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Comparison of Registration Requirement of Generic Drugs in USA, Canada and Europe with Zimbabwe

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Abstract

Generic drug products played an important role in the health care system in global aspects especially in the middle income country and fully developed country. They play important role in the lowering the cost of medicine and provide the low cost treatment in targeted countries. Generic drugs have the same therapeutic value same as the innovator product. This study aims to achieve the comparison of the regulation of generic drug product regulation in Zimbabwe, USA, Canada and Europe. All of the targeted countries follows the common technical document format and also focuses on safety quality and efficacy of the drug product. Regulation of generic drug in Zimbabwe is easy compared to rest of the countries.

Keywords: Common technical document • Medicines control authority of Zimbabwe • USFDA • European medicine agency • Comparative study

Introduction

Pharmaceutical products are the focus of drug regulatory affairs. It is a relatively new field that emerged from government desire to safeguard public health by monitoring the efficacy and safety of goods in a variety of industries, comprising drugs, medical equipment, veterinary medications, agrochemicals, insecticides, cosmetics, and supplementary therapies. The businesses in charge of their development, testing, production, and distribution also want to make sure that the products they offer are secure and meaningfully advance the health and welfare of the general population.

Procedure for registration of pharmaceutical product for submission to the medicines control authority of Zimbabwe

These guidelines are recent changes to the MCAZ draft registration guidelines published in 2008, which were based on SADC and WHO guidelines. Since 2008, few changes in regulatory practice and policy were implemented. The improvements are based on the World Health Organization guideline on submission of documentation for a multisource generic drugs, finished pharmaceutical product FPP: Quality portion and on the international conference on harmonization guidelines.

The international conference on harmonization process has resulted in a sizable harmonisation in the organization of the registration documents with the publication of the common technical document guideline. The common technical document format that is advocated for submitting registration applications has widely accepted by regulatory agencies around the world.

This paper Provides guidelines for the presentation and format of certain types of product dossiers [1].

Literature Review

Guidance on the format and presentation:

Modules:

Module 1-Administrative information and prescribing. information

Module 2-CTD summaries.

Module 3-Quality.

Module 4-Non-clinical study reports

Module 5-Clinical study reports.

Annexs:

Annex I: MC8 FORM.

Annex II: Screening checklist.

Annex III: SMPC/package Insert.

Annex IV: Quantities of samples required for laboratory analysis.

Annex V: Product quality review requirements established generic products.

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Annex VI: Recommendations for conducting and assessing comparative dissolution profiles.

Annex VII: Ingredients gazetted as undesirable in pharmaceutical preparations by the MCAZ.

Language:

All application forms must be completed in English.

The most recent edition of the "uniform requirements for manuscripts submitted to biomedical journals," published by the International Committee of Medical Journal Editors, should be followed for citing references (ICMJE). If the article is published, copies of the whole article and any pertinent reference pages should be supplied [2].

As required, English translations must be offered.

Data presentation:

Page size: A4 (21 × 29.7cm)

Font: Times New Roman

Font size: 12

Mode of submission: One hard copy and one electronic copy.

To avoid information being hidden by the binding technique, the left hand margin should be appropriately wide. In order to be clearly readable after photocopying, font sizes for text and tables should be in a style and size that both are large enough [3].

Guidance on presentation: Applicants are must require to submit 2 copies of the dossier. For the simple information access, paper copy is required to submit [4].

The documentation should be organized in searchable files, with each section of the dossier marked with tabs that are clearly noted. Lever arch files are not acceptable.

The non-proprietary name, proprietary name, and applicant's company name should all appear on the label of the binder. Additionally, each binder's label could have the following details for easy reference: What that binder's volume number is each volume's portion, as well as the application's submission date.

Name “PQR”
Applicant “ABC”
Module 3-Quality
Volume 1 of 3
Module 3.1-3.2.S.3
Month/year 02/1999

If an applications are not submitted in the suitable format or that is incomplete or illegible will be rejected [5].

Types of application: New chemical entity application (biological and bio-similar medicines are included under this group).

- Generic drug application.
- Line extension application.

Payment of fees:

Mode of payment: Fees may be paid by check, bank draught, telegraphic transfer, or direct deposit into the authority account by applicants.

Fees are not refundable once it is received; these rules include applications that are turned down or applications that an applicant voluntarily withdraws [6].

Electronic review documents: Documentation submitted electronically on CDs or DVDs must be in microsoft word required for templates/summaries (such as QOS-PD, QIS, or BTIF) or text-selectable PDF format.

