant or a holder of a certificate of registration for a medicine to medical practitioners and other health care professionals to convey important information about medicines.

Such letters can be requested by the MCC or initiated by the applicant.

A DHCP letter that contains any safety information about a medicine must be submitted to the MCC for review.

Process for DHCP-letter:

- The applicant submits the draft DHCP letter to the National Adverse Drug Event Monitoring Centre (NADEMC) with full motivation, and a copy to the Central Pharmacovigilance Office.
- Every draft DHCP letter must be accompanied by the most recently approved package insert for the medicine concerned.
- If the consequence of the new information is an amendment to the package insert, the applicant must include the proposed package insert simultaneously, in which the proposed changes are indicated. The applicant must also submit such a proposed package insert for evaluation to the Clinical Unit of the secretariat at the same time.
- The NADEMC shall inform the DHCP letter review group of the proposed DHCP letter and provide the review group with all the necessary documents and information.
- The DHCP letter review group will ensure that the draft DHCP letter is reviewed as quickly as possible, as but no longer than 30 days after receipt, in order for the process to be completed.
- The proposed envelope for the DHCP letter will be reviewed by the DHCP letter review group to ensure that it contains the appropriate markings relating to the content.
- The DHCP letter review group will inform the applicant of any amendments to the proposed DHCP letter.
- If no agreement can be reached between the DHCP letter review group and the applicant on the content of the letter within 5 working days, the matter will be referred to Council or EXCO, whichever meets the soonest.
- The target group(s) for receipt of the DHCP letter must be clearly identified by the applicant at the time of submission and agreed upon by the review group. Following distribution, applicants must be able to identify which members of the professions have been targeted in this mail communication.
- The DHCP letter must be distributed within 7 days of the applicant being informed of approval by the review group.
- In cases where an approved DHCP letter is to be distributed following a package insert amendment, a copy of the approved amended package insert must be distributed with the DHCP letter.
This includes cases where an urgent safety amendment is made to a package insert.

- The DHCP letter review group will inform the Pharmacovigilance Committee at its meeting immediately following approval of the DHCP letter.
- The Pharmacovigilance Committee will present all approvals of DHCP letters as part of its report to Council.
- The approved DHCP letter shall be posted on the MCC website.
- The information relating to a DHCP letter may be issued as a Medicines Safety Alert.

**Medicines Safety Alert:**

- A Medicine Safety Alert contains information about an important medicine safety issue. It may relate to new safety information or may emphasize information already known.

- A Medicines Safety Alert will usually be published in one or more local popular journals read by health care professionals, as well as on the MCC website.

**Cancellation and Withdrawal of Applications or Registered Medicines:**

Council has resolved that:

1. Under no circumstances will the cancellation of the registration of a medicine be re-instated after the holder of a certificate of registration has requested for such cancellation through a written application to the Registrar of Medicines and after the cancellation has been effected and confirmed in writing by the Registrar. Should the applicant desire to re-register the medicine, then he/she must submit an application for registration of a medicine in accordance with section 15 of the Medicines and Related Substances Act, 1965 (Act 101 of 1965), as amended.

2. Any applicant who wishes to withdraw an application for registration of a medicine at whatever stage of processing, may do so in writing to the Registrar, and once such application is approved and confirmed in writing, any re-submission will be considered as a new application.

3. All holders of certificates of registration of medicines and all applicants must carefully consider any decision to cancel or withdraw, as the case may be, before applying to the Registrar.

**3) GMP (GOOD MANUFACTURING PRACTICE)**

Includes:

- Guidelines for GMP for medicines in south Africa
- Guidelines on inspection.
- Guidelines for the preparation of site master file
- Isolator technology
- Cephalosporin manufacturing
- Penicillin manufacturing
- Aerosol manufacturing
- Radiopharmaceutical manufacturing
GUIDELINES FOR GMP FOR MEDICINES IN SOUTH AFRICA:-

- Facilitate the removal of barriers to trade in medicinal products, to promote uniformity in licensing decisions and to ensure the maintaining of high standards of quality assurance in the development, manufacture and control of medicinal products
- It was agreed to harmonise the rules of GMP applied under Pharmaceutical Inspection Convention (PIC) and the Pharmaceutical Inspection Co-operation Scheme (PIC/S)
- Medicines Control Council of South Africa accepts the European, British or United States Pharmacopoeia.

