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ATTENTION! READ IT CAREFULLY! ON THE (IN)EFFICIENCY OF WARNING LABELS

DOUTORADO

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Florianópolis
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UNIVERSIDADE FEDERAL DE SANTA CATARINA
CURSO DE PÓS-GRADUAÇÃO EM INGLÊS: ESTUDOS LINGUÍSTICOS E LITERÁRIOS

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ABSTRACT

Warning labels and Patient Information Leaflets (PILs) play an important role in risk prevention. However, there is evidence that if they are inefficient, consumers are forced to make inferences that may well be different from those intended by the author. Unfortunately, mis-inferences can lead consumers to adopt behavior that results in serious consequences, which could have been avoided by efficient warnings. A recent area in the Law (Tiersma, 2002), product liability, which deals with cases where the consumer suffers any kind of injury, has been attracting the interest of some Forensic Linguists, who have been working as expert witness aiming at evaluating whether the warning labels and PILs inform consumers clearly about either the potential risks or how to use the products safely. Thereby, this study analyzes warning labels and PILs in order to identify the characteristics that can weaken or strengthen warnings. The analysis takes into account the components and structure of efficient warnings in order to check whether individual warnings have all the necessary information. The study then analyzes, with the support of Systemic Functional Linguistic (SFL), how the information is conveyed, that is, if it can successfully influence consumer's behavior. However, there is evidence that the manufacturers are reluctant to provide accurate information about the risks and their consequences in order to protect their profits. But, at the same time, they have to be in agreement with the requirements proposed by the Regulatory Agencies. Thus, in order to cope with these problems, they adopt some strategies to conceal the risks and consequences.

Keywords: Warnings, Patient Information Leaflets (PILs), efficient warnings, Forensic Linguistic, product liability.

RESUMO

As Advertências e Bulas têm um papel fundamental na prevenção de riscos. Entretanto, há evidências de que se elas forem ineficientes, os consumidores são forçados a fazer inferências que podem ser diferentes do significado pretendido pelo autor. Infelizmente, inferências errôneas podem levar os consumidores a adotar um comportamento que resulta em sérias consequências, que poderiam ser perfeitamente evitadas com o uso de advertência eficientes. Uma área relativamente recente do direito (Tiersma, 2002), responsabilidade pelo produto, trata de casos onde o consumidor/a sofre algum tipo de lesão, tem atraído a atenção de linguístas forenses, cujo trabalhado como peritos objetiva avaliar se uma advertência informa os consumidores claramente sobre os riscos potenciais ou como usar os produtos com segurança. Sendo assim, este estudo analiza os rótulos de advertências e as Bulas a fim de identificar as características que podem enfraquecê-las ou fortalecê-las. A análise leva em conta os componentes e a estrutura das advertências eficientes a fim de verificar se as advertências individuais possuem as informações necessárias. O estudo então analiza, com o suporte da Linguística Sistêmico Funtional (LSF), de que forma as informações são transmitidas, isto é, se elas podem influenciar o comportamento dos consumidores. Entretanto, há evidências de que as empresas fornecem as informações sobre os riscos e suas consequências com certa relutância a fim de proteger seus lucros. Mas, ao mesmo tempo, elas devem estar de acordo com as exigências das agências regulatórias. Assim, com o intuíto de lidar com esses problemas, as empresas adotam estratégias para ocultar os riscos e suas consequências.

Palavras-chaves: Advertências, Bulas, advertencies eficientes, Linguística Forense, responsabilidade pelo produto.

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INTRODUCTION

As tatuagens temporárias de hena negra
podem aumentar o risco de alergias
Não ingerir Paracetamol com bebidas
alcoólicas
TOME CUIDADO AO ABRIR, O VAPOR
É MUITO QUENTE! BOM APETITE!!!

The texts above are examples of real product warnings. The first is from a hair dye label, the second from a medicine leaflet and the last one from the label on a popcorn packet.

Given that the main purpose of a warning is to communicate safety information, to lead the users to adopt safer behavior (Wogalter, 2006), an intriguing question emerges: are the above warnings able to lead users to adopt safety behavior? This question also leads me to inquire whether product liability cases actually take into account the efficacy of the warnings attached to the product.

Some of the product liability cases reviewed in this investigation do show that the defendants first ask whether the plaintiff ignored the warnings. However, there is no discussion, let alone dispute about the readability and comprehensibility of the warnings. A typical example is the case of an 11-year-old-girl who had her face scalded by the steam that came out of a popcorn bag and suffered second degree burns on her eyelid and a corneal ulcer in her left eye[1]. The plaintiff had her claim for compensation denied since the girl was held to have failed to comply with the warning on the popcorn bag (see above). Apparently no one questioned the fact that the warning was neither signaled nor noticeable, that is, it was placed at the end of the instructions for use without a signal word to attract the attention; or whether it gave instructions about how to avoid the hazard. In fact, the consequence of the hazard was not even mentioned. The user had not only to infer that the 'hot steam' could scald and severely but also to work out how to to avoid an unstated hazard.

The case above also raises the question about what warnings are, and based on the principle that there is not a clear-cut definition of

[1] CASE: Andrezza Vilas-Boas dos Santos vs Supermercado Mundial LTDA e YOKI alimentos S/A. **Ap. Civ. 0014682-21.2006.8.19.0203** Retrieved from: http://s.conjur.com.br/dl/camara-civel-tj-rj-nega-pedido.pdf

warnings (Dumas, 1990), it is necessary to visit different areas of investigation that deal with warnings, such as ergonomics, forensic linguistics, linguistics and pragmatics, in order to have a better picture. Although some areas share the same purpose, that of improving the efficiency of warnings, each one approaches it based on their own theories and constructs, which will be briefly presented in Chapter Two. In order to conduct this investigation I will adopt a forensic linguistic approach, which is a *multi- and cross- disciplinary field* (Coulthard & Johnson, 2007), and for this reason I will also draw on different areas in order to shed light on my main area of enquiry: the efficiency of warnings.

1.1 CONTEXT OF INVESTIGATION

My interest in Forensic Linguistics was first aroused when I was a 'special student' in Dra. Viviane Heberle's course '*Tópicos Especiais em Análise do Discurso: Análise Crítica do Discurso*', and I read Dr. Coulthard's article 'Forensic Applications of Language Description' (2000). When I began my doctoral studies at UFSC, I had the opportunity to be Dr. Coulthard's advisee, which allowed me to enter the fascinating world of Forensic Linguistics. Studies on warnings immediately called my attention, mainly because for being a compulsive reader of labels I had always believed that they were inefficient.

Unfortunately, being a compulsive reader and a 'warnings researcher' did not prevent an injury to my three-year-old granddaughter, who was severely burned by a firework. I have to confess that I only remembered to read the label after the accident and to my surprise I was in fact not able to read it, due the font size that was literally smaller than a tiny ant (see the picture below). We had always played with fireworks with our daughters, which led us to infer that we did not need to read the labels. However, reading the label would not have helped in this case, because the accident was in fact the result of a technical problem with the firework, not a user mistake. Nevertheless, if the label had informed about the potential severity of the burns, perhaps we would not have allowed our granddaughter to hold it. Thus, this brief story shows how beliefs can influence our daily behavior, which highlights the fact that warning messages should be conspicuous, clear, readable and particularly attractive to readers, only then can the warning hope to change reader's beliefs, otherwise, the warning message will not be complied with.

Picture 1.1: Fireworks Label

According to Tiersma (2002: 54), “product liability is a relatively recent development in the law”. Products can present many risks and the manufacturers and sellers can be held liable if a consumer suffers an injury. In order to improve safety, manufacturers adopt many methods of hazard prevention, such as good design, training and the use of warning labels. However, warnings seem to be a special case, since they function to transfer the responsibility for hazard prevention to the consumer. That is, once manufacturers fulfill the role of providing safety information, the consumer becomes responsible for interpreting and heeding the warnings. This seems unfair, especially when the warnings are unclear or fail to inform consumers about either the potential risks or how to use the products safely.

There are numerous lawsuits reported in the forensic literature where the analysis of warnings was required with the aim of verifying whether the texts warned consumers effectively. That is, the analyst looked to see if the warning was visible, if the language was clear, if it provided all the necessary information, and if the sequence and design gave prominence to the most important information, see: Shuy (1990 and 2008); Dumas (1992, 2000 and 2010), Tiersma (2002) and Coulthard (2012). Interestingly, these studies provide suggestions with the aim of improving communication of safety information, which will be discussed throughout this investigation.

By contrast, the liability cases in Brazil, at least to my knowledge, tend to focus on the provision of information, more specifically, whether the warning labels have the information required by the regulative organizations, as the Pop Corn Case illustrated in the beginning of this chapter. There is no reasoned discussion about disputes regarding how this information is conveyed, albeit the Brazilian CDC (Consumer Defense Code[2]) art. 6 III which stresses that the:

[2] *Código de Defesa do Consumidor.*

> Consumer has the right to receive adequate and clear information about different products and services, with correct specification of quantity, characteristics, composition, quality, price, as well as the potential risks[3]

But, it appears that the CDC evaluation of 'adequate and clear' information relies solely on the correct specification of the information mentioned above, which although important is not sufficient to communicate the risks successfully. It also needs to attract the reader's attention and be communicated in ordinary language.

Investigations that focus on warnings and Patient Information Leaflets (PILs) in Brazil are from various areas: pharmacology and toxicology (Presgrave, 2008), design (Azevedo, 2006) - these studies either analyzed whether the warnings actually included the information required by ANVISA, or examined the type of information they did convey and whether this information was satisfactory (see Chapter 2); Linguistics (Guiradelli & Santos, 2010; Cintra, 2012) - Guiradelli and Santos (2010) analyzed the deontic modality of the PILs. According to the authors, deontic modality refers to the language of the norms, which allowed them to analyze the values of permission, obligation and prohibition expressed in the PILs. Cintra (2012) analyzed and compared Brazilian and German medicine leaflets (see Chapter 4). There are also other studies that investigated PILs (Paula et al, 2009; Fujita & Spinillo, 2008; Fujita, 2006), but these were concerned with matters of design (see Chapter 4).

I have, however, found no studies focusing on how the information is conveyed, in terms of linguistic features that can facilitate the understanding of and compliance with the warning(s). In order to fill this gap, I will analyze some medicine leaflets in Chapter 4 and product warning labels in Chapter 5 in order to verify if readers are able to receive, understand, and comply with the information.

1.2 IDENTIFICATION OF THE PROBLEM

The number of people who suffer consumer accidents [4] is astonishing; for example, there were 36 million accidents in the United States in 2012, alone roughly one for every 9 inhabitants. Unfortunately,

[3] My Translation.
[4] "Consumer accidents occur when a product or a service cause injury to the consumer's health". INMETRO.

accurate information about the numbers and consequences of consumer accidents is not available in Brazil. A system for monitoring accidents was created by INMETRO in 2006. The victim needs to access INMETRO's web page to report the accident, but few people know about it and even fewer actually bother to do so. Only at the end of 2013 did the Ministries of Health and Justice announced the creation of a hospital-based system to register accidents and their causes. Certainly, such data should help the state and the manufacturers to improve safety measures.

Accidents occur for many different reasons, but principally due to products that were poorly designed, consumers who handled the products wrongly, or ineffective information about how to use the product properly. Sometimes this information is not visible, or it is difficult to read because of physical properties such as font size, color, allowance of 'white space', etc. At other times the texts are linguistically too complex for an 'ordinary person' to understand. There are also, obviously, cases of consumers who can read and understand the information, but choose not to comply with it.

Both the readers' willingness to read and to comply with what they read depends on what information is presented in the text, on how this information is presented and on what the readers understand and believe. They may simply give up reading if they face difficulties, such as blurred text and small font size or if they cannot understand the text, due to complex sentences and technical terms. Moreover, if they believe that the information is irrelevant, they might also avoid reading. There are many other factors that can influence the reader's compliance, and it appears that the writer's position regarding the risks, that is, their evaluation of the level of severity of the risks, the importance of following the directions given and the likelihood of the risks occurring, is paramount if the goal is to obtain compliance with the warnings.

Now, after reading a lot of warnings and a great deal about warnings, I realize that my self-concept of being an 'attentive reader' should be reviewed, mainly due to the fact that my favorite painkiller, 'Paracetamol', is not as safe as I had imagined. Let me explain: I have chronic sinusitis and I usually take Paracetamol to relieve my headaches. But, shamefully, I have to confess again that I had never read the PILs for Paracertamol. However, one day I decided to read the PILs of a box of Paracetamol that my husband bought in the USA. I was astonished to find that overusing it can cause severe liver problems, and that the

combination of paracetamol and alcohol can lead to liver failure. The *British Journal of Clinical Pharma*cology[5] reported research involving 663 patients with liver damage and concluded that 75% of the damage had been caused by the use of Paracetamol. This finding motivated me to investigate how the PILs of Paracetamol and 5 other over-the-counter medicines warn about the risks, because I assume that, like me, there might be many other people who do not read the PILs of painkillers.

I also decided to investigate the warnings of three other kinds of personally relevant products: fireworks, for the reasons I have already mentioned; hair dyes, because my daughter wanted to have her hair dyed and I had to reread how to do the 'patch text' in order to understand it; and finally, food labels, in order to be able to provide an adequate diet for my granddaughter, who has diabetes.

1.3 THE PURPOSE OF THE RESEARCH

The main purpose of this Research is to evaluate the adequacy of product warning labels. However, in order to evaluate them, it is necessary first to analyze comparatively two sets of guidelines for warning labels and PILs, one set from Brazil (ANVISA[6], ABNT[7], INMETRO[8]), and the second from the United Kingdom (NHS[9], MHRA[10]). In this way, it will be possible to verify both whether the warnings and PILs contain the information required by the guidelines and whether some warnings are communicatively superior to others.

Besides evaluating warnings, it is essential to take into account the message and the recipients (consumers), which are intrinsically related. Thus, this study also aims at evaluating the textual features to verify if they: 1) increase the difficulty in understanding the texts; 2) attract the consumer's attention; 3) influence compliance. Finally, based on the results, this study intends to provide suggestions to improve the guidelines and the product warning labels.

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[5] Retrived from: http://www.jornalciencia.com/saude/corpo/1130-paracetamol-um-perigo-para-o-seu-figado

[6] ANVISA (*Agência Nacional de vigilância Sanitária*);

[7] ABNT (*Associação Brasileira de Normas Técnicas*);

[8] INMETRO (*Instituto Nacional de Metrologia, Qualidade e Tecnologia*);

[9] NHS (National Health Service);

[10] MHRA (Medicines and Healthcare Products Regulatory Agency);

1.4 THE RELEVANCE OF THE RESEARCH

The evaluation of the guidelines, the warning labels and the PILs will provide a general picture of how safety information is conveyed in Brazil and the UK. Thus, based on these results, it will be possible to give evidence-based advice on how to improve warnings, which consequently should reduce the injury rate.

1.5 OBJECTIVES

The main objective of this investigation is to evaluate the efficacy of warning messages conveyed in Brazilian product labels, as well as Brazilian and English PILs, which leads to the following specific objectives:

- Investigate real cases of consumers who suffered accidents in order to verify if they occurred due to problematic warnings;
- Analyze whether the warnings are in agreement with the guidelines;
- Investigate whether the warnings draw attention and are intelligible;
- Analyze whether the warning messages have all the components necessary to inform the consumers about the risks and the ways to avoid them;
- Investigate whether the textual features and the vocabulary and/or grammatical choices influence the comprehension of and compliance with the warnings;
- Compare the PILs from Brazil and the United Kingdom;
- Provide recommendations to increase the effectiveness of warnings.

This study will offer a better understanding of product warning labels and PILS, focusing in particular on the characteristics that can weaken or strengthen a warning. Furthermore, the results will provide an alert both to the regulatory agencies, which will then be able to better review their norms in terms of comprehensibility, and to the manufacturers, who can produce warnings and PILs that communicate more efficiently.

1.6 RESEARCH QUESTIONS

The objectives of this investigation can be translated into one general research question:

Are both the PILs and the warnings adequate to warn the consumers about the potential risks of the products? which unpacks into five specific ones:

1) Are the PILs and the warnings written according to the guidelines?
2) Are the guidelines (ANVISA, MHRA, ABNT) adequate to ensure that good quality warnings are produced?
3) What are the similarities and differences between the Brazilian and UK PILs?
4) Which characteristics make the warnings stronger or weaker?
5) Which characteristics can increase the likelihood of reader compliance?

