Original Research Article

Journal of College of Medical Sciences-Nepal, Vol-20, No.2, Apr-Jun 2024
ISSN: 2091-0657 (Print); 2091-0673 (Online) Open Access
DOI: 10.3126/jcmsn.v20i2.59866

Status of Primary Labeling of Medicines Manufactured by Nepalese Pharmaceutical Industries

Binaya Shrestha,[1] Anjan Palikhey,[2] Kamal Kandel[2]

[1]Department of Pharmacology, Kathmandu Medical College, Kathmandu, Nepal, [2]Department of Pharmacology, Universal College of Medical Sciences, Bhairahawa, Nepal.

ABSTRACT

Background

Proper medication labeling is essential to meet regulatory requirements and guarantee the safety of patients using the medication. This study aimed to observe the status of primary labeling of medicines manufactured and marketed by Nepalese pharmaceutical industries.

Methods

A prospective study was conducted between June 2022 to October 2022 in Kathmandu Medical College. Total of 372 primary labeling of medicines manufactured by Nepalese pharmaceutical companies were assessed as required by Drug Standard Regulation, 2043 (1986 AD) of Nepal.

Results

This study assessed the primary labeling of 372 medications produced by 46 pharmaceutical companies in Nepal. Most of the primary labeling had stated manufacturing company's name, address, and country, the production serial number for the drug, and recommended storage methods. But only 22(5.9%) of them specified the sub-category and appropriate drug classification was found on 352(94.6%) primary label.

Conclusions

The current study revealed that the status of the primary labeling is satisfactory as majority of the label contained the essential criteria required by Drug Standard Regulation, 2043 (1986 AD) of Nepal.

Keywords: drug packing; medical labeling; pharmaceutical industries.

INTRODUCTION

The labeling of medicine is a legal requirement designed to provide patients with crucial information,[1] including brand names, medication type, strength, quantity, recommended use, instructions, indications, contraindications, and potential side effects, all vital for patient safety.[2] Ensuring accurate medication labeling is of utmost importance for patient well-being. However, in Nepal, there are identified deficiencies in recognizing and reporting these requirements. Therefore, it is crucial for the Department of Drug Administration (DDA), the national regulatory authority for medicines, to enhance its oversight.[3-5] In Nepal, allopathic drugs are categorized into three categories, as category Ka(a), Kha(b) and Ga(c).[6] But there have been cases where different companies categorize the same generic medication differently, although limited data is available on this issue in existing literature.[7-8] Therefore, our research aims to observe the status of primary labeling of medications produced and marketed by Nepalese pharmaceutical companies

METHODS

A prospective study was conducted between June2022 to October2022 in Kathmandu Medical College. Ethical approval was taken from the Institutional Review Committee (Ref: 2905202209). Those medicines that were manufactured and marketed by Nepalese pharmaceutical companies available at pharmacy of Kathmandu medical college, a tertiary

Correspondence: Dr. Binaya Shrestha, Department of Pharmacology, Kathmandu Medical College, Kathmandu, Nepal. Email address: binaya110@yahoo.co.uk, Phone:+977-9841471602. **Article received:** 2023-09-09. **Article accepted:** 2024-06-30.

hospital located in Kathmandu, Nepal, was assessed. The sample size was calculated by using the formula $n= Z^2 p(1-p)/e^2$ where n=minimal sample size, Z=1.96, e= 0.05. Taking p (prevalence) as 40%, the sample size required for this study was 369. A total of 372 primary labeling of medicines manufactured by Nepalese pharmaceutical companies were included in the study. The status of primary labeling of medicines was assessed as required by Drug Standard Regulation, 2043 (1986 AD) of Nepal. The regulation states that the marketed medicines for human use should contain 16-points information in primary labeling that includes Drug name and quantity; Category and sub category of the drug; System of medicine; Name of active ingredient, quantity and the pharmacopoeia; Name of the drug production company, address and the country; Serial number for the establishment of drug industry; Serial number for the production of the drug; Batch number; Date of production; Date of expiry; Price; Storing methods (techniques) and management of the drug; Caution in Group "a" and "b" (may not be sold without the prescription of a registered medical practitioner); Quantity; Method of use; and additional information on External preparation (only for external use). A checklist was created to evaluate the fore-mentioned requirements of primary labeling of various types of dosage forms. Further analysis was done by entering the collected data in MS excel.

RESULTS

This study assessed the primary labeling of 372 medications produced by 46 pharmaceutical companies in Nepal. The various dosage forms evaluated are illustrated in (Figure 1).