Discussion

Summary of Product Characteristics (SmPC)

Use the Annex III format for the SmPC. The following target audiences should be represented by two different types of SmPC:

- Health professionals' access to product information.
- Information on the product for patient.

Submissions should include copies of all package inserts and any other materials that are meant to be given to patients together with the product. These need to be clear and understandable, and they should be written in English [7].

The authority shall decide which category a medicine should fall under when it is distributed, in accordance with the sixth schedule of the medicines and allied substances control regulations.

The categories are:

- **Narcotic medicines or dangerous drug (mentioned as “N”):** Items with substances that are listed as such in the law and which may be regulated by the international narcotics board.
- **Prescription Preparations (P.P.):** These medications can only be obtained with a prescription.
- **Specially Restricted preparations (S.R.):** The prescription must be approved by a medical superintendent at one of such institutions, and possession is only permitted in pharmacies at central hospitals.
- **Pharmacist Initiated Medicines (P.I.M):** Drugs that a pharmacist may order and distribute without a prescription.
- **Pharmacy Drugs (P):** These products are available from licensed pharmacies only
- **Household Remedies (H.R.):** All approved trade supermarkets, dispensaries, and pharmacies carry the medications in this category.
- **Veterinary Medicines (V.M.G.D.):** This category of veterinary medications is offered by all stores with a licence.

Declaration by the applicant: The applicant or a responsible individual they nominate who meets the requirements in terms of education and experience should make a declaration. It is emphasised that only someone who can vouch for the application's accuracy should sign on the applicant's behalf. False or deceptive declarations will result in legal action [8].

Failure to make the declaration will lead to rejection of the application.

Screening checklist: The candidate is required to finish a screening checklist in Annex 2. Before accepting it for review by MCAZ, the authority will first determine if the application is complete. Applications that are not complete will be denied, and a full application will be expected from the applicant. For products that don't pass screening, the Authority may charge a re-submission fee [9].

Manufacturing and marketing authorisation, international registration status:

List the countries in which:

- The FPP has been granted a marketing authorization.
- The FPP has been withdrawn from the market.
- An application for the marketing of the FPP has been rejected, deferred or withdrawn it is necessary to provide the registration information from your home country. If the medication is not registered in the country, there should be an explanation given. Including any withdrawals, cancellations, suspensions, or revocations, registration status in the nation of manufacturing should be stated. It is equally important to state the causes of these [10].

Labelling:

- The name of the finish pharmaceutical product.
- Route of administration.
- A list of API with a statement of the net contents of the container, including the number of dosage units, weight, or volume, and the amount of each API present in a dosage unit.
- List of excipients known to be of safety concern for some patients, e.g. lactose, gluten, metabisulfites, parabens, ethanol.
- Instruction on use.
- Batch number of product
- The manufacturing AND expiry date in an un-coded form.
- Possible handling precautions or storage requirements. In the distribution network, it should be possible to meet the designated storage conditions.
- Directions for use, and any warnings or precautions that may be necessary.
- The name of the manufacturer and address of the manufacturing site.
- For containers of capacity less than or equal to 10 ml that are marketed in an outer pack such as a carton, and the outer pack bears all the required information, the immediate container need only contain items (a), (b), (c), (f) and (g) or a logo that unambiguously identifies the company and the name of the dosage form or the route of administration [11].

Comparison of technical requirement amongst Zimbabwe, USA, Canada and Europe (Tables 1 and 2).

Countries	Fess product submission	CTD follows	Validity of registration	Timeline for registration
Zimbabwe	$2,500	Paper CTD	12 months	480 days
USA	$225,712	e CTD	5 years	18 months
Canada	$10,666	e CTD	5 years	15 months
Europe	282100 euro	e CTD	5 years	12 months

Table 1. Comparison of technical requirement amongst Zimbabwe, USA, Canada and Europe.

Administrative document	Countries			
	Zimbabwe	USA	Canada	Europe
Package insert	Required	Required	Required	Required
Art work	Required	Required	Required	Required
Certificate of pharmaceutical product	Required	Required	Required	Required
Site registration application	Required	Required	Required	Required
Application for GMP inspection	Required	Required	Required	Required
Application form	Required	Required	Required	Required
Letter of authorization	Required	Required	Required	Required
Site master file	Required	Required	Required	Required
Summary product characteristics	Required	Required	Required	Required
Free sale certificate	Required	Required	Required	Required

Product information already approved in any state/country	Required	Required	Required	Required
Quality document	Required	Required	Required	Required
API document	Zimbabwe	USA	Canada	Europe
Container closure system	Required	Required	Required	Required
Stability	Required	Required	Required	Required
Certificate of suitability	Required	Required	Required	Required
Drug master file	Required	Required	Required	Required
Manufacture of drug substance	Required	Required	Required	Required
Quality control of drug product	Required	Required	Required	Required
Manufacture of the product: Required in all the countries				
In process product: Required in all the countries				
Finished product: Required in all the countries				

Table 2. Key registration requirement for Zimbabwe, USA, Canada and Europe.