1.7 OUTLINE OF THE DISSERTATION

Chapter 2 presents the theoretical foundation that is the basis of this investigation. In an attempt to provide a definition of warnings, different areas of study are visited, such as: Ergonomics, Pragmatics, Linguistics and Forensic Linguistics. Then, a discussion of the components and characteristics that render the warnings efficient is presented. The last two sections of the chapter present some cases in the area of Forensic Linguistics (Shuy, 1990 and 2008; Dumas, 1992 and 2010; Coulthard, 2012) and Ergonomics (Laughery &Wogalter, 2014), as well some studies in the areas of design (Azevedo, 2006) and Pharmacy (Presgrave et al., 2008; Presgrave, Camacho & Villas-Boas, 2009).

Chapter 3 describes the criteria for data collection and analysis.

Chapter 4 consists of the analysis of the PILs, and is divided into three sections. The first presents the Guidelines provided by MHRA (England) and ANVISA (Brazil) and the analysis of the Structure of the PILs; the second presents the analysis of the warnings and the characteristics that can weaken and strengthen them; and the third provides the analysis of modality in order to verify how the interpersonal meanings are construed.

Chapter 5 presents the analysis of product warning labels, and is also divided into three sections, each one focusing on a different product: fireworks; hair dyes and food labels.

Chapter 6 offers suggestions for improving the warnings of product labels, PILs and also the guidelines.

Chapter 7 presents a summary of the results and revisits the research questions.

CHAPTER TWO
REVIEW OF LITERATURE

Forensic Linguistics is a recent discipline that was born in 1968 with Jan Svartvik's report, which showed, through authorship analysis, that the incriminating statements "had a grammatical style mensurably different from that of the uncontested parts of the statements" (Coulthard, 2000: 317). The first years of the discipline were marked by few studies that demanded a great intellectual effort, as it required the creation of a method of analysis. The discipline evolved rapidly in the last years and linguists are regularly required to act as expert witnesses in a great varied of cases (ibid).

As mentioned in chapter 1, forensic linguistic is a "multi- and cross- disciplinary field" (Coulthard and Johnson, 2007:06) that draws on different disciplines, such as: law, phonetics, discourse analysis, morphology, syntax, sematics and pragmatics, to solve problems related to two main questions: "What does a given text say?" and "Who is its authors?" (Coulthard, 2000:318). This study concerns the first question aiming at verifying how the warnings inform consumers' about risks. Section 2.4.2 provides a brief summary of cases in which forensic linguists were called to express their opinions about the efficiency of the warning labels.

2.1 WARNING DEFINITION

There are various methods that can be employed to avoid hazards, and the use of warnings is just one of them. In fact, Wogalter (1999) observes that other methods of hazard prevention are more efficient than warnings and should be employed as a first alternative. The best method is "to remove or design out the hazard so that users are not [even] exposed to the danger" (Wogalter, 1999, p. 93). However, it might be impossible to remove all potential hazards and/or it might increase the product cost unacceptably. Besides, allowing an unsafe product to continue in the marketplace may bring more benefits to consumers than actually banishing it. The next method is to "place some kind of barrier between people and the hazard" (Wogalter, 1999, p. 94), and the last one is to provide individuals with specific training to inform them how to use the product properly. However, sometimes these methods are not viable or even possible and for this reason a warning is required.

Manufacturers are responsible for hazard prevention and legally responsible if the consumer suffers any harm or damage. However, warnings seem to be a special case, since as we noted above, they transfer the responsibility for hazard prevention from the manufacturer to the consumer. This seems unfair especially when the warnings are unclear or fail to inform consumers about the potential risks.

The literature concerning warnings is vast and comes from different areas of expertise, like linguistics, human factor analysis and design. I will address these three areas to have a better understanding of the nature of warnings. I will first provide an overview of the literature related to warnings, which I divided into three parts: in the first part I discuss what is involved in the definition of a warning. Then I will make a brief overview of Systemic Functional Linguistics (SFL) with a focus on modality, which will be used in the analysis to investigate how interpersonal meanings are construed in warnings; in the second I address the components of an effective warning; and in the last I discuss the characteristics of effective warnings, some product liability cases and studies that involve the adequacy of warnings.

As mentioned above, there are many academic areas concerned with warnings. In the human factors literature, Wogalter (2006, p. 03) states that warnings are "safety communications used to inform people about hazards so that undesirable consequences are avoided or minimized". In this vein, they not only inform about the risks, but also persuade the readers to use the product properly.

In the area of forensic linguistics, Shuy (2008) argues that warnings: "should identify and describe the nature and danger of the risk. Then they should tell the reader how to avoid it. Finally they should communicate those things in clear and understandable language" (p. 72). Thus, there is a consensus in both areas that the communication of hazards, as well as how to avoid them, is crucial to warnings.

However, a comprehensive definition of the term 'warning' has not yet been produced. Dumas (1992, p. 267) asserts that "no discipline recognizes a clear, unambiguous definition of warning". The author points out that this vagueness is a consequence of the fact that the act of warning may be "confused with instructing, persuading and advising". For example, the warning provided by Dumas (ibid) 'keep the product out of the reach of children' has at the same time the triple functions of warning, instructing and advising. In this way, it is possible to say that the activity of warning possesses more than one function (ibid).

Although there is no clear-cut definition of warning, the proposals of Searle (1969) are, for authors like Dumas (1992) and Shuy (1990), an

essential departure point for any discussion of the subject. Searle developed his description from Austin's theory of speech acts, which will be discussed below.

2.1.1 Speech Act Theory

Speech act theory was developed by the linguistic philosopher Austin (1962), who argued that when people communicate, they not only produce grammatical utterances, which used to be the main concern of linguists at the time (Coulthard, 1983), but also perform actions by means of these utterances (Yule, 1997). His theory starts from a distinction between constatives and performatives. While constatives are sentences that describe things, look like statements and can be evaluated as true or false, as in "the king of France is bald" (Coulthard, 1983:13), performatives are utterances that have the verb in the simple present active form with a first person singular subject (Coulthard, 1983) and are neither a description nor a statement but perform an action, in the sense that in saying the speaker is doing something. Although they are not subject to a judgment of truth or falsehood, they are evaluated in relation to certain conditions, "they need to be said in the proper context or environment, proffered by someone authorized to do so, and uttered in the performative manner" (Gales, 2010, p. 07). For example, if an ordinary person utters the statement 'I declare you man and wife', the act is not performed since s/he does not have power to do so. Furthermore, the statement must be uttered in an appropriate situation. Thus, this utterance would be regarded as infelicitous (Guimarães, 2002).

However, there is a group of performatives, which does not have these features, that is, "there are no rule-governed conventions restricting their use, as the speech act 'promise', since anyone can make a promise to anyone in any place at any time" (Coulthard, 1983, p.14). Likewise, the form 'I + present simple active', as in 'I promise to come', is not applied to all speech acts. The utterance 'guilty' is an example of the kinds of utterance that do not have the structure just mentioned and for this reason, they can create a problem of recognition. On the other hand, explicit performatives are easier to recognize since the action is announced by a performative verb, as in the warning 'I <u>warn</u> you that the dog is angry'. But, there are cases when the performative verb may either differ from the speech act or create difficulties for the hearer in identifying which speech act is actually being performed, like 'I promise

you that if you don't finish your homework you won't watch TV', which seems to be a threat rather than a promise.

Austin, then, presents three kinds of acts that can help in the identification of the performative. He states that uttering is actually performing three acts simultaneously:

A locutionary act: it is the act of saying something; an illocutionary act: it is the act performed when someone says something; a perlocutionary act: it refers to the effect produced on the listener, which is a consequence of the locutionary and illocutionary acts (Coulthard, 1983). For instance, in the warning: 'Danger! Bathers in this area are at a greater than average risk of shark attack' seen on a beach sign, the locutionary act refers to the enunciation of the statement about the risk of sharks whereas the illocutionary act is the act of warning; finally, the perlocutionary effect is the reader choosing to follow the information, or not. Evidently, the speaker cannot control the effect of their utterance.

Searle (1969) developed his theory from Austin's ideas. He counter-proposes that when people communicate they perform two acts: a propositional act and an illocutionary act. But he rejects the locutionary act proposed by Austin (apud Coulthard, 1983). While the propositional act corresponds to the content, which includes predicating and referring, the illocutionary corresponds to the acts performed through language, such as: promising, warning and threatening. Searle observes that many propositional acts can be performed in one illocutionary act, as in these three acts of promising: "I promise I'll buy a car, I promise I'll visit you, I promise I'll help you" (Guimarães, 2002, p. 41). At the same time, one propositional act can be performed by means of various illocutionary acts: "John did his homework"; "Did John do his homework?"; "Do your homework, John".

Searle points out that some illocutionary acts can be performed without being marked by a performative verb at all, such as 'hot', written on a cup of Starbucks coffee. In this way, a distinction between indirect and direct speech acts is proposed. In the first type, there is no relationship between the form and the function, whereas in the second type there is. Although both types might lead to miscomprehension, the probability of such a problem is greater with indirect speech acts. For this reason, direct warnings are to be preferred if the aim is to ensure listener/reader understanding, which Searle calls 'illocutionary effect'.

Starting from the premise that "talking is performing acts according to rules", Searle (1969, p. 22) builds the structure of illocutionary acts by providing a systematic analysis of the act of

making a promise. This construct is based on the propositional content and a set of conditions: preparatory, sincerity and essential. From these conditions, it is possible to extract the rules that govern a particular speech act. In this way, in order to be understood, a person should produce an utterance under these rules.

Searle uses the same framework to analyze other types of speech act. According to him, a warning must be about a future event, which is the propositional content. Then, some conditions are necessary for the recognition of a warning: that the speaker has reason to believe that the event will occur and that it is not in the hearer's best interest; that it is not obvious to participants that the event will occur; and that "the utterances change your state from non-informing of a bad event to informing" (Yule, 1997, p. 51). Thus, a warning that does **not** inform about a bad event fails for not taking into account one important conventional condition. Therefore, Dumas (1992) classifies this statement on a US cigarette packet "Quitting smoking now greatly reduces serious risks to your health" as a non-warning and suggests that it looks like a promise since the consequence is to the advantage of the hearer/reader.

2.1.2 Similarity

The uncertainty about a definition of warning also starts with the issue that the boundaries between *warning, threat* and *promise* are not clear-cut. There are some points when they converge (Fraser, 1998), for example: all of them refer to a future action, but only threats and warnings aim to direct or influence the addressee's behavior (Storey, 1995; as cited in Chong Ho Shon, 2005).

Fraser proposes that a warning involves the speaker expressing to the addressee:

> 1 the belief that some unfavorable state of the world exists, or will exist;
> 2 the belief that this state of the world is unfavorable to the addressee's best interest;
> 3 the intent to inform the addressee before a harmful effect can ensue. (1998: 164).

As can be seen, it is expected that a warning brings "to the addressee's awareness a state of the world", which is unfavorable (Fraser, 1998, p. 165). Sometimes this awareness may cause

apprehension or even fear, as in the case of this warning on a gas grill "Flammable gas under pressure leaking LP gas may cause a fire or explosion if ignited" (Coulthard, 2012). However, the fear caused by this warning derives from the state of the world, it is not created intentionally by the speaker/writer with the aim of threatening or intimidating. In fact, the sender aims to inform the hearer/reader about the harmful effect of flammable gas.

Fraser's definition is similar to Searle's in two main points, 'the belief that a bad event will occur' and that 'it is not in the addressee's best interest'. However, Fraser's definition seems to encompass the purpose of warnings, given that "the intent to inform the addressee before a harmful effect can ensue (1998: 164)" includes implicitly that an action should be performed in order to avoid a bad event, and that this action is triggered by the warning, whereas Searle's definition seems to be only at the level of information, i.e., "the utterance changes your state from non-informing of a bad event to informing" (Yule, 1997: 51).

Fraser also (1998, p. 171) proposes a threat definition, where the speaker must express:

> 1. The intention to personally commit an act;
> 2. The belief that the results of that act will affect the addressee in an unfavorable way;
> 3. The intention to intimidate the addressee through the awareness of the intention.

It can be perceived that in a threat, the speaker commits him/herself to do the action, as in: "If you don't stop seeing Juliet, I'll kill you" (Salgueiro, 2010, p. 217). The similarity between threats and warnings lies in the second condition, since in both types the result is unfavorable to the addressee. A crucial condition that determines whether a given utterance functions as a threat is power and authority (Fraser, 1998). However, the person who makes a threat must also have the necessary conditions to carry out the threat. If an ordinary person says, "I'm going to write you a parking ticket" (Chong Ho Shon, 2005, p. 831), the threat will be infelicitous, because the person has no authority to utter such a threat statement.

Sometimes the line that divides *warning* from *threat* is tenuous and the distinction between them can only be made depending on the speaker's intention: if s/he aims at intimidating the addressee, it is a threat; but, if s/he aims at informing the addressee about a harmful

event, it is a warning (Fraser, 1998). For example, the statement "If you don't improve your performance, you will lose your scholarship" can be either a threat or a warning, it depends on the listener's perception of the speaker's intention, that is, the hearer can believe that the speaker is being either benevolent and wants only to warn about a bad situation, or that he speaker is cruel, aiming at intimidating the listener. But, as pointed out by Coulthard (1983, p. 19) "neither listener nor analyst can ever be sure of the speaker's intention, because it is never available for examination", and for this reason, an attempt to differentiate a warning from a threat might be unsuccessful. For this reason, other sources of information need to be taken into account, like the context. Gales (2010, p. 14) argues that it is difficult, if not impossible, "to construct a context-independent definition of threat (Storey, 1995, p.74)".

Fraser proposes that warnings, promises and threats can be differentiated if benefit and control are also taken into consideration, as in the table below.

The act is oriented	**Threat**	**Warning**	**Promise**
To the speaker's benefit	No	No	No
To the addressee's benefit	No	Yes	Yes
To the speaker's detriment	No	No	No
To the addressee's detriment	Yes	No	No
Speaker controls outcome	Yes	?	Yes
Addressee controls outcome	?	?	?
Speaker committed to act	No	No	Yes

Table 2.1 (Fraser 1998, p. 166)

Warnings are also like promises when they refer to an act that can benefit the addressee. It should be pointed out that, in the case of warnings, the action is normally going to be undertaken by the addressee, who can choose whether to perform the action, or not. In the case of promises, the action is undertaken by the speaker, who is committed to perform it. At this point, promises and threats converge, since in both types, the speaker is committed to perform the act. The difference between them derives from the fact that promises are beneficial for the addressee and threats are detrimental. When the focus is turned to the speaker, Fraser states that none of the speech acts shown in his table benefit him/her, a fact that is contested by some authors, like

Gales (2010), who argues that once the speaker has the power over the listener, s/he is benefitting from the exchange.

Finally, when the addressee's control is considered, some uncertainties emerge when warnings, threats and promises are conditional, since s/he is able to control the outcome, as in the threat "drop your gun or I'll shoot you". Nonetheless, the speaker can break the condition on the threat and shoot even if the addressee drops the gun. Of course, in this case, the speaker would violate the Gricean Maxim of quality, "which requires the speaker to tell the truth and the hearer to assume the truth is being told [However, this maxim] is not always adhered to in the case of threats (Storey, 1995; as cited in Gales, 2010, p.11)".

The Gricean Maxim of quality mentioned above is derived from a cooperative principle that orients conversational contributions:

> Make your conversational contribution such as is required, at the stage at which occurs, by the accepted purpose or direction of the talk exchange in which you are engaged. (Grice, 1975: 45).

Based on his general principle, Grice, then, distinguishes four main categories: Quantity, quality, relation and manner.

1. Maxim of quantity refer to the amount of information to be provided, and requires the writer to:

> Make the contribution as informative as is required;
> Do not to make the contribution more informative than is required (Grice, 1975: 45).

Violation of this Maxim is frequently observed in warnings, mainly due to lack of information, forcing the readers to infer the missing information. As pointed out above, too much information also violates this Maxim as it can confuse readers. The great amount of information provided by most PILs clearly confuses readers.

2. Maxim of quality concerns the truth of what is being uttered, and requires the writer to:

> Do not say what s/he believes to be false.
> Do not say that for which s/he lack adequate evidence (ibid: 46).

3. Maxim of relation refers to the relevance of the information. Shuy (1990: 296) notes that "relevance to the writer (..) may be quite different from relevance to the reader". This is because writer and reader have different purposes, knowledge and experiences. For this reason, the writer needs to write their texts based on the reader's needs.

4. Maxim of manner concerns to "how what is said is to be said" and requires writer to (Grice, 1975: 46):

> avoid obscurity of expression;
> avoid ambiguity;
> be brief (avoid unnecessary prolixity);
> be orderly.

