Journal of Pharmacreations

PharmaCreations

Pharmacreations | Vol. 1 | Issue 3 | July-Sep - 2014
Journal Home page: www.pharmacreations.com

Review article ***Open Access***

An overview of drug regulatory system in South Africa

***Nadipineni Ashok Kumar and R.Suthakaran.**
Dept. of Pharmaceutical management and regulatory affairs, Vijaya college of Pharmacy, 11-187, Shapur Nagar, IDA, Jeedimetla, Hyderabad-500055, India.
***Corresponding author: Nadipineni Ashok Kumar**
E-mail id: nashokkumar30@rediffmail.com

Abstract
The regulatory authority of South Africa was a new force in leading global initiatives in access to affordable quality of medicines, the development of a regulatory agency during 1970's, by ministry of health, South Africa has made a new era in regulating the quality of medicines it made an important regulation for establishing the medicines control council (MCC) under the supervision of ministry of health. The main aim of this article is to know the medicines control council regulatory proceedings in the drug approvals and clinical trial approvals in the country, and to review the drug approvals are in a standard manner with diversified or different committees of the MCC review process.

Key words: MCC, ministry of health, MCC committees, 1970, South Africa.

INTRODUCTION
South Africa has established a new regulatory authority in 1970, which it was now internationally famed, the regulatory agency, medicines control council was established under the medicines and related substances control act, 101 of 1965, to regulate and control the medicines in South Africa the medicines control council was headed by and under the control of ministry of health, and its main purpose is to regulate the safety and therapeutic effectiveness of the all medicines and to oversee whether these medicines are meeting their affordable qualitative standards[1].

MCC Organization structure
Medicines control council (MCC) was operated by members of the control Council, the council was headed by chairperson and vice-chairperson. The MCC organization structure was arranged with committees:

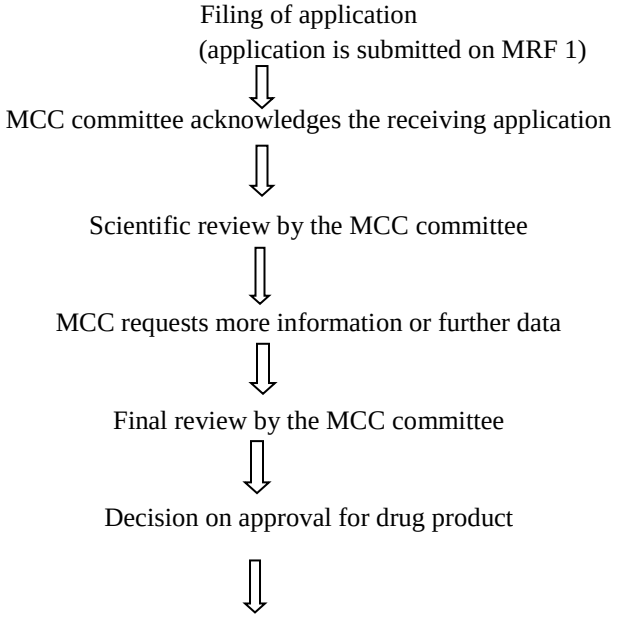
1. Pharmaceutical and analysis committee
2. Central clinical committee
3. Names and scheduling committee
4. Biological medicines committee
5. Clinical trials committee
6. Pharmacovigilance drug safety committee
7. Veterinary clinical committee
8. Veterinary product policy committee
9. Complementary medicines committee
10. African traditional medicines committee

Totally the medicines control council has 11 technical committees with 146 members from various institutions from the country the skills of the council and its committees are wrote into the law and these committees are expertise in toxicology and safety of medicine, clinical pharmacology,

biotechnology, pharmaceutics evaluation and internal medicine, virology, pharmaceutical chemistry, immunology, veterinary science, complementary medicine and law[2].

