Strength and weakness of drug facts economics essay

In OTC drugs, there is variation in labeling OTC drugs. Those OTC drugs which are exported to foreign countries are labeled in perfect manner, but that is in revise in Indian market. In India, OTC drugs are distributed in pitiable manner and it exhibits the lack of regulations in labeling. It is required to improve the labeling of OTC drugs. For achieving high-quality labeling, the following information should be included in the labeling requirements of OTC drugs.

1. The purpose of the drug

2. Detailed warning messages

3. Inactive ingredients

4. Dosage instructions

5. Users’ Contact data, equipped to get information for their queries

The Drug and Cosmetic Act was executed in 1945. At that time, the literacy rate, which depicts the literacy (who can be read and write) percentage of a population over the age 15, was very low. The prerequisites of labeling were depended on general public education and circumstances. After that, there was a great improvement in both literary rate and the usage of OTC drugs. Stated by the surveys, India is currently in 11th position in the global OTC market, and it is believed to be in the 9th position in following five years. All these represents the need of modification which is required in the Drug and Cosmetic Act established in 1945, in order to improve the level of OTC drug labeling.

History of OTC labels

The manufacture, distribution, sale and import of drugs and cosmetics in India are regulated by the following legislations:

The Drugs and Cosmetics Act, 1940 (DCA) and its subordinate legislation

‘ Drugs and Cosmetics Rules, 1945’ (DCR)

Drug (Prices Control) Order, 1995

Drugs (Magic Remedies) Objectionable Advertisement Act, 1954

Pharmacy Act, 1948

The above-mentioned legislations are regulated by the Central Government (Ministry of Health & Family Welfare) and are enforced through Food and Drug Administration (FDA) the State Government. Even though, OTC drugs do not have separate labeling requirements in India, all drug products should have a minimal information present on the label of the innermost container of any drug and on every other layer in which the container is packed , as per rule 96 of the Drugs and Cosmetics Rules, 1945 (DCR), except homeopathic medicines. The following are the minimum labeling requirements:

- Name of the drug: Proper (generic) name, immediately followed by Trade (brand) name

- Net content of drug in the container

- Content of active ingredients/single dose or dosage unit

- Name, address and license number of the manufacturer

- Distinctive Batch number or Lot number for the product

- Manufacturing and Expiry date

- Maximum Retail Price (inclusive of all taxes)

In India, People’s habit of taking drugs differs from place to place. Around30%-45% of people prefer pharmacist and self treatment for their illness like cough, cold, pain, fever, injuries and digestive disorders. India is famous for Ayurveda and some other long-established systems of medicine. The aim of the evaluation conducted by Rama Krishna Chaitanya Aluri from Manipal College of Pharmaceutical Sciences, based on nearly 200 OTC drug labels, is to check the suitability of information on the labels for successful self-treatment by consumers.

Recent changes in drug facts

Recently, the FDA conducted extensive research on how consumers use OTC drug product labels, while comparing to the drug facts labels on advanced countries. The clarity of the labels was one major problem, especially for older Americans, who purchase almost 30% of the OTC drugs, sold in The United States. To determine the best way to order this information on OTC drug labels, a recent research has been conducted. Vigilante and Wogalter (1997) pragmatically decided an ordering of OTC label components based on users’ beliefs about what was (?)

Strength and weakness of Drug Facts

Having over-the-counter medication will save you time from visiting the doctor every time you have a little sniffle or an ache or pain. There are many safe drugs which can take care of most of your everyday illnesses like the following:

colds

coughs

aches and pains

upset stomach

diarrhea

allergies

These types of drugs are not the drugs themselves – it’s the people! A lot of horribly unobservant people do not take the time to read directions in order to know how to take the medicine properly. There are many cases where people use over- the-counter medicines erroneously and poison themselves.

