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Procedures for Dossier Preparation and their Marketing Authorisation in Zimbabwe Country for Complementary Drug

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Abstract

The Medicines Control Authority of Zimbabwe (MCAZ) is the authority to regulate from the Ministry of Health. It is established through an Act of Parliament which gives these bodies the `power to regulate the quality and sale of Complementary medicines. The objectives of this study were to evaluate the current regulatory review process of the Medicines Control Authority of Zimbabwe (MCAZ), identify key milestones and target timelines, evaluate overall performance from 2017 to 2019, identify best practices in review, evaluate the quality of decision-making processes and identify challenges and opportunities for improvement. Complementary medicine has always been at the heart of most Zimbabweans. That most of the drug is located close to the African community makes it very attractive, user-friendly, cost-effective and flexible in adapting to the dynamics of modern societal trends. The aim is to understand the need for professionalization of complementary medicine. The guidelines were studied from the website. We studied the guidelines to prepare a checklist and dossier preparation to submit to the authority of Zimbabwe.

Keywords: Medicine Control Authority of Zimbabwe; Complementary Medicine; African Community; Dossier

Introduction

Dossier

The word 'Dossier' means a collection or file of documents on a particular subject, especially a file containing detailed information about a person or subject. The process of criticizing and evaluating the documentation of a pharmaceutical product containing its detailed administrative, chemical, preclinical and clinical information and authorization granted by the country's regulatory agencies to support its marketing or approval in the country is called "Marketing approval or registration", "registration or " product licensing'. "Registration dossier" of a pharmaceutical product is a document that contains all the technical data (administrative, qualitative, non-clinical and clinical) of the pharmaceutical product to be approved/registered/sold in the country [1].

Complementary Medicine

Any of a range of medical therapies that fall beyond the scope of conventional medicine but may be used alongside it in the treatment of disease and ill health. Complementary medicine is a term used to describe types of treatments you may receive along with traditional Western medicine. Examples of complementary medicine include massage, meditation, music therapy, and dietary supplements [2].

Complementary Medicine has always been at the heart of most African people and in particular the Shona people of Zimbabwe. Statistics show that in Africa, 50 percent of the population regularly uses alternative therapies, natural herbs being the most used.

The fact that most of the medicine is found within the vicinity of the African community makes it very attractive, user friendly as well as it being cost effective and flexible in adapting to the dynamics of modern society trends. The paper highlights that in Zimbabwe, there is growing popularity of the herbal medicines due to the healing properties attributed to them. Other reasons are affordability of medicines, as compared to biomedical therapy and user friendliness of the herbs [3].

Zimbabwe Regulatory Authorities

The Medicines Control Authority of Zimbabwe (MCAZ) is a statutory body established by an Act of Parliament, the Medicines and Related Substances Control Act (MASCA) [Chapter 15.03]. MCAZ is the successor to the Drugs Control Council (DCC) and the Zimbabwe Regional Drug Control Laboratory (ZRDCL). The DCC was established by an Act of Parliament in 1969: The Drugs and Related Substances Control Act [Chapter 15.03], after which the ZRDCL became operational in 1989. The Medicines Control Authority of Zimbabwe is responsible for protecting public and animal health by ensuring the availability drugs and related substances and medical devices are safe, effective and of high quality thanks to the enforcement of standards by manufacturers and distributors.

The Evaluation and Registration Department (EVR) of the MCAZ assesses applications for medicinal products. The EVR Division assesses the safety, quality and efficacy of medicines intended for marketing, sale and distribution in Zimbabwe in accordance with the requirements of MASCA [15:03], MASCR SI 150 of 1991, MCAZ Registration Guidelines, Registration Committee policies and approved internal procedures (SOPs), which are in accordance with the MCAZ Quality Management System (QMS). EVR is comprised of the Human Medicine, Complementary Medicine and Veterinary Medicine Units responsible for assessment and registration of human, complementary and veterinary medicines including post-registration variations [4].

Regional Collaborative Work

The Evaluation and Registration Department of MCAZ is involved in the joint work of the Southern African Development Community (SADC). This initiative, also known as Zazibona, is a joint process for 16 SADC countries in which national regulatory authorities jointly assess medicines for registration purposes. The aim of the process is to support a collaborative model for facilitating access to quality medicines through the sharing of work in drug evaluation and inspection of drug manufacturing and testing facilities. Currently, 9 of the 16 member states are actively participating countries, namely Zambia, Zimbabwe, Botswana, Namibia, South Africa, Malawi, Tanzania, Mozambique and the Democratic Republic of the Congo. The remaining 7 of the 16 Member States do not actively participate in dossier evaluation, but are involved in training programs and information sharing on products that go through the collaborative process [4].

