Available online at www.elixirpublishers.com (Elixir International Journal)

Social Studies

Elixir Social Studies 184 (2024) 57142 - 57146

ISSN: 2229-712X

Packaging and Labeling of Pharmaceutical Products to Implement Quality Assurance in Tanzania. A Case of Pharmaceutical Markets in Arusha Region

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ARTICLE INFO

Article history:
Received: 25 February 2024;
Received in revised form:
15 March 2024;
Accepted: 21 March 2024;

Keywords
Pharmaceuticals Products,
Packaging,
Labelling,
Quality assurance,
Market.

ABSTRACT

Packaging and labeling practices are among challenges facing consumer of pharmaceutical products today. Some manufacturers, however, do not indicate all the required information on the products. This study used survey method to characterize the pharmaceutical products in the market, and it was conducted using a systematic procedure known as a checklist. Parameters like dates of manufactures, expiring dates, and general instructions were spread using excel from the checklist. Data were analyzed using Statistical Package of Social Sciences (SPSS). Conclusively, 22% of the pharmaceutical products showed only expiring dates, 14% of the pharmaceutical products showed manufacturing dates only and 64% of the products showed both skills, production and expiring dates. It was recommended that customers should clearly check for important information and proper packaging before buying the pharmaceutical products, also authorities should not only control products in the market but also in industries, checking for the Good Manufacture Practice.

Introduction

Pharmaceutical products need more detailed information when packing and labelling than any other products like foods though sometimes there are various similarities in their packaging. Safety and integrity of the packaging of these products require necessary licensing to control their packaging and labelling. Labels ensure the health and safety of customer. The label identifies all the necessary information provided alongside the product including the product name and purpose, dosage and use instructions, ingredients, both active and inactive warnings and potential advice side effects. Such information must feature on more than one side of the products (Pareek and Khunteta, 2017). On package, the label must be unabbreviated and in a positive way that does not obscure the printed information.

Currently, most people just buy the drug from pharmaceutical market without any advice from an expert this is because they simply know that a typical medicine can cure a certain disease or alleviate a symptom, therefore, they can buy and use it.

Objectives of the Study

Main Objective

This study investigated the packaging and labelling of the pharmaceutical products in implementation of quality assurance in the market.

Specific Objectives

To study and describe established pharmaceutical packaging, labeling and good quality within the pharmaceutical market in Arusha.

1. To assess the appearance of the pharmaceutical products packaging and labelling in Tanzania.
2. To explore the current barriers that prevent the implementation of quality assurance of the pharmaceutical products in the market.

Research Questions

i. What are the norms for the selection of materials for pharmaceutical packaging and labeling?

ii. What are the important items found on label of pharmaceutical products that prevent the implementation of quality of pharmaceutical products?

Review of the Literature

Gaps

Various studies have investigated the assessment of pharmaceutical products. Praveen (2014) conducted a study on the review on pharmaceutical packaging materials. The study attempted to identify the perfect makings on a pharmaceutical package, it listed the quality of pharmaceutical packaging that should have adequate mechanical strength in order to survive handling, closing, filling and transportation. Packaging materials should also not react with the substances stored in it. The package material should be with an outline that can be sophisticated and also the substances can be easily pinched from it, also it should not trickle alkali in the substances. Container should not support mold growth. It must tolerate the heat when it is to be pasteurized. The container contents should not be absorbed by the container. The container materials should be inert neutral. Any part of the container or closure should not react with each other. Ending should be of harmless nature and chemically steady with container contents. It should provide desired degree of safety from environmental dangers (Praveen, 2014).

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Another study was conducted by Shobhit and Kumar in 2012 on applications of Biodegradable Pharmaceutical Packaging Materials. The study indicated that packaging requirements for pharmaceutical products are intricate than those of non-edible material. Study shows main function of packaging materials are to guard contents during storage, transportation and the time of utilization (Kumar and Gupta, 2012). Trends and future, categorized pharmaceutical packaging as primary, secondary and tertiary packaging. Primary packaging is the first packaging envelope, it is in touch with the dosage form or equipment. The packaging needs not to interact with the drug and will provide proper containment of pharmaceuticals, for instance blister packages and strip packages.

Secondary packaging is successive covering or package storing pharmaceuticals packages in it for their grouping for example, cartons and boxes.

Tertiary packaging provides bulk control and shipping of pharmaceuticals from one place to another, examples are containers and barrels (Domenech n.d.).

