Research Paper

Analysis of Patient Benefit Information on the Labels of Non-Prescription Medicines in India

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Self-medication, a rampant reality in developing countries such as India, requires attention to ensure safe use of medicines by patients. It is not always possible to visit a health care provider and not always needed also. Self-medication with non-prescription medicines is a common and accepted practice all over the world. It is therefore essential that adequate information is present on the label of non-prescription medicines so that the consumers can take appropriate decisions to self-medicate rationally. In our study, we analyzed 300 labels of non-prescription allopathic medicines in India, and checked for the presence, organization and ease of location of various important information for the benefit of the patient to make a right choice to consume the medicine. We found that in most of the labels, the information was not presented in an organized, easy to find manner. Further, a lot of information related to warnings, indications, purpose, dosing information, as is mandatory on the labels of non-prescription medicines of various other countries was not present on the labels. The non-availability of the correct information that guides the consumer to use these medicines rationally and responsibly is in a way denial of right to health. It is important therefore that necessary regulations and guidelines be put in place in India to ensure that the labels of non-prescription medicines should contain the necessary important information which is easy to locate, in the best interest of the patient.

Key words: Self-medication, non-prescription medicines, patient information, medicine labels

The terms Over-The-Counter (OTC) or non-prescription medicines refer to medicines that a patient or consumer can buy without a prescription and are considered safe and effective when they follow the directions on the label and as directed by the health care professional[1]. Different countries categorize medicines which do not require a doctor's prescription differently and have their own defined nomenclature for various such categories and sub-categories within them and also the condition and places at which these medicines can be sold[1-6]. A few examples of this nomenclature are 'General Sales Medicines' and 'Pharmacy Only Medicines' in the United Kingdom (UK), Singapore and Australia, 'OTC Medicines' in United States of America (USA), 'Schedule II', 'Schedule III', 'Unscheduled drugs' in Canada, 'Restricted Medicines', 'Pharmacy-Only Medicines', 'General Sale Medicines' in New Zealand. Different countries allow various categories of medicines to be sold only in pharmacies, some of them at pharmacies but only under the pharmacist's advice, and some of them at supermarkets or health food stores or other retailers, where the presence or supervision of a Pharmacist is not required, the consumers have access to choose/select these medicines from the open racks or shelves[1-6].

Self-medication represents an increasingly important area within healthcare in which the patient assumes a greater degree of responsibility for the management of a minor ailment, using non-prescription medicines and it moves patients towards greater independence in making decisions about the management of minor illnesses, thereby promoting empowerment[7]. Self-care of minor health problems is facilitated by the availability of a wide range of OTC medicines[8]. OTC medicines enable the healthcare system to utilize its limited resources on the diagnosis and treatment of more serious diseases and medical conditions that necessitate the direct involvement of a physician, while at the same time providing safe, effective and

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accessible treatment for a range of conditions to consumers and their families[9].

Since it is the consumer or the patient who often makes the decision and chooses a particular non-prescription medicine, it is important that the consumer is aware of some basic information about these medicines. Provision of information about the medicine-written out on the labels and reinforced verbally by the pharmacists to facilitate this decision-making process, would yield better results in terms of safe and rational use of OTC medicines[10]. The accessibility and availability of proper information is a primary and essential component of safe use of medicines and hence a right to health.

One of the immediate and easily available sources of information about a medicine is the label of the medicine itself, or any consumer information leaflet (also called as a Patient Package Insert, or Patient Information Leaflet) accompanying the medicines. Some basic information about the medicines is important for the patient to make responsible choices about its usage. The purpose is to facilitate the quality use of those medicines by consumers and health professionals by ensuring appropriate labeling and seeks to assist in achieving various purposes to minimize risk and assist in appropriate selection of medicines[11]. In order to promote safer use of medicines, several countries have put in place legislative requirements that cater to consumer medicines information on the label, so that they are easy to read and understand[11-15]. They have laid down minute details on various aspects of labeling-for example, text size, spacing and positioning of the information, color and contrast in presentation[11-15].

The Canadian regulations make it mandatory to have the labeling in English and French for non-prescription medicines which are accessible to consumers[2]. The Guidelines of the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK and the European commission also require that the name of the medicinal product must be expressed in Braille format on the label, and the marketing authorisation holder must ensure that the package leaflet is made available on request from patients' organizations in formats appropriate for the blind and partially sighted[16,17].

