ejpmr, 2017,4(06), 619-622

SJIF Impact Factor 4.161

EUROPEAN JOURNAL OF PHARMACEUTICAL AND MEDICAL RESEARCH

www.ejpmr.com

Research Article

ISSN 2394-3211

EJPMR

ASSESSMENT OF COMPLIANCE OF DRUG LABELS IN INDIA WITH 'THE DRUGS AND COSMETIC ACT AND RULES' GUIDELINES

Ashok Kumar Sharma and Amol Khanapure*

Department of Pharmacology, Armed Forces Medical College, Pune, Maharashtra, India.

***Corresponding Author: Dr. Amol Khanapure**

Department of Pharmacology, Armed Forces Medical College, Pune, Maharashtra, India.

Article Received on 15/04/2017 **Article Revised on 04/05/2017** **Article Accepted on 25/05/2017**

ABSTRACT

Background: Information mentioned on innermost container of a drug is most important for the dispenser as well as consumer. The Drugs and Cosmetic Act and Rules mention guidelines for labelling of innermost container of drugs but it has been observed that the compliance to these is often low. Since there are only few studies available to assess the compliance with these guidelines, the present study was planned. **Materials and Methods:** A total of 100 dosage forms from various categories were randomly collected from drug selling / dispensing units or physicians and included in the study for assessment of compliance of their labels with the guidelines mentioned in 'The Drugs and Cosmetic Act and Rules'. **Results:** Proper name was more conspicuous than trade name in 14.82% non-generic preparations; while trade name was under and after proper name in 96.3% in these preparations. Pharmacopoeia name was present in 88% preparations; while correct statement of net contents was mentioned in 69% preparations. Red vertical line was observed in 97.40% preparations. Preparations containing Schedule G drug had compliance for 'Caution' as 100%. Preparations containing Schedule H drug had compliance for symbol 'Rx' as 77.65% and for warning as 98.82%. Preparations containing Schedule H1 drug had compliance for 'Rx' in red and warning in red box as 100%. Other particulars with 100% compliance were content of active ingredients, name and address of the manufacturer, batch number, manufacturing licence number, date of manufacture and expiry, 'Physician's sample- Not to be sold' on preparations which were Physician's sample and 'FOR EXTERNAL USE ONLY' on preparations meant for external application. **Conclusion:** From the above findings, it may be concluded that majority of drug labels were not compliant with the guidelines given by The Drugs and Cosmetic Act and Rules. Strict adherence is necessary to ensure safe, effective and rational use of medicines.

KEYWORDS: Drug labels, The Drugs and Cosmetic Act and Rules, Compliance.

INTRODUCTION

Information mentioned on the drug packages serves as important guideline for its storage, dispensing and consumption. The information mentioned on innermost container of a drug is most important for the dispenser as well as consumer. The Drugs and Cosmetic Act and Rules (as amended up to 31 December, 2016)[1] mention guidelines for labelling of innermost container of drugs. These guidelines are mandatory for all pharmaceutical companies which market their drugs in India. Since it has been observed that the information in drug labels on innermost container is often incomplete and there are not many studies available to assess the compliance of these drug labels to the guidelines mentioned in 'The Drugs and Cosmetic Act and Rules', the present study was planned to assess the compliance of drug labels of pharmaceutical preparations dispensed in India using these guidelines.

METHODOLOGY

A total of 100 pharmaceutical preparations belonging to various dosage form categories, dispensed in India with manufacturing date as 1st January 2017 or later, were randomly collected from drug selling / dispensing units or physicians and included in the study for assessment of compliance of their labels with the following particulars mentioned in 'The Drugs and Cosmetic Act and Rules' (As amended up to 31st December, 2016):

1. Proper name of the drug in more conspicuous manner than trade name
2. Trade name immediately after or under the proper name
3. Recognized abbreviations of the respective official pharmacopoeias and official compendia of drug standards
4. Correct statement of net contents in terms of weight, measure, volume (in metric system) / number of units of contents and number of units of activity
5. Content of active ingredients (excluding those pharmacopoeial preparations where the composition of such preparation is specified in the respective pharmacopoeia and to a preparation included in the National formulary of India):

a. For oral liquids: If a single dose is more than 5 ml - content in terms of minimum single dose, and if the dose is below 5 ml - content in terms of 1 ml (or fraction thereof); otherwise content per single dose being indicated in 5 ml
b. For parenteral liquids: Content in terms of 1 ml or percentage by volume or per dose in case of single dose container
c. For drugs in solid form intended for parenteral administration: Units or weight per milligram or gram
d. For tablets, capsules, pills and like: Content in each tablet, capsule, pill or other unit as the case may be
e. For other preparations: Content in terms of percentage by weight or volume or in terms of unitage per gram or millilitre as the case may be