Different Types of Packaging Materials

Packaging material types are presented on Figure 2, they are blister, tubes, ampules, plastic materials, glass materials and others. The demand for blister material in the market is increasing because it is claimed to be a nice pack as not straight forward for contamination to pharmaceutical products.

Packaging and labelling plays a vital part in storage and transportation of pharmaceutical products. Bundle shape should be easy to handle when transporting the products, one above the other.

Definition of Important Terms

Pharmaceutical packaging and labelling are a means of science, art, technology and economical to offering, protecting, identifying and presentation of pharmaceutical products for distribution, storage, sale and use.

A pharmaceutical package vessel is a piece or device which contains the pharmaceutical product and may or may not be in direct contact with the product. The container which is planned for pharmaceutical purpose must be stable (Praveen, 2014). Packaging of pharmaceutical products has always been global.

Pharmaceutical packaging is an art and science of conserving and caring for pharmaceutical product from harm by enclosing them (Kumar and Gupta, 2012).

A pharmacopoeia is an official book that lists all the drugs that can be used to treat people in a particular country, and describes how to use them (WHO, 2003).

Pharmacopeia has an important function as it describes appropriate medicine substance and therapeutically compositions and defining the standards for quality of medicinal substances and products. The quality of pharmaceutical or medicinal products is defined due to their design development in Good Manufacturing Practice (GMP), validity of their manufacturing procedure and also the quality of standards applied to them during development, manufacturing and the shelf life. Customers often express interest to buy quality products protected by suitable available standards.

Labelling

Every pharmaceutical preparation must comply with the labelling requirements established by Good Manufacturing Practices.

The label on the respective container should include:

The name of the pharmaceutical product, the name(s) of the active ingredient(s); International Nonproprietary Names (INN) should be used wherever possible, the concentration(s) of the active ingredient(s) and the amount or the volume of preparation in the container, the batch (lot) number assigned by the manufacturer; the expiry date, the utilization period, and, when required, the date of manufacture, any special storage conditions or handling precautions that may be necessary; if applicable, the period of use after opening the container, directions for use, warnings and precautions that may be necessary (WHO, 2003).

Methodology

To attain the objectives of this study a survey instrument was designed to gather information about present pharmaceutical products packaging and labelling in the market. Data were collected based on survey of big and small pharmaceuticals found in Dar es Salaam and Arusha regions. The survey was conducted using a systematic procedure known as checklist on which all the important parameters were spread using excel from the checklist.

The following parameters were surveyed. Name of the pharmaceutical product, name of pharmaceutical industry, batch number, major raw material, pharmacopeia in which the pharmaceutical products should indicate among the types, example USP, BP, JAPANESE, INTERNATIONAL and EUROPEAN. Because no pharmaceutical product can be made without the use of these directives. Types of patients like infants, adults and pregnant women, whether the directions of use on product label was given, or not given. Shelf life of the drug, this includes the manufacture and expiring date, and direction for use,

Rationale and Significance of the Study

The study results are expected to fill the knowledge gap of the implementation of the quality packaging and labelling of the pharmaceutical products in the market, but also be convenient for quality products to be used for the goals of quality control and assurance in Tanzania.

Limitation of the Study

The study used survey which involved the researcher to find the market and collect the required data. Study employed checklist and documented all the needed information before starting to analyze data. During the survey the respondents sometimes experienced difficulties because the owners of the drug market did not allow the researcher to get in their premises and collect information about the pharmaceuticals. Sometimes, the researcher found some targeted markets closed as a result failed to collect data from those markets.

To take care of the limitation, the researcher also used documentary review method by reading documents such as the international standards procedures, like pharmacopeia.

Delimitation of the Study

This study focused only on the area of assessment, that is, any pharmaceutical products in the market that were easily reached by the researcher in Dar es Salaam and Arusha town to represent the whole Tanzania mainland.

Study Site

In this study data was collected based on survey of the bigger and smaller pharmaceuticals found in Dar es Salaam and Arusha regions. This survey was conducted using a systematic procedure known as a checklist on which all the important parameters were spread using excel from the checklist.

Significance

This study is to alert people to be aware of not buying the deteriorated pharmaceutical products by mistake by not checking on the important parameters on the product like expiring dates on the product label. Also, for people to see the importance of consulting doctors or physicians before taking drugs as some products need to be prescribed by specialists.

Sample of Study

Sample of the study consisted of 120 pharmaceutical products selected from 39 pharmacies in Dar es Salaam and Arusha.

