Original Article

Drug labeling: The study of compliance of regulatory requirements for prescription drugs in India

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Abstract

Objectives: The objective was to check the compliance of regulatory requirements of drug labeling in India according to guidelines given under the Drug and Cosmetic Rules (D & CRs) 1945, Section 96, 97; drug samples were collected from government drug supply and private practitioners (PPs).

Materials and Methods: A total of 100 drugs were selected randomly from schedule H. They were divided into two groups, each containing 50 drugs: (1) drug samples from drug store of a government hospital, manufactured for Gujarat government and (2) drug samples from PPs which are given to them by pharmaceutical companies. Each drug label was checked according to the criteria given under the D & CRs 1945, Section 96, 97. Data entry was done in Microsoft Excel 2013 and analysis was done.

Results: Major deficiencies were seen in criteria of pharmacopeia (absent in 8% samples from government supply [GS] and 64% in samples from PPs), schedule (absent in 18% GS samples and 32% in PP samples), warning of schedule (absent in 6% GS samples and 4% in PP samples), Rx (absent in 22% GS samples and 28% in PP samples), red line (absent in 14% GS samples), and drug warning (absent in 84% GS samples and 72% in PP samples).

Conclusion: As the study results show lacunae in the contents of the labeling of prescribed drugs in samples from both the groups, there should be strict enforcement of D & CR 1945 and monitoring of drug labels for better and safer use of medicines.

Keywords: Compliance, Drug and Cosmetic Rules 1945, drug labeling, regulatory requirements

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INTRODUCTION

Labeling, in general, is defined as written, printed or graphical matter on any article or container which provides adequate and necessary information about the product. The primary purpose of labeling of medicines is the clear unambiguous identification of the medicine and the conditions for its safe use.[1] It is also an informative tool for stakeholders such as health-care professionals, patients and pharmacists. A drug label is required for marketing of any drug and it is a useful tool for pharmacoeconomic studies.[2]

The safe use of all medicines depends on accurate information on the label and users reading the label carefully and being able to assimilate and act on the information presented. A compliant label can minimize

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the risk of prescribing and dispensing medication errors, enhance consumer safety, avoid consumer confusion and the inappropriate use of medicines (including misuse, overuse and underuse), assist in the safe and effective use of medicines and optimize identification and usability of necessary information.[3]

A regulatory compliant drug label is mandatory for marketing of a drug, which should be in accordance with requirements given by regulators in respective country. Regulatory body of every country has a set of requirements for labeling of drugs. The criteria for drug labeling in India are listed in Drug and Cosmetic Rules (D and CRs) 1945 under Sections 96 and 97.[4] Keeping those requirements under consideration, labels are designed by the manufacturers.

Hence, in this study, compliance of requirements of labeling of prescription drugs is checked in accordance with the laws given by the Government of India in drug samples collected from the government hospital supply as well as drug samples from the private practitioners (PPs) (which are provided to them by pharmaceutical companies).

MATERIALS AND METHODS

A total of 100 drug samples were selected randomly for the study from the drugs listed in schedule H. They were divided into two groups, each containing 50 drugs [Figure 1].

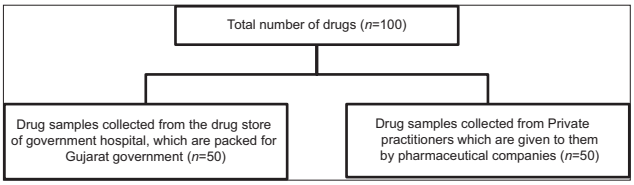

Figure 1: Drugs sample distribution for the study in 2 groups-government drug store and samples from private practitioners

There are 16 criteria which are essential to make a drug label compliant in India (as mentioned below) mentioned under the D & CRs 1945, Sections 96 and 97.[4]

1. Generic name
2. Brand name
3. Pharmacopeia
4. Schedule
5. Warning of schedule
6. Net contents
7. Active ingredients
8. Manufacturer name and address
9. Batch number
10. Manufacturing license number
11. Date of manufacturing
12. Date of expiry
13. Presence of R_x symbol
14. Red line
15. Warning about drug
16. Storage instructions.

Each drug label was checked for each criterion, data entry was done in Microsoft Excel 2013, and the percentage for each criterion was calculated using Excel.

Red line represents drugs included in schedules G, H, H1, and X, narcotic analgesic, sedative-hypnotics, tranquilizers, corticosteroids, hormones, hypoglycemic, antimicrobial, antiepileptic, anticancer, and anticoagulant drugs.[4]

RESULTS

Table 1 shows drug-labeling criteria: their compliance in the samples from government supply (GS) and PPs.

Table 1: Drug-labeling criteria: Their compliance in the samples from government supply as well as private practitioners

n	Criteria	Drug samples from government supply (*n*=50), *n* (%)	Drug samples from private practitioners (*n*=50), *n* (%)
1	Generic name	50 (100)	49 (98)
2	Brand name	17 (34)	48 (96)
3	Net contents	50 (100)	48 (96)
4	Pharmacopeia/formulary	46 (92)	18 (36)
5	Schedule	41 (82)	34 (68)
6	Warning of schedule	47 (94)	48 (96)
7	Name and address of manufacturer	50 (100)	50 (100)
8	Date of manufacturing	50 (100)	50 (100)
9	Date of expiry	50 (100)	50 (100)
10	Active ingredients	50 (100)	50 (100)
11	Batch number	50 (100)	50 (100)
12	Manufacturing license number	50 (100)	50 (100)
13	Rx symbol	39 (78)	36 (72)
14	Red line	43 (86)	50 (100)
15	Warning about drug	8 (16)	14 (28)
16	Storage	50 (100)	50 (100)

