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## MEDICINES CONTROL COUNCIL – A BRIEF MENTION

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### ABSTRACT

In this article address the regulatory guidelines and regulatory framework of the MCC. The NRA triggered to establishment of new legislative organizational structure SAHPRA replacement of MCC. It tasked with regulating of all medicines, medical devices around the country. This also includes clinical trials recent amendments, guidelines for regulatory process of medicine and complementary medicines.

**Keywords: Regulatory agency MCC, legislation and framework, guidelines of MCC**

### ABBREVIATION

SAHPRA-South African Health Products Regulatory Authority, MCC-Medicines Control Council, NCE- New Chemical Entity, NDA- National Department of Health, NRA- National Regulatory Authority, PHCR- Proposed Holder of the Certificate of Registration, MRF-Medicine Registration Form.

### INTRODUCTION

South African NRA was MCC. It is in charge of evaluating, monitoring, controlling, investigating, registering, regulating, and inspecting scheduled drugs and human veterinary medications. MCC's mission is to protect South Africa's

pharmaceutical quality, safety, and efficacy [1].

### ORGANIZATIONS STRUCTURE

The Chairman of the Expert Committees is a member of the MCC, a statutory organization established by the

Ministry of Health. Furthermore, the Council recruited outside experts to participate on several governing bodies for drug registration, regulatory, and regulate actions. 11 expert committees were assembled, as shown in **Figure 1**.

Council members and committee members are experts in a variety of fields, including legislation, which was codified into law, fundamental and biotechnology and clinical pharmacology, pharmaceuticals, primary care, neonatology, paediatrics, immunology, toxicology, pharmaceutical chemistry, and virology [2].

The registrar's office acted as MCC's executive secretary, providing administrative and technological assistance toward the council and its operations. The registrar's office was the NDA's principal directorate, which included pharmaceutical commerce, food control, as well as product control. Within each cluster, four Directorates were: operation and administration, law enforcement and inspection, medical assessment and research, and evaluation of clinical trials. Specialists in medicine, pharmacy, veterinary medicine, science, and administration personnel were among the employees.