Data Analysis

The Statistical Package of Social Sciences (SPSS) was applied to analyze the data collected from the survey. The frequencies and percentages were used to show different types of pharmacopeias and manufactures of pharmaceutical products skills on how to use the product following the instruction from the physician.

Results and Discussion

This section presents the study findings in graphs and are discussed according to the study specific categories.

Figure 3 shows that among the surveyed products the British Pharmacopeia were the most used among the surveyed drugs in the market. Mainly, pharmacopeias found on the label of the drugs in the market were the British Pharmacopeias (BP), United States Pharmacopeias (USP), Indian Pharmacopeias (IP), Japanese Pharmacopeias, European Pharmacopeias and International Pharmacopeias. On the drug monograph in the pharmacopeia this information is to be included: chemical structure drug name (Trade Generic name), and raw material used in the preparation of the drug. No drug can be registered and no industry can start production of pharmaceutical products without providing this kind of information among others. Pharmacopeias show the formula of any drug production, how it can be made in terms of formulas and directions for use, and if it needs prescription from doctors or not (Cartwright, 2016). Each information for an individual pharmaceutical product can be found inside the pharmacopeia. Pharmacopeia is a dictionary of all pharmaceutical products.

It has been found that most of the pharmaceutical products are manufactured from outside the country, however, the domestic manufacturers are in Arusha, Dar es Salaam, and Kilimanjaro; among these manufacturers Dar es Salaam is the larger processor in Tanzania. Figure 4 shows Dar es Salaam is the big manufacturer of pharmaceutical products in Tanzania according to the data collected. Some of the Tanzania Pharmaceutical industries are like Shelys Pharmaceutical Ltd and Elys Chemical Industries Ltd.

Further, data on Figure 5 show that 14% of the surveyed products show the manufacturing date, 22% of the surveyed products show only expiring date and 64% show both the manufacturing and the expiring dates.

Conclusion

The study found that on the consumers, nearly all of this information is faraway outside their mutual understanding. The study also found that label awareness can be directed to facilitate consumers understanding on buying choices of pharmaceutical products.

Poor pharmaceutical packaging and labelling are not only a health hazard, but a waste of money for both government and individual consumers since sometimes products may contain toxic substances that have been unintentionally added and could even cause death.

Different types of patients differ in terms of their directions for use of the pharmaceutical products, this is due to differences in enzymic characteristics and different diseases in their bodies, for instance, infants or the elderly need special care. At their age the risk of toxicity is very high due to the enzyme deficiencies, for elderly people as well especially very old who are often receiving multiple drugs for their multiple diseases, this could greatly increase the risk of drug interactions as well as adverse reaction.

Pharmacopeia indicates that there are some pharmaceutical products which can be taken by only babies, adults, pregnant women, and some can be taken by all; this is clearly indicated by all pharmacopeia, USP, BP, Indian, EU, Japanese and International Pharmacopeia.

Number of pharmaceutical products and directions to use. It was also found that some manufacturers of pharmaceutical products did not indicate the directions for use on their product labels and this does not comply with TMDA or quality control regulations, the reason is that, most products need to be prescribed.

Recommendations

It is recommended that the customer should clearly check for the important information and proper packaging before buying a pharmaceutical product, also authorities should not only exercise control in the market but also in industries to check for the Good Manufacture Practice for all products in their place of production.

The government needs to follow up of the quality of packaging and labelling of the pharmaceutical products to check on whether they adhere to the required regulations in the market in order to control the quality.

It is important for individuals or patients not to take drugs without seeing the doctors first since directions for use on some medicines are not indicated on the label of their packaging.

Generally, consumers or patients need the products which can cure their diseases and not destroy their bodies, it is recommended, therefore, for people to see physicians before taking any pharmaceutical products.

In addition, it is recommended that those who are selling pharmaceutical products in the market have to ensure that packaging materials that are used meet the required standards.

There is a need to conduct an associated study using large sample than those included in this study.