Review in India

History of drug regulations

Drug regulation organizations in existence today, like Drug Laws, Drug Regulatory Agencies, Drug Evaluation Boards, QC Laboratories, Drug Information Centers, etc., have developed over time. Such developments

began centuries ago in some countries, and in others, they are comparatively recent, some of them having started only in the 1990s.

The restrictions under the Drugs (Price Control) Order, 1995 are not directly related to the question of categorization of the drugs as OTC drugs or otherwise. But still, they are required to be considered, as restriction on pricing may influence the decision to launch a drug as OTC drug. It is mandatory to obtain price approval from the Central Government, if the drug is classified as scheduled formulation under the Drug (Prices Control) Order, 1995. Also, Central Government can fix a maximum price at which every manufacturer is required to sell his product. For Example, Aspirin and vitamin preparations are deliberated as OTC products for the purpose of marketing. However, under Drugs (Prices Control) Order, 1995, they are considered as scheduled formulations and are subject to price restrictions, unless these formulations are manufactured at SSI units.

Difference between pharmacy in India and US

OTC in pharmaceutical industry dialect stands for ‘ over-the-counter’ (mainly with reference to drugs). The purchase/sale of drugs across the counter without prescriptions is denoted by this. In fact, in India, every pharmaceutical product market is OTC. People can orally ask for any product and buy it across the counter. In US, there are prescription drugs and over-the-counter drugs. The prescription drugs are strictly sold only on showing the prescription (Rx). Once the products are dispensed as per Rx, a seal is administered, to indicate that the “ Rx has been filled”. If the patient goes in for refill of the Rx, the pharmacist does it only if it is legally permissible. In such cases, a seal or stamp is put on the Rx again, to indicate that the Rx

has been filled once again. But in India, such procedures are not strictly followed. Hence, in a way, the Indian retail pharmaceutical market is OTC – or rather it is better to be called OTX (combination of OTC and Rx).

Strength and weakness of OTC drugs in Indian and US

In India, with the counter medication, there is no need to visit doctor every time for a little sniffle or pain or an ache, so drug facts are good. Several safe drugs are available which cures normal illnesses such as aches, colds, pains and coughs, allergies, and diarrhea and stomach upset.

These types of drugs are the people but not the drugs themselves. People are terribly unperceptive and don’t even care to read the directions mentioned on the drugs before consuming. Several cases happened when people took the counter medicines improperly and resulted in poisoning.

Methodology

Following methods are considered

To know in depth of a particular aspect case study method helps the researchers; in many cases it selects specific location with very small portion as subject. Real time example is considered with limited number of conditions and events for case study investigation. According to Yin 1984, 23 case study definition a formula based calculations comparing with real world using many sources of evidence, relationships in between them are not accurately explained.

Investigation of some case study is done by using longitudinal structures of single event which helps to observe sequence of data, events, reports and

results from a long time, for example child language development investigation.

According to Zaidah, 2003 Firstly useful data is deeply investigated according to situation based upon particular activity. Case study is very effective example knowing the interesting subject for authentic use. Students an opinion has to be focused during leisure hours the average number of particular subject is taken into the count. This kind of example values slightly deviates when n number of variable are consider.

The examination of data is conducted within its context and also within its situation wherein the activity takes place. A case study would always be interested when subject makes it as an authentic text. In order to investigate, the researcher must be able in observing subject environment such as reading in class room or else reading in leisure time. According to zaidah 2003 it mostly focuses on limited number of variables.

Results and Discussion

The research literature consists of few studies in relations concerning medications that can be bought without any kind of medical prescription also named or over the counter as cold/flu medications etc. in spite of the fact that they are widely used and also represents if it is been misused. As proposed by Ferguson, Dodds, and Flannigan, 1994 one such area in which they are been misused that which involves not only overdosing but also interaction with any other substance. For instance: some case studies have documented individuals who seek to relieve depression symptoms by inducing a state of euphoria with multi-symptom cold syrup which contains

chlorphenhydramine, dextromethorphan, and phenylpropanolamine. These substances may induce behavioral and emotional reactions, especially in prone individuals, leading to potentially serious health risks and consequences (Mendez, 1992).

