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STATUS OF MEDICAL SHOPS IN GWALIOR REGION – A SURVEY REPORT

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Abstract: Medical store surveys capture practical, reliable, and valid information about functional health and well-being from the patient's point of view. They can be used across age, disease, and treatment group, and are appropriate for a wide variety of applications. It includes studies of hundreds of diseases, conditions, and populations, and greatly enhances the ability to interpret health survey data in new studies. These surveys are the most widely used tools in the world for measuring patient-reported outcomes. In the present study, the survey has been used as a tool to find out the extent of compliance of D&C Act by the medical store owners.

Keywords: Drug and cosmetic act, status of health care system, regulatory authorities, role of pharmacist, etc.



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INTRODUCTION

In India import, manufacturing, sale and distribution of drug is regulated under Drugs and Cosmetics Act 1940 and Drugs and Cosmetic Rules 1945. At present, bulk drug (Active Pharmaceutical Ingredients) and finished formulations are regulated under the said Act. The practice of pharmacy, today, is one of the most important in the delivery of health services, and pharmacists are the health professionals who have the most detailed knowledge of drugs and how they work. Nearly 540 pharmacy students pass out every year from this area. Many of them open medical shops in Gwalior and nearby areas. These pharmacists play an important role in the upliftment of status of healthcare system in Gwalior region because pharmacist's duty is not simply dispensing the drugs which are prescribed by a general practitioner or other health professional but also to deliver optimal pharmaceutical care, by assessing the suitability of the medication for a particular patient, taking into account their medical history, as well as possible side effects and interactions with other drugs that are being used. Importantly, pharmaceutical care also includes engagement and communication with patients, so they are given a clear understanding of the medication, its purposes, effects and the dosage regime. ^[1]

Within the community, local pharmacists also undertake health promotions, such as providing education sessions on specific areas of health and disease prevention. Some pharmacy practices even specialize in, for example, asthma or diabetes care and provide specific assistance, advice and services. A pharmacist must be able to identify and evaluate important health aspects which may need addressing. Pharmacists are often the first port of call for people to get advice on health in general, as well as specific clinical conditions. This is especially so in rural towns, where the health services may not match those in metropolitan areas. In these towns, where pharmacy practices have been established for many years, the pharmacist is trusted by other members of the community to offer professional advice. ^[2]

Gwalior is the fourth largest city of Madhya Pradesh and is often referred to as the tourist capital of the state. Gwalior is located at [26.22°N 78.18°E](#). It has an average elevation of 197 meters (646 feet). It is also covered by Industrial and commercial zones of neighboring districts (malanpur - Bhind, Banmor - morena) at all the three main directions. ^[3] An official Census 2011 released by Directorate of Census Operations in Madhya Pradesh showed that Gwalior had population of 2,030,543 of which male and female were 1,090,647 and 939,896 respectively. ^[4] To open a retail drug store, the following documents are needed for a new license-

- Application on form 19 of the drugs and cosmetic rules, 1945 with Rs. 5, Non judicial ticket and 3 passport size photographs. Both of these attach with application form.

- Fees to be deposited in State Bank of India/Government treasury under specific head for grant of a retail sale license.
- Photocopies of registration of registered pharmacist for retail license, issued by state pharmacy council.
- Copy of higher secondary marksheet
- Documents regarding premises of shop in 3 copies.
- Document regarding rental premises
- Affidavit of proprietor and affidavit of pharmacist
 - Receipt of freeze
 - Experience certificate of working in any retail shop for 3years
 - Document about electricity connection.
 - Shop act form.

These all documents are submitted in Food and Drug Control Office, district headquarter. An original license or a renewed license to sell drugs, unless sooner suspended or cancelled, shall be valid (for a period of five years on and from the date on) which it is granted or renewed. Every medical shop covered under this survey renewed their license time to time.^[5]

The Indian Pharmacopoeia recommends that the articles should be stored under conditions that prevent contamination and deterioration. Specific directions are given in some monographs with respect to the temperatures at which pharmacopoeial articles should be stored, where it is considered that usage at a lower or higher temperate may produce undesirable results. The storage conditions are defined by the following terms:

- Store in a dry, well ventilated place at a temperature not exceeding 30 °C
- Store in a refrigerator (2 to 8°C). Do not freeze
- Store in a freezer (-2 to -18°C)
- Store in a deep freezer (below -18°C)
- Storage conditions not related to temperature are indicated in following terms:
- Store protected from light

- Store protected from light and moisture

Where no specific storage directions or limitations are given in the monograph or by the manufacturer, it is to be understood that the storage conditions include protection from moisture, freezing and excessive heat (any temperature above 40⁰C).^[6]

A pharmacist on medical shop should always discuss the prescription with the patient before selling the medication like the method of taking each pill, whether this prescription is going to affect any other medication which the patient may be taking at the time so as to know the interactions between them etc. The person dispensing a prescription containing a drug specified in schedule H (and schedule X) shall comply with the following requirements in addition to other requirements of these rules:-

- The prescription must not be dispensed more than once unless the prescriber has stated thereon that it may be dispensed more than once;
- If the prescription contains a direction that it may be dispensed a stated number of times or at stated intervals it must not be dispensed otherwise than in accordance with the directions:
- At the time of dispensing there must be noted on the prescription above the signature of the prescriber, the name and address of the seller and the date on which the prescription is dispensed.^[7]

Prescription auditing should be done which minimizes overuse and misuse of drugs, plan essential drug selection and estimate the drug need of the community. The said data are of great value to health administrators, policy planners, manufacturers, distributors, health professionals and various consumer groups for their decision making.^[8]

Medical shops stores both generic as well as branded drugs for patient's care. There sale is decided on the basis of prescription written by the doctor. Generic drug is identical or bioequivalent to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use. According to the Congressional Budget Office, generic drugs serve consumers an estimated \$8 to \$ 10 billion a year at retail pharmacies. Drug companies must submit an abbreviated new drug application (ANDA) for approval to market a generic product. The ANDA process does not require the drug sponsor to repeat costly animal and clinical research on ingredients or dosage forms already approved for safety and effectiveness. Therefore, their cost is low in comparison to branded drugs.^[9]

Rajasthan is only the state where generic drug outlets are in practice and these outlets are being controlled by the Rajasthan government. Branded drugs are made by big pharmaceutical companies. Once developed, it must be tested on human objects through clinical trials. After

this process if drug is proved to be efficacious it is submitted to FDA for approval. Once the FDA has approved a drug, it is granted 20 years of exclusivity. This means that no other product can be released onto the market to compete with it during this time. In US, doctors will write only about the drug molecule and the brand will be declared by the pharmacist.^[10]

The Drug Price Control Order (DCPO) is an order issued by the government under the essential commodities act which enables it to fix the prices of some essential bulk drugs and their formulations. This was introduced in 1970 and was implemented in 1979. The National Pharmaceutical Pricing Authority (NPPA) set up in 1997, implements the provisions of the DPCO. Apart from fixing the prices, it is also responsible for monitoring and enforcing these prices. The authority announces two types of prices: ceiling and non-ceiling prices. The prices are fixed by the NPPA. It issues questionnaires to various manufacturers, looks at their cost-audit reports and, wherever necessary, even undertakes plant visit to verify the data, thereafter, taking into consideration the actual costs and technical parameters, a fair price is decided. This price also provides for a specified return to the manufacturer.^[11]

The expired date may or may not be harmful for the consumers but always have less efficacy than the product within the shelf life as per IP the concentration of the drug should be $\pm 5\%$. There is nothing in the rules to make obligatory upon a licensee to destroy or throw away the stock as soon as it crosses the date of expiry. If for claiming rebate from income tax and sales department the licensee keeps expired date medicines in his stock with the due precaution that everybody should know that the same were not intended for sale then he cannot be said to have committed any offence.^[12]

Medical shop should always be visited by medical representative and drug inspector regularly for their better maintenance. Medical representative is a key link between medical and pharmaceutical companies and health care professionals. They work strategically to increase the awareness and use of a company's pharmaceutical and medical products in settings such as general practices, primary care trusts and hospitals. Their main work at the medical shop is to conduct retail chemist prescription audit (RCPA). The word audit means any exercise that tends to look at inspect versus output and at the infrastructure that governs both.