Figure 1. Typical Blister Pack

Source: Pharmaceutical in the Market

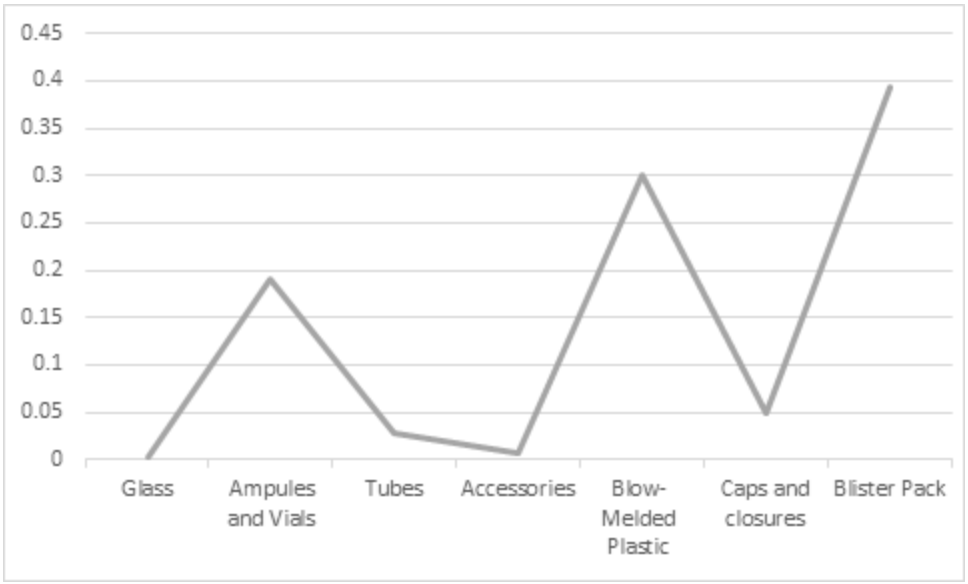

Figure 2. Types of packaging materials Adapted from FIND/SVP Inc. (New York City)

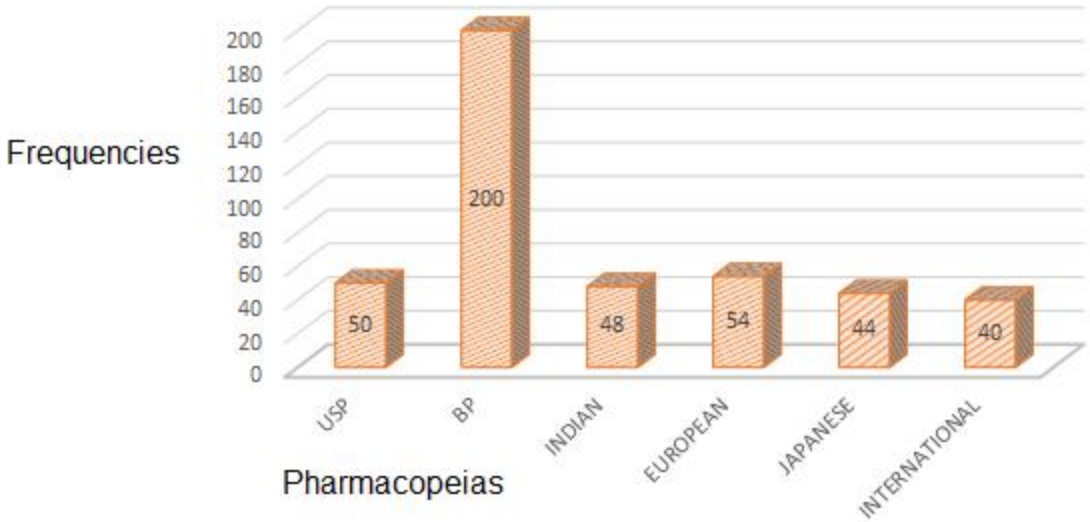

Figure 3. Frequencies of the Pharmacopeias from surveyed products

Source: Field data (2023)