Both warnings and PILs seem to violate this Maxim due to the amount of technical terms that render the texts obscure.

2.1.3 Characteristics of Warnings

Another feature that can render warnings ambiguous is the fact that a "warning may be either direct or indirect and either literal or nonliteral" (Dumas, 2010, p. 365). Many of them depend on the context, for instance, in the statement 'there is a policeman at the corner' (Mey, 2001), the hearer will only interpret it as a warning if s/he committed a traffic violation, while some warnings need a certain degree of inference in their interpretation, such as "Cigarette smoke contains carbon monoxide" (Dumas, 1992, p. 269). In this statement, the reader needs first to know what carbon monoxide is and the effect of this substance on his/her body, in order to further infer that it is harmful to his/her health.

Dumas also posits a distinction between *categorical* and *hypothetical* warnings. The first has the purpose of advising, that is, informing "hearers or readers that certain results will follow certain modes of behavior" (2010, p. 365) as in "the Surgeon General has determined that smoking is hazardous to your health" (Dumas 1992, p. 278), whereas the second implies a request, following the structure "if X, then Y" implicitly, like in the statement "smoking causes lung cancer, heart disease, emphysema, and may complicate pregnancy" (p. 278).

Tiersma (2002) suggests that there are two types of warning: *imperative* and *informational*. The first is clearer in relation to the prevention of danger, like in the hair dye warning 'do not use to dye

eyelashes or eyebrows', which indirectly tells the reader that the product involves some kind of risk, but the actual risk is not made explicit. The second has the function of informing, that is, it advises that a product may pose some type of risk, as in the hair dye warning 'this product can cause an allergic reaction, which in rare instances can be severe'. However, it is less clear in relation to prevention. In both types, the reader needs to infer some meaning, either in relation to the risk or about how to avoid it.

So, which type of warning is more effective, imperative or informational? Tiersma (2002) states that it depends on the situation, that is, there are some occasions when an imperative warning would be inappropriate or "politically problematic" (p. 64). The author also reinforces that an "effective cigarette warning would be both imperative and informational: 'do not smoke cigarettes, smoking can kill you'" (p. 64). Dumas and Tiersma agree that when it is impossible to use both types of warning, the imperative is to be preferred, since it tells the consumers how to avoid the risks. On the other hand, sometimes the use of both types is redundant, and might generate doubts in the consumers, because they may wonder if they have understood the warning properly, since the same information is apparently presented twice in different formulations.

As can be seen, there is no consensus in relation to the definition of a warning, even in the same field. As I am interested in warnings of consumer products, I should take into account **the readers**. Thus, my definition is based on the definitions proposed by three authors. I agree with Searle (1969) when he says that a **warning is about a bad future event**, and with Shuy (2008) when he notes that a **warning should tell the nature of the risk and how to avoid it**. He also adds that this information **should be written in clear and comprehensible language**. Finally, as the readers need to comply with the warnings, I conclude the definition citing Tiersma's, in that a warning should **catch the reader's attention**.

2.2 MODALITY

As mentioned in the previous section, a warning is about a bad future event, where the sender is in charge of 'informing' the receivers about it, by either telling them of the hazards (informational warnings) or telling them how to avoid the hazards (imperative warnings). This dichotomy is also presented in Halliday's Systemic Functional

Linguistics (1994) under the names of 'information' and 'goods-&-services'.

When discussing the purposes of a communicative exchange, Halliday (1994) proposes four basic speech roles, which are divided accordingly to the type of commodity being exchanged. The first type of exchanged is **information**. Thus the participants can either (1) **give** or (2) **demand** information. The second type of exchanged is **goods-&-services**. The participants can either (3) **give** goods-&-services or (4) **demand** goods-&-services (see Table 2.2).

role in exchange	commodity exchange	(a) goods-&-services	(b) information
(i) giving		offer Would you like this teapot?	statement He is giving her the teapot.
(ii) demanding		command Give me that teapot!	question What is he giving her?

Table 2.2: Basic speech roles (Halliday, 1994: 69)

One important function of the message is "its meaning as an exchange" (Halliday, 1994: 68), where language is seen as a two-way system (Thompson, 2002), that is, when the subjects involved in the communication interact. For this reason, Halliday (ibid) notes that "an act of speaking is something that might more appropriately be called an **interact**" (p. 68). For instance, with a command, the writers of warnings and PILs expect the readers to follow it. In this case, the commodity exchanged is non-verbal, because "what is being demanded is an (…) action" (ibid: 68). On the face of it, it is possible to say that in both warnings and PILs, the writers wish the readers to adopt behavior that can minimize or prevent risks, basically through statements and commands.

As can be seen, the participants involved in the communicative exchange are the writers, who are specialists and represent the manufacturers, and the consumers, who are ordinary readers who sometimes possess little linguistic knowledge and very often little knowledge about the content. Obviously, there is a great difference in terms of knowledge and therefore power between the participants. The mood analysis informs about how the relationship between the participants is established, whereas modality informs how assertive the writers are in their proposition and proposals.

According to Halliday (1994: 356), "modality refers to the area of meaning that lies between yes and no – the intermediate ground between positive and negative modality". The examples below illustrate an (i) unmodalised warning and a (ii) modalised one.

(i) Do not take Paracetamol tablets and tell your doctor if you are allergic; (A10)

(ii) Taking painkillers for headaches too often can make them worse; (A10)

As can be seen, a choice is not given to the reader in (i), whereas in (ii), a probability is raised with the addition of the modal operator 'can'.

Halliday distinguishes two types of **modality**, the first, named **modalisation**, concerns the exchange of **information** and "relates to how valid the information is in terms of **probability** (how likely it is to be true) or **usuality** (how frequently it is true)" (ibid, 57). Warnings and PILs contain both types of **modalisation**, as can be seen in the examples below.

'This medicine contains: Methyl and propyl parahydroxybenzoates – some people are allergic to these (the allergy may happen some time after starting the medicine)' (A3).

'Taking a painkiller for headaches too often or for too long can make them worse' (D 14).

The first is an example of probability, in which the employment of the modal operator 'may' suggests that the likelihood of an allergy is low whereas the second exemplifies usuality by the use of the mood adjunct 'often'.

The second type of modality, which is called **modulation**, concerns the exchange of **goods-&-services** and "relates to how confident the speaker can be in the eventual success of the information" (Halliday, 1994: 57). Modulation is also present in warnings and PILs, especially in terms of **obligation**, as in (D13) below. The modal operator 'should' employed in the second warning also puts on the consumers a higher pressure to follow the direction, although it would be even higher if the modal operator 'must' were employed.

'You should check with your doctor or pharmacist if you are not sure' (D13).

On the other hand, the second axis of modulation, called **inclination**, which "concerns the degree of willingness or inclination of the speaker to fulfill the offer" (Halliday, 1994: 57), rarely appears in warnings and PILs.

"...take them to your local pharmacist who *will* dispose of unwanted medicines for you". (Hegedüs, 2008: 131)

Value is an important component of *modality,* which "signal[s] a higher or lower degree of certainty about the validity of a proposition; or a higher or lower degree of pressure on the other person to carry out a command" (Thompson, 2002: 59). There are three values, **high – median – low**. The analysis of value is paramount in this investigation, given that the degree of pressure can certainly influence the reader's decision to comply with the warnings and PILs. Whenever the writers modalize/modulate the proposition/proposal they raise a certain amount of doubt in the minds of the readers, even if a high modal marker is used. In order to exemplify, Halliday (1994: 363) notes that, paradoxically, the addition of 'certainly' in "*Mary's certainly left, (...)* adds an element of doubt". The table below summarizes the values.

	Probability	Usuality	Obligation	Inclination
High	certain	always	required	determined
Median	probable	usually	supposed	keen
Low	possible	sometimes	allowed	willing

Table 2.3: Three values of modality

"Aspirin should not generally be given to children under 16, but doctors may occasionally prescribe it" (C17)

The use of modality is glaring in the warning above. First, the command is twice modalised by the use of the modal operator 'should' and the modal adjunct 'generally', which weaken the command. In the second part of the warning, the combination of 'may' and 'occasionally', two modals with a low value, is used to justify the prescription of aspirin.

Polarity can be manifested in clauses in terms of negative or affirmative. Negatives can be expressed with the addition of the elements (n't or not) or even with the modal adjuncts 'never' or 'hardly' (Thompson, ibid). Moreover, negatives can be further distinguished in terms of (i) direct or (ii) transferred (Halliday, 1994: 359).

(i) I think Mary doesn't know.
(ii) I don't think Mary knows.

TYPE	modalization	probability
		usuality
	modulation	obligation
		inclination
ORIENTATION	subjective	
	objective	
	explicit	
	implicit	
VALUE	median	
	outer	high
		low
POLARITY	positive	
	negative	direct
		transferred

Table 2.4: Halliday's Modality system (Halliday, 1994: 360)

This network of modality proposed by Halliday generates a set of "4 x 4 x 3 x 3 = 144 categories of modality" (Halliday, 1994: 359).

2.3 COMPONENTS OF WARNING LABELS

In order to offer the industry an appropriate standard, some organizations provide guidance about how to produce an efficient warning. ANSI (American National Standard Institute) and ISO (International Organization for Standardization) are the best known standards. In Brazil, the ABNT[11] (*Associação Brasileira de Normas Técnicas*) is the Brazilian organizations responsible for technical standardization. It is important to note that these organizations are not responsible for the guidelines, but they certify the quality of the products. Although ISO is an international organization, many Brazilian products apply for this certification, which enhances national and international competition. The guidelines are provided by government agencies, such as ANVISA in Brazil and MHRA in the UK (a description of them will be offered in chapters 3 and 4).

[11] http://www.abnt.org.br/certificacao/o-que-e

ANSI's requirements for safety labels consist of four textual components: 1) a signal word, like: *notice, caution, warning, danger*; 2) the identification of the hazard or an action statement; 3) information about how to avoid the hazard; and 4) the possible consequences of not avoiding the hazard. Furthermore, it also recommends, but does not require, the use of symbols. Figure 1 below illustrates the arrangement of these components:

1) the signal word *caution;*
2) the identification of the hazard, *hot surface*;
3) the information of how to avoid the hazard, *do not touch*;
4) and the consequences of the hazard, *contact with skin may cause burns*.

There is also an image that illustrates the nature of the hazard. It is important to note, however, that the modal verb *may* is used in the *consequence* statement, weakening the warning (Dumas, 1992).

Figure 2.1: ANSI – hot surface

ISO adopts a different strategy. First, both the use of signal words and the provision of text describing the hazard and hazard prevention are only recommended; second, by contrast, the use of symbols is required. Probably, this is due to the fact that symbols communicate to consumers who speak different languages. Hellier and Edworthy (2006) state that manufacturers who want to explore global markets prefer the ISO guidelines. The pictures below illustrate this. As can be seen, there is no text. The symbol has an enclosing border; and the color identifies the level and type of risk (Wogalter et al., 2006). For example: Prohibition – black symbol and white background; danger – yellow; mandatory – blue; emergency – green; firefighting – red; chemical – orange; transport of hazard material – light blue.

Figure 2.2: ISO warning

Although there is a strong tendency for warnings to occur without text, ISO also combines text with non-textual elements, as illustrated in the picture below. Like the ANSI warning presented above, this warning also modalises the consequence statement.

Figure 2.3: ISO picture and text

Tiersma (2002, p. 60) observes that not only are symbols limited, since “they communicate only a narrow range of messages”, but their interpretation may also vary from culture to culture. The picture below illustrates how symbols can be misinterpreted.

Figure 2.4: Accutane

Figure 4 is from a famous medicine for acne, Accutane, which can cause severe birth defects in the babies of women taking this drug. The laboratory designed the picture intending to inform: “do not take the drug if you are pregnant”, but some patients interpreted the message as: “it might help you to avoid getting pregnant” and used it for preconception care. As a consequence, several women in the United States had babies with birth defects (Wogalter, 2006).

The next four sections will discuss the characteristics of each component cited in this part and the features that can render the warnings more efficient.

2.3.1 Signal Words

It is a consensus in many regulatory standards that signal words should be employed in order to alert people about possible hazards and to indicate the degree of danger. In the US, the use of a signal word is recommended by most guidelines like ANSI and SAE (The Society of Automotive Engineers). These words are “selected based on degree or level of hazard seriousness, specifically, the probability and severity of harm associated with not following the safety message” (Hall, et al., 2006, p. 02). The most frequently used signal words are: *danger, warning* and *caution* (Wogalter, Jarrard & Simpson, 1994), and this might be influenced by the guidelines in ANSI-Z535 4 that recommend the employment of the following words:

> DANGER indicates a hazardous situation which, if not avoided, **will** result in **death or serious injury**.

> WARNING indicates a hazardous situation which, if not avoided, **could** result in **death or serious injury**.
> CAUTION, used with the safety alert symbol, indicates a hazardous situation which, if not avoided, **could** result in **minor or moderate injury**.
> NOTICE is used to address practices not related to personal injury. (Kundinger, 2008, p. 15).

These same guidelines recommend the use of colors in the signal word panel, for example: danger (red), warning (orange), caution (yellow) and notice (blue). Furthermore, the use of an alert symbol, an exclamation mark inside a triangle, to refer to any type of personal injury is also employed. In this way, danger, warning and caution should be preceded by an alert symbol.

Figure 2.5: ANSI signal words

ISO safety signs use the same signal words and colors as ANSI. The only difference is that the alert sign is black with a yellow background. But, as mentioned before, there is one ISO-format that employs only the symbols, without a signal word.

However, there is no consensus regarding the level of hazard conveyed by the signal words (Wogalter, Jarrard & Simpson, 1994). Shuy (2008) observes that the definitions provided by the dictionaries use one term to define another, as can be seen below in a search in the Merriam Webster on-line dictionary where the word *danger* in used in the definitions of *warning* and *caution*. Furthermore, the definitions below provide no indication of the severity of the danger.

- danger: the possibility that you will be hurt or killed;
- warning: something (such as an action or a statement) that tells someone about possible danger or trouble;
- caution: care taken to avoid danger or risk: a careful attitude or way of behaving;
- notice: information that tells you or warns you about something that is going to happen;

Some studies revealed that there are no meaning differences between danger, caution and warning, while some reported a reliable difference of connoted hazards between danger and caution. However, as observed by Wogalter, Jarrard & Simpson (1994), these studies did not include the context, that is, the terms were tested in isolation, which could interfere in the results. In order to fill this gap, Wogalter, Jarrard & Simpson (1994) conducted a study that took context into account. They first designed labels for a series of different products, ranging from aspirin to hair-styling mousse. Then they employed different signal words for each warning, such as: lethal, danger, warning, caution and note. They also produced a no-warning and a no-signal-word condition, that is, a label that employed neither warning nor a signal word. A signal icon was also used, but only with the words danger and lethal. Finally, the participants were asked to evaluate the labels and answer some questions regarding hazard perception. The results revealed that:

1) the no-warning condition produced the lowest condition for hazard rating;
2) there were significant differences between the terms 'lethal' and 'note';
3) no major differences were found for the intermediate terms, 'warning', 'caution' and 'danger';
4) the use of a signal icon seemed to have no effect on subjects' perception of hazard when added to the term 'danger'; however, when the icon was added to the word 'lethal' the level of hazard perception increased.

Shuy (2008)[12] presents the results of a case in which he testified as an expert witness, which reveal that the manufacturers used the signal words inappropriately. The case involved a family who was poisoned by carbon monoxide in a recreational vehicle (RV) (see section 2.3.1). He points out at least two ways, which the manuals employed the terms 'danger', 'warning' and 'caution' inadequately, which reduce their effectiveness. Whereas on the one hand the manual pointed out to serious risks that were not signaled by these words, on the other hand it overused or/and misused the terms, that is, the terms that relate to serious personal injury or death are used to refer to equipment damage, for example: the signal word 'danger' was used to warn readers that they "should not use jumper cables to start the engine" (s.p.), which clearly would not result in personal injury. Shuy (2008) observes that using the signal word 'danger' indiscriminately, when there is not imminent risk

[12] Shuy (2008) was retrived from his webpage and there is no page numbers.

of death or serious injury, can create “a strong probability of confusion in the mind of readers about the gravity and nature of the hazard”, (s.p.) which reduces the efficacy of the warning.

Some authors argue that the color should be linked to the level of the danger (Martin, 2003), but there is disagreement about what level of hazard each color represents. Whereas some studies reveal that warnings printed in black with a red background were the most conspicuous, other studies argue that yellow would be the best option due to the level of visibility.