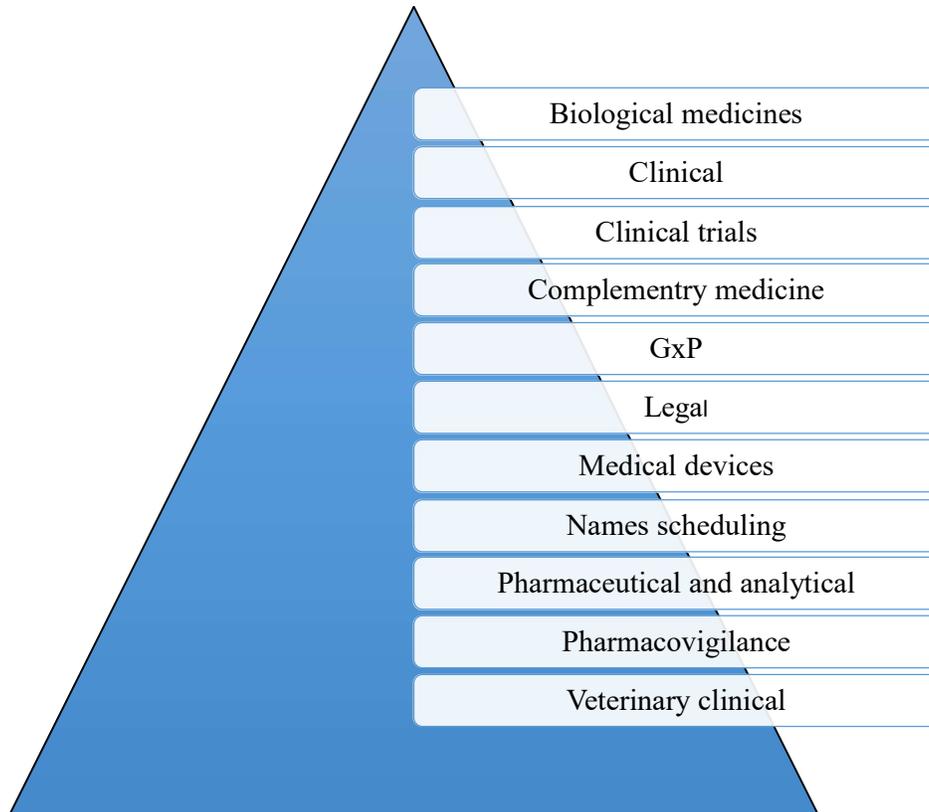


Figure 1: MCC Committees

## Regulatory Review Procedure

The laws and requirements of the Medications Act, including the regulations and published guidelines, control the drug registration in South Africa. Legislative frameworks require the NRA to examine medications, multisource, generic, and NCEs pharmaceuticals, biological drugs, supplementary medicines, and veterinary medicines, prior to product marketing.

Technical dossiers must be submitted by applicants to establish safety, quality, and effectiveness of such medications designed for sale in South Africa. The Medicines Act's Section 34, which governs the protection of secret, governs the confidentiality of information given to the NRA. The Process of MCC's regulatory review is shown, with a basic depiction of the evaluation and authorisation of applications authorised within the regulatory review cycle [3].

The NRA evaluated pharmaceutical registration applications using both internal and foreign expertise. The various expert committees considered a thorough evaluation of safety, quality, and efficiency data, as well as the reviewers' inspection results, to provide recommendations on whether to approve the product's proprietary name, schedule the API component, and the assessment of the applicant's GMP status, the API manufacturer, and the pharmaceutical

manufacturer. The MCC made the ultimate decision on authorisation or refusal.

## Guidelines for Medicine Registration

The provisions of the 1965 Medication and Related Substances Act (101 of 1965) of these Act are to be read in connection with the instructions about the form and information needed to make and submit an application for the registration of drugs. The Medications and Related Substances Control Act's legislation and requirements govern how medicines are registered in South Africa.

These guidelines specify the information necessary for the registering "medicines" including an applications to be alter a register licenced medicines. The submitted detailed details assessed in accordance with the legal terms of legislation. The purpose of these Guidelines is to help applicant to prepare documents for the registration of human-use pharmaceuticals.

Legally, all claims must be supported by evidence that meets all technical requirements for the product's quality, safety, and effectiveness for intended uses. The instructions are meant to make it easier for the applicant to comply with the Act's obligations. When a deviation from a recommendation is made, an expert report submitted with the application should include a thorough justification outlining the reason(s) for the

deviation as well as the logic behind the other technique.

Whenever candidates have any doubts should contact the approval of MCC & explanation the application form before sending it; contact information may be found on the website. Before completing the application form, applicants always should consider to the most recent versions of applicable regulations for Medicine Registration and their relevant documentation.

Guidelines are continually developing as a consequence of scientific advances and the Harmonization of requirements for regional and worldwide regulatory agencies Harmonization of requirements for regional and worldwide regulatory agencies. MCC strives to keep its technical standards and assessment criteria with best worldwide medicine regulatory practices by updating the guidelines on a regular basis.

PHCR Regulation 22 of the Act governs criteria to apply for registration of a medicament. If the applicant is an unregistered pharmacist, a registered pharmacist as specified by the Pharmacy Act (Pharmacy Act 53 of 1974 as amended) must co-sign the application.

The professional pharmacist or certified pharmacists in charge of regulatory relations who is familiar with every aspect of medicine may serve in this

capacity. This individual should be a full-time employee of the organization. In accordance with Act 53, the responsible pharmacist and the pharmacist who signed the dossier both require evidence of registration [4].