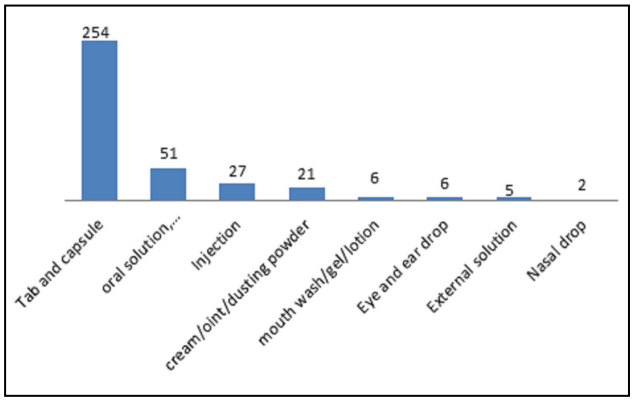

Figure 1.Various dosage forms that are evaluated.

Primary labeling of all the pharmaceutical products had mentioned the brand name and active ingredients. However drug quantity was present in 371(99.7%) and price has been mentioned in 366 (98.4%) (Table 1).

Table 1. Availability of general information in the primary labeling. (n=372)

Criteria to be displayed in primary label	Frequency (%)
Brand Name	372 (100)
Drug Quantity	371 (99.7)
Active ingredients	372 (100)
Price	366 (98.4)

The findings also indicated that 20 (5.4%) primary labels did not include pharmacopoeial information, while nearly all of the primary labeling provided details such as the drug manufacturing company's name, address, and country, the production serial number for the drug, and recommended storage methods (Table 2).

Table 2. Availability of pharmaceutical information in the primary labeling. (n=372)

Criteria to be displayed in primary label	Frequency (%)
Drug production company, address and country	372 (100)
Serial number for production	372 (100)
Batch number	370 (99.5)
Date of production	368 (98.9)
Date of expiry	366 (98.4)
Storage	372 (100)
Pharmacopoeia	352 (94.6)

Only 48 instances (12.9%) of the primary labels contained information regarding on direction of use and 5.6% had stated system of medicine. Moreover, it is worth noting that around one percent (1%) of the products were discovered to present deceptive information regarding caution. For instance, they falsely indicated that OTC drugs (Group "c") should not be sold without the prescription of a registered medical practitioner. None of the products mentioned serial number for establishment of pharmaceutical industry (Table 3).

Nearly all of the primary labels stated the drug's category, but only 22(5.9%) of them specified the sub-category. The appropriate drug classification was found on 352(94.6%) primary label (Table 4).

Table 3. Availability of information related to clinical use of the medicine in the primary labeling. (n=372)	
Criteria to be displayed in primary label	**Frequency (%)**
System of Medicine	21(5.6)
Quantity to be used	368 (98.9)
Caution in group a and b (not to be sold without the prescription of a register medical practitioner)	259 (69.6)
Misleading informations	3 (0.8)
External preparation (only for external use)(n=40)	39 (97.5)
Method of Use	48 (12.9)

Table 4. Assessment of information related to drug category in the primary labeling. (n=372)	
Criteria to be displayed in primary label	**Frequency (%)**
Category of drug	
Legible	371(99.7)
Illegible	1 (0.3)
Sub-category of drug	22 (5.9)
Appropriateness of drug category	
Appropriate	352(94.6)
Inappropriate	19(5.1)
Illegible	1(0.3)

DISCUSSION

The pharmaceutical industry in Nepal is on a continuous growth trajectory, boasting more than 15,000 registered products, over 300 registered manufacturing facilities, and over 16,000 pharmacy outlets. This expansion places a heightened demand on the regulatory authority (DDA) to enhance their oversight and streamline their operations.[9]As a result, there has been a recognized gap between regulatory provisions and actual practices, as highlighted in previous studies.[3-5] To address this issue, it is imperative to regularly assess the primary labeling of medications. Numerous studies have underscored the pivotal role of labeling and packaging in medication errors.[2, 10] consequently, ensuring proper labeling of marketed medicines is crucial for adhering to regulatory requirements and safeguarding patient medication safety.[11] In the present research, almost all of the primary labels included information such as the name of the pharmaceutical company, its address and country of origin, the production serial number for the medication, and recommended storage guidelines. This aligns with the findings of a study conducted in Sri Lanka by Jayasinghe et al., where all labels similarly featured the aforementioned criteria.[12] During this study we also noted that three primary labels (1%) contained cautions related to group 'C' medications, potentially leading to confusion. This finding is different to the study conducted in Chitwan district, Nepal where seven percent of the label contained cautions in group C medications.[1] The majority of the products observed in this study lacked usage instructions, which are crucial for preventing medication errors, particularly with modified-release products. For example, it is essential to include labels such as "swallow the tablet whole without breaking or crushing" for controlled-release tablets and "chew the tablets before swallowing" for chewable tablets to ensure that patients use them as intended. Drug Standard Regulation, 2043 (1986 AD) mentions that the label of the medicines should contain pharmacopoeial information which essentially reflects standard of the product was missing in some (6%) of the labels. Perhaps, this issue should be of serious concern for stakeholders because this is considered important for drug safety and is of special concern for consumers. In the current study majority of products had not mentioned sub-category of drugs on their labeling. Similarly, most of the products were found to lack information on system of medicine they belong to. Practice of categorizing drugs as Ka(a), Kha(b) or Ga(c) was observed in almost all the label. This finding is similar to the study conducted in Chitwan district, Nepal.[1] The study showed lack of essential criteria in some of the labeling. Studies in SriLanka[3]and Malaysia, [4] have also reported insufficient labeling of dispensed medicines as required by the regulatory authorities. This study represents the inaugural endeavor in Nepal to evaluate the situation of insufficient primary labeling and offers recommendations to stakeholders for its improvement.