6. Name of the manufacturer and the address of the premises of the manufacturer where the drug has been manufactured (for drugs contained in an ampoule or a similar small container, it is enough if only the name of the manufacturer and his principal place of manufacture is shown)
7. Distinctive batch number preceded by the words 'Batch No.' or 'B. No.' or 'Batch' or 'Lot No.' or 'Lot'.
8. Manufacturing licence number preceded by the words "Manufacturing Licence Number" or "Mfg. Lic. No." or "M.L."
9. Date of manufacture and date of expiry of potency (under the conditions of storage specified therein)
10. 'Physicians sample- Not to be sold' for every drug intended for distribution to the medical profession as a free
11. Quantity of alcohol in terms of the average percentage by volume of absolute alcohol in the finished products if any preparation contains not less than 3 per cent by volume of alcohol
12. Red vertical line of not less 1mm width, on the left side running throughout the body of the label, without disturbing the other conditions printed on the label for narcotic analgesics, hypnotics, sedatives, tranquilizers, corticosteroids, hormones, hypoglycemics, antimicrobials, antiepileptics, anticancer drugs and all other drugs falling under Schedules G, H & X except preparations intended for animal treatment, intended for external use, ophthalmic preparations and ear drops, sterile preparations such as sutures, dressings and preparations intended for parenteral use
13. License number under which the drug is imported, preceded by the words- "Import License" and the name and address of the importer for drugs and their preparations including combinations with other drugs imported into the country
14. Following instructions / caution on medicines for internal use-

a. 'Caution: It is dangerous to take this preparation except under medical supervision' conspicuously printed and surrounded by a line within which there shall be no other words if it contains a substance specified in Schedule G

b. Symbol 'Rx' conspicuously on the left top corner of the label and also the following words: 'Schedule H drug- Warning: To be sold by retail on the prescription of a Registered Medical Practitioner only' if it contains a substance specified in Schedule H

c. Symbol 'NRx' conspicuously in red on the left top corner of the label, and also the following words: 'Schedule H drug -*Warning:* To be sold by retail on the prescription of a Registered Medical Practitioner only' if it contains a substance specified in Schedule H, and comes within the purview of the [Narcotic Drugs and Psychotropic Substances Act, 1985 (61 of 1985)]

d. Symbol 'XRx' conspicuously in red on the left top corner of the label and also the following words: 'Schedule X drug -*Warning:* To be sold by retail on the prescription of a Registered Medical Practitioner only' if it contains a substance specified in Schedule X

e. Symbol 'Rx' conspicuously in red on the left top corner of the label, and also the following words in a box with a red border: 'SCHEDULE H1 DRUG – WARNING.
- It is dangerous to take this preparation except in accordance with the medical advice.
- Not to be sold by retail without the prescription of a Registered Medical Practitioner' if it contains a drug substance specified in Schedule H1

15. 'FOR EXTERNAL USE ONLY' on the container of an embrocation, liniment, lotion, [ointment, antiseptic cream,] liquid antiseptic or other liquid medicine for external application
16. 'Not for human use; for animal treatment only' and a symbol depicting the head of a domestic animal if the medicine only for treatment of an animal
17. 'For External Use only' and preparation contains industrial methylated spirit if latter is present in medicine

RESULTS

Among 100 preparations included in the study, 65 were tablets/capsules/pills, 12 were oral liquids, 6 were parenteral liquids, 3 were solid forms intended for parenteral administration and 14 were preparations for external application.

There were 19 generic preparations and 31 physician's samples in the studied lot of preparations.

Proper (generic) name was more conspicuous than trade name in only 12 preparations out of 81 non-generic preparations (14.82%), however, 78 preparations

(96.3%) of these non-generic preparations had mentioned trade name after or under the proper name. The 3 preparations which didn't mention trade name at the desired place were among those 69 preparations which have mentioned trade name more conspicuously than proper name.

Name of the official pharmacopoeia (i.e. the abbreviations like IP/BP/USP) was present in 88 out of 100 preparations.

Correct statement of net content was mentioned in 69 out of 100 preparations while content of the active ingredients was mentioned correctly in all the 100 included preparations.

Name and address of the manufacturer, batch number, manufacturing licence number, date of manufacture and expiry were mentioned correctly in all the 100 preparations.

All 31 physician's samples (100%) had "Physician's sample- Not to be sold" overprinted.

No study preparation contained more than or equal to 3 percent by volume of alcohol.

Red vertical line was observed in 75 preparations (97.40%) out of 77 preparations expected to have it. Twenty three preparations exempted from red line were preparations for external use, ophthalmic preparations, ear drops, and preparations intended for parenteral use.