<table>
<thead>
<tr>
<th>CHAPTER</th>
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<tbody>
<tr>
<td>1</td>
<td>Quality Management</td>
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<td>Personnel</td>
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<td>Premises And Equipment</td>
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<td>6</td>
<td>Quality Control</td>
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<td>7</td>
<td>Contract Manufacture And Analysis</td>
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<td>8</td>
<td>Complaints And Product Recall</td>
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<td>9</td>
<td>Self-inspection</td>
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Annex

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Note:-
The general information provided is same as that of Indian GMP (Schedule M of Drug and cosmetic act).
GUIDELINES ON INSPECTIONS INVOLVING THE GMP INSPECTORS:

- Regular inspections are performed at the applicant/manufacturer of such medicines by inspectors appointed by the Director-General of Health in order to ensure compliance with quality control and Manufacturing Principles (GMP).
- All GMP inspections are carried out in accordance with the approved procedure to ensure compliance with the SA Guide to GMP, PIC/S guidelines on GMP and WHO Guide to GMP.
- Inspections may be announced or unannounced.
- Inspections of each site are carried out every two to three years depending on the risk associated with the products manufactured at the relevant site.

An inspection is conducted covering the following areas at the manufacturing site.

<table>
<thead>
<tr>
<th>Applicant Inspection</th>
<th>Plant Inspection</th>
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<tr>
<td>• Assessment of the SMF</td>
<td>• Water system</td>
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<tr>
<td>• Assessment of the Quality Manual</td>
<td>• Receiving area</td>
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<tr>
<td>• Assessment of the Validation Master Plan, Protocols and Reports</td>
<td>• Warehouse</td>
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<td>• Assessment of Contracts</td>
<td>• Sampling area</td>
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<tr>
<td>• Master Documents and Specifications</td>
<td>• Dispensary areas</td>
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<tr>
<td>• Annual Product Review</td>
<td>• Production areas</td>
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<tr>
<td>• Standard Operating Procedure</td>
<td>• Quality Control laboratories</td>
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<tr>
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<td>• HVAC systems</td>
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<td>• Documentation including SOP’s</td>
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<tr>
<td></td>
<td>• Validation Master Plan, Protocols and Reports</td>
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<td>• Assessment of the Quality Manual</td>
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<td>• Annual Product Review</td>
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<td>• Master Documents and Specifications</td>
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After completion of the inspection, an inspection report is written and sent to the inspected company within three weeks of the inspections.

GUIDELINES FOR PREPARATION OF SITE MASTER FILE (SMF)

- The Site Master File is prepared by the manufacturer and contains specific information about the quality assurance, the production and/or quality 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 operations, e.g. analysis, packaging, etc.
- Site Master File should be succinct and, as far as possible, not exceed approximately 25 to 30 A4 pages.
- The Site Master File should have an edition number and an effective date.
4) HUMAN MEDICINES:-

The aim of these Guidelines is to assist applicants in the preparation of documentation for the registration of medicines for human use. The types of medicine include a new medicine for a new chemical entity (NCE), a multisource (generic) product, a product line extension, and a biological medicine.

**TYPES OF APPLICATION**

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

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 and dosage regimen.

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.

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

4. Multisource/generic applications and innovator line extension applications
   a. that include comparative dissolution studies as proof of efficacy
   b. that include any other comparative studies as proof of efficacy
   c. others, not mentioned above e.g. liquids/solutions.

5. Biological medicines

**APPLICATION FOR THE REGISTRATION OF MEDICINE**

An application may be made by any of the following:

a) a person, company, residing and doing business in South Africa;

b) a close 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.

If the applicant is not a registered pharmacist or pharmacy the application should be co-signed by a registered pharmacist.

An application shall be made on the appropriate form obtainable from the registrar & shall be accompanied by:-

1. Properly completed screening form
2. A copy of latest inspection report that is not more than 2 years old from regulatory authority of the medicines country of origin.
3. proof of the existence of the manufacturing site
4. any other information as the council may demand

The application form shall contain at least the following information:-

a) Particulars of the applicant :-
   - Name
   - Business address
   - Postal address
   - Telephone no
   - Fax no
e-mail address
contact details of responsible pharmacist

b) Particulars of medicine:
- Proprietary name
- Dosage form
- Strength
- Route of administration
- Country of origin
- Name of manufacturer

A medicine must comply with technical requirements as determined by the council. Separate application is required for each individual dosage form of a medicine.

**SUMMARY BASIS FOR REGISTRATION APPLICATION (SBRA)**

The SBRA 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 product. It is to be presented as a summary only. Hence, e.g. no articles or reports should be incorporated into the SBRA, nor should such papers be attached to it either, as these belong with the full submission.

If clinical/pre-clinical data are submitted without pre-clinical and clinical expert reports, a Summary Basis for Registration Application (SBRA) should be included in the application for registration to expedite the review process of the safety and efficacy of the medicine.