In Brazil, NR[13] 26 regulates the colors to be used in workplaces. According to this guideline the color **red** should not be used to mark danger, due to lack of visibility if compared to **yellow** and **orange**. Instead, **red** is adopted to indicate ‘protection and firefighting equipment and devices’, whereas **yellow** is used to indicate ‘warnings’. It is important to note that **yellow** is also used in traffic lights with the meaning of caution, and is largely known by the population as an alert color, while **orange** is used to indicate the movable parts of machines and dangerous chemical products.

2.3.2 Hazard Identification

Hazard identification should describe the nature of the hazard, for instance: *high voltage*; and it can also indicate the level of severity of the hazard, such as: *highly combustible area*.

Figure 2.6: Hazard identification 1

[13] (NR -Norma Regulamentadora)

Figure 2.7: Hazard identification 2

The identification of hazards is an essential component of warnings since people are found to pay more attention when the danger is explicit. Studies have shown that explicit information about the danger can enhance compliance. Otsubo, for example (1988, as cited in Azevedo, 2006), notes that the greater the perceived hazard, the greater the caution.

Although issues like visibility and comprehensibility are crucial, they are not unique, that is, individuals may be able to read and understand warnings, but nevertheless, they may choose not to read these labels. Bearing in mind this kind of consumer, Wogalter, Desaulniers and Brelsford (1986) conducted an investigation to verify whether the consumers' perceptions of hazards can influence their behavior. They were able to demonstrate that perceived hazardousness is strongly "related to the tendency to look for warnings" (p. 1197) and willingness to read them, which supports the need for more explicit warnings. Furthermore, if individuals are more likely to read those warnings which make danger explicit, products that do not inform about danger tend to be less read, since people may assume that the products are less hazardous and consequently, compliance is reduced.

As already noted above there are some warnings that employ symbols, colors and shapes, instead of a verbal component, to inform about the danger. This kind of warning follows ISO guidelines for safety signs and is commonly used in many European countries. Although some studies show that warnings with symbols are more noticeable (Bzostek and Wogalter, 1999; as cited in Duarte et al., 2014), these warnings also face problems of comprehensibility.

Duarte et al. (2014) conducted an investigation with the aim of testing comprehensibility of a set of 17 *symbol-based safety signs* following ISO 9186 criteria. The 90 participants were divided into three groups: adult workers, college students, and individuals with cerebral palsy, who were asked to answer some questions related to their comprehension of the safety signs, which included their interpretation of

the shape-color meaning, given that not only shapes, but also colors can inform about risks. For example, the well-known prohibition sign has a "round shape; black symbol on white background, red edging and diagonal line" (ibid: 69).

Figure 2.8: Prohibition sign

Results revealed that most of the signs were not fully comprehended, since some participants were able to understand the symbols, but not the shape-color code, or vice versa. The authors also noted that "prohibition and danger shape-color codes are better comprehended than other codes" (p. 76) given that they appear more frequently in our daily life, especially in some road signs.

Duarte et al. (2014) also raise the issue of the level of warning comprehensibility, which should be 85% for ANSI and 67% for ISO/TC 145 standard (ibid: 67). This means that when warning signs are tested, they should meet the established percentage of corrected comprehension. For example, ISO/TC 145 suggests the use of seven categories to establish the level of comprehensibility.

> (1) Correct understanding of the symbol meaning is certain (estimated probability of correct understanding over 80%).
> (2) Correct understanding of the symbol meaning is very probable (estimate probability of correct understanding between 66% and 80%).
> (3) Correct understanding of the symbol meaning is probable (estimate probability of correct understanding between 50% and 65%).
> (4) The meaning which is understood, is opposite to the intended.
> (5) Any other response.
> (6) The response given is don't know.
> (7) No response is given. (ibid: 69)

The problem is that when this criterion is reached, "no [further] efforts are taken to redesign them (the warnings)" (p. 75), which means that 33% of consumers will not understand them. Consequently, these individuals may not manipulate the product safely. The signs used in Duarte et al's. studies, although selected because of perceived problems of legibility, were carefully designed since they conformed to the ISO-9186, but even so few of the warnings reached the 67% ANSI or ISO/ TC 145 comprehensibility level criterion, which in my view, is already low.

It is important to note that not only warning signs, but also written messages and PILs need to be evaluated. Likewise, they should reach the minimum level of comprehensibility stipulated by the regulative agencies. However, both the level of comprehensibility and the criteria adopted to evaluate it are a constant target of criticism. In this respect, Clerehan et al. notes that the readability criterion for PILs simply "uses an equation based upon average sentence length and average number of words of three or more syllables per sample" (2005: 334), which disregards other important factors, such as text structure and the vocabulary used.

2.3.3 Instructions on How to Avoid Hazards

Knowledge about a hazard is not enough to ensure safe behavior, if the consumer is unaware of the instructions on how to avoid the hazard. The warnings below provide instructions on what to do: *Watch your step*; and on what not to do: *Do not operate with guard removed*. Both warnings use the imperative, which is clearer in relation to the prevention.

Figure 2.9: Instructions 1

Figure 2.10: Instructions 2

Sometimes a warning is adequate, but it is located in a place where it is difficult to see. It is common to see warnings right after a set of instructions without a signal word, or even worse, written in tiny letters that are difficult to read. Consequently, they will go unnoticed.

On the other hand, there are some conspicuous warnings that are written in highly complex sentences and difficult terms that not only discourage reading (Shuy, 2008) but also lead to misinterpretation.

Explicitness is another important issue that should be taken into account in the design of an efficient warning. This means that the directions must inform what the individual has to do, or not to do, to avoid the hazard. For example, the statement "use in a well-ventilated area" (Wogalter, 1999, p. 100) is too vague – what constitutes 'well-ventilated'? A preferred option would be "Use in a room with forced air or with at least two open windows" (Wogalter, 1999, p. 100).

The sequencing of the information can also interfere with the consumer's perception of the warning. This is the case in particular with warnings that have many instructions. According to Shuy (1990, 2008), the most crucial information should be placed before the less crucial. Wogalter (2006) notes that besides listing the more crucial information first, it should also be made more conspicuous, by using a larger font or color. In this way, the consumer's attention would be attracted to the most important information.

2.2.4 Consequences

Finally, warnings should inform about the consequences of not avoiding the hazard. The warning below informs about the most serious consequence: *improper use may result in serious injury or death,* which can persuade users to be more careful. However, the warning could be more efficient if the symbol were different, that is, a person falling from

scaffolding would better inform about the risk. Furthermore, the presence of the modal marker may also weaken the warning.

Figure 2.11: Consequences 1

In the warning below, both the symbol and the verbal component inform about the consequence - they complement each other. Whereas the verbal component explores the action, *moving parts can crush or cut*, the symbol depicts it by showing in which way the accident can occcur and which part of the body can be affected.

Figure 2.12: Consequences 2

Providing information regarding consequences can also increase hazard perception (Borade, Bansod & Gandhewar, 2008). This data is important because as noted by Wogalter, the probability of reading a warning rises when people perceive a hazard. Moreover, warnings that state “how badly a person can get hurt, rather than (or to a lesser extent) the likelihood of getting hurt” (Young, Brelsford and Wogalter, 1990, p. 503) are also preferred since knowing the seriousness of the risk is more persuasive. On the other hand, manufacturers seem to be careful when talking about explicit consequences based on the evidence that they may deter consumers from buying their products.

Thus, as can be seen, all the components of a warning are interrelated and the absence of one component can reduce the efficacy of a warning.

2.2.5 Model

In order to organize the factors that influence the effectiveness of warnings and to show why a warning may fail to inform about a hazard, Wogalter presents a model of warning derived from cognitive psychology, called C-HIP (Communications-Human Information Processing). As can be seen below, the model is divided into a sequence of stages: attention, comprehension, beliefs and attitudes, and motivation. Although the model is presented in a linear form, the feedback loops on the right indicate that one stage can influence the others, for example: when a reader believes that a product is safe s/he may not look for a warning. Laughery and Wogalter (2014, p. 5) state that this case "would involve a feedback loop in which the Beliefs/Attitude stage affects the Attention stage".

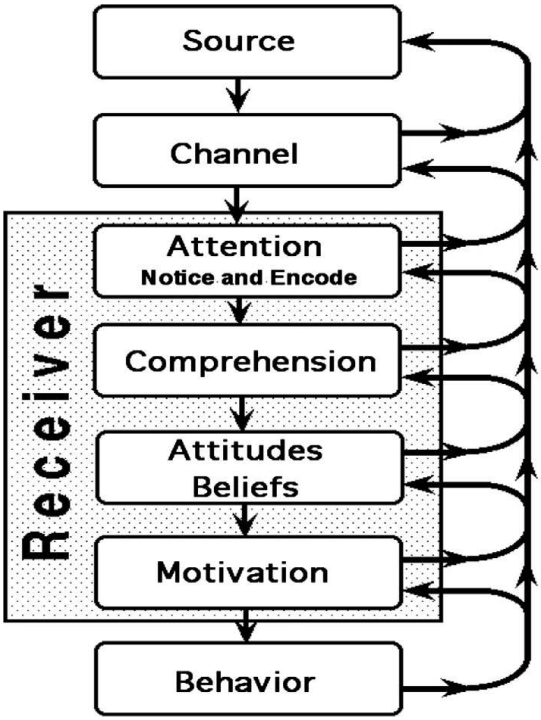

Figure 2.13: C-HIP model

Thus, an efficient warning should first be noticed. Many factors can contribute to attract the consumer's attention, such as: placement, color combination, the use of a signal word and signal icon, and even the use of pictorial elements. An interactive warning, in which the consumer needs to remove the warning before using the product, is a valid alternative for some warnings that may go unnoticed.

Second, the warning should be understood by the lowest level of the target audience, which is one of the most discussed characteristics in the literature.

The third is related to people's beliefs and attitudes. There is a tendency to ignore a warning if the product is already known, like most household products, cosmetics and some widely used medicines like painkillers. If a person already believes that the product is not dangerous, then s/he will probably not read the warning. For this reason, the warning needs to attract attention and the message needs to be persuasive in order to change that belief.

The fourth stage involves motivation, that is, the message has to motivate the consumer to comply with the instructions. The motivation may increase if a person perceives that the product may cause severe injuries. Thus, explicitness is preferred. Another determining factor is cost in terms of time, effort and money; for instance, a person may not comply with a warning that instructs them to wait some minutes before opening a popcorn bag. As pointed out by Wogalter (1999, p. 104), "if people perceive the cost of complying to be greater than the expected benefits of not complying, then they are less likely to comply".

Laughery and Wogalter (2014, p. 5) note that "the C-HIP model and others like it have been used for organizing, guiding and reviewing warnings research".

2.4 ADEQUACY ISSUES

Warnings can be viewed from at least two perspectives: that of the manufacturer and that of the consumer. In the first case, "warnings may function largely as a defense against litigation" (Dumas, 1992; as cited in Lehto & Miller, 1986, p. 16). From the second perspective, the issue of adequacy emerges. The adequacy of warnings is one recurrent factor in the literature. There is a consensus among many authors (Shuy, 1990; Tiersma, 2002; Dumas, 2010; Coulthard, 2012) that an adequate warning should be intelligible and attract the attention of the user/reader. Tiersma (2002) observes that

> An adequate warning is one 'in such form that could reasonably be expected to catch the attention of a reasonably prudent man in the circumstances of its use' and whose content is understandable and conveys 'a fair indication of the nature and extent of the danger' to that person (p. 55).

The authors mentioned above address the issue of providing us with valuable insights, citing real cases. Dumas (1992) lists some cases in which the manufacturers failed to fulfill the requirement of adequacy. Whereas some involve lack of information in relation to the level of danger (Bituminous Causality Corp. v. Black and Decker Corp., 1974) and how to avoid it (Wallinger v. Martin Stamping and Stove Co., 1968), others are concerned with the poor location of the warnings on a

product (Griggs v. Firestone Tire and Rubber, 1975), which may make the visualization problematic.

There are several instances that show which features in a text may lead to miscomprehension, such as the use of complex syntax in "Quitting smoking now greatly reduces serious risks to your health" (Dumas, 1992, p. 291) and the use of technical words such as 'do not use the product if you have ever used progressive hair dye'. Lack of information can also stimulate wrong inferencing and be an impediment to readers' understanding. So, what is the departure point to write a warning?

Coulthard (1994, p. 19) asserts that "a writer cannot begin at the beginning of everything". Based on this, it is not possible to write everything about a given risk in a warning, especially because the writer has to deal with space constraints. In order to decide what information should be included and how it should be textured, the writer needs to imagine a reader as the departure point of his/her writing. In this way, s/he can assume what the reader already knows (given), what needs to be stated (new) and how this information (given-new) should be conveyed to the reader. In the case of consumer products, such as cigarettes, microwave popcorn and medicines, it is impossible to predict the reader - s/he can have either a low or a high knowledge/ content level, and for this reason, the writer "should take into account the lowest ability levels of the target population" (Wogalter, 2006, p. 07).

Wogalter (2006) presents several rules to improve the design of warnings to make them more efficient. They should be brief, but at the same time provide the necessary information. In this way, brevity and explicitness should reach a 'happy medium'. Moreover, given that it is impossible to list all the risks, "higher priority should be given to hazards that are:

> a) more severe,
> b) more likely to occur,
> c) not known by the target audience" (Wogalter, 2006, p. 07).

2.4.1 Brazilian Warning Studies

Azevedo (2006) investigated the manuals of 10 household appliances sold in 2004 and 2005 in order to verify the adequacy of their graphic and informational characteristics. The study analyzed 20 warnings of each type of household appliance, totaling 200 warnings.

The analysis focused on six variables related to the informational content: signal word, hazard indication, consequences, direction, relationship between the text and the picture, type of directions; and five variables related to the graphical aspects: area delimitation, emphatic element, symbolic element, picture style, and picture representation.

Results showed that out of the 200 warnings, only 13 employed signal words. *Attention* was the most frequent (8 times), while the terms *warning* and *caution* were only used twice and the word *danger* only once. Although more frequent than the signal word, the written message about hazard identification appeared in only 38 warnings examples. The explicit consequences of not avoiding the hazard were included in 37 warnings examples. On the other hand, all warnings included instructions on how to operate the appliances correctly. Azevedo concluded that 'low employment' of 'signal words, danger identification and consequences' can lead consumers to use the products incorrectly, which can result in dangerous consequences.

Presgrave et. al (2008) evaluated the labeling of 158 household products in order to verify their adequacy, which was assessed according to the information they provided. Their findings revealed that 75% of the warnings were inadequate. First, relevant information, such as first aid instructions, was missing; second, some warnings were confusing due to label design, which impaired visualization; finally, some offered non-explicit instructions, like "drinking abundant water" (p. 687), whereas the crucial problem in this statement lies in the word 'abundant'. How much does 'abundant' mean? What different people understand by 'abundant' may not be the same. The authors point out that the correct procedure should be "immediately drink 240 ml of water or 120 ml for a child, but not exceeding this quantity and drink slowly" (p. 687). They also observe that drinking more than this quantity can in fact be dangerous.

Presgrave, Camacho and Villas-Boas (2009) investigated nine (9) legal documents about sanitary legislation in Brazil in relation to household cleaning products, aiming to discover the information they prescribed. The authors concluded that the documents should be revised in order to make the warnings more efficient, since important information was not required by some documents, for instance: the message 'keep the product in its original container' was required in only five out of nine documents and an emergency telephone number was required by only one.

2.4.2 Product Liability Cases

Some cases that involve the efficacy of warning labels will now be reviewed. They focus on different products such as: menstrual tampons (Shuy, 1990); cigarettes (Dumas, 1992, 2010); Loctite adhesives (Dumas, 2000); a gas grill (Coulthard, 2012); a recreational vehicle (Shuy, 2008); and a floor stainer (Laughery and Wogalter, 2014). Most of them, except the last one, have involved analysis by forensic linguists.

Shuy (1990) reported about the warning label on some menstrual tampons, with the aim of verifying if the label clearly associated the use of the tampons with 'toxic shock syndrome' (TSS). His analysis started from the question: "Is it made in a comprehensible manner?" (p. 293), that is, whether consumers would understand the warning. Shuy concluded that in order to be effective, the sentences should be reduced in length, since they were too long and complex. Moreover, the order of the sentences should be revised for two main reasons. First, the most important information was in the middle of the text, "well hidden within the text" (p. 298) and could go unnoticed by a less attentive reader. Shuy (1990) observed that "good communicators put their gist on the table early" (p. 296). Second, the temporal sequence was not followed. In this way, a reorganization of the informational chunks might not only attract more attention, but also be more comprehensible. In addition, there were no explicit connections between the sentences, which would force the consumer to make inferences, some of which could well be incorrect inferences. Finally, most of the information in the warning was related to the TSS. But what is important for the consumer is the connection between TSS and the use of tampons, not simply TSS itself.