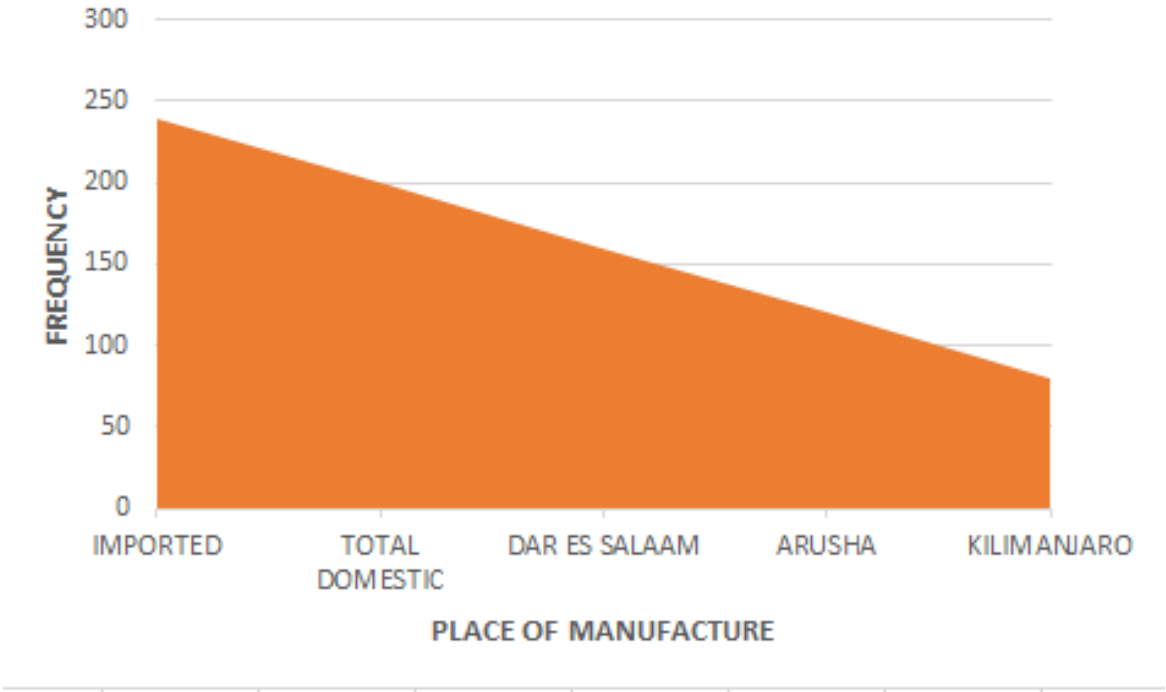

Figure 4. The statistics of domestic and imported manufacture of pharmaceutical Products

Source: Field data (2023)

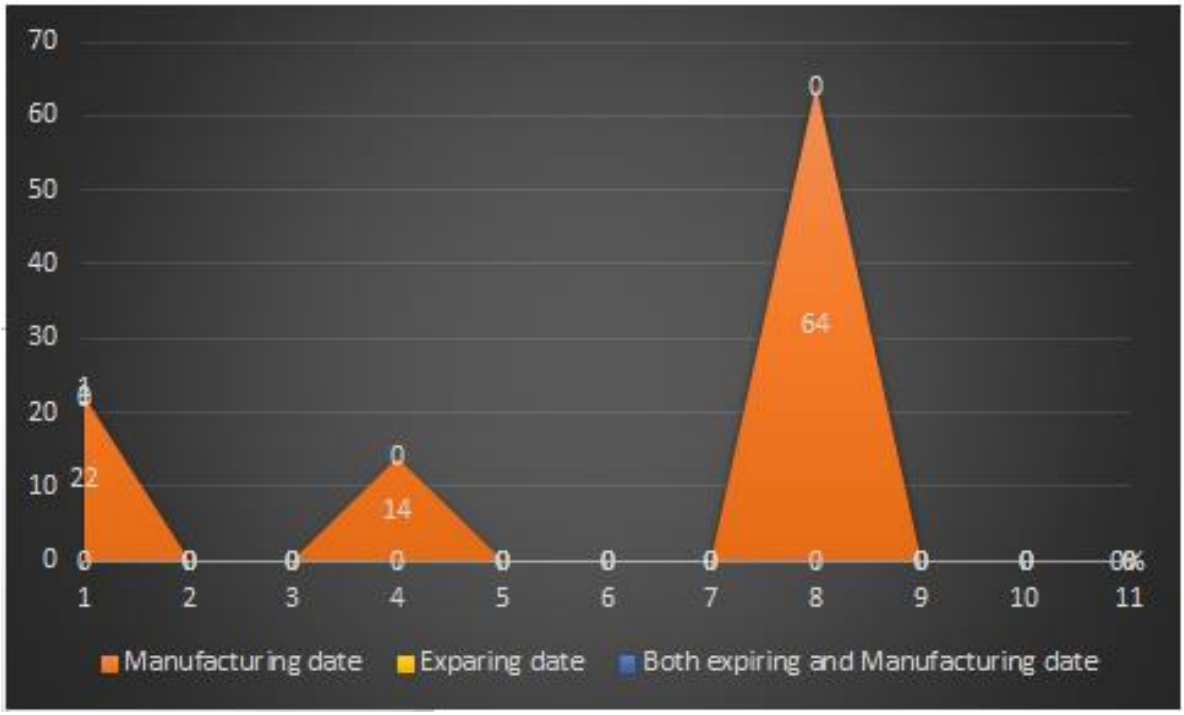

Figure 5. Manufacturing and expiring dates

Source: Field work 2023

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