The Dangerous substance interactions have received some attention in the psychiatric disorders area. A questionnaire administered to 139 patients diagnosed with either depression or social phobia revealed that 40% of them used OTC cold/flu remedies which had negative interactions with their prescribed medications (Sweet et al., 1995). Another study examined the rate of consumption of TV advertised OTC medications by 471 college students. The results showed that, in addition to frequently using one or more such medications they did so without talking to their physicians about it or specifically determining the conditions under which they were taking such medications. These findings led the authors to emphasize the need to further study the effects of the media on the use of potentially risky OTC medications (Burak and Damico, 2000)

The Indian OTC pharmaceuticals market generated total revenues of $2. 5 billion in 2006, this representing a compound annual growth rate of 8. 3%for the five year period spanning 2002- 2006. In comparison , the US and Chinese OTC pharmaceuticals markets grew with CAGRs of 4. 3% and 7% over the same period , to reach respective values of $21. 2billion and $11. 9billion in 2006. Traditional medicines proved the most lucrative for the Indian OTC pharmaceuticals market in 2006, generating total revenues of $679. 3 million. In comparison, sales of cough and cold preparations generated revenues of $492. 6 million in 2006.

Category

%Share

Traditional Medicine

27

Cough and cold preparations

19. 80

Vitamins and Minerals

11. 60

Medicinal skin plants

2. 60

Others

26. 03

Indian OTC pharmaceuticals market Share: % share, by value, 2004**

Company

%share

Pfizer Inc

5. 10

Sanofi Aventis

5. 10

Johnson &Johnson

2. 0

Other

85. 10

Inorder to obtain a better way of getting work done and make companies focus on packaging a better pharmacist approach through a better training sessions. By having, better access through labellng and packaging of OTC drugs through government and other pharma companies ensuring a better management of ailments through OTC medication. By developing a better approach of companies launching a better way of public education campaign fulfilling needs of OTC drugs and educating them to empower better way of medication. With all leading pharma companies launching their public education campaigns to fill the knowledge gap in proper selection and use of OTC drugs, it can be a classic case of PPP where the ultimate winner will be the consumer

Suggestions and improvements in OTC labeling in US

Based on Institute of Medicine IOM, 2008 medication label standardization U. S pharmacopeia health literacy launched container label prescription for consumer’s advice. Gerald McEvoy and Schwartzberg were the chairman’s of

American Society of Health System Pharmacists. According to them labels should contain the following principle:

1. Easy, understandable prescription and directions for consumers use.

2. Worldwide medicines should contain prescription label based upon exported country’s standards and basic exporters are clinicians, health literacy experts, academic researchers, government health agency representatives and pharmists.

According to IOM, 2008 every year millions of drugs are misused, even after mentioning source of information and safety precautions clearly on the label. Sometimes written and oral consultations information may or may not present on the panel, in case of Rx container label should strictly contain doctor’s prescription for consumer’s safety.

As per U. S. Pharmacopeia Health Literacy Instruction Container Labeling Advisory Panel recommend the following:

Recommendations

Arrange the label prescription in such a way that it always stays as a centre in comforting the users. The direction of a drug is given neatly and orderly in making the customer easily understand the prescription and to make use of them in a safe and also effective use. usefull information is given on the label of drug and they are as follows:

Useful directions are present at the top of the panel.

Medication details are present at bottom.

Most important precautions like dosage.

Administrative instructions are placed with specific style.

The proposed labeling consists of various components and they study these components by making use of certain facts of drug. And labeling format is as follows:

1. Label to include: the Active ingredient all along with its strength:

Results:

All the 100 labels are examined and mentioned in the active ingredients along with their potency/strength.

2. Label to include: Therapeutic category/purpose:

Its 55% of labels are disclosed in therapeutic category.