United States Food and Drug Administration (US FDA) established standardized content and format for the labeling of OTC medicines, commonly referred to as the drug facts label[12]. When using an OTC medicine, reading the drug product's labeling is important for taking care of the consumer or family member. The label states what the medicine is supposed to do, who should or shouldn't take it, and how to use it. The labeling of OTC medicines in the USA had long contained the usage and safety information for consumers. With the introduction of the OTC "Drug Facts" label regulation by the US FDA since May 2002, the information is more uniform and easier to read and understand. The drug facts label guideline/regulation lays down in great detail the contents and the format of this labeling[18]. The Drug Facts label uses simple language and an easy-to-read format to help people compare and select OTC medicines and follow dosage instructions. The following information must appear in this order; the product's active ingredients; the purpose; uses (indications); specific warnings including when the product should not be used under any circumstances, and when it is appropriate to consult with a doctor or pharmacist and also describes side effects that could occur and substances or activities to avoid; dosage instructions-when, how and how often to take the product; the product's inactive ingredients, and important information to help consumers avoid ingredients that may cause an allergic reaction. Similarly, the Canadian drug facts table for non-prescription medicines is a labeling format with clear and detailed guidelines laid down for the contents and layout of the information about the medicine[19].

In the Indian drug regulations, the drugs and cosmetics Act 1940 and rules 1945 thereunder, the terms "OTC medicines", or "non-prescription medicines", or "prescription medicines" are not listed or defined[20]. Those medicines which can be sold only against a prescription of a registered medical practitioner fall under different schedules (*viz*.: G, H, H1, X) of the Act and are listed under these various Schedules in the Rules. The manner of labeling of medicines is described under rules 96 and 97. As per these rules, it is mandatory that such medicines carry on their label a warning: "To be sold by retail on the prescription of a registered medical practitioner only". By convention, these are commonly referred to as 'prescription drugs' or 'prescription medicines'. Those medicines on whose label such a warning is not written, it is implied that they can be sold by retail without the prescription of a registered medical practitioner. And thus, by the same convention they are commonly referred to as "non-prescription medicines" or "OTC medicines".

Thus, in India, there is no official category called "non-prescription medicines" or "OTC medicines" as exists in most countries. So also, there is no separate compilation of a list of medicines which can be sold without a prescription.

Rule 96 also specifies that the following appear on the label in a conspicuous manner on the label of the innermost container of any drug and on every other covering in which the container is packed: name of the drug ('proper' name of the drug in a more conspicuous manner than the trade name), net content, content of active ingredients, a batch number, date of expiry of potency, manufacturing license number, name of the manufacturer and address of the premises where the drug was manufactured. Rule 97 specifies the wordings/warnings to be included on labels of drugs under Schedule G, H, H1, X and the words "For External Use Only" for preparations for external use. The regulations do not specify any instructions or mandate to be printed on the label of medicines related to the purpose/therapeutic category, indications, directions for use, special precautions, contraindications, possible side effects and warnings (other than label warnings for specific drugs like paracetamol, aspirin and some prescription medicines). Also, it is not mandatory to include any package insert meant for the reading or utility or guidance of the patient or consumer.

'Labeling ensures that the critical information necessary for the safe use of the medicine is legible, easily accessible and that users of medicines are assisted in assimilating this information so that confusion and error are minimized'[17]. The label of a medicinal product has a very important role to play in conveying information to the patient about various important aspects of the medicine. Hence insufficient medication information on the label could cause poor patient outcomes due to the consequences of their misuse and possible adverse effects[10]. These challenges in India have to be contextualised based on the fact that the non-prescription medicines are relatively safe, but it does not make them risk-free[21]. Demographic variables (gender, health status, literacy level) and the types of information consumers seek determines how they look for information related to symptoms treated by the medication, dosage instructions, side effects and others[22].

In a country like India, the health literacy of the majority of the population is not optimum, and when combined with the issues related to literacy in general, it causes profound problems in terms of proactively seeking information about medicines. Additionally, when labels are printed only in English, it possibly leads to using medicines without due diligence given to directions of using medicines or the depicted warnings, which lends itself to the need for patient awareness programs supported by pharmacists[10].

One of the studies on labeling on 100 OTC medicines in India reported that the therapeutic category was not available on 59 % of the labels and when seen in the context of poor legibility for most calls for action in this area to safeguard safety and health issues of the patients. In addition, crucial information related to contraindications were missing in 87 % and 90 % labels did not provide details on adverse effects of the medicine[23]. On similar lines, another study reported 73.75 % of the labels of 1290 OTC medicines, which did not report on the therapeutic category of the medicine and only 26.25 % mentioned the warnings of the medicine, while 98.75 % OTC labels did not provide warnings related to information important for pregnant and lactating mothers[24].

Even though there is no separately defined category of non-prescription medicines in India, or a specific directive or manner of labeling such medicines, it is important that the labels of such medicines have information on them which will help the consumer make the correct choice about using these medicines and also using them in the correct manner. The present study was thus undertaken to analyses the labels of medicines in India which do not need a doctor's prescription for purchase and to check for the manner of presentation of information on the primary and secondary package labels, the local languages used as well as for the presence of various information about the medicine and its usage, so that the patient can make safe and responsible choices for self-medication for minor ailments, in the Indian context.