Drug inspector has some important powers-

a) Inspect -

- i) any premises wherein any drug or cosmetic is being manufactured and the means employed for standardizing and testing the drug or cosmetic;
- ii) any premises wherein any drug or cosmetic is being sold, or stocked or exhibited or offered for sale, or disturbed;

- b) take samples of any drug or cosmetic -
- i) which is being manufactured or being sold or is stocked or exhibited or offered for sale, or is being distributed;
 - ii) from any person who is in the course of conveying, delivering or preparing to deliver such drug or cosmetic to a purchaser or a consignee;

Drug Inspector should visit the medical shop-

- to procure and send for test or analysis, if necessary, imported packages which he has reason to suspect contain drugs being sold or stocked or exhibited for sale in contravention of the provisions of the act or rules there under;
- to investigate any complaint in writing which may be made to him,
- to maintain a record of all inspections made and action taken by him in the performance of his duties, including the taking of sample and the seizure of stocks, and to submit copies of such record to the controlling authority.
- To make such enquiries and inspections as may be necessary to detect the sale of drugs in contravention of the act;
- When so authorized by the state government, to detain imported packages which he has reason to suspect contain drugs, the import of which is prohibited.

To open a drug store, a license is always granted to a competent who-

- is a registered pharmacist or
- has passed the matriculation examination or its equivalent examination from a recognized board with the four years experience in dealing with the sale of drugs or
- holds a degree of a recognized university with one years experience in dealing with drugs.

[12]

MATERIAL AND METHODS

A survey is a systematic method of collecting data from a population of interest. It tends to be quantitative in nature and aims to collect information from a sample of the population such that the results are representative of the population within a certain degree of error. The purpose of a survey is to collect quantitative information, usually through the use of a

structured and standardized questionnaire. The following method was adopted for the current survey:

1. Questionnaire was prepared
2. Students are send to different areas of Gwalior and nearby regions:
3. Questionnaires were given to people and asked them to fill it.
4. Questionnaires were collected back
5. the data collected was processed and analyzed

RESULT AND DISCUSSION

It was found through the survey that 98.33% of the medical shops stored the drugs as per the instruction of the manufacturer whereas 1.67% has casual behavior towards storage conditions. (fig.1)

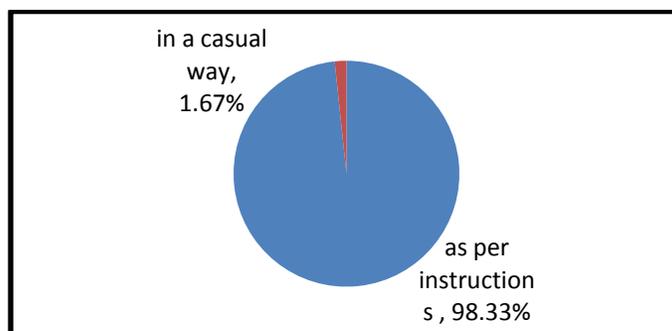


Fig. 1 Storage of drugs

It has been observed that in 81.67% of the medical shops the drugs are sold only on the production of prescription but 18.33% of the medical shops sell medicines without having prescription. (fig.2)

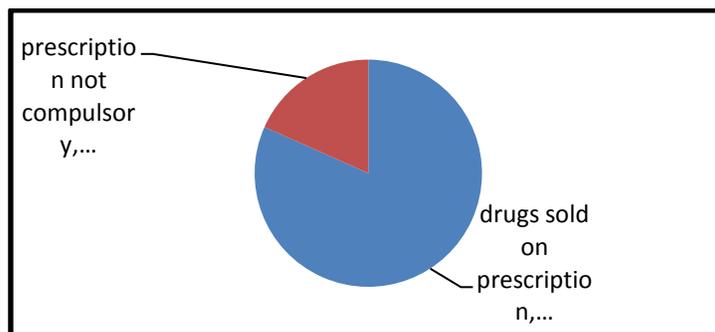


Fig.2 Selling of drugs with prescription or without prescription

In our survey it was found that 83.33% of the shops sell the drug at Maximum Retail Price (MRP) printed on the label. 16.67% of the respondents sell the medicines at a rate higher than the MRP depending on the state of awareness of the customer. (fig.3)