Applicants should 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 SBRA should be cross-referenced with the documentation submitted to the Medicine Control Council.

**EXPEDITED REVIEW PROCESS (FAST-TRACK)**

The Medicines Control Council may, under certain circumstances, (as in most other national drug regulatory authorities) speed up the registration process for specific medicines that have important therapeutic benefit and which are required urgently to deal with key health problems.

In such cases, an accelerated review system is applied. The applicant should submit an expedited review request to the Minister of Health and a copy thereof for the attention of the Registrar of Medicines, before submitting the full application. Products that will be considered for expedited review are:

- Medicines on the Essential Drugs List (EDL)
- New Chemical Entities that are considered essential for national health but do not appear on the Essential Drugs List.

**ABBREVIATED MEDICINE REVIEW PROCESS (AMRP)**

The AMRP is a system initiated by Council to limit the evaluation time of pharmaceutical products that are registered in countries with which the Council aligns itself, if the evaluation report is readily available.

- The abbreviated medicine review process is based mainly on the expert reports of the pharmaco-toxicological and clinical data. It should be noted that the AMRP is an abbreviated evaluation process and not an abbreviated application.
- Only new chemical entities registered with one or more of the authorities with which the Council aligns itself will qualify for AMRP.
The applicant should obtain the Expert Reviewers’ reports on safety, quality and efficacy from the relevant medicines regulatory authority.

The certificate of approval of registration of the new chemical entity by one of the recognized registering authorities should be included.

Written confirmation that the proposed package insert is based on the package insert and the complete dossier of the licensing country is required.

Apart from the approved package insert on which the submission is based, the package insert of the other countries where registration has been approved, should also be submitted.

Written confirmation that the data submitted to the MCC are identical to that submitted to the authority which has granted approval should be given. Raw data of experimental and clinical studies should be excluded.

A letter authorizing the MCC to contact the relevant MRA for an evaluator’s report or assessor’s report should be included.

Expert reports on chemical-pharmaceutical, pharmaco-toxicological and clinical documentation should be included.

Relevant correspondence between the applicant and the registering authority including the negative (e.g. queries, non-acceptance of certain claims/statements) as well as the positive correspondence should be included.

Written confirmation that the formulation applied for is identical to that approved by the registering authority should be given.

Applications for AMRP can only be accepted if the product has been approved by the said authorities within the last three years of the license in the licensing country.

**EXPERT REPORTS**

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.

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

**RECALLS OF MEDICINES**

The guidelines for recall/withdrawal of medicines is the result of an agreement between the holder of the certificate of registration/parallel importer of the medicine and the Department of Health: (Medicines Control Council) (MCC) in South Africa. Its purpose is to define the action to be taken by the Cluster: Medicines Regulatory Affairs: Directorate: Inspectorate and Law Enforcement and the holder of the certificate of registration /parallel importer of the medicine, when medicines for reasons relating to their safety, quality and efficacy are to be removed from the market.

- **Recall** - means the removal of specific batch/batches of a medicinal product from the market for reasons relating to deficiencies in the quality, safety or efficacy.
- **Withdrawal** - means the total withdrawal of a medicinal product from the market.
- **Recalls** are classified into both the class according to the level of health hazard involved (risk to the patient) and Type which denotes the depth or
extent to which the product should be recalled from the distribution chain, e.g. Class I, Type C recall, etc.

Class I
Class I is for defective/dangerous/potentially life-threatening medicines that predictably or probably could result into serious health risk/adverse events or even death.

Class II
Class II is for medicines that possibly could cause temporary or medically reversible adverse health problem or mistreatment.

Class III
Class III is for medicines that are defective and are unlikely to cause any adverse health reaction.

Type A
A type A recall is designed to reach all suppliers of medicines (all distribution points) i.e. wholesalers throughout the country, directors of hospital services (private as well as state hospitals), retail outlets, doctors, nurses, pharmacists, authorised prescribers and dispensers and individual customers or patients through media release (radio, television, regional and national press).

Action: Recall letter to all distribution points plus media release.

Type B
A type B recall is designed to reach wholesalers throughout the country, directors of hospital services (private as well as state hospitals), retail outlets, doctors, nurses, pharmacists, authorised prescribers and dispensers.

Action: Recall letter to all distribution points.

Type C
A type C recall is designed to reach wholesale level and other distribution points (e.g. pharmacies, doctors, hospitals) this can be achieved by means of representatives calling on wholesalers and/or retail outlets. If it is known where the product in question had been distributed to, specific telephone calls or recalls letters to arrange for the return of the product could be made.

