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Ambiguity in Risk Communication: A Forensic Study of Patient Information Leaflets

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Abstract: Self medication is a dangerous phenomenon and it gets worse when drugs whether prescriptive or non-prescriptive can be bought easily from pharmacy stores, so it becomes mandatory to warn the customers from the potential risks of the product but ambiguity in language hinders the process of comprehension and results in wrong interpretation. This ambiguity is in fact a strategy to save the manufacturers from litigation and to gain bigger profits. In order to highlight the strategies, fifteen patient information leaflets of both prescriptive and non- prescriptive medicines were collected randomly from pharmacy stores which were not older than 2016. The leaflets were analyzed in the light of the framework proposed by Wogalter (2006) for medicine information leaflets. The results confirmed the presence of various strategies i.e., use of passive voice, long and complicated syntax, vague vocabulary, unknown abbreviations and modal markers that lend ambiguity to the text. It is need of the hour to scrutinize the warning and precaution sections in Patient Information Leaflets. The Drug Regulatory Authority must also provide a template for designing patient information leaflets to maintain uniformity among national pharmacy companies.

Keywords: Ambiguity, Risk communication, Forensic linguistics

1. Introduction

Product liability law is one of the emerging fields in the western countries which empowers the consumers to get informed about the products which have become an integral part of their daily lives starting from household commodities to health care items including medicines. The manufacturers highlight the benefits and advantages of their product and conceal the negative effects on the users. These producers use eye catching statements to grasp the attention of the people thus, increasing the sale value and gaining bigger profits. In Pakistan, an issue was raised against tea whitener companies in the year 2017.The tea whitener is not milk but people used to mistook it for milk since the packing and the color of the tea whitener is same as milk. Unknown of the fact, the common masses used to feed their children on these tea whiteners as the prices were low as compared to other milk products. The use of tea whitener instead of milk especially at their growing stage can only prove harmful to the health of children. The product as to save themselves from litigation only mentioned a statement i.e. "not suitable for children" which is unclear and ambiguous. In March 2018, the chief justice of Pakistan

ordered the tea whitener companies to inform people about the ingredients and clearly mention that it is not milk hence unsuitable for children. This new statement seems to be more explicit and clear. This issue has unveiled different strategies of the manufacturers to sell their product.

In Pakistan, where self-medication is a common phenomenon and drugs whether prescriptive or non-prescriptive can be bought easily from pharmacy stores, so it becomes mandatory to warn the customers from the potential risks of the product but the ambiguity in language hinders the process of comprehension and results in wrong interpretation just like in the case of tea whiteners. This ambiguity is in fact a strategy to save the manufacturers from litigation and to gain bigger profits.

2. Literature review

Product liability law is one of the most interesting areas within forensic linguistics. Ryan (2003) defines product liability as "the legal liability that arises out of the design, manufacture, distribution, sale and disposal of a product". Both the manufacturer and the seller are considered liable if the product harms a person while using it. In these type of cases, the plaintiff has to prove whether the harm is caused by the product or not. Polinsky and Shavell (2009) assert the significance of product liability law by enlisting its three major benefits. Firstly, the manufacturer will improve the quality of the product to avoid any harm. Secondly, the price of the risky products will be increased and lastly compensation will be offered by the manufacturer if any harm occurs to the consumer of the product.

Generally, the field of Forensic linguistics encompasses all the areas where language is used in legal process such as courtrooms, police investigation but in product liability cases, a forensic expert deals with the text of a warning message(R. W. Shuy, 1998). As it is the job of a scientist or psychists to examine the ingredients and their possible effects of any product on a user, but the role of a linguist becomes evident when messages on usage and warning are conveyed by the manufacturers. Determination of meaning in any legal context is one of the fundamental roles played by forensic linguistics. Moreover in Russia, a great number of litigation cases ranging from ransom, suicidal and threat notes to verbal extremism and defamation are solved by employing the various strategies and tools of forensic linguistics. The use of Forensic linguistics by language experts help in disfiguring "ambiguity, disguise and language manipulation" to solve language based crimes.(R. Shuy, 2002).