Drug approval process

For obtaining an approval in South Africa an application is submitted on the medicines registration form 1 to the medicines control council, MCC committee acknowledges the receiving application, the MCC evaluates the submission and usually raises a queries or requests further data or additional information, after producing the additional information the MCC makes review on further information, once the review is completed, registration of the product will be approved or rejected is informed to the applicant. The time taken for evaluation varies depending on the burden of work and evaluation process review, usually the time period for innovator drugs is 24 months where as for generic medicines is 12 months[3]



Drug approval requirements:

The required documents for drug approval are submitted in eCTD format, electronic submission is the valid format for South African regulatory authority. This electronic documentation format describes how to organize applications based on international conference on harmonization of technical requirements for registration of pharmaceuticals for human use[4]. eCTD mainly comprises of 5 modules:

Module 1: administrative information: this module contains documents specific to the each region.

Module 2: summary of dossier: the CTD dossier contains clinical summary and non clinical summary, clinical overview and non clinical overview reports and a statement of GCP compliance is also included in the clinical overview.

Module 3: Quality documents: module 3 contains clinical, pharmaceutical and biological data, it also contains full report of biopharmaceutical studies including methodology and validation of bioavailability studies.

Module 4: Non clinical study reports: module 4 of the dossier contains pharmaco toxicological data

Module 5: clinical study reports: it contains clinical data such as pharmacodynamics, and pharmacokinetics reports, safety and efficacy of the medicine[4]

Clinical trial regulatory process in South Africa

The clinical trial application requires careful compilation of drug specific and protocol specific summaries, and justifications, in South Africa the clinical trials application is filed to the MCC clinical trials committee, for the compilation of clinical trial application a scientific expertise is required, the application is acknowledged and reviewed by the external reviewers and MCC's clinical trials committee, the studies on bioavailability and bioequivalence are processed at a faster rate through in house review then all reviewer recommendations are verified by council during 8- annual meetings, the time period for review of clinical trial application is 8-12 weeks and the time period involved for bioequivalence studies is 4-weeks, the review process of clinical trial application ends with approval at council meeting and all the clinical trials are compulsorily enlisted on South African national register prior to ethics committee application. This national research register is maintained by the national health research ethics council[5].

Registration and licensing requirements for manufacture and sale of drugs

Drug products in South Africa must be registered by the MCC, this regulatory agency was setup under medicines and related substances control act 101 of 1965 as amended, to regulate manufacture and sale of drug products and medicines.

Registration requirements for company

All companies are registered under the companies act and with South African pharmacy council, and the company should get an operating license from MCC the company must file an application which is compiled in a specified format given by MCC for registration and for carrying operations in South Africa. Companies should also compile a master file application which contains detailed description of company, (for example. Company address, its organogram, including skills, experience of staff responsible for production, testing, storage, distribution of drug products.) The dossier of the product which is compiled in a specified format by company's applicant must be submitted to MCC and it was approved by MCC after that it was completely regarded as a legal contract, If any amendment or new changes in processes made by the company must be approved by MCC.

CONCLUSION

The establishment of medicines control council has led to several changes in regulating the quality of medicines and the organization structure was arranged according to the department wise with committees for reviewing and approving the new drugs, generic drugs. Clinical trials, this organizational structure implementation lead to fast track evaluation and approving of drug products, the drug approval process is arranged according to 8 annual meetings with a scheduled time of 24 months for new drugs and 12 months for generic drugs, the scientific review of MCC played an important role in the drug approval process and its approval process quite novel when compared with different countries approval process,

REFERENCES

1.http://www.mccza.com/about/default.asp
2.http://www.mccza.com/MCC/default.asp
3.http://newdrugapprovals.org/south-africa-mcc/
4.http://www.mccza.com/genericDocuments/2.21_ZA_eCTD_Module_1_Technical_v1.pdf
4.http://www.mccza.com/genericDocuments/2.24_Guidance_General_Module_1_Jul12_v5.pdf
5. http://www.triclinium.net/our-environment/regulatory-process-for-trials-in-south-africa