Out of 100 studied preparations, 6 contained substance specified in Schedule G, 85 contained substance specified in Schedule H and 9 contained substance specified in Schedule H1. All 6 preparations containing schedule G drug (100%) had mention of 'Caution' in their label. Out of 85 preparations containing Schedule H drug, the symbol 'Rx' was present in 66 preparations (77.65%) while warning was there in 84 preparations (98.82%). All 9 preparations containing schedule H1 drug (100%) had Rx in red and warning in red box. In 97 out of 100 preparations, warning/caution was written in a box.

A total 14 preparations out of 100 included were for external application. All 14 (100%) had 'FOR EXTERNAL USE ONLY' in label.

There was no preparation, which was for animal use, imported or which contained industrial methylated spirit in the studied lot.

DISCUSSION

In this study, proper name was more conspicuous than trade name in only 14.82% preparations, though 96.3% preparations mentioned trade names after or under proper names. It is mandatory by guidelines that the proper name of the drug is to be printed or written in a more conspicuous manner than the trade name, if any and the latter is to be shown immediately after or under the proper name. Pharmaceutical companies tend to promote their medicines by trade name rather than by proper name so as to increase the sale of their product. Practitioners have a tendency to prescribe one particular brand of medicine probably because of their past experience and trust in the quality; similarly patients too stick to one particular brand due to repeated prescribing and their satisfactory past experience with that product. However, the space on drug labels is often limited; even then pharmaceutical companies often use quite a good space for trade name and the space for other information like warnings, etc. is left out less and such information often go inconspicuously.

Recognized abbreviations of the respective official pharmacopoeias and official compendia of drug standards were mentioned in 88% preparations. The role of a pharmacopoeia is to furnish quality specifications for drug substances and general requirements for dosage forms.[2] These specifications and requirements are necessary for the proper functioning or regulatory control of drugs and form a base for establishing quality requirements for individual pharmaceutical preparations in their final form.

Correct statement of net content was mentioned in 69% preparations. There are many preparations with same ingredients but in different amounts hence will have different dosing schedule. If the information on net content (weight, measure, volume, number of units of contents or activity) is missing, then it may result in incorrect use of medicines by patients i.e. underdosing / overdosing which may result in increased risk of failure to respond and adverse effects.

Caution was mentioned in all 6 preparations (100%) included in the study which contained schedule G drug. Symbol 'Rx' in 77.65% and warning in 98.82% was observed in studied preparations which contained Schedule H drug. All 9 preparations (100%) included in the study which contained Schedule H1 drug had 'Rx' in red and warning in red box. Warning/caution was written in a box in 97 preparations out of 100. Red vertical line was observed in 75 preparations (97.40%) out of 77 preparations expected to have it. The significance of writing symbol "Rx / NRx / XRx" and Warning in Schedule H, H1 and X is that these preparations should be sold by retail on the prescription of a registered medical practitioner only. If the symbol or warning is missing in any label then pharmacist may treat the preparation as over the counter (OTC) product and patients may be exposed to the undue risk due to adverse effects of these medicines. If the warning is not written in the box, the chance of its being overlooked by pharmacist and patient is high.

All the 14 preparations (100%) meant for external application had mention of 'FOR EXTERNAL USE

ONLY' in label i.e. enough care has been taken to avoid use of these preparations by wrong route.

Findings of our study are in line with previous published study by Bhalerao S et al[3] who studied 190 Ayurvedic drug labels using Drugs and Cosmetics Act, 1940 guidelines and demonstrated that, Ayurvedic drug container labels were not compliant with most of the requirements specified in the Act.

From the above findings, it has been concluded that, the majority of the labels on the drug preparations marketed in India, did not fully comply with The Drugs and Cosmetic Act and Rules guidelines. Strict adherence is necessary to ensure safe, effective and rational use of medicines. Committees at national / state level(s) should be formed to audit the adherence to guidelines periodically. Stringent measures like imposing of penalty for non-compliance should be in place.

Apart from this, it is also suggested that mentioning of following information may also be made mandatory component of the label : (a) Route of administration (as consumption of pessaries & suppositories by oral route is not uncommon) (b) Special directions like 'Not to be chewed or crushed' / 'To be chewed before swallowing' / 'Not to be swallowed' / 'To be kept below tongue' / 'Should be taken with food or empty stomach' (c) Storage directions with most suitable temperature range (d) Treatment of overdose.

REFERENCES

1. The Drugs and Cosmetics Act and Rules. Cosmetics, 2005; 1940: 1–635.
2. Wieniawski W. Role and functions of the International Pharmacopoeia. Ann Ist Super Sanita. Italy., 1975; 11(3–4): 204–10.
3. Bhalerao S, Munshi R, Tilve P, Kumbhar D. A survey of the labeling information provided for ayurvedic drugs marketed in India. Int J Ayurveda Res., 2010; 1(4): 220–2.