Action: Specific telephone calls, recall letters to/representatives calling at distribution points if known where the medicines have been distributed.

PATIENT INFORMATION LEAFLET
This guideline is also intended to provide information to applicants on the requirements regarding the readability, format and content of the PIL for use by consumers once approved. The primary objective of this guideline is to ensure that the PIL is written in clear and understandable terms for the patient and is clearly legible.

Readability of the Patient Information Leaflet:-
1. Print size and type
The information appearing in the PIL to be provided to the consumer should be printed in at least 8-point character size, leaving a space between lines of at least 3 mm. Words in full capital/upper case letters should be avoided in
the text but may be used for headings. The type of print chosen should be such as to ensure maximum legibility.

2. Layout
It is well established that sentences spanning the entire width of a page are more challenging to read than shorter columns. The PIL layout should therefore be in a column format, e.g. consisting of 3 columns on an A4 page.

3. Print colour
Characters in the text of the leaflet should be printed in black and must be clearly distinguished from the background. A different type or colour may be used for headings. Red colour print should be reserved for warning only.

4. Syntax
As far as possible, lengthy sentences (i.e. more than 20 words) should be avoided. It is recommended that lines of a length exceeding 70 characters not be used. Different fonts, upper and lower case, length of words, number of clauses per sentence and length of sentences can all influence readability

5. Paper
For long leaflets, paper size of A4/A5 is preferable. The weight of the paper should be no less than 40g/m². Thinner paper may be too transparent and thus difficult to read.

5) LICENSING

HOW TO OBTAIN A LICENCE APPLICATION FORM AND INFORMATION TO SUBMIT

4.1 Standard application forms for manufacturer’s licences (ML) are available from the Registrar of Medicines or the Medicines Control Council’s website www.MCCZA.COM.

4.2 An application for ML should be accompanied by the prescribed application fee and in the case of a new Manufacturer an inspection fee. The application shall provide acceptable documentation proof obtained from:
   ▪ the SA Pharmacy Council
   ▪ the Director-General of Health

4.3 The application for ML should include the qualification of staff to manufacture, store, distribute and sell medicines, scheduled substances or medical devices and documentary proof of the ability to comply with with good manufacturing practices (GMP) as determined by Council.

4.4 The application should include, as proof of the compliance with GMP, a Site Master File (SMF).

4.5 The application should include:
   • A copy of the local area plan of the location of the business premises
   • A plan of the actual layout of the business premises
- An inventory of equipment to be used in conducting the business
- A manual of procedures and practices to be implemented to ensure the safety, efficacy and quality of medicines or scheduled substances or medical devices to be manufactured or distributed and sold.

4.6 The application should specify the medicines, scheduled substances or medical devices to be manufactured or distributed and sold.

4.7 The Council will only issue a ML when it is satisfied, usually following an inspection of a site by the GMP Inspectors, that the information contained in the application is accurate and in compliance with requirements of the legislation and good manufacturing or distribution practices.

4.8 Where appropriate, the MCC may refuse to grant a licence. In such cases the Registrar will notify the applicant to furnish the Council with such additional documentation or information as the Council may require. The notification will set out the reason for the proposal and give the applicant a period of not less than 28 days to respond. The applicant may make written representations. Before making a final decision on its proposal the MCC will take the applicant’s written representation into consideration.

POWERS TO SUSPEND OR REVOKE MANUFACTURER’S LICENCES

a. The MCC may revoke, amend or suspend a licence when a statutory condition of that licence is no longer being met. The MCC will give the licence holder notice of its proposal and set out the reasons. In most cases the licence holder will be given a period of not less than 20 days to respond. The licence holder may give notice to the MCC of his/her desire to be heard, or make written representation to the MCC with respect to the proposals.

b. Where it appears to the MCC that public safety is at risk, the MCC may suspend a licence with immediate effect for such a period as the Council may determine, or revoke the licence in question.

c. Licence provisions may be varied on the application of the licence holder.

7) MISCELLANEOUS:-

GUIDELINES FOR IMPORTATION & EXPORTATION OF MEDICINES

No person shall order any medicine from abroad for personal use unless the Medicines Control Council has granted the said person an authorization in terms of section 21 of the Act to import during a specified period a specified quantity of the particular medicine, which is not registered with Council.

Council may in writing authorize any person to import and sell during a specified period to any specified person or institution a specified quantity of any particular medicine, which is not registered. This permission is however
subjected to confirmation from a medical professional that the product is needed and that no similar product is available in the country.