3. Label to include: Uses /indications for which medicine can be utilized:

Even though a significant percentage (75%) mentioned the indications intended for the medicine, 25% of the labels failed to do so.

4. Label to include: Warnings related to common unpleasant effects, drug interactions, contraindications, precautions, over dosage, when it is appropriate to seek medical advice and also in special conditions like pregnancy & breast-feeding. This also includes cautions in keeping them away from children.

Results:

90% of the labels failed to enumerate the adverse effects of the medicine.

86% did not state what is to be done in case of overdose

92% gave no Information regarding usage in pregnancy and Breastfeeding

87% of the labels did not mention of the possible drug interactions, contraindications and precautions.

73% labels did not even advise to seek medical guidance.

Only 36% labels mentioned that the medicine is required to be kept out of the reach of children.

5. Label to include: Directions including how much to be take n, dosage interval, and maximum dose allowed per day and the dose for children:

Almost half of the medicines (46%) did not mention the amount to be used, while 34% did not mention the dosing interval. 85% of the medicines did not state the maximum dose allowed. Out of the 15% which did state the maximum dose, 20% were ambiguous with the details. It was also observed that 70% of the medicines failed to specify the dose for children. Only 1 label included

Instructions for use in Devanagiri script.

6. Label to include: The product’s inactive ingredients help the consumers in avoiding ingredients that may cause an allergic reaction.

None of the labels included the inactive ingredients.

7. Label to include: Storage conditions.

Even though a large percentage (88%) of the labels provided the storage conditions, 64% of them were imprecise and difficult to understand. Nearly 85% of the labels were found without a specific temperature. Furthermore, storage conditions were often mentioned using terms which the common man are not familiar with. The exact temperature was rarely mentioned.

Besides, we also assessed the label for 2 more criteria :

1. Label to include: Legibility to find out whether the label is easily readable, read with difficulty or with the aid of a magnifying glass.

40% of the medicine labels were clearly read only with the aid of a magnifying glass as the font size was too small. 22% of drug labels were read with difficulty leaving just around 38% which

could be read easily. This suggests that 62% of the labels are read with much effort.

1. Label to include: Additional information through patient package inserts, information on secondary packages (wherever applicable): Patient package inserts are useful for providing additional information to the patient. Out of the 100 medicines examined, only 3 included a patient package insert. Many a times, secondary packagings of medicines are also given to the patient as additional protection for their medicines or as attractive packs. These secondary packages can also be used to convey valuable information to the

patient. In 56% of the cases, a secondary package was found to be available to the patient, yet only 36% of them gave more information on its label than the primary package.

Conclusion

The OTC drug offering is incomplete with out empowering public on its rational use through Well planed strategic marketing initiative revolving around the aliment, the knowledge to diagnose and manage the same. In this empowerment process which can be considered as CSR, the objective should be prevention and holistic awareness creation leading to health and wellbeing than just offering the minimum needed information to use one’s products.

Thus by educating public (consumer) on how to manage common ailments and finally how to prevent them, the pharma companies can achieve its real goal of health for all and improve the quality of people’s life In India, OTC products are marketed and advertised liberally, with a view of educating the maximum number of consumers, and promoting treatment of minor ailments at home using OTC products as first line of defense. It can be anticipated that, more Rx to OTC switch will increase number of drugs in OTC category in near future. Hence it may be valuable to conduct more research on group of Consumers, who consume OTC Products freely and either switch from the existing brand or continue to earlier brand. A study on marketing of OTC products, used by post office and postman, can also be a studied as a channel of marketing of OTC drugs at national area.

Since, the Customer and Consumer are being the same in the OTC drug marketing, companies must instantly address the information needs more effectively and uninterruptedly. Once the awareness level is enhanced, the acceptability of OTC drugs will improve. The knowledge about allopathic OTC drugs has to be disseminated by manufacturing companies, in order to ensure drastic reduction in the high information asymmetry existing now-a-days, especially when the knowledge of the traditional medicine is rooted in the culture.

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