The linguists analyze the language of the warning provided with the product to see if the product follows the template issued by concerned regulatory authority. Besides the format of the warning, the forensic linguists also check the comprehensibility level of the warning by focusing on ambiguity, vague word choice and complex syntax(Tiersma, 2002). To cater to the needs of users belonging to different cultures and background, symbols and pictograms are also employed in order to convey warning but this also poses a number of issues. Different people of different cultures have different perception about symbols and pictograms which can lead to different interpretations and may bring a manufacturer to go through litigation process.

The term warning has been defined differently in various fields of inquiry. Searle (1979) defines warnings as "statements about future events or states which are not in the hearer's best interest, and which are uttered in situation in which it is not obvious to both the hearer and the speaker that the event will occur or that the state will transpire". In Searle's view, warnings are either categorical or hypothetical. In his view, hypothetical warnings are explicit and clearly predictive as compared to

categorical warnings. Hypothetical are in IF-THEN relationship like if you do not adhere to X, then Y will take place. Dumas (1990)reported that adults who speak English consider hypothetical warnings as stronger than categorical warnings. Lehto (1992) divides varying perspectives into two broad categories. The first view refers to the society as a whole in which warnings are just seen as a vehicle to reduce health damage and accidents by making people equipped with the knowledge of the risks associated with the product. The second view points to the affected parties e.g. manufacturers and consumers. According to Lehto (1992), warnings from the manufacturer's point of view work as a safety tool from lawsuits and litigation. Lehto (2000) also reports warnings can also serve as a replacement for a careful design. Now adequacy is required when consumer perspective comes into consideration. Within adequacy, linguistic factors hold a significant position and measure the extent to which the users follow the warnings mentioned on the product. These linguistic factors include syntax, semantics and pragmatics along with other important variables such as font size, placement and visibility of warnings. Dumas (1990) reported the following adequacy requirement violations in his study on cigarette packages: the failure to explain the intensity of danger, failure to place the warning at a reasonable location, failure to give enough information on avoidance of the danger and the failure to retain "the integrity of the warning by including statements that nullify its impact".

Warnings as proposed by Laughery and Wogalter (1997) not only inform the users but also shape the behavior and influence people's decisions and judgements. Within warnings, the terms risk, hazards and danger are often used. Hazards are those circumstances which may result in illness or injury. The term danger and hazard are related to some extent. If a thing is dangerous, it would give rise to some degree of hazard whereas a risk is defined as the likelihood of occurrence of any mishap. So, perception of risk is very significant as it involves the awareness about hazards, dangers and safety procedures. To avoid any hazard, public safety is ensured by risk communication.

2.1- Risk communication

Risk communication is one of the emerging communication models that transfers information to the public about the issues relating to health hazards and safety. It also focuses on the agents which are a threat to the environment. The concept of risk communication evolved in 1980 in which the hazards were communicated to the common public and the aim was to just warn people but now it is not just one way process. Now it involves participation from both the speaker and the audience as Richardson, Floyd, Jones, and Sheate (2003) define risk communication as a combination of conflict resolution and public participation.

According to Gamhewage (2014), the goal of risk communication is to develop an awareness about the danger to health or oneself through disseminating information or warning which will lead to protective behavior. This is also consumer's rights to know beforehand the dangers and possible hazards in order to mitigate the harmful effects of the product. Several laws under consumer protection act have been passed to bind the manufacturers to warn the users about their product. Another law is product liability law in which the manufacturer is responsible for any damage to the consumer. The manufacturer faces the penalty in case of any hazard if he has not warned or communicated the risk while selling an object. The type of information is always available with the medicine in the form of leaflets or mentioned on the outer covering of the products.

There are three theories on the basis of which a manufacturer can be blamed and liable to pay for the damages.

2.2 Breach of warranty

A warranty is a form of promise or an affirmation which builds a trust in consumers that the warrantor is liable if any damage or defect occurs. Under the product liability act, warranties can be of three types: express warranty, implied warranty of merchantability and implied warranty of fitness for a purpose.

Express warranty can be made both in writing i.e. sales contract and in spoken form i.e. negotiations. It is a sort of affirmation about the quality of the product by the seller which becomes a significant part of the bargain. On the contrary, the implied warranties are imposed by law and presumed by both the shareholders and stakeholders. It is further divided into implied warranty of merchantability which is a confirmation by the seller that the product is fit for ordinary use for which such products are generally used and implied warranty of fitness for a particular purpose. It refers to the knowledge of the seller about the product and the reason to use the product as the buyers rely on the sellers to help them select and provide suitable products. In this way, the seller gives an affirmation and warranty that the said product is fit for the particular purpose.