MATERIALS AND METHODS

In the present study, we analyzed the labels of various medicines which do not require a prescription for purchase in India. From a relatively large community pharmacy in Goa, stocking around 10 000 stock keeping units, medicines that could be sold without a prescription (those that did not bear on their label that a doctor's prescription is needed for sale) were chosen for the study. It was ensured that the product picked up was an allopathic medicine (drug). We

identified 300 such products and included them in the study.

Each of these 300 products was checked for presence of a package insert, immediate outer (or secondary) packaging and its label contents and the primary immediate label itself (either printed on or pasted on the immediate/primary packaging). The label of each of these products was analyzed in detail and checked for various aspects such as the format of presentation of the information, active ingredient (s), purpose (s), indications/uses, warning (s), directions, other information (e.g. storage), inactive ingredients and questions or comments. The other parameters analyzed were the type of dosage form, number of active ingredient (s), language (s) used on the label, presence and comparative sizes of the brand (trade) and generic (proper) names, and presence of pictographic information.

RESULTS AND DISCUSSION

The 300 non-prescription medicines (products) chosen for the study belonged to 82 different pharmaceutical companies, belonging to various categories like cough and cold remedies, analgesic-anti-pyretics, gastrointestinal tract remedies, vitamin, mineral and supplements, preparations for dermatological problems, stop-smoking aids, ear wax removal aids, mouth and dental preparations, and across various dosage forms. Of the 300 products studied, 85 (28.33 %) of the products are advertised to the consumers (public) in some form or the other-media, social media and in pharmacy displays. While 215 (71.33 %) of the products are not advertised.

Both the immediate (primary) label and the secondary package label (where available) of the 300 products were examined. Of these, 144 (48 %) of the products were to be sold along with the secondary package (e.g. tube in a box (40), bottle in a box (85), individual strip in a box or a shoulder pack (19)). Of these 144 products, on 57 (39.58 %) of the secondary packages, the information had a greater text size than that on the primary (inner) label and also had some extra information on them (e.g. pictographs of how to use the product, or additional information about the uses). The other 87 (60.42 %) of the secondary package labels offered the advantage of only an increased text size of the label wordings-thus making it easier to read. The remaining 156 (52 %) products were without an immediate secondary packaging and of these, 43 (27.56 %) were tablets or capsules and often sold as individual strips and the consumer did not get access to the larger boxes. The larger boxes of the strips did have the information provided which was more easily readable than that on the individual strips but lacked any additional necessary information like special precautions, contraindications, other warnings and directions for use.

The number of active ingredients in each product ranged from 1 to 35, of which 142 (47.3 %) products had a single active ingredient, 61 (20.3 %) had 2 active ingredients, 33 (11 %) had 3 active ingredients, 33 (11 %) had 4 active ingredients, and the remaining 31 (10.3 %) of them had active ingredients numbering from 5 to 35 (those having 5 or more active ingredients were mainly products of preparations of various vitamins, minerals and other supplements).

Out of the 300 products, 162 (54 %) of the products were for oral (systemic) use *viz*. including capsules, tablets, dry powders for reconstitution, oral drops, syrups, suspensions, solution and gel, and also included 4 lozenges and 3 chewing gums. Also, 105 (35 %) products were for external use (skin ointment, cream, gel, paste, solution, lotion, powder, spray, shampoo, tincture, ear drop, and nasal drop) and on all of them the wordings “For External use only” were mentioned. Another 24 (8 %) of the products were for use in the mouth orifice (mouth wash, gargle, paste, gel and gum paint), and of these, 8 (33 %) had on their label the wordings “For External Use Only”, while 8 (33 %) of them had the wordings for “For Dental Use Only” or “Use in the Mouth only”, and 5 (20.83 %) of them had written on them both the warnings: “For External Use Only”, and “For Dental use Only”; and 3 (12.5 %) of them had the wordings “Not to be Swallowed”. Another 6 (2 %) of the products were for rectal use and on 2 (33.33 %) of these, the wordings “For Rectal Use Only” were written, while on the other 4 (66.66 %), the wordings “For External Use Only” were written. Another 3 (1 %) of the products were for vaginal use and on all the three labels the wordings “For External Use Only” was mentioned.

Presence and size of generic (proper or common) and brand (trade) names on the label including of the 300 products, 11 (3.6 %) of them had only the proper name (as defined under rule 97 of the drugs and cosmetics rules) on the label, and this was printed both in English and Devnagri (a local Indian Language script). On 145 (48 %) of the labels, the trade name was written only in English, while on 140 (46 %) of the labels, the trade name was written in English and Devnagri. However, of these 140 labels, the trade name in Devnagri (along

with a mention of the dosage form in Devnagri) was written on 42 (30 %) of the labels, while on the remaining 98 (70 %) of the labels, only the trade name (without the mention of the dosage form) was written in Devnagri. It was observed in the majority of the labels that whenever the trade name was written in Devnagri, it was in a much smaller font than the trade name written in English on the label of the same product. On 4 (1.33 %) of the product labels, the trade name was written in English as well as in other Indian languages (ranging from 7-12 different Indian languages). However, the font size of these names was smaller than the English names.