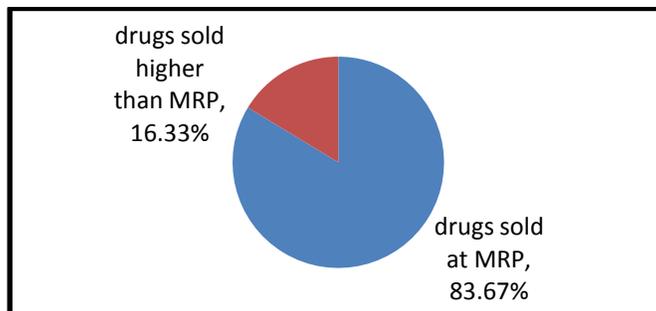


Fig.3 Selling of drugs at MRP

It was found that 98.33% medical shopkeepers check the expiry date whereas 1.67% are still careless about it. (fig.4)

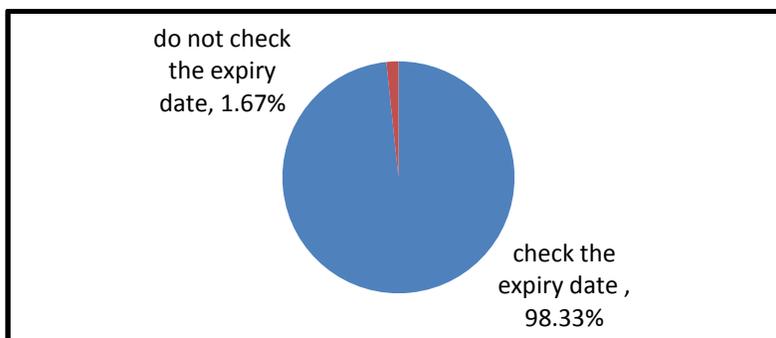


Fig.4 Checking of expiry date

The pharmacist at medical shop as a moral duty should always explain about the drug, its route of administration, dosage frequency, when to be taken, and other related issues like drug should be taken empty stomach or after having food, taken with water or milk, and other necessary aspects. During our survey it was found that 91.67% of the pharmacist explains about the medicines before selling it but 8.33% just sell it without any concern. (fig.5)

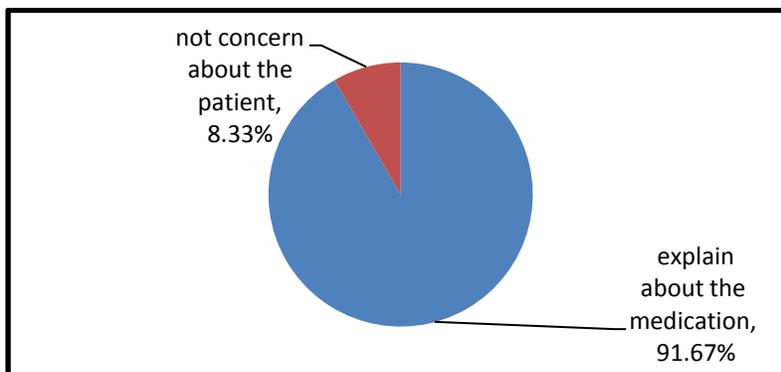


Fig.5 Interaction with the patient

It was observed that 45% of the medical shops sales only branded drugs whereas 55% sales both but no result were found for generic drugs. (fig.6)

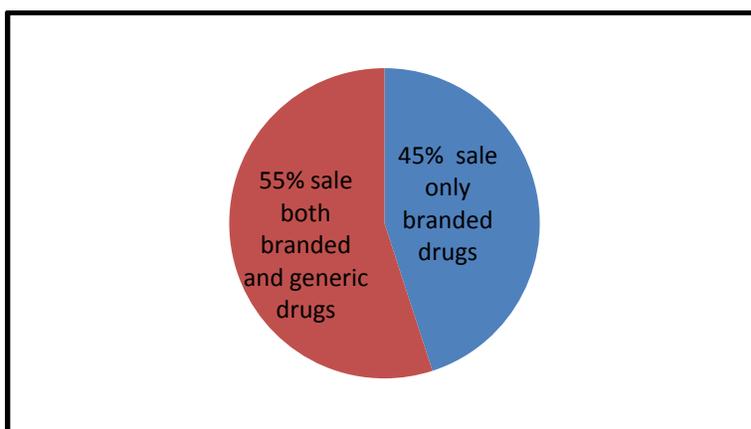


Fig.6 Selling of branded and generic drugs

In the pharmacy profession the drugs should be sold against the prescription at the medical shop. Prescription involves each and everything in writing duly signed by the responsible person. The shopkeeper as an ethic should always follow the prescription and then sale a drug. But during this survey it was found that 90% of the medical shop sales the drug against the prescription and still 1.67% sale which are cheap and another 8.33% sale according to the wish of the patient. (fig.7)