2.3 Strict liability

It is a recent development in product liability law. In this theory, a person is liable if the product has caused an injury to the user. The focus is on the product only without taking into account the conduct of the manufacturer or any affirmation. Two things are considered: the product being defective and the use of product has led to an injury. So a plaintiff just has to prove that the product is the cause of injury and as a result the manufacturer faces the penalty regardless of how much care does he take in the manufacturing and distribution of the product.

2.4 Negligence

This theory refers to the negligence on part of the manufacturer who fails to follow adequate measures put forward by law for the well-being of common people. It encompasses safe production and distribution of the product from the manufacturer to the seller and finally to the consumer. In other words, it is the obligation of the manufacture to care for its consumers. A manufacturer is expected to be careful in the preparation of the product in appropriate environment and under the supervision of experts. The design of the product i.e. ingredients must also be kept in view so that it fits in the intended purpose. He must exercise extra care in inspecting the ingredients of the product which can lead to harmful effects on human beings and environment. The last duty of the manufacturer as suggested by Kauffman (1969) is to give proper and adequate instructions for its proper usage and warn the users for possible threats clearly and unambiguously.

In other words, a warning must be adequate in terms of necessary warning, size, color, font size and location. It should mention the “hazards from reasonably foreseeable misuse of the product and, where appropriate, antidotes for misuse” (Madden, 1986), According to Ross and ADAMS (1983), now the latest trend is examine the “warning defects under a reasonableness standard regardless of whether the claim is brought in strict liability, negligence or contract/warranty”. One of the warning defects is related to language. The language must be as simple as to be comprehended by an average user and should convey not only the nature of possible hazards but also the extent of it. This type of information and warnings can be seen with the product in the form of a leaflet/booklet or on the outer covering of product’s packaging. These booklets and leaflets are designed to empower the consumer about the potential risks and benefits

2.5 Patient information leaflets and Pakistani law

In the field of medicine, these leaflets are named as "patient information leaflets" or abbreviated as "PILs" which is technical document providing information about chemical composition, dosage, precautions and possible side effects. It is obligatory for every manufacturer to provide PIL designed on a specific template as instructed by Health Ministry of a country. In Pakistan, Ministry of National Health Services Regulations & Coordination plays its role in monitoring drugs design and their manufacturing. The Drug Regulatory Authority has directed the manufacturers to insert patient information leaflets in self-care product, over the counter medicines and food supplements. According to the notification (2017) of Drug Regulatory Authority of Pakistan under Act, 2012 (XXI of 2012), the PILs must include "product information, posology& administration, recommended indications, side effects, contraindications, warnings, precautions, and interactions provided warning or contraindication shall be imprinted at prominent place in a more conspicuous manner." The notification draft (2017) also instructs the manufacturers to mention "warning and caution statements in bold type on contrasting background so that the ordinary person can easily read and understand it. As OTC medicines are sold without prescription from the doctor so the Drug Regulatory Authority directs the pharm manufacturer to give a special place to warning and caution statements so that a common person may easily see and comprehend it. This implies that language of PILs must be simple by keeping in mind the users. According to R. W. Shuy (1998), an adequate warning must name the hazard or risk, inform how to avoid it and what to do if a damage or injury occurs.

2.6 Related studies

Various studies have been conducted in the field of pharmacy to see the effectiveness of patient information leaflets as much priority is given to patient centered care nowadays. Hamrosi, Raynor, and Aslani (2013) conducted a study to explore the needs of patients and their expectation about written medicines information. A survey on 62 participants was conducted by providing them the written medicine information from Australia and other English speaking countries. The findings show that the participants need to make informed choices and to ascertain the suitability of medicines. The leaflets were long and technical and the participants were interested in acquiring accurate side effect information. The researchers also concluded that the written medicine leaflets serve as a tool to empower patients

But these written medicine leaflets or Patient information leaflets are not easy to read as reported byBradley, Singleton, and Po (1994) in their research which they conducted to check the readability of over the counter medicines. Fifty leaflets were analyzed which were available in U.S markets. The participants' age ranged from 10-20 years. The results showed that there is a need to make the instructions as easy as possible.