Besides the trade names in Devnagri, the directions for usage on 1 of the product labels, and the purpose of the product on 2 of the product labels was written both in English and Hindi, and 1 of the product labels had a one-line instruction for reconstitution of the ORS powder written in 14 languages including English (however the text size of these instructions was very small and difficult to read with the naked eye). Other than this, the rest of the matter was in English on all the labels. On only one of the labels, the trade name was written in Braille.

In our study we also found that the trade name and the proper name of many of the products were written in more than one place on the label. In such cases, in order to compare the sizes, the biggest font/text size (height) of the trade and proper name on the label was selected for comparison.

Height of the text of the trade name is smaller than the height of the text of the proper name. Out of the 300 products, on 67 (22.3 %) of the product labels, the text size of the trade name was smaller than the text size of the proper name. However, of these 67, the text of the trade name on 46 (68.66 %) of the labels was bolder (thicker) than the text of the proper name, while on 2 (2.98 %) of the labels, the text of the proper name was bolder, while on 19 (28.36 %) labels, the thickness of the trade and proper names was the same.

Equal heights of the texts of the trade and proper name including on 118 (39.33 %) of the product labels, the text size of both the trade and proper names was equal, however, of these 118, the text of the trade name was bolder (thicker) than that of the proper name in 83 (70.33 %) of the labels.

Height of the text of the trade name bigger than the height of the text of the proper name including on 104 (34.67 %) of the product labels, the height of the text of the trade name was taller as well as bolder (thicker) than the proper name. On many of these labels, it was more than 1.5-3 times taller and bolder than the text of the trade name.

It was also observed that on several labels, irrespective of comparative text sizes, the trade name was printed in colors which were more attractive or printed on a background which made it more attractive and easier to see than the proper name.

Locating various information on the labels it was observed that the information on the labels on the majority of the products was not presented in a well-organized manner and so it was not so easy to locate.

Locating the 'Purpose' and 'Indication (s)' on the labels including the "Purpose" of the product is stated based on the general pharmacological category (ies), or the principal intended action (s) of the product. Of the 300, the purpose was mentioned on the labels of 154 (51.33 %) products. Out of these 154 labels, the purpose written on 35 (22.73 %) of the product labels appeared to be general and not very specific. Also, no purpose was mentioned on the label of 146 (48.66 %) of the products. On the labels on which the purpose was written, none of them carried the distinct heading "Purpose". The purpose on 2 of the product labels was also written in Hindi, besides in English. Indication (s) or Use (s) including whether the indications were mentioned or not on the 300 product labels, and if mentioned, in what manner they were written are shown in Table 1 and Table 2 respectively.

TABLE 1: MENTION OF 'INDICATIONS (USES)' ON THE PRODUCT LABELS (N=300)

Indications (Uses)	Number of labels N (%)
Mentioned	152 (50.22)
Not mentioned	146 (48.6)
Mentioned to 'refer the package insert'	2 (0.66)
Total	300

TABLE 2: THE MANNER IN WHICH THE 'INDICATIONS (USES)' WERE MENTIONED ON THE PRODUCT LABELS (N=152)

Manner of writing indications (Uses)	Number of labels N (%)
Only listed	108 (71.05)
Listed with explanation	9 (5.92)
Listed with a pictograph (s)	23 (15.13)
Only explanation	7 (4.61)
Explanation with a pictograph (s)	1 (0.66)
Listed, with explanation, and pictograph (s)	4 (2.63)
Total	152

Header for identifying the indications (uses) including of the 152 products which had the indications (uses) mentioned on them, 65 (42.76 %) of them had a header "Indications" or "Uses" on them, of which 59 (38.8 %) of them were in a font or color which was bolder, and/or of a different color), thus making them easier to locate, while 6 (3.9 %) of them of the same font size and thickness as the listed indications. 25 (16.44 %) of the listed indications did not carry any heading or mention, while 64 (42.1 %) of them had wordings such as "Benefits", "Safe for", "Relieves", "For", "Effective for", "Helps in", "Ideal for", "Promotes", "Protects", "Works on", etc., written prior to the uses which indirectly "imply" that the words following them are the uses of the product.