Dumas (1992) conducted an empirical investigation in order to offer evidence in the case of Roysdon v. R. J. Reynolds Tobacco Company (1996) with the aim of verifying the adequacy of cigarette packet warnings in the USA. She first study reviewed the literature on warning and formulated twelve (12) hypotheses. Then, to test these hypotheses, she adopted two procedures: 1) she designed a questionnaire and asked 27 students of linguistics to categorize the warnings "as either categorical or hypothetical" (ibid: 278), rank them according to strength and translate them into their own words; 2) she designed nine cigarette packages and conducted a structured interview to verify the respondents' perception of them. She decided to use red and white colors on her designed pack, given that the selected packages labeled were red and white. In relation to the warnings, she adopted the 1970 warning, the

four rotational warning in force at the time of research, two fabricated 'disease-specific' warnings and two with the word POISON "in combination with the drawing of a skull and crossbones" (p. 297).

Her results revealed that hypothetical warnings were not only easily recognized as such, but were also perceived as stronger than categorical ones, which suggested that hypothetical warnings are better. Her analysis identified the characteristics that render warnings stronger, such as: disease-specific warnings, extra linguistic factors (font, color, space, contrast, location, format), simple syntax, ordinary vocabulary and semantically strong words such as 'poison'; and the characteristics that can work to weaken warnings, like: complex syntax; non-warnings, that is, those that do not have the conditions of a warning proposed by Searle (1969), for example, if it refers to a good event; modal qualifiers which reduced the probability of the named effect (*can, may*); and technical terms. Dumas (1992) concluded that the cigarette packet warnings in the United States "vary considerably in strength, ranging from fairly strong to silly" (p. 300). Furthermore, they fail to warn about the possible "negative cardiovascular effect of cigarette smoking" (p. 300). Finally the weak features identified in her investigation were present, such as: (1) the use of modal qualifiers; (2) unusual syntax; and (3) the use of technical terms.

Dumas (2000) reports the results of two cases she testified in as an expert witness, which involved the manufacturer *Loctite Corporation* and some of the workers of a company that used the Loctite product, who developed *disabling contact dermatitis* arguably as a result. She analyzed the warning labels on the glue that had caused the disabling dermatitis and the Material Safety Data Sheet (MSDS) in order to assess their adequacy and she concluded that both were inadequate: the information on the MSDS was highly technical (provided two types of precaution, the use of gloves (rubber or plastic) and the avoidance of 'prolonged skin contact'); the warnings informed about skin irritation, but they failed to inform about how severe the irritation could be or how to treat it. Furthermore, it provided irrelevant information that would not lead the reader to infer that the product posed serious health risks.

Coulthard (2012) comments on his contribution to a case involving the manufacturer of a Gas Grill designed for outside use and a man whose son was severely burned when using the Gas Grill, which had been installed inside the house. Coulthard's report involves the interpretation of four warning labels attached to the appliance, which revealed that they permitted a co-operative reader to infer that the appliance could be installed inside, if the gas cylinder was left outside,

even though this was contrary to the company's claim that the labels stated clearly that the Gas Grill should never be used inside.

Coulthard justifies his assertion by pointing out that among the four labels, three were concerned with danger associated with the cylinder, whereas only one was concerned with the installation of the grill. Two labels related to the cylinder, not only pointed out the nature of the risk, but also communicated to the reader how to avoid the danger. Besides, these warnings were under the heading of 'danger', which is used to indicate the possibility of death or serious injury. On the other hand, the single label that refers to the grill installation does not have these features and thus might lead the reader to infer that it is the cylinder alone that is a source of risk.

Nevertheless, Coulthard argues that there is a contradiction in the grill installation label, since it gives the consumer two options of installation. The first message "outdoor cooking appliance for outdoor use only" is clear in relation to outdoor installation. But the second "If installed indoor, detach and leave cylinder outdoors" contradicts the first, since it allows the user to install the grill indoors provided that the cylinder remains outdoors.

Shuy (2008) presents a discussion about a case in which he testified as an expert witness, which involved a family who was poisoned by carbon monoxide in a recreational vehicle (RV). He compared the ANSI requirements with three owner's manuals: 1) the manufacturer of the generator installed in the RV, 2) the manufacturer of the RV and 3) the manufacturer of a generator, which was not used in the RV. According to Shuy, only the last manual met ANSI standards.

On the other hand, Shuy points out that the manuals of the first generator omitted important information about 'sleeping in the RV while the generator is operating' and 'the use of a carbon monoxide detector'. Moreover, the same manual also failed to provide specific information about the 'generator exhaust obstruction'. For instance, the expression 'adequate ventilation' is imprecise and leads to the question: is an open window enough? In the same vein, the manual recommended periodic inspections, but what does periodic mean? Besides, it did not mention which items should be inspected. Like the Generator manual, the RV's instruction was characterized by the omission of important information and by a lack of explicitness. Further, both manuals adopted the strategy of writing some parts of the text with capitalized letters with the aim of emphasizing important points. However, as pointed out by Tinker (1969, as cited in Shuy, 2008, n.p.) multiple lines of "all capital letters provide visual interference to predictable print type and discourage the reader

from attempting to read the text". Shuy, then, concluded that both manuals did not conform to ANSI standards.

Laughery and Wogalter (2014) provide an example in which a person used a floor stainer on the dining room hardwood floor and not only had his house destroyed by fire but also suffered severe burns on his body one hour after applying the product. Laughery and Wogalter cite that "the fire marshal's investigation concludes that the fire was likely caused by vapors, which traveled along the surface of the floor to a water heater wherein the pilot light ignited it" (p. 06). The product label informed:

> Flammable
> Risk of Burn Injury
> Use with adequate ventilation.

However, the victim argued that the term *flammable* "did not suggest more than a common candle flame" (p. 06). Laughery and Wogalter (2014) note that the term leads to misinterpretation, and is often confused with the term *combustible,* which is 'actually less of a fire hazard than flammable" (p. 06). The warning would be more effective if it were more explicit in relation to the risk, that is, it should inform about the gravity of it. Furthermore, the instructions seem to be too vague and deficient, given that the victim had opened the window expecting thereby to provide 'adequate ventilation'.

CHAPTER THREE
METHODOLOGY

This dissertation is organized into two studies, the first deals with Patient Information Leaflets (PILs) and the second with product warning labels. Although the purpose is the same, i.e., verifying the in(efficacy) of the warnings, I decided to divide the discussion of data into two different chapters. The main reason for this division is the quantity of PILs I have collected, which allowed me to build two corpora: one in English and one in Portuguese. In this way, I was able to compare the data of the two languages in order to have a better view of how safety information are conveyed in two distinct countries. The data of the second study consist of Portuguese products, mainly due to space and time constraints. Moreover, the amount of product labels analyzed is smaller if compared to the PILs due to two reasons: First, the large quantity of PILs available on-line facilitates the construction of the corpora; second, the analysis of the product labels was more detailed, which limited the amount of data.

3.1 PILs (PATIENT INFORMATION LEAFLETS)

Given the large number of medicines available in the market, I needed to devise criteria to reduce the data to a manageable quantity. I opted to focus on 'painkillers' for two main reasons, first, they are widely used; second, some of them can be bought without a medical prescription and therefore without any instructions for use from a prescribing doctor. In order to narrow down the data further, I selected only over-the-counter medicines (OTC), those sold without a prescription. For such medicines, the PILs are the main source of information, and for this reason "it is important to make these inserts as effective as possible" (van der Waarde, 2004:76).

However, before presenting the selected medicines, I need to mention a problem I faced in the progress in this investigation. As already pointed out, I have two corpora, one in English and one in Portuguese. I collected the English data during my 'sandwich program' in Birmingham, UK. Only when I came back to Brazil, did I collect the Portuguese data, and I set out to select the same medicines. To my surprise, the medicine 'codeine' has the status of an OTC medicine in

England, whereas in Brazil, it is only sold under prescription. Nevertheless, I decided to retain it.

The English corpus consists of 87 leaflets: Paracetamol 17, Codeine 24, Aspirin 14, Ibuprofen 10, Diclofenac 15, Naproxen 7, which were downloaded from the website www.medicines.org.uk/emc/, between August and October 2014. The Brazilian Portuguese corpus consists of 64 leaflets: Paracetamol 23, Codeine 3, Aspirin 3, Ibuprofen 9, Diclofenac 24, Naproxen 2, which were downloaded from the website http://www.anvisa.gov.br/datavisa/fila_bula/index.asp, between February and March of 2015. I collected only the PILs that had been revised in 2013 or 2014, avoiding outdated PILs, given that the guidelines constantly undergo small changes.

I also analysed the guidelines for medicines provided by governmental agencies for each country:

UK MHRA[14] – (2001/83/EC); (2004/27/E); (2010/84/EU).
Brasil ANVISA[15] – (RDC 47/2009).

3.1.1 Analysis

In order to evaluate the efficacy of the PILs, the analysis will take into account not only macro but also microelements. In this way, I will first verify whether the data are in agreement with the guidelines, which dictate the information that must be conveyed, the sequencing of this information and sometimes the actual phrasing. Then, I will verify the components of the warnings. However, as mentioned before, the efficacy of warnings cannot be judged solely on the basis of these elements. Equally important is how the information is phrased, because the understanding of the message will depend on it. Thus, issues like the complexity and vagueness of the clauses are paramount and will be taken into account. Finally, I will identify and classify the manifestations of Modality (Halliday, 1994) in order to verify how interpersonal meanings are constructed.

The 3.4.3M version of AntConc (Anthony, 2014), which is a "freeware corpus analysis toolkit for concordancing and text analysis" and available at http://www.laurenceanthony.net/software/antconc/ was

[14]Retrieved from: http://www.mhra.gov.uk/home/groups/commsic/documents/websiteresources/con007679.pdf
[15] Retrieved from: http://www.anvisa.gov.br/medicamentos/bulas/rdc_47.pdf

used in the analysis. I used two of the sub-programmes in the analysis: wordlist and concordance.

3.2 PRODUCT LABELS

3.2.1 Data

3.2.1.1 *Fireworks Labels*

There are many different kinds and brands of fireworks, many of which are not registered. In this analysis, I only selected products that are registered, because they have to comply with the requirements, and for this reason they have labels with instructions and warnings. I also selected different types of firework (see the table below), in order to verify how they convey information about very similar risks and consequences. I gave priority to fireworks that are bought by adults with the aim of entertaining children, which is the case of all those in the table below. I also analysed the guidelines for fireworks, which are provided by the Brazilian Army (R-105) and ABNT (NBR 7500).

	NAME	KIND	CLASS	MANUFACTURER
1	Candela Romana 30 Baladas	Roman candle	B	ACME Fireworks CO. LTD.
2	Chuva de Prata n. 6	Sparklers	B	Artesanato de Fogos Vitória
3	Sputinik	Fountains	B	Indústria e Comércio de fogos São João
4	Apito com Vara	Rockets and Missiles	B	Indústria e Comércio de fogos São João

Table 3.1: Fireworks labels

The first warning label is on the product, which might be the reason for the small size. The font size is almost impossible to read without lenses. The color combination of the background (red) and letters (white) also impairs reading. However, the headings are yellow and uppercase, facilitating visualization and reading.

The second warning product label is written on the side of the box, given that the product is only sold in a box, containing 10 items. The font size is bigger than that of the first brand, but still difficult to read. The color combination of the background (light yellow) and letters (black) facilitates visualization.

The third product label is also written on the side of the box. The font size is bigger and facilitates visualization. Moreover, the background (dark blue) and the lettering (white) are easy to read. The headings are highlighted by the use of uppercase font, written in white with a red background.

Finally, the last warning label is almost impossible to read, due to the font size. The color combination, white lettering on a light blue background also hampers reading. The headings are yellow, which catch the attention, but the small font size demotivates any attempt to read it.

3.2.1.2 Hair Dye Labels

The data for this study consist of: ANVISA[16] guidelines for hair dye (RDC Nº 211/2005), three warning labels, and four liability cases.

The three hair dye warning labels analyzed in this study, namely: *Keune - tinta color*, *Alfaparf - Evolution of the Color*, and *L'Oreal Paris - Imédia Excellence*, will be referred to as A, B and C respectively.

The first brand (A) is made in Holland and is not sold in drugstores and supermarkets. It clearly states that it should be used by professionals. There are three warning labels: one is printed on a sticker, which is pasted on the side of the package; there is another warning on the back of the package; and a third one in a leaflet.

The sticker contains the information required by ANVISA, such as the six mandatory warning statements (see below for more details), the list of substances, the register number of the Ministry of Health, the batch number, the manufacturing and expiry dates, the name of the technician in charge as well as fourteen more warning statements that were not required by ANVISA. The warning on the back contains thirteen 'information chunks' (the term used by Shuy to designate one or more sentences about the same information); and the warnings in the

[16] ANVISA - Agência Nacional de Vigilância Sanitária. The Brazilian government Agency for the Control of Health Products. Agência Nacional de Vigilância Sanitária. Retrieved from: http://portal.anvisa.gov.br/wps/wcm/connect/dfa9b6804aee482bb7a1bfa337abae9d/Resolução+RDC+nº+211,+de+14+de+julho+de+2005.pdf?MOD=AJPERES

leaflet itself contain forty-three information chunks and are written in 13 different languages.

The second brand (B) is made in Brazil and contains two warning labels. One label is printed on one side of the package. It contains the six mandatory warnings, the list of substances as well as seventeen extra warnings. There are also warning labels printed on the package in five different languages. Like the first brand, this dye is recommended for professional use only and generally sold in cosmetics stores. The second warning label is printed inside the package and contains twenty-one information chunks. Printing the warnings inside the package can be problematic because it can become illegible if the package is opened badly.

The third brand (C) is also made in Brazil. Like the second, the warning is printed on the side of the package, this time containing twenty-three information chunks. However, by contrast with A and B, this brand is sold in almost all supermarkets, drugstores and cosmetics stores. Like A, it has an informative leaflet containing thirty-nine information chunks.

It is important to point out that the warnings on the outside of the package of all three brands contain fewer information chunks than the warnings on the leaflets or those inside the package. The differences between them will be illustrated in Section 4.1.

The liability cases are presented in the table below.

CASE	PRODUCT
Deise Torres VS. UNILEVER	Hair dye
Valdecir Martins VS. PROCOSA	Hair dye (Garnier Nutrisse)
Maria Costa VS. Biofitogenia Laboratorial	Hair dye (Cor e Tom)
Daniela Cristina Prado de Almeida Leandro VS. Procter & Gamble Do Brasil S/A E Belfam Indústria Cosmética Ltda	Hair dye (Koleston Tintura creme)

Table 3.2: Hair dyes Labels

3.2.1.3 Food Labels

The data for this investigation come from the ANVISA guidelines and the labeling on food products, which will be detailed below. As mentioned in chapter one, the point of departure for this analysis is the diabetic's need for information when buying food.

The ANVISA guidelines for food are largely influenced by the *Codex Alimentarius* (food code) established by the FAO (Food and Agriculture Organization of the United States) and the WHO (World Health Organization) aimed at protecting consumers' health by providing a set of standards, guidelines and codes of practice for food security. The *Codex Alimentarius* commission has 187[17] members, 186 member countries and 1 member organization.

This analysis first aims to discover whether the food labels conform to the requirements of these documents, then it will be verified whether the food labels contain the necessary information that consumers' with food restrictions (diabetes) need to know to adopt a healthy diet. In this way, some suggestions for improving these documents will emerge as a result of the analysis. The following documents, which will be presented in chapter 5, are used in the analysis: RDC (*Resolução da Diretoria Colegiada*) 259/2002[18]; RDC 54/2012[19]; RDC 360/2003[20]; *Portarias* 27[21] and 29[22]/ 1998; and *Instruções Normativas* SDA 30/1999.

The food labels were selected for analysis during the month of September 2015. Given that the diabetic's diet is not restricted to diet products, I also selected some regular products, which were also collected during the month of September 2015.