CONCLUSIONS

The current study revealed that the status of the primary labeling is satisfactory as majority of the label contained the essential criteria required by Drug

Standard Regulation, 2043 (1986 AD) of Nepal. The current study also tried to emphasize regulatory body should be stricter in monitoring primary labeling of Nepalese pharmaceutical products.

Conflict of interest: None

Funding: None

REFERENCES

1. Poudel, R.S., Shrestha, S., Thapa, S. et al. Assessment of primary labeling of medicines manufactured by Nepalese pharmaceutical industries. J of Pharm Policy and Pract 11, 13 (2018). https://doi.org/10.1186/s40545-018-0139-9.
2. Guchelaar HJ, Kalmeijer MD, Jansen ME. Medication error due to ambiguous labeling of a commercial product. Pharm World Sci. 2004 Feb; 26(1):10-1. https://doi: 10.1023/b:phar.0000013517.84814.58. PMID: 15018253
3. Poudel A, Mohamed Ibrahim MI, Mishra P, Palaian S. Assessment of the availability and rationality of unregistered fixed dose drug combinations in Nepal: a multicenter cross-sectional study. Glob Health Res Policy. 2017 May 8; 2:14. https://doi: 10.1186/s41256-017-0033-z. PMID: 29202082; PMCID: PMC5683238.
4. Bhupendra Kumar Poudel, Itsuko Ishii, Balkrishna Khakurel, Assessment of regulatory compliance in selected pharmacy outlets of Nepal, Journal of Pharmaceutical Health Services Research, Volume 7, Issue 1, March 2016, Pages 31–36. https://doi.org/10.1111/jphs.121
5. Gyanwali P, Humagain BR, Aryal KK, Pandit A, Acharya T, Bista B, Dhimal M, Karki KB. Surveillance of Quality of Medicines Available in the Nepalese Market: A Study from Kathmandu Valley. J Nepal Health Res Counc. 2015 Sep-Dec;13(31):233-40. PMID: 27005718
6. Department of Drug Administration.Drugs Standard regulation, 2043(1986). http://dda.gov.np/content/drug-standard-regulation-standard-regulation-2043. Assessed 12 Oct 2022
7. Athuraliya, N., Walkom, E.J., Dharmaratne, S. et al. Assessing medication packaging and labelling appropriateness in Sri Lanka. J of Pharm Policy and Pract 9, 38 (2016). https://doi.org/10.1186/s40545-016-0091-5
8. Neoh CF, Hassali MA, Shafie AA, Awaisu A, Tambyappa J. Compliance towards dispensed medication labelling standards: a cross-sectional study in the state of Penang, Malaysia. Curr Drug Saf. 2009 Sep; 4(3):199-203. https://doi: 10.2174/157488609789006921. Epub 2009 Sep 1. PMID: 19534650.
9. World Health Organization, Regional Office for SouthEast Asia. Medicines in health care delivery Nepal: Situational analysis 2014. http://www.searo.who.int/entity/medicines/nepal2014.pdf. Assessed 10 Dec 2022.
10. Orser B. Reducing medication errors.CMAJ. 2000 Apr 18;162(8):1150-1.PMID: 10789632; PMCID: PMC1232368.
11. Hellier E, Edworthy J, Derbyshire N, Costello A. Considering the impact of medicine label design characteristics on patient safety. Ergonomics. 2006 Apr 15-May 15; 49(5-6):617-30. https://pubmed.ncbi.nlm.nih.gov/16717013/
12. Jayasinghe, M., Srilal, T.L.I., Prasadi, D.G.P. et al. Regulatory requirements and labeling of commercially available prescription (oral) medicines in Sri Lanka: there is room for improvement. J of Pharm Policy and Pract 15, 13 (2022). https://doi.org/10.1186/s40545-022-00409-z
13. Brass EP, Weintraub M. Label development and the label comprehension study for over-the-counter drugs. Clin Pharmacol Ther. 2003 Nov;74(5):406-12.https://doi: 10.1016/S0009-9236(03)00239-X. PMID: 14586381.

Citation: Shrestha B, Palikhey A, Kandel K. Status of Primary Labeling of Medicines Manufactured by Nepalese Pharmaceutical Industries. JCMS Nepal. 2024; 20(2): 158-61.