Document comparative study

The above given table give the information about the similarities and differences in the regulatory requirement for registration of drug in to the above mention countries, Zimbabwe, USA, Canada and Europe. Filling of CTD is common in all of the countries e CTD accepted in Canada, Europe, and USA while in the Zimbabwe paper CTD is submitted. As described in the table submission timeline and validation of registration are different USA, Europe validity is from 5 years and in Zimbabwe it is only valid from 12 month (1 year). Registration fees are differing country to country. Some of the requirement for registration is same for all of the above mention country Zimbabwe, USA, Canada and Europe [12].

Conclusion

Above information are performed between regulated and semi regulated countries. Main aim to comparison of registration requirement between regulated and semi regulated and differentiate them. The registration requirement is more stringent in USA, Canada and Europe compared to Zimbabwe. Now a days Zimbabwe and other southern countries are focusing to upgrade standards and have regulation as per regulated countries e.g., USA, Europe and Canada. In Zimbabwe people are mostly suffering from cholera, malaria, rabies, HIV, AIDS and Typhoid. Which makes the increasing the demand for drug in market. Also help to gather knowledge of various technical documents and to give exposures of the various guidelines of respective countries.

References

1. Sithole, Tariro, Gugu Mahlangu, Sam Salek, and Stuart Walker, et al. "Evaluation of the regulatory review process in Zimbabwe: challenges and opportunities." *Ther Innov Regul Sci* 55 (2021): 474-489.
2. Sithole, Tariro, Sam Salek, Gugu Mahlangu, and Stuart Walker, et al. "Comparison of the registration process of the medicines control authority of Zimbabwe with Australia, Canada, Singapore, and Switzerland: Benchmarking best practices." *Expert Rev Clin Pharmacol* 15 (2022): 109-119.
3. Masuka, Josiah Tatenda, and Star Khoza. "An analysis of the trends, characteristics, scope, and performance of the Zimbabwean pharmacovigilance reporting scheme." *Pharmacol Res Perspect* 8 (2020): e00657.
4. Kontoghiorghes, George J. "Differences between the European Union and United States of America in Drug Regulatory Affairs Affect Global Patient Safety Standards and Public Health Awareness: The Case of Deferasirox and Other Iron Chelating Drugs." *Medicines (Basel)* 8 (2021): 36.
5. Patil, Aishwarya, and Anjali Thakre. "Overview of drug regulatory affairs and drug approval process in US, Europe, India and Canada: A review." *Int J Drug Regul Aff* 8 (2020): 36-43.
6. Botros, Sylvia, Mina Botros, and Nancy Botros. "A comparison of the drug approval process in the united states and canada." *Int J Drug Regul Aff* 10 (2022): 1-8.
7. Kumar, Devender, Shivali Rahi, and Arpana Rana. "Comparative study of updated clinical trial regulations in india with respect to Australia, Europe, Japan and US." *Int J Drug Regul Aff* 9 (2021): 48-61.
8. Dalla Torre Di Sanguinetto, Simon, Esa Heinonen, Janine Antonov, and Claus Bolte, et al. "A comparative review of marketing authorization decisions in Switzerland, the EU, and the USA." *Ther Innov Regul Sci* 53 (2019): 86-94.
9. Kashyap, U Nitin, Vishal Gupta, and HV Raghunandan. "Comparison of drug approval process in United States and Europe." *J Pharm Sci Res* 5 (2013): 131.
10. Czech, Marcin, Aleksandra Baran-Kooiker, Kagan Atikeler, and Maria Demirtshyan, et al. "A review of rare disease policies and orphan drug reimbursement systems in 12 Eurasian countries." *Front Public Health* 7 (2020): 416.
11. Lunawat, Sandeesha, and Krishnamurthy Bhat. "Complex generic products: Insight of current regulatory frameworks in US, EU and Canada and the need of harmonisation." *Ther Innov Regul Sci* 54 (2020): 991-1000.
12. Charyulu, Narayana R, Anoop V Narayanan, and Amitha Shetty. "Comparison of generic drug registration strategies between health Canada and Gulf Cooperation Council." *J Generic Med* 18 (2022): 82-87.

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