The results of different studies affirm that the language of patient or consumer information leaflets are not reader friendly owing to the font size, placement and especially language. Cutts (2015) suggests some rules for writing PILs for mass audience. According to Cutts (2015), the sentence length of a sentence should not exceed to 15-20 words, simple and known words which can be understood by parents/grandparents, prefer active voice, use labelled diagrams and avoid acronyms and footnotes. Another important point is to organize the content in reader friendly manner.

After reviewing the relevant literature, it becomes evident that patient information leaflets have been analyzed and examined a lot to see the legibility and effectiveness and how they can benefit a patient. The results affirm that the warnings in PILs are inadequate and unclear. On the other hand, little research is conducted on how these patient information leaflets serve as way of escape from litigation for the pharmaceutical manufacturers. Ross (1983) is also of the view that manufacturers design and provide adequate warnings to save themselves product liability claims. Most of the researches have reported the use of technical language and ambiguity and various attempts to make it simple and comprehensible but this ambiguity from the perspective of the manufacturer has not been yet explored so the present study will look into the various elements which lends ambiguity to the text and a means to save the pharmacy companies from court proceedings.

3. Method

The present study is descriptive and exploratory in nature as it aims to explore various strategies used by the manufacturers to create ambiguity. The study also intends to describe how choice of words and syntax lend incomprehensibility on part of the user. The analysis is done qualitatively by analyzing word level and clause level of fifteen patient information leaflets of prescriptive and non-prescriptive medicines as in both cases precautions and warnings are mandatory. The medicines are collected randomly from Islamabad pharmacy stores. The sample size of prescriptive and non-prescriptive medicines is not older than 2016. Only national pharmaceutical companies are included to check uniformity in warning and precaution format. However, it will also shed light on the effectiveness of Drug Regulatory Authority of Pakistan in enforcing the pharmacy companies to abide by the rules and follow the instructions.

For Ross and ADAMS (1983), a manufacturer may be considered liable if the given warning is not legally adequate. Three characteristics make a warning legally adequate: placement of warning so that it catches the attention of the user, use of such languagethat is understandable and nature of hazard (Tex.App. 1974)

Wogalter (2006) in the book, “Handbook of Warning” has presented a “warning design guidance” after reviewing literature on warnings. He has mentioned six important aspects in a warning namely signal word, message panel format, wording, pictorial symbols, testing and other. As the present study is linguistic analysis so the aspect of wording is adopted for the current study. According to Wogalter (2006), the design guidelines for wording are as follows:

- Give information about the hazard,instructions on how to avoid hazard, and consequences of failing to comply
- Use short, familiar words
- Use as little text as necessary to clearly convey the message
- Use short statements rather than long complicated ones
- Use explicit—tell exactly what the hazard is,what the consequences are,what to do or not do.
- Use concrete rather than abstract words
- Use active voice rather than passive voice

- Use headline style:Remove unnecessary connector words
- Avoid words or statements that might have multiple interpretations
- Avoid abbreviations unless you are sure the target audience knows the meaning
- Use multiple languages when necessary.

In order to check the legal adequacy of the warning in the light of the criteria reported by Ross and ADAMS (1983),the second characteristic i.e. language is analyzed which is used to convey the warning and precaution in patient information leaflets. The language is examined on the basis of the criteria proposed by Wogalter (2006) mentioned above excluding the concrete versus abstract nouns or words since the medicines symptoms and consequences like pain or dizziness are abstract nouns and cannot be excluded from the leaflets.

The data analysis show that all the fifteen patient information leaflets section contain hazards and avoidance but only five leaflets make a mention of consequences. A number of unfamiliar wordsare used relating to scientific terminology and difficult words which can be substituted with easy and familiar words. Six of the leaflets used different heading for different hazards by making the precaution and warning section longer. Rest of the leaflets contained a ten to twelve sentences dealing with hazards and avoidance. Four leaflets were written in simple sentences without using unnecessary connectors and embeddedclauses. As opposed to Wogalter (2006) guidelines,passive voice is prevalent among the fifteen leaflets under analysis.A few instances showed the use of active voice in describing hazards.Avoidance and consequences are seen in passive voice.All the leaflets contained words having multiple interpretation which makes the text ambiguous and unclear.As proposed by Wogalter (2006) for the use of multiplelanguages but the data show the use of just English language on the leaflets.