Locating various 'Warnings' on the labels including the special precautions or contraindications before or during usage. A total of 74 (26 %) of the labels had a warning in the form of special precautions or contraindication. Of these, only 6 (8.11 %) of the product labels listed in detail some of the special precautions or contraindications before or during usage of the product, while 68 (91.89 %) of these mentioned some contraindication or special precautions (before or when using the product). Out of these 74 labels which had these warnings, 18 (24.32 %) of them had no header stating that they were contraindications or special precautions, while 58 (78.38 %) of them had a header (of which 56 (96.55 %) of them were in bold). On the other hand, 226 (75.33 %) of the labels had no mention of any special precautions or contraindications mentioned on them. Out of these 300 products, 20 (6.67 %) of the products contained Paracetamol. And all except 2 (10 %) of these 20 had on them the mandatory warning to be mentioned on the label of Paracetamol containing products: "Taking more than the recommended daily dose may cause serious liver damage or allergic reactions (e.g. swelling of the face, mouth and throat, difficulty in breathing, itching or rash)". One product contained Aspirin and it carried on it the mandatory warning regarding cautious use during the last trimester of pregnancy.

Activities or substances to avoid while using the medicine including out of the 300 products, 29 (9.66 %) of the product labels had a mention on them of any activities or substances to avoid while taking or using the medication; while 271 (90.33 %) of the product labels had no such mention. Possible side effects including out of the 300 products, only 5 (1.6 %) of the labels mentioned the possible side effects which could occur, while one of the labels mentioned that the medicine has "no side effects". The remaining 294 (98 %) medicine labels had no mention of possible side effects.

Stop use and ask a doctor including out of the 300 products, 254 (84.6 %) of the labels did not state any possible signs of toxicity or other reactions, or that if there is no improvement in the condition, one should stop use of the product and contact a doctor. While 46 (18.6 %) of the labels had a mention of such signs and reactions or situation or a time frame as to when the patient should contact a doctor.

We also checked whether the 300 products listed on the other warnings. These include information related to 'Usage during pregnancy and/or lactation', 'Keep out of reach of children', and 'In case of over dosage or accidental ingestion, contact the doctor or poison center'. Table 3 shows the numbers of product labels on which these various warnings were written.

Locating 'Directions' written on the label including the directions for usage of the product include the dose, frequency of dosing, duration, maximum daily dose and how the product is to be used. Our study of the 300 labels revealed that many of them did not contain the complete directions. Studying the manner in which the directions were placed on the label revealed that on 165 (55 %) of the product labels, the directions were placed along with the other matter in the labels in the form

of text. Out of these, 118 (71.52 %) had the heading 'Directions' or 'Dosage' written in bold, while on 39 (23.64 %) of them the heading was written but not in bold, while 8 (4.85 %) of the labels did not have the heading. On 21 (7 %) of the labels, the 'Directions' or 'Dosage' was in the form of a Chart or Table, while 2 (6 %) of them were placed in a Box. On 3 (1 %) of the labels it was stated that the 'Directions for Usage' be referred to in the package insert, while 109 (36.33 %) of the labels either did not have any directions, or stated that the product be used as directed by the physician. It was observed that the 'Directions' placed in the form of a Table or Box were very easy to spot on the label, whereas those written along with the text were easy to find if they had a heading which was in bold text, or of a bigger font, or of a different color, which made the heading stand out. Those which did not have a heading, or if the heading was not in bold text, or where the matter on the label was of a small font and the printed matter was more (crowded), it was often difficult to locate the 'Directions'. Table 4 presents the various components of the 'Directions' which were included on the labels.

Instructions as how to dilute, disperse, apply, administer or consume including this information is important for the consumer to know how exactly to use or consume the product. Out of the 300 product labels, there were no such instructions on 167 (55.6 %) of the labels, while 3 (1 %) labels mentioned that the package insert be referred for the same. Of the 130 (43.33 %) labels on which the instructions were mentioned, labels of 75 (57.69 %) products had incomplete, or inadequate instructions for proper usage (though 12 (16 %) of these labels contained pictograph(s) related to usage instructions), while 55 (42.31 %) of the labels had complete instructions, of which 11 (20 %) of these labels had additional pictographs related to the instructions to use.

Locating other information including of the 300 products, 157 (52.33 %) of the product labels had no inactive ingredients listed, while 30 (10.33 %) products mentioned the preservative (s) used in the product, 111 (36 %) mentioned the approved color (s) used, and 2 of the products had both the preservative (s) and color (s) written on them. A few of the products listed the flavor, stabilizer, antioxidant used, while a few listed inactive ingredients like the base used to make up the volume (e.g. starch, talc, glycerol, alcohol). Out of the 162 products (155 for oral (systemic) use, 4 lozenges, and 3 chewing gums)), 23 (14.2 %) of the product labels stated that they did not contain sugar (sugar free), while 46 (28.4 %) of these products did not directly state that they contained sugar, but it was implied from the fact that the labels mentioned that the liquid oral preparations was made in a syrup base and an oral tablet stated that it was sugar coated. On the remaining 93 (57.41 %) of the 162 labels, presence or absence of sugar could not be verified. Only one of the labels stated that the preparation was "Sodium Free", while none of the oral preparations had any label warning regarding the content of calcium, magnesium, potassium in them.