### **Registration and overview of application**

The following Sub-PARTS provide a description of the application and the criteria for registration: [5]

- a. Reference the Pharmaceutical and Analytical Guideline for Part 2A's availability of pharmaceuticals and biologicals.
- b. Data of clinical and pre-clinical are provided without pre-clinical and clinical experts reports, PART 2B include a summary of the reason for the registration application in the registration application to speed up the examination of the drug's safety and efficacy. (See clinical recommendation)PART 2C Summary of Overall Quality.
- c. Refer to the pharmaceutical and analytical guideline for the expert's pre-clinical reports in part 2d, the expert's clinical reports in part 2e, and the pharmaceutical and analytical report in part 3.
- d. Preclinical studies, Part 4: Consult the Clinical guideline.
- e. Clinical research in Part 5: Consult the Clinical guideline.

**Pre-registration**

The Unit for Pre-Registration is in charge of applications, reactions to decisions, issues involving a drug while it is being considered for registration.

**Post registration amendments**

The unit is responsible for

a) Name and address updates, as well as applicant transfers

b) Modifications to the producers, packers, and research labs (FPRC and FPRR)

c) A modification in a company's name after consulting the Names Committee

d) Modifications to the registration dossier relating to drugs

e) Registered drugs are revoked and drug registration applications are withdrawn

**Clinical assessment**

The Clinical assessment Unit is in charge of

a. Pre-clinical and clinical data evaluation

b. Clinical aspects of the package insert and any necessary modifications to the package insert assessment

**Clinical trails**

The Clinical Trials Unit evaluates

a. Applications for clinical trials and changes to clinical trials

b. Clinical trial adverse events

c. Applications for unregistered medicines used by named patient & unregistered medicines for clinical trial purposes

**Complementary medicine**

The unit of is regulating

a. Assessment and examination of the registration of supplementary medicines applications

b. Collecting the original & follow-up replies to the contact notification that was issued in the Number 23128 of Government Gazette

c. Applications for amendments to the Register for Complementary Medicines are evaluated and reviewed

d. Issuing temporary licences for the production, marketing, and the administration of complementary medicines

**Preparation and submission of an application**

1. The MRF1, which is available from webpage for the MCC or the Registrar of Medicines, should be used applications for the registration of medications must be submitted [5].

2. Each application page must  
- Be numbered and printed in black done in a size of the font

is at least as legible as black on white in Arial 10 point, and all copies, including those with figures, tables, and photos, to be easily readable. It is best to stay away from using shading, coloured fills, backgrounds, or print, such as in tables.

- Display the HCR, the name of the product, dosing type, strength in the header.

The pages have to be numbered with the MRF1 system. For example, 3B.3. Except for the patient information booklet and the packaging insert, double-sided copies are permitted.

3. Each part of the dossier shall be identified by a tab that is clearly labelled on the application for registration of a dossier.
4. A table of the contents should be included in each PART or Sub-PART.
5. The registration application has to be properly bound to the left to allow for speedy page insertion and/or updating. Left margins of the document should be sufficiently extensive to permit reading after copying & binding. The applicant may choose to have the document bound, however ring binders and lever arch files are not accepted.

The binding should maintain its integrity while allowing for easy handling and evaluation of papers.

The dossier should be bound in sections no bigger than 4 cm, depending on the binder of choice

6. As stated in section 5 of this guideline, copies of the covering letters for the screening and final submissions, as well as the entire presentation results letters must be attached to the applications dossier.
7. The original covering letter should be submitted with any checks or other documentation of payment in a separate envelope. There should be no further files attached.
8. The Trade Metrology Act's metrication criteria should be followed.
9. The boxes in which the MCC receives paperwork must be properly labelled. The following information has to be shown on every box:
  - a. Name of the applicant
  - b. The product name or the applicant's product identification number (at the applicant's choice) (e.g. NCE-04NOV01)
  - c. The box's contents, such as file numbers, PARTs, samples, cover letters, and checks.
  - d. Box count, such as 1 of 10