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[17] Retrieved from: http://www.codexalimentarius.org/members-observers/en

[18] Retrieved from: http://www.ibravin.org.br/downloads/RDC_259%20de%2020%20de%20setembro%20de%202002.pdf

[19] Retrieved from: http://portal.anvisa.gov.br/wps/wcm/connect/630a98804d7065b981f1e1c116238c3b/Resolucao+RDC+n.+54_2012.pdf?MOD=AJPERES

[20] Retrieved from: http://portal.anvisa.gov.br/wps/wcm/connect/ec3966804ac02cf1962abfa337abae9d/Resolucao_RDC_n_360de_23_de_dezembro_de_2003.pdf?MOD=AJPERES

[21] Retrieved from: http://portal.anvisa.gov.br/wps/wcm/connect/9180ca00474581008d31dd3fbc4c6735/PORTARIA_27_1998.pdf?MOD=AJPERES

[22] Retrieved from: http://portal.anvisa.gov.br/wps/wcm/connect/2a1d950047458eca97dbd73fbc4c6735/PORTARIA_29_1998.pdf?MOD=AJPERES

DIET PRODUCTS
Creme de avelã com cacau (2)
Doce de leite (1)
Cookies (1)
REGULAR PRODUCTS
Biscuits (1)
Cereal Corn Flakes (2)
Whole rice (1)

3.2.2 Analysis

As with the PILs, the analysis of the product labels will take into account not only the macrostructure but also the microstructure of the labels, given that both can influence the legibility and comprehensibility of and compliance with the safety messages. So, the analysis will begin with the required compounds, then moving to the structure of the clauses, to finally arrive at modality features/choices.

CHAPTER FOUR
PATIENT INFORMATION LEAFLETS

"Risk of heart attack or stroke: Ibuprofen may increase the risk if you take **large amounts** for a **long time**. The risk **is small**. Take the **lowest amount** for **the shortest possible time** to reduce the risks" (C5)

4 INTRODUCTION

The warning above exemplifies how information about risks is typically conveyed in most PILs. As can be seen, it has two essential components that guarantee the efficiency of warnings: information about the risk: "Risk of heart attack or stroke"; and a direction about how to avoid it: "take the lowest amount for the shortest possible time to reduce the risks". But a closer analysis reveals many factors that can weaken the warning, such as the modal operator 'may' that expresses possibility (Dumas, 1992) and vagueness (Tiersma, 2002), which forces the consumer to infer the actual quantities which fit with 'large/lowest amount' and the periods 'long/shortest time'. Given that each person has his/her own evaluation of quantity and time, it is possible to infer that each person will take the medicine based on their own interpretation, which might to be different from the writer's intention. Consequently, the success of the treatment can be affected.

This brief analysis shows that there are many factors that can influence the efficacy of PIL warnings, which range from their structure and components to their lexicogrammatical choices. In order to better evaluate these, I will divide the analysis into three sections. The first section 4.1 deals with the structure of the PILs themselves, in terms of the sequencing, information and wording of some of the warnings, which are strictly controled by the regulatory agencies. The second section 4.2 presents the analysis of the warnings, their components and the characteristics that can strengthen or weaken them. Finally, the last section 4.3 provides an analysis of modality choices, focusing on how writers express their evaluation of the propositions and proposals, which can influence compliance with the warnings.

4.1 THE STRUCTURE OF PILs

Askhave e Zethsen (2008) observe that PILs are ‘mandatory genres’ and for this reason they are inherently a complex genre. The authors point out that mandatory genres “emanate from a legal directive and are introduced into the community by regulatory force” (170). In the case of PILs, the communicative purpose, the content and the pattern are defined by official documents, which is an additional challenge for the writer, who also needs to adapt the language for the ordinary reader, that is ‘translating’ the technical content into plain language. Moreover, differently from other types of genre that are constantly redefined and which evolve within the discourse community according to participants’ needs, ‘mandatory genres’ are ‘ready’. That is, they are “introduced into society rather more abruptly, and are expected to be adopted and put to use from day one” (Askhave & Zethsen, 2008:170). In this case, the discourse community does not participate in the negotiation of this type of genre, and for this reason, recipients may face difficulties in accessing them. Generally, a small number of participants are consulted in advance before the adoption of the PILs because they need to be tested and to achieve a mimimum intelligibility score of 80% according to the European guideline. However, this does not mean that the target discourse community participates in the negotiation of the PILs.

Thus, any attempt to improve both the readability and findability of PILs comes into conflict with the restrictions imposed by the guidelines. Pander Maat and Lentz (2010) point out that, despite the constraints imposed by such documents, there is evidence that writers can improve both the readability and findability. In order to test improvements, the authors conducted an empirical investigation with two groups of participants. One group was tested using 3 original PILs, the second group was tested using redesigned PILs. A set of evidence-based Document Design principles was used to redesign the PILs, which included:

- Integration of information on the same topic;
- Addition of cross-references between passages on the same topics;
- Addition of two headings in the section ‘how to use’;
- Introduction of a clearer hierarchy of section and subsection headings (presented in bold with different font sizes);
- Transformation of sentences into an introductory segment followed by a bulleted list;

- Sequencing of the side effects in terms of frequency and severity;
- Simplification of complex sentences;

Moreover, instructions were rewritten in order to put the main idea at the beginning of the paragraph.

Participants had to answer 15 scenario questions, that is, questions that "required the participants to apply information contained in the leaflet to real life situations. For example, participants were told to imagine that they were allergic for 'titiandioxid' and then had to find out whether they would be allowed to take Rosuvastatin." (Ibid: 114-115). Results reveal that the second group had a higher score in two items: comprehension while the original scored .936, the revision scored .968; and localization of information the participants needed 63.1s to find information in the original PILs, while with the the revision PILs this time decreased to 39.0s. Moreover, the localization success increased from .789 (original PILs) to .873 (revision PILs). Although the study is restricted to only three PILs, it shows that it is possible to improve readability, even under the imposed rules provided by the guidelines.

The studies mentioned above address the PILs and the guidelines used in the European Union (EU). The European Medicine Agency (EMA) prescribes the same rules for all countries. In order to illustrate the rules related to structure, I selected one PIL from the UK, Portugal and Spain, whose headings are presented in table 4.1 below.

English	Portuguese	Spanish
1. What Beechams Powders do	O que é Tylenol e para que é utilizado	Qué es Paracetamol Kern Pharma y para qué se utiliza
2. Check before you take Beechams Powders	O que precisa de saber antes de tomar Tylenol	Antes de tomar Paracetamol Kern Pharma
3. How to take Beechams Powders	Como tomar Tylenol	Cómo tomar paracetamol Kern Pharma
4. Possible side effects	Efeitos secundários possíveis	Posibles efectos adversos
5. How to store Beechams Powders	Como conservar Tylenol	Conservación de Paracetamol Kern Pharma
6. Further information	Conteúdo da embalagem e outras informações	Información adicional

Table 4.1: EU headlines

As illustrated in the table above, the headings are almost identical, the differences lie in the structure of each language, except in section 6, where the heading in the Portuguese PIL adds the information "*conteúdo da embalagem*". Thus, it is possible to say that the PILs are in agreement with the EU guidelines in relation to the headings of the documents.

However, I believe that the problem of *mandatory genres* regarding both production and reception, assuming that participants face problems of comprehension, are found in other countries, like Brazil. In order to better evaluate both the English and the Brazilian PILs chosen for this study, it is important to have some knowledge of the rules that govern them. Therefore, the following sections will present the organs responsible for the guidelines for PILs in the UK and in Brazil, as well as the guidelines and directives that rule them.

4.1.1 Uk's Guidelines

The UK Medicines and Healthcare products Regulatory Agency (MHRA) "is responsible for regulating all medicines and medical devices in the UK" (home page: http://www.mhra.gov.uk). The UK guidelines follow the European Community template which is set out by the European Medicine Agency (EMEA) in Title V of Council Directive 2001/83/EC "which was amended by Council Directive 2004/27/EC and

Council Directive 2010/84/EU" (homepage of MHRA). Significant changes occurred in relation to the goal of the PILs, especially in EU-Directive 2004/27/EC. Van der Waarde (2005:01) notes that "since 1992 (92/27/EC), the focus was on *making information readable and understandable*", and that the Directive 2004/27/EC innovated adding that "information must be provided in order to: *enable the users to act appropriately*" (01). Thus, patients not only need to understand the message, but also to act properly when taking the medicine. It is believed that the way the message is conveyed can strongly influence patients' actions. Section 4.3 below is devoted to the analysis of modality and aims at verifying whether its use can influence the reception of the message.

The UK guidelines follow the European Community template, set out by the European Medicine Agency (EMEA). The template takes into account four aspects: 1) content, which is based on the Summary of Product Characteristics (SPC); 2) sequencing of information; 3) headings; and 4) wording.

The European Union directive for Patient Information Leaflets (PILs) states that they have to include six sections, under the headings stated below. The sequencing of the sections should be strictly followed. (All examples are taken from the PIL presented in Appendix 1).

1. What the drug is and what it is used for;
2. What you need to know before you take it;
3. How to take it;
4. Possible side effects;
5. How to store it;
6. Content of the pack and other information.

4.1.2 Descritpion and Evaluation

The first section provides information about the drug, presenting the main ingredient, such as Paracetamol, as well as the group it pertains to, such as analgesics and antipyretics. Moreover, it also informs about the therapeutic indication, as 'it can be used to relieve headache, migraine, (…)'. The problem is that the use of the technical terms, *analgesics* and *antipyretics*, may confuse readers who do not know them. Moreover, it is intriguing that the writer explains the technical term 'Paracetamol' with more complicated and less known terms (see A5 below). Maybe the use of painkiller, instead of analgesics, would be more appropriate.

This medicine contains Paracetamol which belongs to a group of medicines called **analgesics** and **antipyretics**, which act to relieve pain and reduce fever. (A5)

The second is the longest section and it is mainly about warnings, precautions and contra indications. Generally, the information is divided into three sub-sections: '*Do not take it if'; 'Take special care with […]';* and *'Ask your doctor before you take this medicine'.* Whereas the sub-section '*do not take it if*' is clear in relation to the actions that should be taken to avoid the risk, the sub-section '*Take special care with […]'* is vague, given that it leaves room for different interpretations, since the information is not explicit. That is, the patient needs to infer which kind of care they should take, because the word '*special*' is imprecise. Moreover, the fact that an over-the-counter medicine has a sub-section titled *'Ask your doctor before you take this medicine'* is worthy of attention. It gives the impression that the manufacturer is transferring the responsibility to both readers and doctors, aiming to avoid litigation. In this way, if the patient suffers any hazard, the manufacturer would not be responsible. The extract below (See Appendix 1 for full text) categorises those patients who need to "ask their doctor" before taking the medicine.

- if you suffer from **high blood pressure, asthma, allergic disease, kidney** or **liver problems.**
- if you are taking any prescribed medicines; particularly **methotrexate;** blood thinning drugs **(anticoagulants)** or blood pressure lowering treatments **(ACE inhibitors); oral hypoglycaemics** (to lower blood glucose) or medicines for treating **gout** such as **probenecid** or **sulfinpyrazone; ibuprofen** or other painkillers known as **NSAIDs** (e.g. **iclofenac**); **SSRI antidepressants** (such as **fluoxetine**); treatments for **epilepsy** (such as **phenytoin** or **valproate**); **beta-blockers** (e.g. **atenolol**); **acetazolamide**; if you are taking any water tablets **(diuretics)** or steroid hormones **(corticosteroids); antacids;** or have an intolerance to some sugars.

Although it seems to concern only a few people, the warning in fact addresses a significant number of people, given that, according to the World Health Organization (2013), in 2013 more that 1 billion people around the world had high blood pressure. The same organization also reveals that more than 300 million people suffer from asthma. In this way, the status of being an over-the-counter medicine should be reviewed, because the number of people who should consult a doctor before taking paracetamol is substantial. Besides, the warning fails for

not informing the reasons for consulting a doctor. As a reader, I would infer that it can avoid a hazard, but I have no idea what the hazard is. So, I would assume that it is a minor hazard. I also believe that the number of people who ask their doctors before taking paracetamol is negligible, since when we need to take a painkiller, we cannot wait one or more days to consult a doctor. So, why include a warning that will not prevent a hazard?

The layout of the extract above may impair the search for specific information, given that it is organized in a prose format. It is a serious problem that can affect especially those consumers who need to take more than one type of medicine. Some 'possible side effects' sections also use this layout. In this respect, van der Waarde (2008: 39) notes that in the case of side effects, "it would be very difficult for a patient to figure out which medicine is likely to be the cause".

The third section informs the reader about the method of administration, the doses and the duration of the treatment. However, it is common to encounter expressions like 'little' as in 'mix the powder with a little water and stir before drinking' (see appendix 1), which are vague and can confuse readers. As we have seen above in Section 2.3.2 Forensic Linguists have reported cases where vague information led the reader to interpret the message in the wrong way, resulting in unsafe behaviour (Dumas, 2000; Shuy, 1990). In this sense, Shuy (1990: 294) notes that "a cardinal principle of comprehension is that the writer should not cause the reader to have to infer the intended meaning".

Vague language is also seen in the fourth section, which offers information about side effects. As can be seen in the extract below (from Appendix 1) the patient is informed about the risk, which is sometimes serious, but the way the frequency is informed may confuse the readers, since it is a vague expression.

- **Occasionally** the blood does not clot well, which **may** result in bruising or bleeding, or yellowing of the skin and eyes **may** occur. Other side effects **may** include lethargy, weakness, shortness of breath, and **generalized** swelling or water retention, ringing in your ears or temporary hearing loss.

The fifth section presents the forms of storage, but the patient also finds the following information:

Do not use this medicine after the 'EXP' date shown on the pack.

Clearly, the patient would not expect to find this warning in this section. It would be more appropriate in section 2, because the patient should check the 'EXP' date before taking it.

Finally, the last section contains information about the medicine itself, that is, the ingredients and the presentation of them, as:

Active ingredients Each powder contains: Aspirin 600 mg and Caffeine 50 mg. **Other ingredients** Lactose, maize starch, colloidal anhydrous silica, sodium lauryl sulphate, saccharin sodium, sodium cyclamate and spice flavour.

Packs of […] contain either 10 or 20 powders.

However, such important information should be presented earlier, more precisely, in section one.

Although it seems, at first sight, reasonable to have 'information about the medicine' first, followed by 'what the patient should know before taking it', and only then 'information about how to take it', some studies reveal that this order fails to meet readers' expectations. Considering the premise that the writer should take into account the readers, their knowledge and expectations when writing a text, it seems paramount to investigate their preferences. Pander Maat and Lentz (2011) evaluated the reader's expectations about the structure of PILs by carrying out two card-sorting studies: 'closed sorting task and open sorting task'. In the first study, they assessed the participants' expectations regarding the template headings using 'scenario questions'. That is, participants were provided with "questions on medication use and were asked under which template headings they expected to find information on each question" (198). Results revealed that the participants experienced problems in finding information about ingredients given that only 65% of them located the ingredients successfully. This result can be explained by the fact that most ingredients are placed in the last section, whose title 'further information' does not actually allude to ingredients.

The second study accessed participants' 'schemata' of PILs regarding their structure by using an 'open sorting task', which consisted of 75 cards, covering 34 topics, with sentences that were taken from original PILs. First the participants had to group the cards that they thought belonged together, produce headings for these groups and finally, sort the groups. Results showed that the participant's preferences regarding order were different from those required by the EU and MHRA, in that the third section 'How to take it' was moved to the second place. This result might be due to participants' purpose when reading PILs, as they are more prone to be interested in learning about the dosage (section 4.2 presents some studies results about the participants' purposes).

Some information was also grouped together; for instance, information about other ingredients, which appears in section 6 of the PIL, was moved by participants to section 1. Some participants suggested a section titled 'contact your doctor', while some deleted altogether the sections 'what you need to know before you take it' and 'further information'. These results showed that participants prefer more specific topics, such as: pregnancy and breastfeeding, and driving and using machines, which are actually subsections of the section 'what you need to know before you take it'. Besides, the number of sections also changed, from 6 to 11, confirming participants' expectations for explicitness.

I agree with what Pander Maat and Lentz (2011) mentioned above, when stressing that the structure of PILs can influence their efficacy in a number of ways; for example, it can highlight the most important information and facilitate the searching for specific information. These factors are extremely important because not all patients read the entire leaflet; instead, they search for specific information.

The English PILs, like the other EU PILs, have an initial section, which first alerts about the importance of the PIL and then shows its contents.