Medicines		Information			Familiar Words	Little text	Syntactic Simplicity	Active/Passive Voice	Unnecessar connectors
		Hazard	Avoidance	Consequences					
1	Cartigen	Yes	Yes	No	No	Yes	No	Passive	Yes
2	Cytopan	Yes	Yes	No	No	No	No	Passive	Yes
3	Gravinate	Yes	Yes	Yes	No	Yes	No	Passive	Yes
4	Gabica	Yes	Yes	Yes	No	No	No	Both	Yes
5	Nims	Yes	Yes	No	Yes	Yes	No	Passive	Yes
6	Claritek	Yes	Yes	Yes	No	Yes	No	Passive	Yes
7	Metrozine	Yes	Yes	No	Yes	Yes	Yes	Both	No
8	Envepe	Yes	Yes	No	No	Yes	Yes	Both	No
9	Amoxil	Yes	Yes	Yes	No	No	No	Passive	Yes
10	Leflox	Yes	Yes		No	No	No	Passive	Yes
11	Movax	Yes	Yes		Yes	Yes	Yes	Passive	No
12	Risek	Yes	Yes	No	No	Yes	Yes	Both	No
13	Metodine	Yes	Yes	No	No	No	No	Both	Yes
14	Loprin	Yes	Yes	No	No	No	No	Passive	Yes
15	Nuberol	Yes	Yes	Yes	Yes	Yes	Yes	Both	No

Two precaution sections of the two medicines which seem to be representative of the sample size have been discussed in detail in order to highlight the strategies used by the manufacturers.

Warning Design Guideline	Medicines	
	Cytopan	Gabacia
Give information about the hazard, instructions on how to avoid hazard, and consequences of failing to comply	As with other NSAID containing products, diclofenac sodium+ misoprostol combination should be used with caution in patients with a history of cardiac decompensation,hypertensionor other conditions predisposing to fluid retention.	Pregabalin should be discontinued immediately if symptoms of angioedema such as facial, perioral or upper airway swelling occur.
Use short, familiar words	Severe hepatotoxicity may develop without a prodrome of distinguishing symptoms	Pregabalin should be discontinued if myopathy is diagnosed or suspected or if markedly elevated creatine kinase level occurs
Multiple Languages	English only	English only
Use short statements rather than long complicated ones	No adjustment of the dose of diclofenac sodium+ misoprostol combination is necessary in the elderly for pharmacokinetic reasons although many elderly may need to receive a reduced dose because of low body weight or disorders associated with aging	Pregabalin may cause dizziness and somnolence and therefore may have an influence on the ability to drive or use machines or may increase the occurrence of accidental injuries especially in the elderly population
Use headline style	Renal effects, Hepatic effects etc	Weight gain,angioedemaetc
Use short, familiar words	Severe hepatotoxicity may develop without a prodrome of distinguishing symptoms	As it may potentiate the impairment of motor skills and sedation of alcohol
Use active voice rather than passive voice	Patients with cardiovascular disease or risk factor for cardiovascular disease may be at agreater risk	Patients should be told to avoid consuming alcohol
Removeunnecessary connector words	Diclofenac sodium + misoprostol combination should not be used in woman of childbearing potential unless the patient requires nonsteroidal anti-inflammatory drug therapy andis at a high risk	

	of developing gastric or duodenal ulceration or for developing complications from gastric or duodenal ulcers associated with theuse of the NSAID	
Avoid words or statements that might have multiple interpretations	Patients on prolonged corticosteroid therapy should have their therapy tapered slowly. Diclofenac sodium+ misoprostol combination should be used with caution in patients with pre-existing asthma	After discontinuation of long term and short term treatment with pregabalin withdrawal symptoms have been observed in some patients.

The first guideline by Wogalter (2006) asserts the mention of hazard, avoidance and its consequence. The above examples show that hazards have been mentioned but avoidance and consequences are missing. The word "caution" and "discontinue" are used which are not appropriate or in other words helpful to the user if any hazard occurs.