TABLE 3: SPECIFIC WARNINGS MENTIONED ON THE PRODUCT LABELS (N=300)

	Number of products with specific warning on the label		
	Regarding usage during Pregnancy and/or Lactation N (%)	Keep out of reach of children N (%)	In case of overdose or accidental ingestion, contact the doctor or poison centre N (%)
Mentioned on the label	21 (7)	180 (60)	9 (3)
Not mentioned on the label	249 (80)	120 (40)	291 (97)
Paediatric preparation (so warning need not be mentioned)	30 (10)	-	-

TABLE 4: VARIOUS DOSING DIRECTIONS MENTIONED ON THE PRODUCT LABELS (N=300)

	How much to use/take per dose N (%)	How often to use/take the dose N (%)	For what duration to use/ take N (%)	Maximum daily dose N (%)	Consuming of oral preparation with respect to food/time N (%)
Mentioned	143 (47.67)	144 (48)	41 (13.67)	20(6.67)	24 (8)
Not mentioned	73 (24.33)	73 (24.33)	258 (86)	186 (62)	138 (46)
Mentioned "As advised by the physician"	81 (27)	80 (26.67)	1 (0.33)	-	-
Mentioned "See the leaflet"	3 (1)	3 (1)	-	-	-
Products meant for external use (so need not be mentioned)	-	-	-	94 (31.33)	138 (46)

Storage temperature including out of the 300 product labels, the temperature conditions at which the product should be stored were not mentioned on 38 (12.6 %) of the labels, while on 96 (32 %) of the labels the storage temperature was mentioned as "Store in a Cool Place", while on 165 (55 %) of the labels, the storage temperature was indicated either as "Store below 25°" or "Store below 30°", and on only one label the temperature storage range (both lower and upper) was mentioned. Contact information including out of the 300 products, 190 (63.33 %) of the products had neither a contact number or contact Email id of the company written on the label, while 99 (33 %) of the products had on them both the contact number and Email id, while 4 (1.33 %) of the labels had only the phone number and 7 (2.33 %) of them had only the Email id.

Package inserts including out of the 300 products, 11 (3.6 %) products had in them package inserts carrying information about the product, meant for reading by the patient. Out of these 11, the information provided in 7 was only in English, while 4 of these had information in English and Hindi. Additional 3 (1 %) products had a package insert meant for medical professionals.

Patient safety and the therapeutic outcome of medicines depend on the proper use of the medicines. This also applies to non-prescription medicines, which the consumers or patients are making their own choice to buy and use. They are often making these decisions with very little understanding of the disease condition or the medicine. Therefore, correct labeling of the medicines plays an important role in this. After purchasing the medicine, the consumer or patient primarily depends on the information available on the label of the medicines. The information provided on the label thus becomes more significant in case of a non-prescription or OTC medicines. Such information is useful for the patient to make appropriate decisions for self-medication, before and while using the medicines.

From our study Results, it was evident that the information on both the primary and secondary labels were inadequate in many ways in terms of the information that guides the consumer to use the medicines responsibly and rationally. While the labels did fulfill the requirements of the Indian regulations, most of the labels did not fulfill a large number of important parameters which conveyed important information about the medicines, as stipulated by the regulations of various countries[13,14,16-18,25].

The World Health Organisation has been assertively advocating to increase the public awareness and engagement on the importance of patient safety, these activities are more focused in hospital settings and at the point of care[26]. The pharmaceutical care and related activities in community pharmacy are unfortunately not addressed appropriately particularly in India. However, when a patient is purchasing medicines that do not require a prescription, the responsibility of patient safety shifts from a healthcare team and system to the pharmacist dispensing the medicines and the patient. However, there is also a possibility that the patient may not always get the necessary guidance from a pharmacist, who unfortunately may not even be available in a pharmacy.

Medicines are identified on the basis of their name-which could be generic (common or proper) name or the trade (brand) name. The rule 97 of the drugs and cosmetics act and rules, specifies that the proper name of the drug shall be printed or written in a more conspicuous manner than the trade name, if any, which shall be shown immediately after or under the proper name[20]. However, as can be seen from the Results, the trade name of the product is bigger and bolder than the proper name in 35 % of the products and bolder in 27.66 % of the products, thus drawing less attention to the proper name. Also, printing the trade names in attractive colors and backgrounds made them more prominent, and thus easier to catch the eye than the proper names, even though they are less tall or less bold than the trade names.

It is very unlikely that labels printed in English will deliver the necessary information to the consumer and thereby become a primary barrier itself, and thus not safeguard patient interest. In this study it was revealed that almost all the label contents were printed in English, while only the trade name of the medicines was printed in Devnagri (Indian vernacular) script for 46 % of the medicines, and 4 product labels had the trade name written in other Indian languages (but that too in a smaller font size). It was also found that the generic name of the medicines was in Devnagri only on 11 labels. India is a country with 22 official languages, and many more regional languages. Besides, there is also a problem of low literacy rates. Thus, a large number of the population cannot make use of the information on the labels. The language literacy as well as the health literacy levels of patients buying these medicines has to be considered by the regulators and also by the pharmaceutical manufacturers in setting norms and guidelines and printing the necessary information on the labels.