Material and Methods

General Description of Registration Processes

Drug regulation generally covers the following areas:

- Pre-market assessment and evaluation of the quality, safety and efficacy of the medicinal product, including compliance of manufacturing sites and processes with Good Manufacturing Practice (GMP) standards.
- Assessment and control of all components of the pharmaceutical supply chain. Maintaining a register of available products and post-marketing surveillance activities, including random sampling of registered medicinal products for quality control and pharmacovigilance.
- Promotion, advertising and provision of information about medicinal products [5].

Requirements of Product Registration Dossier According to Guideline

- **Section A:** Administrative Requirements
- Registration Status
- Good Manufacturing Certificate
- Manufacturing Certificate
- Product Permission
- Details of Applicant
- Details of Manufacturer
- Details of Zimbabwe Local Technical Representative
- **Section B:** Particulars of product
- All information about Product included in Section B.
- **Section C:** Composition of product
- Information of Composition used in the product (Reference, Quantity of constituents, Functions)
- **Section D:** Safety and Quality assurance
- Botanical Identification of Plant
- Biological Information of Plant
- Product Toxicology Information
- **Section E:** Efficacy
- **Section F:** Post Market Surveillance [4]

Methods for Registration of Complementary Medicine in Zimbabwe

For the registration process in Zimbabwe a complete application consists of

1. Dossier
2. Application fees
3. Product samples, submitted in their original container as intended for the patient. The sample should be labelled as it will be on the final product.
4. Completed C.M 1 form.
5. Declaration by the applicant

The samples should be accompanied by a copy of certificate of analysis, product specifications and analytical methods. The applicant should provide reference standards, degradation products and related impurities for a full monograph analysis. The samples should be labelled as the final product planned for the market [6].

Results and Discussion

The regulating body were identified: The Medicines Control Authority of Zimbabwe (MCAZ). The authority derives their power to regulate from the act of law, MCAZ from statutory instrument 97 of 2015 Chapter (15.03). The results will be presented under six sections: (Section A) Administrative; (Section B) Particulars of product; (Section C) Composition of product; (Section D) Safety and Quality assurance data; (Section E) Efficacy; (Section F) Post Market Surveillance. Applicants are required to submit two copies of the documentation (one hard copy and one electronic copy {electronic copy if available}. Paper copies of the application should be bound for easy access to information [7].

Each section of the documentation must be identified using clearly marked cards and the documentation should be stored in accessible files. Lever binders are not acceptable. Each binder should be labelled with the non-proprietary name and the protected name of the FPP (eg: Tribulus Terrestris Saponins "Trade Name" 5% w/v) and the name of the applicant's company. For ease of reference, they may be on the label of each binder (if space permits) the following information: the volume number of the given binder (from the total number of volumes for the given module, the section(s) contained in each volume and the date of application (month and year), e.g. unprotected name FPP [4].

Section A: Administrative Requirements:

- Cover Letter
- A completed and signed C.M.1 form
- Declaration by applicant
- Manufacturing and marketing authorization registration status (Good manufacturing Practice, Manufacturing Licences, Product Permission)
- Proof of payment

Section B: Particulars of product

- All information about Product included in Section B

Section C: Composition of product

- Information of Composition used in the product (Reference, Quantity of constituents, Functions)

Section D: Safety and Quality assurance

- **Safety:** The active ingredient related information ex: Botanical identification, Geographical source, Harvesting and collection of plant etc.)
- **Quality Assurance:** Active raw material, Excipients and Finished Product details for ex: Specification, Standard Test Procedure and Certificate of Analysis documents are required.
- **Declaration Certificate:** If any Animal oriented constituent is used in product declaration of certificate used.

Chemical Contaminants	
Heavy metals	Mercury
	Lead
	Cadmium
	Arsenic
	Chromium
Microbial contaminants	
Micro-organisms	Fungi
	Parasites
	Bacteria
Residual organic solvents	Methanol
	Acetone
	Ethanol

Table 1: Common herbal medicine contaminants WHO (2007).

Stability Study Data: Stability data must demonstrate stability of the medicinal product throughout its intended shelf life under the climatic conditions for climatic zone IVb

Accelerated Stability testing	40°C ± 2°C, Relative Humidity: 75 ± 5
Long term testing	30°C ± 2, Relative Humidity: 65 ± 5

Table 2: climatic conditions for climatic zone IVb.

Packaging: The product shall be packed in containers which will safeguard the hygienic and other qualities of the complementary medicine. The containers, including packaging material, shall be made only of substances which

are safe and suitable for their intended use.

Section E: Efficacy
In the case of complementary medicines, the requirements for proof of efficacy will depend on the kind of indications for use and individual experiences as recorded in reports from physicians or traditional practitioners. Clinical evidence will be required in cases where traditional use has not been documented; scientific literature validated by clinical trials.

Section F: Post Market Surveillance
A satisfactory post-market surveillance plan must be provided in the applications for approval of complementary medicine [4].

Conclusion

The study revealed that obtaining a market authorization for the registration of a drug in any territory necessitates a specific format, and that each country follows a specific guideline in addition to its own regulations set by the respective drug regulatory authority.

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