Use of short and familiar words is important as medicines are consumed by general public who are not as learned as a physician, or a pharmacist is. The words like elevated and potentiate can be replaced with high, increased respectively.The word hepatoxicity and hepatic,renal can also be substituted with kidney and liver to make the comprehensibility easier.

Statements with embedded clauses are used in some of the paragraphs that make the sentences longer and difficult to grasp and as opposed to the warning design guideline. The use of unnecessary connectors makes the sentences long and complicated

The headline style has been used in these two PILs as suggested by Wogalter (2006).It attracts the attention of the reader and easy to read.

Mostly the sentences are in passive voice instead of active voice. The modal markers "should be" and "may be" are used which reduces the responsibility of the manufacturer if any accident occurs.Another strategy used by the manufacturers that is evident from the examples is the use of words having multiple interpretations.The words such as prolonged, long term and short term are ambiguous as one cannot specify the exact duration from these words and phrases. The word, "caution" can be seen repetitively in the data which is unclear.

4. Findings and Discussions

After the analysis of the data, it becomes evident that there is no uniformity among the leaflets. Some of the leaflets contain warning and precaution sections while some just have precautions. The length, sequence and format also vary which affirm that there is no prescribed rule and format by Drug Regulatory Authority of Pakistan for the manufacturers for warnings and precautions. According to the

notification draft (2017), warning and caution statements should be in bold and in contrasting backgrounds but the data show non observance as no contrasting background is used. The font size is just the same as of other headings. Only one leaflet of "cytopan" has put the warnings in a separate box which calls the attention of the reader, but no contrasting color or background is used. According to warning design guidance, the manufacturers should use multiple languages where necessary. In Pakistani context, multiple languages may refer to sign language in the form of caution symbols or use of Urdu language as it is widely understood by the inhabitants of Pakistan. In the light of this criteria,the leaflets only make use of English languagethus, failing to comply with the rules. Moreover, the words used in the leaflets are unfamiliar which are not commonly used by the people in everyday lives. The word hepatic injury can be substituted with liver injury as the word liver is more familiar to ordinary man. Renal impairment is also found in most of the warning and precaution section. The word kidney seems easier and more known to people as compared to renal.Hypoglycemia is another technical word which can be substituted with increase in blood glucose. Apart from technical or medical terms, words like mask,inhibit,potentiated, elevated, concurrent etc. are used which may pose problem for common people. There are simple words which can be used to ensure clarity but the use of technical terms and unfamiliar words is a strategy to decrease comprehensibility about hazards and improve sale rate.

Abbreviation usage is discouraged in warnings unless the target audience knows the meaning. The data show the presence of some abbreviations like CNS, CYP3A4, HMG-CoA, INR, GI,ACE etc. which may be familiar to a doctor or a pharmacist but not to a common man. Instead of CNS, the full form central nervous system is comprehended by everyone. The use of abbreviation without providing full form is another strategy to lend ambiguity to the things. As it is evident that central nervous system is a common word but CNS does not seem so. Another abbreviation HIV has been used in the leaflet of Claritek.This abbreviation is known by everyone and needs no explanation or full form. As prescribed by the warning design (1998),abbreviations should be avoided unless the target audience knows it. The unknown and vague abbreviations affect comprehension and make a text unclear. Pires, Vigário, Martins, and Cavaco (2015) also discourage the use of abbreviations in medicinal package leaflets as it can lead to misunderstanding and medication errors.

Another important strategy employed by the manufacturers is to write such words or statements which can give different meanings and interpretations. When a words offers a wide array of interpretations, this lead to ambiguity (Ovu, 2011). The word "caution" has been used in every leaflet but the literal meaning of caution according to online Cambridge dictionary is to "great care and attention". The statements as "Caution should be taken when using Fluoroquinolones" or "combination should be used with caution in patients with a history of cardiac decompensation".In both the instances, the word caution is ambiguous. If we go with the literal meaning,what kind of care or attention one must take? Does caution ask the patient to stop taking the medicine or does it require the patient to give gap of hours or days between different medicines? Here caution is ambiguous but for manufacturer, if caught liable, can give any shade of meaning to the word caution. Another word which seems vague and can give a number of meanings in a sentence is prolonged. For instance, a sentence "prolonged and repeated use of Clarithromycin may result in super infectious with insusceptible organisms". Here the term prolonged is ambiguous. Does prolonged mean a month, six months or a year? The terms short term and long term in "after discontinuation of short term and long term treatment with pregabalin withdrawal symptoms have been observed in some patients" again lack clarity. Can we assume that the

target audience will interpret "short and long term" accurately? For everyone, these terms mean differently.

