A Detailed Study on Drug Laws And Lawful Compulsions for Pharmacist in Pharmaceutical Profession

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Abstract

Before 1984, a person who was able to read a prescription and assist the Physician in compounding was considered a pharmacy professional eligible to run a medical store.lt was only after 1 September 1984 that the term Registered Pharmacists came into existence. A good authoritarian Affairs skilled will have a 'right first time' approach and will play a very imperative part in coordinating scientific effort with regulatory demands throughout the life of the product, helping to maximise the cost-effective use of the company's resources. A pharmacist should always abstain from doing all such acts and activities which are not in consonance with the demureness and propriety of pharmaceutical profession. A pharmacist busy in profession has to be a liberal citizen capable with a fair knowledge of the land and he should strive to countenance and defend them. He should be mainly aware with the enactments pertaining to food, drug, pharmacy, health, hygiene and the like and try to abide by them in every phase of his life.

Keywords: *Prescription Physician, Registered Pharmacists.*

Introduction

Authoritarian Affair highlights the various lawful compulsions that are necessary for pharmacists with regard to the variety of drugs, management of prescriptions, providing, keeping records, and operating in this framework by implementing Good Pharmacy Practice (GPP).

The Drugs and Cosmetic Act, 1940(D & C Act), was enacted to regulate the import, produce, deal and allotment of drugs and cosmetics. The Act includes laws governing the setting up and operation of a pharmacy. The Act intends to avoid production and distribution of unacceptable drugs, Control the manufacture, deal and allocation of drugs and ensure standard and excellence drugs, check the licenses of premises from which medicines are sold/ distributed, Bring cosmetics in its purview, to regulate their import, manufacture, distribution and sale.

The Drugs Prices Control Order, 1995(DPCO,1995), is an order that lays down set of laws with respect to the fixation of prices of mass of drugs and formulations. The order covers details like obsession of maximum sales prices of mass of drugs, Calculation of trade price of formulations, Fixation of trade price and ceiling price of scheduled formulations, Maintenance of records, Penalties for contravention of provision of the Order.

The Consumer Protection Act, 1986(CPAct, 1986) is one of the most progressive and complete pieces of legislation enacted for the safety of consumers. The objective of these user Protection Councils will be to support and protect the rights of the customers.

The Infant Milk Substitutes, Feeding Bottles And Infant Foods Act, 1992 provides for the instruction of manufacture, provide and delivery of baby milk substitutes, feeding bottles and infant foods with a view to protect and promote breastfeeding and ensure the proper use of infant foods. Under this Act, "Health care system" means an organization engaged, either directly or indirectly, in health care for mothers, baby or pregnant women, and includes health workers in personal practice, in a pharmacy, in a medicine store and any company of health workers. According to this Act, no pharmacy should Advertise, or take part in the publication of any hoarding, for the supply, sale or supply of baby milk substitutes, infant foods or feeding bottles.

Prescription medicines and importance of adherence to laws

A) Schedules or categories of drugs

The Drugs and Cosmetics Act, 1940 (D & C Act) and Rules there under classifies medicines into different schedules or categories. Schedules are lists of drugs according to their condition of sale in the pharmacy

a) Narcotic Drugs and Psychotropic Substances (NDPS)

A pharmacy may obtain agreement to store medicines under the categories of manufactured medicines and can stock psychotropic.

Manufactured drugs contain a list of medicines which:-

- Can be sold only against the recommendation of a Registered Medical Practitioner (RMP).
- Under no conditions, should these medicines be dispensed without a prescription.
- Have the symbol NRx conspicuously displayed on the left top corner of the label
- Have to be stored under lock and key and the key must be kept with the Chief Pharmacist or pharmacist in charge.

Narcotics and other specified drugs that may be abused are governed by special legislation and regulations.

The following security measures are suggested in the pharmacy:-

- A safe or reinforced, double locked cabinet fitted with a light (preferably with a red bulb) that comes on when the door is opened.
- A special register recording details of each receipt or issue with 2 signatures, physical counting of medicines after each entry, and signatures at "handover/ takeover".

b) Schedule X drugs:

This list of medicines needs caution while dispensing, and the pharmacist should ensure that these medicines are not sold without a prescription.

c) Schedule C and C (1)

Schedule C-The drugs under this schedule include biological and special products. A appropriate bill of sale has to be made against their sale.

Schedule C (1)-The drugs under this schedule include other special products. Those medicines from this schedule listed in Schedule H are to be sold against the prescription of a R.M.P., and against a proper bill of sale.

d) Schedule G

- Medicines listed drugs carry on the tag a caution:
- 'Caution: It is unsafe to take this preparation apart from under medical supervision.'
- These can be sold without the recommendation of a doctor/ R.M.P.

e) Schedule J

Schedule J specifies the diseases and ailments, which a medicines may not purport to stop to cure. Schedule J include medicines related to AIDS, Angina Pectoris, Fairness of skin, progress in height of children/ adults, Premature ageing, Sexual impotence

B) OTC Medicines

OTC drugs are drugs that can be sold without the recommendation of a Registered Medical Practitioner. These can be recommended by a pharmacist or requested/purchased by a client independently.