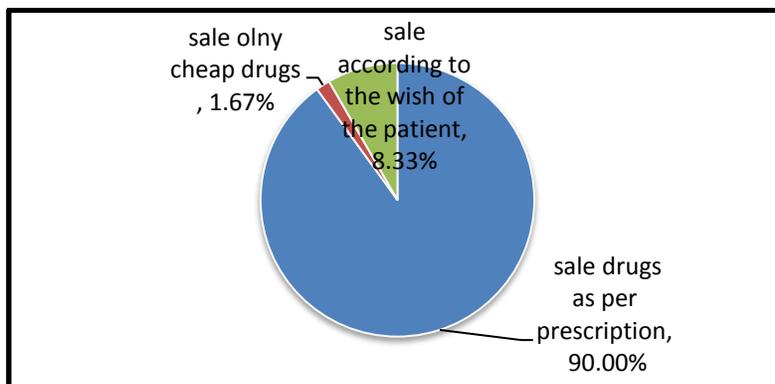


Fig.7 Selling of drugs as per prescription

Medical shop is the place where anybody can approach anytime according to their need and requirement. It is normally seen that pharmacies near government hospitals open for 24 hrs and private nursing homes have their own shops which open for 24 hrs but other medical shops in the city have their own arrival and closure time. In this survey it was found that 21.67% open their shops at night and 78.33% not. 26.67% opens their shop at 8:00 am, 21.66% at 10:00 am, 20% at 9:00 am, 15% at 7:00 am and few opens between 7:30 am to 11:00 am. (fig.8)

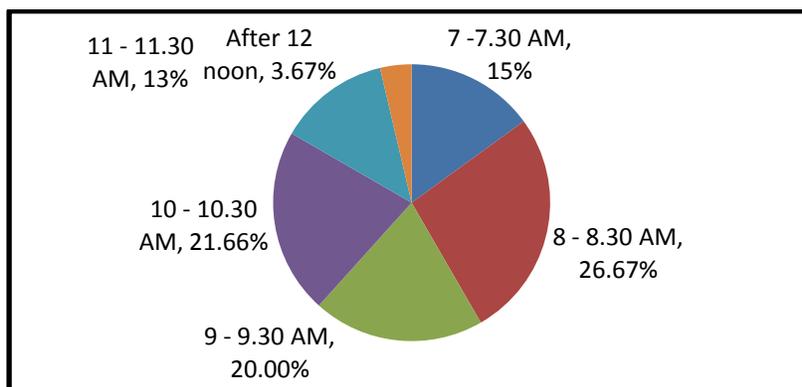


Fig.8 Time of opening the store

Similarly, 33.33% close their shop at 10:00 pm, 21.67% at 11:00 pm, 13.33% at 9:00 pm and rests have timings between 7:00 pm to 12:00 am. (fig.9)