In addition to the language used to print labels being a barrier for patients, another aspect that plays a role is the extent to which the information is placed in an organized manner. In this study, as shown in the results, it was difficult to locate crucial information about the medicines (purpose, indication (s), directions), because it was either not placed in a uniform and organized manner, and/or did not have appropriate and bold headings. This is another cause for concern when literacy and health literacy of patients buying non-prescription medicines are concerned. This study's Results show that the purpose (category) of the medicines and the indications (uses) of the medicines were not mentioned in almost 50 % of the labels (Table 1-Table 3). So, even for those consumers who are able to read these labels, they will not be able to know the exact indications for the medicines. Hence this can lead to misuse or inappropriate use of the non-prescription medicines.

So also, as can be seen from Table 4 in the Results, only 7 % labels had the 'Directions' written in the form of a table which made it much easier to locate, while 55 % of the 'Directions' were placed within the text, and having a heading, and a bold one made it easier to locate them.. The recommendations of the US Pharmacopeia Health Literacy and Prescription Container Labeling Advisory Panel include the need for cues like highlighting, bolding, to improve readability[27].

The fact that 36.33 % of the labels either did not have any directions for use or stated that the product be used as directed by the physician is not in favor of making the products available without a prescription. Even if the medicine was a prescription medicine, at least the directions for usage or administration should be put on the label. Also, it is a good practice to have it printed on the label or package insert so that the patient can refer to it whenever needed or in doubt about how exactly to use it. Even when directions were present on the labels, it is seen from the results that the dosing and usage instructions are incomplete, with more than 50 % of the labels not having information as to how much and how often the medicine is to be used. This will make it difficult for the consumer to take the medicine appropriately. Despite of clear-cut guidelines, even in country like USA, a descriptive study on 200 pediatric liquid non-prescription formulations found inconsistencies between the dosing directions on the label and markings on the measuring device accompanying the product[28]. Another study on these same 200 formulations checked for content format of active ingredient information and dosing instructions on the principal display panel and drug facts panel, and concluded that the format and contents of the labels could be improved to facilitate understanding of such information by the parent[29].

The US Pharmacopoeia standards for container labels of prescription medicines are made to promote patient understanding about their dispensed medication[30]. These include organizing the label in a patient-centered manner, emphasize instructions and other information important to patients and place them in a standard format so that the patient expect the same format each time and make it easier to understand, present the information in simplified language and give explicit instructions, and simplifying the language so that the patient understands. The same aspects can be extrapolated to labels of non-prescription medicines and this too will make things easier for the patients.

The campaign that World Health Organization (WHO) promotes of 'Know, Check, Ask'[31], for patient safety highlights the role of patients and healthcare professionals, by advocating that patients make the effort to know the medicines they are taking, and if unsure, the need for them to ask their pharmacists. The campaign also highlights the need for pharmacists to ask their patients if they understand the essential safety details of the medicines they are consuming. Our study results highlight that not all the labels provided clarity in terms of information required for patient's safe use of non-prescription medicines. Important information related to warnings and precautions such as-contraindications, special precautions, activities or substances to avoid when taking medication, possible side effects, when to stop using the product as well as when to contact the doctor, though crucial, were still not incorporated in the label. A study reported on how end user feedback was being obtained to design evidence-based labels so that the Australian therapeutic goods administration could implement a standardized OTC medicine label[32]. Such patient-centered and evidence-based attempts are crucial for incorporating consumer perspectives.

In the present study we found that a large percentage (80 %) of the labels failed to mention if the medicines can be used during pregnancy or by lactating mothers. Maternal medication use is receiving attention so as to pay attention on potential adverse effects on fetal and infant health[33]. In USA, the FDA's drug labeling which used the classification of A, B, C, D and X as risk categories for patients who are pregnant and lactating, has now been replaced by the FDA Pregnancy and

Lactation Labeling Rule (PLLR). This PLLR requires manufacturers to use narrative text to describe risk information, clinical considerations and background data for the drug. The new rule now includes three categories *viz*., pregnancy, which includes labor and birth; lactation; and females and males of reproductive potential[34].

Some patients could develop allergic reactions or have known allergies to one or more ingredients in the medicine. While the active ingredients are almost always mentioned on the label, our results showed that other than the preservative and colors used (in close to 50 % of the products), the inactive ingredients were not written on the label in more than 50 % of the products. So, in such situations, the patient is unable to know all the inactive ingredients in the product being used, so as to avoid using the product if, he is already known to be allergic to a particular inactive ingredient. It is encouraging to note that in India, the food safety and standards (packaging and labeling) regulation, 2011 and the cosmetics rules, 2020 have made it mandatory to list all the inactive ingredients on the label of food supplements and cosmetics respectively[35,36]. A similar step to make it mandatory to list all the inactive ingredients on all the medicine labels would certainly be beneficial for the patients.