In the following sentence, the phrase high doses can give different meanings to different people. High doses can be more tablets of greater potency at a time or the use of medicine for a long period. "During the administration of high doses of Amoxycillin, it is advisable to maintain adequate fluid intake." The adjective with the word fluid not only qualifies a noun but lends obscurity.

Manufacturers also use another strategy as mitigating device which play two functions i.e., to save themselves from litigation and to improve their sale by using words that mitigate the effect of the hazards.

"Rarely Nimesulide has been reported to be associated with serious hepatic reactions, including very rare fatal cases".

In this sentence, the words serious and fatal have negative connotations but "rarely" and "rare" act as mitigating devices which weaken the effect of the hazard conveyed. On one side,the hazard has been conveyed which can save the pharma companies from a lawsuit and on another side, the mitigators have reduced the strong connotation of the words to improve marketing valve of the product.

Modality also plays a part in disseminating unclear and obscure information. The use of epistemic modal marker "may" shows possibility (Hegedus,2008) which also weakens the effects of hazards while reading about a medicine. "Skin reactions of allergic type may occur" or "It may cause drowsiness". In these statements, may is used with inanimate subjects. Here the epistemic modal marker "may" shows the speaker's judgement about a proposition i.e. a possibilityto cause skin reactions or dizziness. The use of modal marker with inanimate subjects makes the statements unclear as compared to the use of modal marker "can".The use of "can" shows an ability to cause a harm (Hegedus,2008) but when "may" is used, the potential of causing harm is lost and only a slight possibility is left. This creates a confusion in the minds of the reader as to whether medicines have the ability to harm the patient or in which cases this harm will be possible. The epistemic modal may is also used with adverbs like "Tendinitis may rarely occur". As discussed above, "may" shows a possibility but when accompanied by an adverb rarely further weaken the possibility. The emphasis on possibility serves as marketing strategy to increasesale.On the other hand,the manufacturer has conveyed the effect of medicine so nobody could challenge them.

Another modal marker "should" is used with passive voice. According to Hegedűs (2009), "should" shows a mild obligation than the modal marker "must". It gives a suggestion instead of obligating the patient to do the said action. The use of "should" serves as a tool for self-defense for the manufacturers in lawsuits. For instance, "Pregabalin should be discontinued if myopathy is diagnosed". Here the manufacturers distance themselves by using "should" and passive voice and now it is up to the patient to do the necessary action. In addition to recommendations, prohibition is also provided by the modal "should" which gives rise to unclear instructions. "Clarithromycin, isan inhibitor of metabolizing enzyme CYP3A4, should not be used in patients with a history of acute porphyria." The act of prohibiting is a form of warning and phrase "should not" is not a strong indicator of an effective warning as Ross and ADAMS (1983) suggest that magnitude of the harm must be explained. Moreover, it fails to transmit correct and clear information which will help the manufacturers to build false trust in the audience and to "refuse to accept responsibility and defend themselves against problem resulting from misuse." (Hegedűs, 2009)

Tiersma (2002) suggests the use of imperatives as an effective means of communicating warnings but the data show long sentences in passive voice.Hegedűs (2009) reports that passive voice creates personalization thus maintaining a distance between manufacturers and the target audience.

"Patients should be told to avoid consuming alcohol while on pregabalin". Here passive voice is used to avoid any imposition. This statement also puts the responsibility over the doctor to ask the patient to stop taking alcohol. Now it the doctor who is to be blamed if any harm occurs to the patient. The manufacturer is free from any liability. Nowhere is mentioned that this leaflet is for doctors only but the above statement is addressing the doctor hence distancing themself from the user. According to Bianco (2015), the use of passive voice in leaflets is a deliberate action to impede comprehensibility of the target audience and calling attention towards the harm instead of the originator of that harm.