> **Please read right through this leaflet before you start using this medicine.**
>
> Keep this leaflet, you may need to read it again.
>
> If you have any questions, or if there is anything you do not understand, ask your pharmacist.
>
> **In this leaflet:**
>
> 1. What Beechams Powders do
> 2. Check before you take Beechams Powders
> 3. How to take Beechams Powders
> 4. Possible side effects
> 5. How to store Beechams Powders
> 6. Further information

The MHRA has proposed the inclusion of this section to "ensure that patients are aware of key information on the safe and appropriate use of a product" (Dolk et al., 2011: 47) and to encourage patients to read the PILs (Raynor et al., 2007). Besides, it is believed that readers activate their prior knowledge when they read this section, which can contribute to a better comprehension.

The content of all PILs is based faithfully on the Summary of Product Characteristics (SPC), which is essentially a report of clinical

studies. This report, written by medical experts and addressed to experts, contains a detailed summary of the medicine, as well as its effects and side effects. According to Askehave and Zethsen (2003: 32), "the law requires a close relationship between these two texts [the SPC and the PIL] in the name of consumer protection". However, the authors point out that this 'close relationship' can cause significant communication problems, since the recipients of the two texts, which belong to markedly different genres, are also different. Whereas the intended recipients of the PILs are ordinary readers, who may possess little previous knowledge about the content, effects and side effects of the particular PIL, and indeed may not even be competent readers, the recipients of the SPC are experts. Thus, the document that emerges from this text conversion process can be highly deficient communicatively when read by the intended audience.

On the other hand, the linguist Grabowski (2013) reported different results. He investigated the use of key words and the phraseology of 463 PILs and 146 SPCs and pointed out that they "reveal a high degree of linguistic variation" (pp. 392). He states that, unlike SPCs, PILs are addressed to the general public, in that the pattern of keywords expresses recommendations (e.g. take), refers to users (e.g. you), specifies the pharmaceutical form of medicine (e.g. tablets) and has general language keywords (e.g. if, any). In terms of phraseology, Grabowski's results reveal that PILs have a high number of sentences formed by four words where three are identical and only one is different, for example 'tell your doctor *', 'ask your doctor *', which "express obligations and directives in the case of any problems with the use of a medicine" (pp. 399). According to the author, these results not only indicate that the communicative purpose of alerting patients about side-effects and instructing them to use medicines properly is fulfilled, but also that they are "written in a plain-user-friendly style" (pp. 396). However, although lexis plays an important role in the comprehension of PILs, I believe that evaluating their communicative efficacy based exclusively on lexis is insufficient, since there are many different dimensions that should be taken into account, such as syntax, semantics, and design. Moreover, Grabowski's findings contradict most studies that assess the efficacy of leaflets, which claim that they are not reader-friendly, either in terms of readability (Didonet & Mengue, 2008), or findability (Pander Maat & Lentz, 2011).

In order to check the similarities between the SPC and the PIL, I will briefly compare these documents. Table 4.2 below shows their

sections and subsections. The sections that present similar content are highlighted in the same color.

	SPC		PIL
			Name, qualitative composition, Pharmaceutical form
1	Name of the medicinal product		What Beechams Powders do
2	Qualitative and quantitative composition		Check before you take Beechams Powders 2.1 Do not take 2.2 Take special care with Beechams Powders 2.3 Ask your doctor before you take this medicine 2.4 If you are pregnant or breast feeding
3	Pharmaceutical form		How to take Beechams Powders
4	Clinical particulars: 4.1 Therapeutic Indications 4.2 Posology and method of administration 4.3 Contraindications 4.4 Special warnings and precautions for use 4.5 Interaction with other medicinal products and other forms of interaction 4.6 Pregnancy and lactation 4.7 Effects on ability to drive and use machines 4.8 Undesirable effects 4.9 Overdose		Possible side effects
5	Pharmacological properties 5.1Pharmacodynamic properties 5.2 Pharmacokinetic properties 5.3 Preclinical safety data		How to store Beechams Powders
6	Pharmaceutical particulars 6.1 List of excipients 6.2 Incompatibilities 6.3 Shelf life 6.4 Special precautions for storage		Further information

	SPC		PIL
	6.5 Nature and content of container		
7	Marketing authorization holder		Marketing authorization holder
8	Marketing authorization number (s)		The manufacturer
9	Date of first authorization/ renewal of the authorization		Date of revision of the text
10	Date of revision of the text		
	The manufacturer		

Table 4.2: SPC and PILs sections and subsections

As can be seen, there are some sections of the SPC that are not presented in the PIL, such as sections: 2 (quantitative composition); 4.7 (Effects on ability to drive and use machines); 4.9 (Overdose); 5 (Pharmacological properties); 6.2 (Incompatibilities); 8 (Marketing authorization numbers); and 9 (Date of first authorization/ renewal of the authorization). Although some of them clearly address only the experts, as sections 5 and 6.2, others would certainly make the PIL more efficient, as sections 4.7 and 4.9. It is important to point out that all PILs provide information about 'overdose' and some about the 'effects on ability to drive and use machines'. But such information is not under a special heading, as is the case in the SPC, and for this reason, they may pass unnoticed.

On the other hand, the sections with similar content are under different headings. For example: 'Contraindication' is renamed 'Do not take', which is easier for a lay reader to understand, as well as 'What Beechams Powders do', which substitutes 'Therapeutic Indications'. On the other hand, 'special warnings and precautions for use' is renamed 'Take special care with Beechams powder', which is weaker, and for this reason, readers may fail to recognize it as a warning and consequently ignore the message. Finally, the section 'Interaction with other medicinal products and other forms of interaction' is renamed 'Ask your doctor before you take this medicine', which is also easier for a lay reader.

The sequence is almost the same, except section 3 (PIL), named 'How to take Beechams Powders', whose SPC correspondent comes earlier. The main difference in relation to the content is due to the fact that the SPC explains the cause of some hazards as shown below:

Contraindication: (…) patient with severe hepatic or renal failure. Aspirin is known to cause sodium and water retention, which may exacerbate hypertension, congestive heart failure and renal impairment.

Aspirin – caffeine is not recommended for use during pregnancy due to the possible increased risk of spontaneous abortion and low weight associated with total caffeine consumption above 200mg per day.

The presentation of the 'causes of the hazards' is an important component that can not only attract the reader's attention, but also raise the reliability on the warning. However, the warnings above present a higher level of complexity due to the employment of specialized language (congestive heart failure), complex structure (passive voice) and long sentences.

Certainly, PILs should inform the reader about the reasons of the hazard. This way, s/he would be more willing to comply with the warning, given that s/he knows in which ways the medicine can harm him/her. For example, the PIL warns "Do not take Beechams Powders if you are pregnant or breastfeeding, except on medical advice". But it fails to inform about the severity of the hazard. The reader is unaware of the risks associated with taking the medicine. The SPC, on the other hand, provides this information, as in "(...) possible increased risk of spontaneous abortion and low weight (…)".

A brief comparison between the documents shows that the language employed in the SPC is more technical and complex than the PIL, especially in relation to more specialized content, as the reasons of the hazard, interaction with other medicinal products, undesirable effects and pharmacological properties. It is important to note that this content is restricted to SPC. A comparison of sentences that are about the same content could better unveil the similarities and difference between the SPC and the PIL. In the examples below, the passive voice was turned into active voice, which facilitates comprehension. However, the structure 'avoid excessive intake' is also complex.

Excessive intake of caffeine should be avoided while taking this product. (SPC)

Avoid excessive intake of caffeine, while taking this medicine. (PIL)

The warnings below are a good example of simplified language. The use of imperative is preferred, as pointed out by Dumas (1992), given that it is easily recognized as a warning. Besides, the direction of the PIL below is clearer and easier to follow.

Product should be discontinued if pain gets worse or lasts more than 10 days (or lasts more than 3 days for fever). (SPC)

Do not use for more than 10 days for pain relief (or more than 3 days for fever) (PIL)

There are cases in which both documents use the same warning (see below).

There is a possible association between aspirin and Reye's Syndrome when given to children. Reye's syndrome is a very rare disease which affects the brain and liver, and can be fatal. (Both)

However, it is interesting to note that only the SPC provides information about the indication of aspirin to children under 16 (see below).

For this reason aspirin should not be given to children aged under 16 years unless specifically indicated (e.g. for Kawasaki's disease). (SPC)

There are cases where the main difference lies in the internal sequencing of the sentence, like the example below, in which the direction comes first in the PIL.

If you suffer from asthma, allergic disease, kidney or liver problems consult your doctor before taking this product. (SPC)

Ask your doctor before you take this medicine: if you suffer from high blood pressure, asthma, allergic disease, kidney or liver problems. (PIL)

Thus, although the PILs present some changes that can facilitate comprehension, such as the use of active voice, imperative mood and ordinary terms, they still present some problems that can impair comprehension. The UK regulatory agency (MHRA) published a report, titled '*Always read the leaflets'*, which recognizes that some readers have difficulties in understanding the leaflets, and offers a discussion of how to improve the PILs. However, as pointed out by van der Waarde (2005: 11), the "format, content, and layouts of the current template are inappropriate for both 'users' and 'applicants'". So if even the template presents some deficiencies, how is one to produce an efficient PIL?

4.1.3 Brazilian Guidelines

In Brazil ANVISA (*Agência Nacional de Vigilância Sanitária*[23]) is responsible for producing the guidelines of medicine leaflets. The directive RDC 47 in 2009 regulates the PILs, and states information should be distributed into three main sections:

[23] National Sanitary Surveillance Agency.

- Identification of the medicine;
- Information to the patient;
- Legal sayings;

The first section is devoted to information regarding the medicine, and differently from the UK PILs, that inform only about the main ingredient, the Brazilian one lists all the ingredients. The second section, devoted to the patient, is the most important one and it is organized into a question/answer format, aiming at facilitating consumers' comprehension. It also indicates that the relationship between the writers and patients is taken into account (Clerehan et al., 2005). In this way, the section consists of nine questions and answers (see below).

1) What is this medicine used for?[24]
2) How does this medicine work?
3) When shouldn't I take this medicine?
4) What should I know before taking this medicine?
5) Where, how and how long can I keep this medicine?
6) How should I use this medicine?
7) What should I do when I forget to take this medicine?
8) What risks can this medicine cause me?
9) What should be done if someone uses a higher dose of this medicine than indicated?

The last section, 'legal sayings', contains information regarding the pharmacist, manufacturer and the warning [25] '*Siga corretamente o modo de usar, não desaparecendo os sintomas procure orientação médica*'.

The directive states how the message should be conveyed, not only in relation to the pattern, but also in relation to the wording, as can be seen in Art. 6°, below:

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[24] *1) Para que este medicamento é indicado?*
2) Como este medicamento funciona?
3) Quando não devo usar este medicamento?
4) O que devo saber antes de usar este medicamento?
5) Onde, como e por quanto tempo posso guardar este medicamento?
6) Como devo usar este medicamento?
7) O que devo fazer quando eu me esquecer de usar este medicamento?
8) Quais os males este medicamento pode me causar?
9) O que fazer se alguém usar a quantidade maior do que a indicada deste medicamento?

[25] *Siga corretamente o modo de usar, não desaparecendo os sintomas procure orientação médica.*

> Art 6
> In relation to the content, the insert must have the information provided in attachment I of this directive, following the established order and items.
> § 1° The patient package inserts must have the items related to: medicine identification, information to the patient, and legal sayings and the text must;
> I – be organized in a question/answer format;
> II – be clear and objective without repeated information;
> III – be written in accessible language, with concise and clear wording, according to the guide for the writing of inserts, with the aim of enabling the patient's comprehension.
> IV – have explanatory terms after technical terms, for the patient's comprehension.

Although there is a concern with the readability of the PILs, the term 'clear language' seems to be vague for at least two main reasons which are intrinsically linked: 1) each writer may interpret the term 'clear language' in a different way; 2) the definition of 'what clear language is' will depend in part on the readers, whose level of content and linguistic knowledge can range from the lowest to the highest. The document does not mention the readers' level and for this reason it is difficult to determine what clear language means. It is important to point out that there is no provision for a 'clearness evaluator', that is, the writer judges the level of adequacy by his/her own.

The directive also states that the language should be accessible, but this time the term is accompanied by the explanation "with concise and clear wording". However, it is redundant and it can confuse the writer, because it first states that the language should be 'clear', then it states that it should be 'accessible', but accessible, according to the document, actually means *clear* language. A search in the on-line dictionaries 'Aurélio' and 'Michaelis' leads us to the following definition:

Claro: O que não deixa dúvidas; o que se entende bem. (Aurélio)

Claro: Fácil de entender (Michaelis)

Acessível: compreensível, inteligível (Michaelis)

Finally, the directive asserts that the writer should follow the instructions of the 'Guide for Insert Writing' in order to facilitate the

reader's comprehension. The guide is more precise in relation to the rules that make a text more accessible to the reader. These rules take into account not only the lexical choices, such as the explanation of technical terms, but also the structure of the sentences, such as the preference for the active voice and short sentences. However, it seems that providing the explanation of the technical terms renders the reading tiring. Why should the technical terms be kept? Maybe, providing only the explanation for them would be more beneficial.

4.1.4 Comparison

A comparison between the English and the Brazilian PILs reveals some differences regarding the organization of the information. The English PILs have an initial section, which is not present in the Brazilians ones.

After this initial section, the English PILs contain 6 sections, which were already discussed above. The Brazilian PILs, on the other hand, do not have this initial section and are organized into only three main sections. The Brazilian first section 'Medicine identification' combines some information placed in the first and the last sections of the UK PIL, which are related to the medicine ingredients, and is in accordance with Pander Maat and Lentz's (2011) results, since the participants of their study grouped these sections together. Clearly, the Brazilian PILs present the ingredients of the medicine more efficiently than the English PILs.

The second main section of the Brazilian PIL, named 'Information to the patient', which is formed by 9 sub-sections, corresponds to the 5 first sections of the English PIL. See table 4.3 below, which shows the headings of the English PILs on the left, in their required sequence. The headings of the Brazilian PILs are on the right and are also in the required sequence. As before, colors are used to highlight the headings with similar content. In this way, it is possible to visualize how the same topics (headings) appear in both PILs.

HEADINGS OF THE ENGLISH PILs		HEADINGS OF THE BRAZILIAN PILs	
			- Section 1
1	- What the drug is and what is used for;	a	- What is this medicine used for?
		b	- How this medicine works?
2	- What you need to know before you take it;	c	When Shouldn't I take this medicine?
		d	- What should I know before taking this medicine?
		e	- Where, how and how long can I keep this medicine? (5)
3	- How to take it;	f	- How should I use this medicine?
		g	What should I do when I forget to take this medicine?
		h	- Which risks this medicine can cause me?
4	- Possible side effects;	i	What should be done if someone uses a higher dose of this medicine than indicated?
5	- How to store it;		
6	- Content of the pack and other information.		

Table 4.3: English vs Brazilian's headings

They have almost the same information, with the exception of section 2 of the Brazilian PIL 'How this medicine works?' (see below) that does not appear in the English one.

Paracetamol reduz a febre atuando no centro regulador da temperatura no Sistema Nervoso Central (SNC) e diminui a sensibilidade para a dor. Seu efeito tem **inicio 15 a 30 minutos** após a administração oral e permanece por um período de 4 a 6 horas.

However, except for the information regarding time effect, the remaining information seems to be unnecessary to consumers.

As can be seen in the table above, the Brazilian PIL appears to be more specific in the headings, which demands less effort from the consumer, who does not need to infer where the information is in

relation to given issues. For example, a consumer takes more than the recommended dose and needs to read the PIL in order to know both the symptoms and the actions that should be taken. If s/he reads the English PIL, s/he needs to either infer that this information is in the section 'how to take it', or even read the entire PIL. On the other hand, if s/he reads the Brazilian one, s/he needs to scan the PILs to find the information in section 9, under the heading 'What should be done if someone uses a higher dose of this medicine than indicated?'.

However, there is evidence that both the English and the Brazilian headings are inadequate. Pander Maat and Lentz (2011), when discussing the EU pattern, point out that "there is a mismatch between the wording of the headings and readers' interpretations" (197). Possibly, the same problem can be observed in the Brazilian PIL. According to the authors, one problem derives from the fact that the headings are "phrased very generally". At this point, it is necessary to remember that some readers do not read the entire leaflet; instead, they scan it looking for specific information, such as: 1) can I take more than one tablet to relieve the pain?; 2) how long can I take it?; 3) can I take it if I drive?; 4) can I take if I consume alcohol? Since neither the English nor the Brazilian PILs have headings that address such questions, the readers need to either infer the location or read the entire leaflet.