Indicating the presence of other crucial ingredients like sugar on the label is also important so that the consumers, especially diabetics can be alerted and they can make the decision to choose or not to choose the product or look out for another product which does not have sugar. In the USA, the Code of Federal Regulations for 'labeling requirements for over-the counter drugs' lay down norms to mention as a warning the amounts of sodium, potassium, calcium, magnesium, on the labels of medicines, so that patients who have restrictions to have any of these elements because of specific illnesses, can be alerted to the same by reading the OTC medicine label[18]. However, this practice was not seen in our study-with only one label stating that the product was free from sodium.

The storage conditions including the temperature at which the products should be stored are very crucial for the stability and effectiveness of the product. Different medicines may have to be stored at different temperature conditions, and the best way to know is if it is written on the label of the product. It is also important that the temperature conditions are mentioned specifically in terms of numbers and non-technical jargon. For e.g. if "Store in a Cool place" is mentioned on the label, then the patient is not likely to know what that exactly means. However, our study results showed that only 1 product label had written on it the lower and higher temperature range for storage, while 12.6 % labels had no temperature condition mentioned at all. In a country like India, where the room temperatures may vary from region to region and season to season, it is very much necessary to mention clear-cut and easily comprehensible directions for storage on the labels of all medicines.

The disparity in labeling of products was also seen in products used in the mouth orifice, rectal and vaginal use-the appropriate wordings are not found in many of the labels of such products, and thus can lead to inappropriate use. Thus, as we can see, there is a lack of uniformity as well as deficiencies in the beneficial information which should have been there on the labels of various products. However, from the Indian regulator's point of view, these will not be termed as defects in labeling, because there is no compulsion for inclusion of such information on the label. Whatever additional information beyond the minimum legal requirements that has been put by the manufacturers on the product labels has been done by them on their own initiative and not out of compulsion. While some have included information, many have not. Thus, there is an urgent need to have in place clear rules or guidelines in India, on lines with other countries, which would make it mandatory to include minimum specific information, in a recommended format on the labels of non-prescription medicines. This will go a long way in providing important information to the consumer, and a strong step towards improving rational use of medicines.

Considering the size of the individual product, the availability of limited space for displaying vital information on the label is an acceptable fact. However, in our present study, we observed that the space available on many of the labels was not judiciously used to provide information related to various warnings, directions for use, and other important aspects. To address the issue of limited space, it is a common practice in several countries to have accompanying package inserts meant for patients along with both prescription and non-prescription medicines. The Indian regulations do not make it mandatory to include or provide package inserts for patients-neither along with prescription or non-prescription medicines[20]. In the 300 products which we included in our study, a package insert meant for the patient was found only in 11 (3.6 %) of the products, with information in English and Hindi in 4 of them and

only in English on 7 of them.

Considering the importance of reading the labels of medicines, several countries run campaigns which educate the consumers about the contents of the label, and what they should look for, and how they should interpret them. 'What's on my medicine label' are examples of information campaigns in USA and Australia, which create awareness amongst consumers about the importance of reading the label of non-prescription medicines, in order to use them correctly[37,38]. It would be beneficial to have such campaigns in India too; however, it would be more appropriate once provisions are made to ensure that appropriate information is available for the benefit of the patient on labels of non-prescription medicines.

The critical analysis of the various components of the labels thus revealed that the information on both the primary and secondary labels were inadequate in many vital respects. The non-availability of important and appropriate information that guides the consumer to use the medicines responsibly and rationally is in a way denying their Right to Health. It is therefore important that like in other countries, there should also be a specific category and list of non-prescription (OTC) medicines in India too. This should be accompanied by clear and systematic requirements and guidelines for what all needs to be included in the label, including information which can help the consumer/patient to make a proper choice about using the medication and correctly. The guidelines should also lay down specifications which would ensure that the information provided on the label is easy to locate, readable and easily understandable by lay persons. There is also a need to make it mandatory to include package inserts in all non-prescription medicine packages, so that more elaborate information can be included, and also in additional/regional languages in our country. In the interest of the population with visual impairment, it will also be appropriate to make it mandatory to include the name of the product in Braille on the medicine label.

There are some limitations to our study. The product labels were analyzed by skilled pharmacy staff. The perspective and perspective of consumers or patients in examining the labels and ease of location of information could be different. It would add value if consumers would also be involved to provide their perspectives about the manner of presentation of the information on the labels. We also did not assess the readability and ease of reading of the information provided and we also did not assess the correctness of the information provided on the label.

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