The sentences are long and complicated which is also a strategy to affect comprehensibility. For instance, "No adjustment of the dose of diclofenac sodium + misoprostol combination is necessary in the elderly for pharmacokinetic reasons although many elderly may need to receive a reduced dose because of low weight or disorders associated with aging". The sentence is complicated as first it is asked not to make any adjustments in the dose then the phrase reduced dose makes it incomprehensible as what is meant by reduced dose.

The important components which a warning must comprise of, according to Tiersma (2002), are nature of hazard, instruction on how to avoid it and consequences of failing to comply. The data confirm the presence hazards but in some cases consequences are missing and others lack instructions or contain vague instructions. In the following example, hazards and consequences are present but instructions are missing.

"Pregabalin may cause dizziness and somnolence and therefore may have an influence on the ability to drive or use machines or may increase the occurrence of accidental injuries especially in the elderly population."

This precaution is inadequate as hazards and consequences are written but lacks instruction. If the medicine causes dizziness, then how to use it.Which time will be suitable for its intake? No instructions may lead to various and wrong interpretation which can be dangerous for the patients.

There are many instances in which there are no hazards and consequences but vague instructions.

"Caution is recommended if levofloxacin is to be used in psychotic patients or in patients with history of psychiatric disease."

The word caution is vague and ambiguous. This word "caution" is an unclear instruction which can be molded into many ways. It can give different shades of meaning depending on the audience. Even this word can also save the manufacturer from litigation as caution may mean low dosage, avoidance or any substitute or supplementary medicine. But the meaning is unclear giving way to various interpretations.

Another instance in which vague information is present but hazard and consequences are missing that again shows inadequacy of warning.

"Diclofenac sodium + misoprostol combination should be used with caution in patients with pre-existing asthma".

It becomes evident from the above results and discussion that manufacturers do provide warning and precautions but fail to give legally adequate warnings to the people. All these strategies help them to mask the potential risks and hazards from the consumers and benefit themselves not only in litigation but also in the market. The presence of the word "caution" in all the leaflets confirm the fact that the manufacturers make use of such words which can give different shades of meaning in different context and particularly various meanings in various lawsuits.

5. Conclusion

Applying Forensic perspective, the patient information leaflets do contain warnings and precautions as prescribed by DRAP but the presence is not enough. If a warning is not legally adequate then it presence is meaningless, null and void. Legal adequacy requires hazard, consequences and instruction in a warning but absence of any component gives rise to wrong interpretation and implicature which can prove dangerous for the patients. In some cases, these three components are present but are fraught with ambiguity. On one hand, this ambiguity may lead a reader to wrong interpretation of any warning and on the other, it serves as a strategy to mold any sentence according to the case filed by the opponent. To create ambiguity, different techniques are employed by the manufacturers in order to make the text difficult to comprehend. The use of technical terms, long sentences, complex syntax, obscure words which lack clarity and precision are used.Moreover, the use of unfamiliar abbreviations further makes the text complex.

It is clear from the use of passive voice that the manufacturers do not want to take the responsibility of any damage caused to the user. The omission of agent and shouldering the responsibility over the patient and in some cases on the doctor unveil the intentions of the pharmacy manufacturers. In addition to passive voice, instructions are not given as orders but as indirect suggestion by leaving on the patients to comply with the indirect instructions or not. This is a strategy to distance themselves from the users.

However, it is concluded that the presence of ambiguity in warnings and precautions of prescribed and non-prescribed medicines is intentional and serves different needs of pharmacy manufacturing companies. Ambiguity helps to increase sale rate and to avoid any kind of legal proceedings. But if viewed from the perspective of the user,this ambiguity is not consumer friendly. It can give rise to fatal incidents. It is need of the hour to scrutinize the warning and precaution sections. The Drug Regulatory Authority of Pakistan must provide a template for designing patient information leaflets as no template is found which is comprehensive and sets an example for the pharmacy companies. Just mentioning the word clarity for the manufacturers as guideline is also ambiguous as to what sort of clarity is required.

The present study just focuses on warning and precautions of prescriptive and non-prescriptive pills in Pakistan. The same approach can be adopted to the whole document to examine the clarity, precision and comprehensibility. In this research, only the language of PILs is analyzed. The visual aspects such as font size, color, placement and style can also be analyzed forensically which will further uncover various strategies of the manufacturer for their safety and can contribute in providing suggestions for a legally adequate patient information leaflet.

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