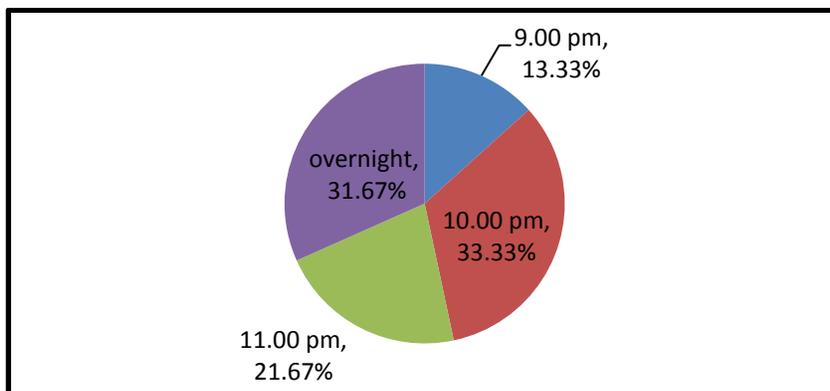


Fig.9 Time of closing the store

Diseases which are caused due to the effects of the season are called seasonal diseases. In other words, diseases caused due to allergy of weather are seasonal diseases. Some of the common seasonal diseases are jaundice, small pox, malaria, measles, dengue fever, conjunctivitis, throat infections, cough and cold etc. People should always have a balanced diet plan to avoid health hazards and similarly proper water intake is also necessary. Other relevant precautions according to the conditions of the diseases should also be taken. In this survey it was found that 75% medical shops store drugs according to seasonal diseases and 25% does not. (fig. 10)

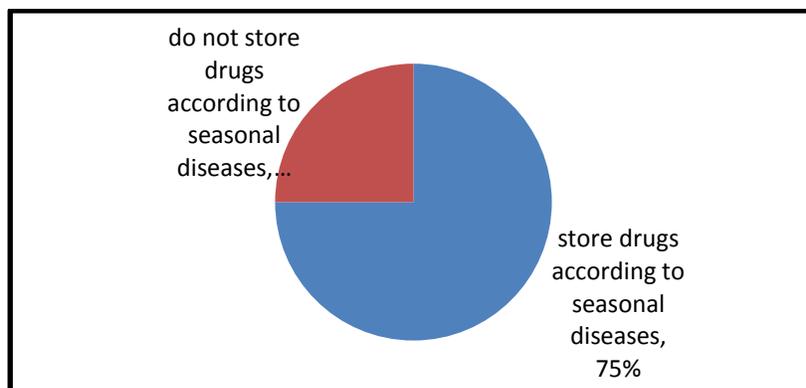


Fig. 10 Storing of drugs according to seasonal diseases

In 98.33% it was seen that MR's visit to the medical shops was regular but still 1.67% of the medical shops does not have their regular attendance. (fig.11)

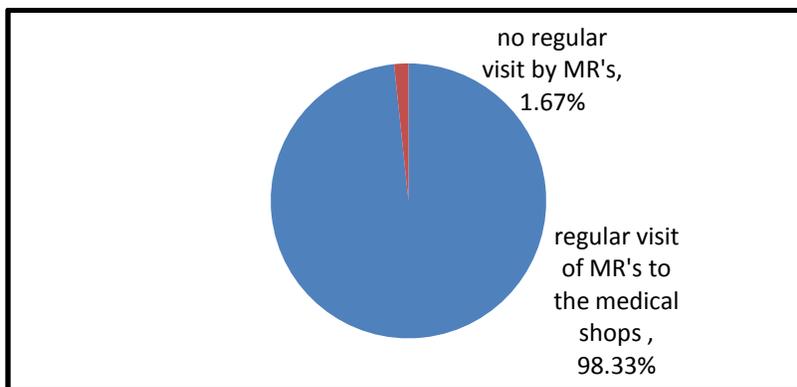


Fig.11 Visit of medical representatives to the shop

Pharmacy is the field which deals about drugs and their related aspects. So, it is very important for the pharmacist to update their knowledge, be in touch with recent developed drugs and other advancements in the field of medical science. It has been found from this survey that 65% pharmacist keep knowledge about recent developed drugs and 80% update their knowledge regularly whereas 35% have no information about recent developed drugs and 20% does not update their knowledge. (fig. 12)

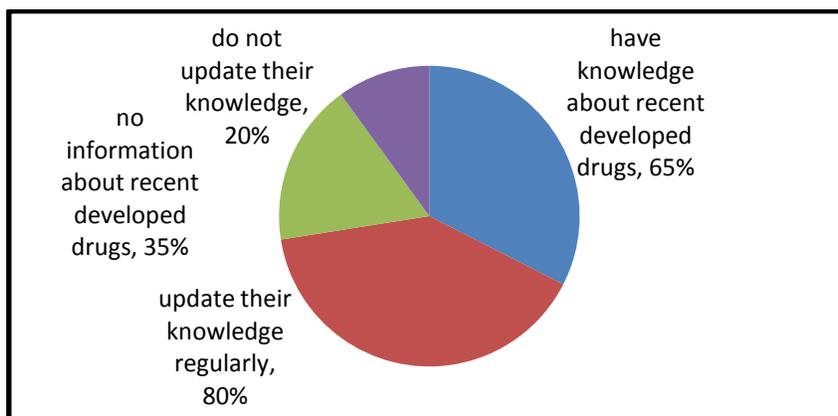


Fig.12 Knowledge about recent developments to pharmacist

According to drug and cosmetic act, license to open a drug store is given to a person having some specific qualification and experience. In the survey it was found that the 50% of the employees with graduate level, 33.34% with 12th level, 8.33% with 10th and post graduate level of education. (fig.13)