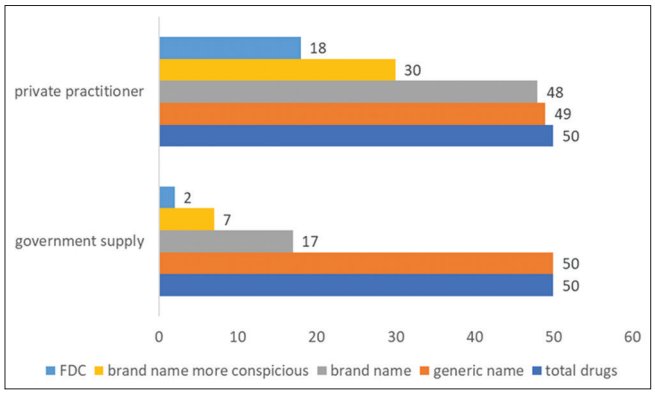

Figure 2: Comparison of drug-labeling criteria in samples from government supply and private practitioners

Brand name was written in 17 of 50 drugs (34%) from GS from which 7 (14%) were written more conspicuously than generic name. In drugs from PPs, brand name was written in 48 of 50 drugs (96%) from which 30 (60%) were written more conspicuously than generic name. On each sample from GS, "Gujarat Government Supply not for sale" was written in English and Gujarati, and on each sample collected from PP, "Physician's sample not to be sold" was written. The total number of fixed-dose combinations (FDCs) was 2/50 in GS and 18/50 in samples from PPs.

Figure 2 shows the comparison of drug-labeling criteria in samples from GS and PPs.

DISCUSSION

Drug label consists of essential components which carry significant importance. Generic name and brand name are required for the identification of the drugs. Schedule and its warning are for drugs belonging to specific schedule and the precautions required for its use. Pharmacopeia, net contents, active ingredients, manufacturer's name and address, batch number, manufacturing license number, date of manufacturing and expiry and storage information are required not only for regulatory requirements but also for the quality control and safety of the prescribed drug.

According to the criteria given in D and CRs 1945, brand name should not be written more conspicuously than generic name.[4] In this study, 14% of samples from GS and 60% from PPs have a brand name written more conspicuously which is not recommended. It is recommended that the drug label should mention pharmacopeia, which gives a standard reference for manufacturing of any drug, which was deficient from the drug samples from PPs compared to GS. The deficit is also observed in criteria of schedule and its warning, which carries more importance for medicines categorized under schedules H, H1 and X. The study sample also has lacunae in the criteria of "warning of drug use" which is an area of concern with regard to safe drug use.

The criteria for drug labeling described in Drugs and Cosmetic Rules 1945 for India are in accordance with the basic criteria for labeling recommended by the WHO.[5] When we compare Indian guidelines to the USFDA guidelines for drug labeling, the points such as initial USFDA approval, recent major changes, adverse reactions (proven as well as new and the contact details of the manufacturer for its notification), drug interactions, use in specific population, and date of last revision of the label are additional which can be added to the Indian label for more complete and updated information which can lead to effective and safe use of the medicines.[6]

In India, if the drugs do not comply with regulatory requirements of labeling, they are considered as "misbranded" drugs (defined under Section 17 – the Drugs and Cosmetics Act 1940 and rules 1945),[4] and there is a provision of prohibition of manufacture and sale of misbranded drugs under Section 18[4] of D and CRs 1945. The monitoring of the drug label falls under the duties of the drug inspector along with notification to the government if the label does not comply with regulatory requirements (Section 22).[7] Any person interfering with drug inspector on his duty is punishable for imprisonment up to 3 years or fine or both (Section 22 (3)). There is also provision of "confiscation" meaning seizing someone's property with authority, for the production or distribution of misbranded drugs under Section 31.

In Australia, violation of the standards of drug labeling is grounds for the secretary to suspend or cancel the registration of the drug along with public notification and recovery of the medicine from the market.[3] In the USA, the Federal Food, Drug, and Cosmetic Act (FDCA) prescribes criminal penalties for misbranded drugs. The potential consequences of an FDCA violation range from a warning to a hefty fine and/or imprisonment, carrying a maximum sentence of 1 year in federal prison and/or a $1,000 fine (21 U. S. C. § 333 (a)) which may extend up to 3 years in prison and/or a maximum $10,000 fine depending on severity.[8]

The review process of a drug label is not specifically defined in India which leads to lacunae in the final label that is out for public use. This study is just the tip of iceberg, as only a few drug samples are collected from the ample of marketed drugs; still, the results show many

deficiencies in labeling of prescribed medicines which is a real area of concern. Looking at the current scenario, strict enforcement of the act and its monitoring is needed. More vigilant inspections and monitoring of drug stores by the drug inspectors are required.

CONCLUSION

A label is evidence of accuracy of scientific content related to the drug. The results of the study show lacunae in the labeling manner of drugs in both the groups – samples from GS and samples from PPs. A label of the prescribed drug must follow the criteria given in the D and CA, and the manufacturer can also add maximum useful information on it. There should be strict enforcement of laws related to labeling content and format of prescribed drugs for better and safer use of medicines.

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Conflicts of interest

There are no conflicts of interest.

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