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- e. Application type, such as routine, expedited (quick track)
  - f. Stickers indicate different stages of screening, such as red for screening and green for post-screening.
  10. In the event of a fast-track review, a copy of the approval letter must be affixed to the front of each volumes.
  11. Upon at the MCC, receipt entire registration application will undergo pre-screening in accordance with the checklist in attachment A, which the applicant must also complete.
  12. The application will be recorded into the system and given a screening number following a successful pre-screening. The applicant will be sent a letter confirming receipt of their application and payment of the screening cost.
  13. The application will be returned to the applicant as incomplete if the applicant fails to meet the pre-screening criteria.
  14. The applications should be subjected to screening in accordance with the MRF2 screening form following successful pre-screening. The screening procedure aims to ensure that all necessary data have been included, but it does not evaluate the data or consider any reasons why any data may have been omitted. The MRF2 headings and the questions under each heading are in conformity with pertinent rules, with the exception of the Inspectorate criteria mentioned. If the interpretation of any given question is unclear, it should consequently be referred to the pertinent guidelines. There must be a reason for the exclusion of the data.
  15. The applicant will be informed of the screening results, such as hold or return as incomplete, along with the reasons. Additionally, the applicant will be informed of the deadlines for submitting any outstanding data or picking up their application. The application will be brought up for an official resolution at the following council meeting in the event that there is a disagreement over any unresolved information or deadlines.
  16. The applicant will be informed of the results of the acceptable screening, the quantity of copies, and the cost of the application. The application number will also be assigned at this time. Applications that have been authorised for a fast-track review (expedited review) should be clearly identified. Any further contact involving an
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expedited review application should include the assigned ref number and a copy of the permission letter.

17. The appropriate number of application copies & any supporting materials needed for the application review should be supplied in the manner outlined in Section 5 of this guideline, Screening and Post-Screening Copies Presentation. This day will be remembered as the day the registration application was submitted.

#### **Guidelines for obtaining manufacturing, import, or export license**

MCC regulates and medical devices, medicines, scheduled substances for human and animal use, by the Medicines and Related Substances Act of 1965 (Act 101 of 1965) and the pertinent regulations enacted thereunder, the Department of Health [7].

The Act, among other things, establishes a licencing, certification, and exemption system for the manufacturing of medical equipment, medicines, and scheduled substances in South Africa. The regulation governing medical supplies is based on the 1965 Medicines and Related Substances Act's requirements (Act 101 of 1965).

Unless excluded, these medications and medical equipment should be registered with the council or possess an

application number (which are referred to as "old Medicines"), and its maker must have the necessary manufacturer's licence. Section 22C of the Medicines Act stipulates the necessity of the manufacturer's licence.

According to the applicable sections of the act and the rules, manufacturers of unregistered medical substances, such as exploratory medicinal products or medication only for export, are likewise under supervision.

The same regulations and procedures applying to the production of veterinary drugs and animal usage of medical device that are registered with the MCC in accordance with the 1965 Medicines and Related Substances Act's provisions [8].

Both full and partial production, as well as numerous division, packing, and presentation procedures, require for a manufacturer's licence. However, if a pharmacist in a licenced community pharmacy or hospital pharmacy performs these procedures only for retail sale under their direction or control, when they are performed in accordance with the guidelines in Section 14(4) of the Act, or additionally, if a hospital pharmacy is involved, when they are executed in accordance with the provisions of Regulation 36, such a licence is not necessary.

## CONCLUSION

The goal of review was to enabling history legislation of South African regulatory authority. The NRA triggered to the establishment of a new legislative organizational structure SAHPRA replacement of MCC. Many opportunities and changed manners to be identified, and it is clear that approaches to address insufficient resources and financial, relationships between the stakeholder, management systems of document, delivery services, and regulation review processes must be reconsidered contribute to making South Africa's regulatory frameworks stronger.

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