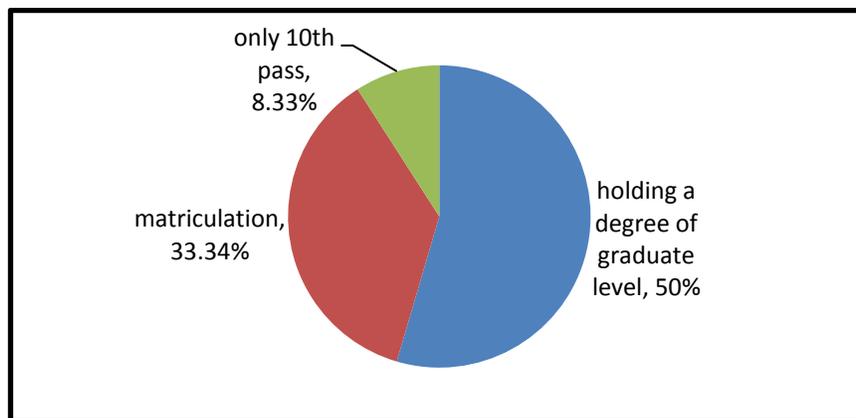


Fig.13 Qualification of a drug store owner

As discussed earlier that inspector has got very important role regarding the manufacturing and sale of the drug. He should always keep an eye on these activities. During this survey it was found that frequency of visit to the different medical shop varied from 1 time to 12 times and 16.67% responded by saying that they don't know how many times does he come. Through this survey, it was found that only 61.67% know who the senior drug inspector is and 38.33% don't know about it.

When goods are being bought against cash, the shopkeeper gives a cash memo. This is like a memorandum record, showing that you purchased something, for which cash is being already paid. Some shopkeepers will also mark a cash memo as 'paid' when you pat at the counter. In a cash memo the items purchased are clearly shown, along with rates and quantities. The cash memo should always be signed by the shopkeeper^[13]. In 90% of the cases cash memo is being given to the patient on purchasing the medicines and 10% before selling the medicines does not give cash memo. It was found after this survey that only in 3.33% of the medical shop the sample has been fined or caught where as in 96.67% of the medical shops no such complaint has been seen. Through this survey it was noted that in 45% of the cases the medical shopkeeper sale any brand drug to the patient which are similar in composition and does not follow the brand mentioned in the prescription. 40% of the medical shops follow the prescription and sale accordingly and 15% casually said don't know.

CONCLUSION: Drugs are stored in the medical shop for the better healthcare of society. Therefore, these drugs should be maintained and stored carefully. From this survey it was found that most of the shopkeepers store drugs properly and read the prescription carefully before dispensing the drug to the patient. But sometimes they give the medicine without prescription and even change the brand by their wish. In most of the cases, they sell the drug at M.R.P. but in some cases they befool the patient and charge as their wish especially generic drugs from different manufacturer. Like Rajasthan, other states should also open generic

outlets so that patient from every sector of society can afford treatment for their deadly diseases. It is observed in this survey that education of the person working on the shop should be paid attention by government authorities. In many stores even high school and higher secondary passed persons are working and dispensing drugs without proper knowledge. Drug inspectors and other authorities should visit the shops regularly and they should be more responsible and accountable for this important part of healthcare system of common people.

LIMITATIONS: The success of every work is limited by some factors; this work has also some limitation although all the precautions and care have been taken. The limitations are:-

- The study has its own limitations because of limited time assigned for completing the project.
- Research was conducted on questionnaire which was of limited questions and therefore, detailed information was not available.
- There may be errors on interview basis.
- The authenticity of data may not be hundred percent as the respondents may have given wrong information to project a good image of themselves.

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