C) Veterinary Medicines

The drugs for treatment of animals are to be labelled with the words "Not for human use and shall be stored in a drawer, separated from the remainder of the location to which clients are not allowed to access.

D) Brand Substitution and Bioequivalence

If a physician prescribes a particular brand of a drug, and the pharmacy substitutes (dispenses) it with another brand of the same drug, it is called brand substitution.

E) The Department of AYUSH, formerly known as the department of ISM and H (Indian System of Medicines and Homoeopathy), under the Ministry of Health & Family Welfare (MoH&FW). "Ayurvedic, Siddha or Unani drug" includes all medicines intended for internal or external use for or in the diagnosis.

Product recalls

Products found to be defective should be quickly withdrawn from the market. The level of recall is

determined by both the degree of risk and the extent of distribution of the product and in India is mainly directed at the distribution chain. On receiving the details of the defective, substandard, spurious batch/batches of a medicine to be recalled from the manufacturer, or the stockiest, or the FDA, the pharmacy should immediately check if the particular batch is in stock, and if so, suspend its sale immediately. Similarly, if the regulatory authority in the country bans a particular medicine or FDC, the Pharmacy should immediately check and remove all the different brands of that particular medicine under consideration. The details of medicines and their batches to be recalled should be available in the quarantine area where stocks are received and checked.

The pharmacy should develop SOPs for recall of medicines

- The progress of the recall procedure in the pharmacy should be monitored every few days to ensure complete compliance.
- All stocks of the recalled products should be stored separately from the saleable stock. These can be stored in the expiry cupboard, segregated from the expired goods and be appropriately labeled "Recalled Goods- Not for Sale".
- The supplier should be notified, and asked to replace defective products.
- All the details of the procedures followed should be duly recorded in a Recall Register maintained specially for the purpose.

Appropriate SOPs should be framed and followed for their acceptance/refusal, and disposal.

- For unused medicines returned by clients, the pharmacy personnel should verify that these were purchased from their pharmacy. They should then be checked for integrity of the packing, the dosage form, and the expiry date and verified with the client whether they were stored in appropriate conditions. This again is at the discretion of each pharmacy.
- Expired medicines should be accepted from clients at the discretion of the pharmacist and be immediately shifted to the expired goods cupboard. These can be stored, segregated from the pharmacy's own expired goods, and be appropriately labeled "Expired Goods returned by clients- Not For Sale".
- It is advisable not to accept returned medicines requiring cold chain storage (refrigeration) because it cannot be ensured that the cold chain was maintained when the medicines were in the hands of the patient/client.
- A 'Returned Goods' register needs to be maintained to record all details of returned medicines.

Objectives

1) To study the importance of adherence to laws.
2) To study the instruction of production, supply and delivery of medicines.

Hypothesis

H0: Good Pharmacy Practices does not play an important role in Retail Medical Stores Management

Data Analysis

To test the hypothesis "Good Pharmacy Practices does not play an important role in Retail Medical Stores Management" one-way ANOVA test is applied taking overall importance of good pharmacy practices as fixed factor and factors representing good pharmacy practices as dependent factors.

Descriptive					
		N	Mean	Std. Deviation	Std. Error
How Important role does the SOP booklet play to carry out day to day business transaction?	Somewhat Important	61	4.0984	0.81045	0.10377
	Neither Important nor Unimportant	39	3.7436	0.81815	0.13101
	Total	100	3.96	0.8278	0.08278
How Important is to have a separate Quarantine area in order to avoid intermixing of newly arrived stock with the existing stock	Somewhat Important	61	3.8852	0.75495	0.09666
	Neither Important nor Unimportant	39	3.8462	0.81235	0.13008
	Total	100	3.87	0.77401	0.0774
How Important is to have a separate Blood pressure, blood sugar tests, weight & height check area?	Somewhat Important	61	2.7541	1.53466	0.19649
	Neither Important nor Unimportant	39	3.1282	1.37992	0.22096
	Total	100	2.9	1.48051	0.14805
How important is to conduct Drug Utilization Study in your area?	Somewhat Important	61	2.3279	1.10637	0.14166
	Neither Important nor Unimportant	39	2.6923	1.05516	0.16896
	Total	100	2.47	1.09595	0.1096

The above table shows that in majority of the cases the total mean value of the factors representing good pharmacy practices is less than 3.5, which states that the majority of the respondents consider these factors as important factor and according to them these factors does not have major impact on effective management of store as well as it does not have impact on increasing the turnover of the store.

Recommendations

1) Providing a separate patient counseling area allows activities related to patient care.
2) The pharmacist also plays a major role in the education of health care providers to the public.
3) Non-pharmacological measures can serve as an alternative to OTC medicines, or make medicines work better.
4) The processing of the prescription should be taken to avoid dispensing errors.
5) A good dispensing environment should be maintained in the pharmacy so as to ensure accurate and efficient dispensing.
6) Stocks received by the pharmacy should be quarantined in a separate area and necessary checks should be performed to ascertain the quality and quantity of stocks received.

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