No person shall import any medicine or Scheduled substance, except through one of the following ports of entry:

(a) Cape Town Airport or harbour;
(b) Port Elizabeth Airport or harbour;
(c) Durban Airport or harbour;
(d) Johannesburg International Airport

A person can only import or sell a medicine or Scheduled substance if such person:-

- Is licensed in terms of the act to import/export medicines
- In case of unregistered medicines is authorized by the council to import/export.

**PARALLEL IMPORTATION**

Parallel importation is defined in the Regulations as

“The importation into the Republic of a medicine protected under patent and/or registered in the Republic that has been put onto the market outside the Republic by or with the consent of the patentee in respect of such medicine”

The expressions “parallel importer”, “parallel imported medicine(s)”, “parallel imported”, “to parallel import”, “to be parallel imported” and “parallel importation permit” shall have the corresponding meanings to ‘parallel importation’.

**GUIDELINES FOR AN E-SUBMISSIONS PILOT OF MEDICINES REGISTRATION APPLICATIONS**

1. **General**
   - The applicant is to supply a comprehensively completed hard copy application of the medicine they wish to get registered.
   - The applicant must make sure that the electronic submission of the application being submitted is an exact replica of the hard copy version.
   - A windows-based notebook to be submitted with the following minimum specifications.
     - Pentium III or higher, 128MB RAM, 20GB HDD and DVD-ROM drive
     - Adobe Acrobat 5.0 (or later)
     - Microsoft Word 2000 (or later)

2. **Version**
   The MRA will use version 4.0 (or higher) of Acrobat Reader with the search plug in.
3. Fonts
We believe that Times New Roman, 12-point font is adequate in size for reading narrative text. Use of a black font colour is recommended. If font colors other than black are used, avoid light coloured fonts.

4. Page Orientation
Pages should be properly oriented. For example, the applicant should set the page orientation of landscape pages to landscape prior to saving the PDF document in final form to ensure correct page presentation.

5. Page Size and Margins
The print area for pages should fit on a sheet of paper that is A4.

6. Source of Electronic Document
PDF documents produced by scanning paper documents are usually inferior to those produced from an electronic source document. Scanned documents are more difficult to read and do not allow us to search or copy and paste text for editing. They should be avoided if at all possible. Due to the integrity of electronic documents and regulation standards, an original hard copy of any source documents can be requested at any given time.

7. Page Numbering
Submission are divided into categories i.e. one document per category, include page numbers to these documents.

8. Naming PDF Files
The applicant can use file names up to 32 characters in length with a 3-character extension. Avoid using punctuation, spaces, or other non-alphanumeric symbols in file names.

9. Security
The applicant may include security settings or password protection for PDF files.

10. Indexing PDF Documents
Use full text indexes to help find specific documents and/or search for text within documents.

11. Electronic Signatures
The Managing Director of the company should account for all electronic signatures on the application:
   - A list of electronic signatures in the dossier should be provided and numbered
   - Details of person who signed, date and place are requirements.

12. Method of Packaging
Each documented category from the application should be on a separate CD-R or DVD-R disk.
LINKS OF MCC

- Government of South Africa
- South Africa - Department of Health
- South Africa - Department of Statistics
- United States of America - FDA (Food and Drug Administration)
- Australia – Health in site (Medicines)
- New Zealand - Medsafe (Regulatory and Consumer Information)
- United Kingdom - MHRA (Medicines and Healthcare Products)
- Australia - TGA (Therapeutic Goods Administration)
- Australia - National Medicines Policy (Consumer Medicine Info)
- World Health Organization – Pharmaceutical Products
- The European Agency for the Evaluation of Medicinal Products
- Pharmaceutical Inspection Convention / Pharmaceutical Inspection Cooperation Scheme

INDIAN PHARMA IN SOUTH AFRICAN MARKET

1. Zydus Cadila
2. Torrent Pharmaceuticals
3. Dr. Reddys Labs
4. Ranbaxy Pharmaceuticals
5. Intas Pharmaceuticals
6. Sun Pharmaceuticals
7. Sanofi aventis
8. Cipla Pharmaceuticals
9. Marico entered SA by buying ENALENI Pharmaceuticals
11. Lupin – Joint Venture with SA company for anti-tuberculosis drugs.

MCC approved CRO's in Ahmedabad

1. Accutest
2. Intas Biopharmaceuticals
3. BioArc Research Labs
4. Zydus Research Center (ZRC)
5. Torrent Research Center (TRC)
6. Cadila Pharma
7. Lambda Research Center
8. Veeda Research Center
9. Synchron Research Labs

REFERENCE:

www.mccza.com