The information in the English PIL regarding the first and the second questions above is under the heading "How to take Paracetamol Oral Infusion", and it seems that the heading is adequate, since they are related. On the other hand, the answers to the third and fourth questions can be found under the heading "Before you take Paracetamol Oral Suspension", which are not related, and force the readers to infer their location. The readers of the Brazilian PIL can find the answers for the first and fourth question in section 4, titled "What should I know before using this medicine?". But it would be more reasonable to place the information regarding the first question in section 6, titled "How should I use this medicine?", because they are about the same subject. The second question, like the English one, is answered in section 6, whereas the third question, about taking the medicine and driving, is not addressed.

Wogalter (2006) notes that when the reading is time consuming, in that the readers need to reread the message in order to understand it, they tend to give up the task. Probably, readers that struggle to find the answers for their queries adopt the same action. For this reason, the headings should, at least, be related to their content. In this vein, the headings, "Before you take Paracetamol Oral Suspension" (UK) and

"What should I know before using this medicine?" (BR), should be replaced by headings that are associated to their content, which would not only facilitate the searching but also catch the readers attention, because being too all-encompassing fails to draw the readers' attention to important issues that pass unnoticed amid less important information. In addition, as mentioned before, warnings are not labelled as such and are placed in more than one section, which can complicate their identification, and consequently minimize compliance.

At this point, it is important to remember that ANSI's requirements for warnings include four textual components: 1) a signal word; 2) the identification of the hazard or action statement; 3) information about how to avoid the hazard; 4) the possible consequences of not avoiding the hazard. As can be seen, the PILs fail for not including a signal word, and although they bring information about the hazard, how to avoid it, the consequences of it and what to do if the hazard was not avoided, the information is spread through the document. For example: when reading section 2, headed "Check before you take Beechams Powder" the patient finds the warning: "Do not take: if you are allergic to **aspirin** or salicylates, **caffeine**, any other medicines know as **NSAIDs** or to any other ingredient (listed in Section 6)", which gives directions to avoid the hazard. Then, s/he is guided to section 6, namely 'Further information' that informs the other ingredients of the medicine, which complements the warning. However, if s/he needs to know which are the symptoms of an allergic reaction [some people may not know if they are allergic], then s/he should be more attentive, since the leaflet fails to provide the reader with this information, which is situated in section 4, headed 'Possible side effects', lines 13-16. It is interesting to note that there are many different side effects, not only those related to allergic reaction. Finally, if s/he wants to know what to do in the case of an allergic reaction, s/he then should return to lines 3-5 of section 4. Thus, in order to have information about allergic reactions, the reader must engage in a 'searching game' that must begin in section 2 and move on to section 6, then to section 4 (lines 13-16) and finally back to section 4 (lines 3-5). Furthermore, to complicate the game even more, some headings also fail to inform properly, given that 'further information' is not the best choice to highlight the ingredients of a medicine.

The sequencing of information can be a serious problem, which can impair text comprehension. In this respect, Shuy (1990: 296) observes that "simply having all the proper pieces of information is not enough", since they should be presented in a way to facilitate both

comprehension and findability. Under this view, it seems adequate to present the most important information first, such as the most serious and frequent risks, because the reader may expect to see them at the beginning.

Both PILs present the goal of the medicine and the ingredients at the beginning, but as already mentioned, the English one splits the information regarding the ingredients; whereas the main ingredient is placed in the first section, the other ingredients are placed in the last one. Interestingly, the following section of both PILs addresses the warnings, though not labelled as such. But earlier versions of the Brazilian PILs had a section headed 'warnings', which has been renamed "When Shouldn't I take this medicine?" and "What should I know before taking this medicine?".

Nevertheless, the main problem lies in the last sections of the Brazilian PIL, given that less relevant information is placed before, as is the case of storage, in section 5, which precedes information about directions for use and potential problems. Moreover, the last section "What should be done if someone uses a higher dose of this medicine than indicated?" should appear before section 7 "What should I do when I forget to take this medicine?", because it is about actions that should be taken when the risk was not avoided.

4.1.5 Summary of the Section

The analysis above reveals that both the English and the Brazilian PILs seem to conform to the guidelines proposed by the MHRA and ANVISA, when structure is concerned. This result is in agreement with previous studies of UK PILs (Meola, 2013).

The UK and the Brazilian PILs have different structures, although they convey similar information. The Brazilian PILs are organized into questions and answers, aiming to get closer to the consumers. They are also slightly more detailed, as they have three extra sections, which facilitate the searching for information, especially information related to overdosing. On the other hand, a closer analysis reveals that the structures of both PILs seem to be ineficient in at least three aspects: headings, sequencing and organization of the information.

Some headings are too general, which makes searching more difficult. They should be more explicit, as they are intended to guide consumers to find information to solve their doubts. Some sections/sub-sections are full of information and for this reason some information can go unnoticed by consumers. In order to facilitate findability, sub-

divisions should be used, as already pointed out by some authors (Pander Maat & Lentz, 2011). Despite being too all-encompassing, some headings are inconsistent, as they are not related to the actual information provided, as section 6 of the UK PILs.

The headings of the PILs also fail for not attracting the consumers' attention. Such a problem is mainly due to the elimination of the signal word 'warning'. As noted in Chapter 2, the boundaries between warnings and other speech acts are not clear-cut (Dumas, 2012), and for this reason, consumers' may fail to recognize them. Moreover, the strategy of eliminating the 'signal word' runs against that employed in many other consumer products, which use it widely, even with less dangerous products. The sequencing of some headings is also inefficient, as more important information is located at the end of the PILs. Clearly, it is contrary to the tenet of providing the most important information at the beginning (Shuy, 1990). It also fails to meet the consumers' expectation regarding what information they prefer to find first (Pander Maat & Lentz, 2009; van der Waarde, 2008).

The location of information related to the same topic in several different sections/sub-sections represents a serious problem, as the consumers can fail to find it. As already noted, few consumers read the entire PILs, and even if they do, most may fail to make the necessary connections to act properly. In order to avoid it, information related to the same topic should be placed together.

The analysis also shows that some PILs present a list of information in prose format, which not only discourages reading but can also 'mask' important information. This strategy occurred more frequently in the 'medicine interaction', 'side effects' and 'do not take if (..)' sections/ sub-sections. In order to avoid it, the information in these sections should be presented in a bullet list.

Based on the premise that "in order to use information about medicines, it is necessary that this information can be found, read, understood and applied" (Rusko, van der Waarde & Heiniö, 2012: 84), it is possible to say that both sets of leaflets are inefficient, as consumers may not find the necessary information, especially that concerning warnings, medicine interactions and side effects. The next sections will discuss the features that can influence the readability, comprehensibility and applicability of PILs.

4.2 WARNINGS IN PILs

As already stated in section 4.1 titled 'PILs Structure', the warnings are not signaled as such, and for this reason, they go by unnoticed. The problem is intensified when the warnings are inefficient, that is, when they fail to accomplish their main purpose of providing safety information to minimize the hazards. I have also discussed in the Review of the Literature chapter some factors that can strengthen the warnings, which can be summarized in Shuy's (2008) definition, that a warning "should identify and describe the nature and danger of the risk. Then they should tell the reader how to avoid it. Finally, they should communicate those things in clear and understandable language" (p. 72). I would like to add another equally important factor, 'attracting the consumers' attention', because the message needs to encourage the consumers' compliance. Thus, this section aims to verify whether the warnings provide all the necessary information to direct the consumers to adopt a safe behavior.

4.2.1 Mandatory Warning – Uk

The Human Medicine Regulations, which are responsible for the PILs' guidelines in the UK, have removed the majority of statutory label warnings for medicines, but retained the "statutory warnings for all medicines which contain paracetamol". The mandatory warnings, although not signalled, alert to the risk of overdose (A), what should be done to avoid the risk (B) and the results of non-compliance (C). This warning is placed in section 3, headed as "How to give paracetamol to your child" (see below).

If you give too much (A)

Talk to a doctor at once (B) if your child takes too much of this medicine even if they seem well (A). This is because too much paracetamol (A) can cause delayed, serious liver damage (C).

All the necessary components to warn the consumers efficiently are present in the mandatory warning, which does not mean that the warning is efficient, because efficiency is not so straightforward. It is necessary to verify how the message is conveyed. As can be seen, 'liver damage' is said to be a 'serious' consequence (C) and pointing it out can draw the consumers' attention to the warning. There are many studies that show that when the consequence is explicitly stated, not only does the probability of reading the warnings increase (Trommelen and Akerboom, 2006, as cited in Wogalter, 2006), but also so do the chances

of compliance (Borade, Bansod & Gandhewar, 2008). Moreover, the warning also states the gravity of the consequence, 'serious', which according to Dumas (1992) strengthens the warning.

However, the combination of the modal operator 'can' and the verb 'cause' serves to weaken the warning, since it expresses a probability. Dumas (1992: 300) points out that warnings that contain 'can' "are ranked as weaker". Hegedüs (2008) notes that the structure 'can + cause + side effect' gives incomplete information and for this reason, it violates the Gricean Maxim of Quantity, given that it informs less than the necessary. She also states that:

> The patients' background knowledge contains the fact that medicines in general can cause side effects, but they require information on the likelihood of side effects appearing and on the range of people who are at risk of side effects and adverse effects. (69).

The warning is also imprecise in relation to the period during which the liver damage can occur, as can be seen in 'can cause delayed, serious liver damage'. The main problem lies in the expression 'delayed', which can be interpreted in different ways, either one day or one week or weeks. Interestingly, the SPC of paracetamol[26] is more precise in relation to the period within which symptoms of an overdose can occur (see below):

"Symptoms of paracetamol overdosage in the first 24 hours are pallor, nausea, vomiting, anorexia and abdominal pain. Liver damage may become apparent 12 to 48 hours after ingestion" (SPC-A2).

This is extremely important, as the consumers will be more aware of the consequences and therefore, more prepared to act faced with an overdose. However, this kind of information is not present in the PILs.

The writers also have to deal with the problem of space constraints, and for this reason, the manufacturers can use this argument to justify any absence of information. However, given that even MHRA recognizes the severity of the consequences of an overdose 'serious liver damage', it seems reasonable to inform about the symptoms of these consequences. Despite that, in the section on side effects, there is no information regarding it - most information concerns the symptoms of

[26] Retrieved from: https://www.medicines.org.uk/emc/medicine/15678 (22/02/2016).

allergies. Moreover, given that the MHRA does not require this information, the lack of it would not represent culpability. Thus, in a lawsuit, the laboratory would not be responsible for not providing enough information because it has provided all the information requested by the Regulatory Agency.

Information about the hazard (A) is an important component of warnings, since, as alredy noted, consumers tend to be more attentive when the hazard is explicitly stated. On the other hand, when the hazard is implicit or indirect, it may undermine the warning. The hazard, 'taking too much of this medicine', is an example of imprecision that might lead the consumers to misinterpret it. That is, the consumers have to infer the quantity of 'too much'. The main problem lies in the fact that this inference can be wrong, for example, some consumers can infer that 'too much' means just one dose more than the amount stated in the 'how to take X' section of the PILs, while others can infer that 'too much' means taking ten times more than the amount stated in the 'how to take X' section. Thus, the way the word 'overdose' is perceived by readers can influence their attitude toward their action.

Finally, the warning gives the directions (B) to minimize the consequences of taking too much medicine, such as 'Talk to your doctor at once', in that 'talk' is a verbal process, which does not imply an action, instead, it is used for the "creation of narrative by making it possible to set up dialogic passages" (Halliday and Matthiessen, 2004: 252) or even for the creation of other discourse types, such as: quote and report in an academic discourse. For this reason, using a verbal process to give directions on how to minimize the consequences might not be the best choice, since it seems a weak verb. On the other hand, the imperative is clear in relation to the action.

The warning above brings information about the hazard (A), the directions to adopt if the warnings consequences were not avoided (B) and the consequences (C). However, at the same time it brings all this information, it is marked by imprecision, which can confuse the readers. It gives the impression that the main purpose of the manufacturers is that of providing the information to be in agreement with the requirements stated by the (MHRA) to avoid lawsuits, rather than communicating consumers safety information successfully. It seems important to remember that this warning is provided by the regulatory agency. In this way, a revision should be considered in order to avoid vagueness and to include the sysmptoms of an overdose.

The manufacturers comply with the requirement of the guidelines, but, as can be seen in table 4.4 below, all of them suffered

some kind of modification. They either phrased the mandatory warning differently (*italics*) or provided more complete information [in brackets] or added totally new information. (D), (E) and (F).

(A) Hazard;
(B) Directions to adopt if the consequences were not avoided;
(C) Consequences;
(D) Directions to avoid the consequences;
(E) Specific directions to adopt if the child takes too much;
(F) Symptoms.

MANDATORY WARNING	**If you give too much (A):** Talk to a doctor at once (B) if your child takes too much of this medicine even if they seem well (A). This is because too much paracetamol (A) can cause delayed, serious liver damage (C).
1 ALVEDON	If you give *too many Alvedon Suppositories to your child* **(A):** Do not give your child more suppositories than stated overleaf (in the section called "How many Alvedon Suppositories to give your child"). **(D)** *Immediate medical advice should be sought in the event of an overdose*, even if *the child* seems well **(B),** *because of the risk of* delayed, serious liver damage **(C).** Your child may need to have a blood test to check how well their liver is working **(E).**
2 BOOTS 6 YEARS	! If you give too much or [if anyone accidentally swallows some of the medicine] (A): *Immediate medical advice should be sought in the event of an overdose*, even if *your child* seems well **(B),** *because of the risk of* delayed, serious liver damage **(C).** Go to your nearest hospital casualty department. Take the medicine and this leaflet with you **(B).**

3 PERFALGAN	**[If you or]** ***your child use more PERFALGAN 10mg/ml, solution for infusion than*** **[you or]** ***your child should use*** **(A):** **talk to a doctor at once if [you or] your child take too much of this medicine even if [you or] your child seem feel well (B). This is because too much paracetamol can cause delayed, serious liver damage (C).** In overdose cases, symptoms generally appear within the first 24 hours and comprise: nausea, vomiting, anorexia, pallor, abdominal pain and a risk of liver injury **(F).**
4 CALPOT	**If [anyone]** ***has*** **too much (A):** *Immediate medical advice should be sought in the event of an overdose*, even if *the child* seems well **(B),** because of the risk of delayed, serious liver damage **(C).**
5 CARE INFANT PARACETAMOL	**If you give too much (A):** Talk to a doctor at once if your child takes too much of this medicine even if they seem well **(B).** This is because too much paracetamol can cause delayed, serious liver damage **(C).**

Table 4.4: Mandatory warnings

The modifications vary from minimal, as in (5), in that 'your' was replaced by 'a', to more substantial, as in (1), (2) and (4), whose lexicogrammatical structures were totally modified. First, it is rephrased in the passive voice in 'Immediate medical advice should be sought in the event of an overdose'; the use of passive voice in warnings gives impersonality, since it does not address the participants, increasing the distance between the writer and the reader. Moreover, the focus is exclusively on the (physical) world rather than on the consumers performing an action to minimize a consequence. This distance and lack of focus on the action may affect negatively compliance with the warnings and consequently their efficacy. Second, the process 'talk' was replaced by 'sought', and 'your child takes too much' by 'in the event of an overdose'. Both replacements demand more effort to be understood, and more knowledge, given that 'overdose' is a technical term, and it is

generally linked to illegal drugs.

The information added to the warnings also varied from minimal, as in (3) with 'you' and (4) with 'anyone', which includes the adult reader, although the medicine is specific for children under 12 years old; to more substantial additions, as in (2), 'if anyone accidentally swallows some of the medicine'. These additions reveal the concern of the manufacturers when adults sometimes take medicines, intended for children.

Finally, 3 new information chuncks were included, as in (1), for example, which states "do not give your child more suppositories than stated overleaf (in the section called "how many Alvedon Suppositories to give to your child")". It is certainly necessary information about how to avoid risks, that if absent, should be inferred by the consumers. It is written in the imperative form and clearly informs the reader about what s/he should not do. On the other hand, the information is incomplete, given that the reader is guided to move to another section to discover the amount of medicine that s/he or the child should take. It appears that the need to read more than one section in order to receive the complete message is a characteristic of leaflets, which can weaken them, given that it not only demands some effort from the consumer who needs to look for the complementary information, but also confuses her/him if the section is not well signalled.

The second addition also occurs in (1), with the warning "Your child may need to have a blood test to check how well their liver is working", which may concern some readers given that they may believe that taking a blood test is generally related to serious problems. Furthermore, it is not clear when the consumer should do the test, particularly given that the modal operator 'may' conveys uncertainty. At the same time, it is important to provide it, because, if adopted, can relieve further concerns. It is impossible to know how consumers will receive the message, if it will cause worries or not, or even if it will encourage the reader to comply with the warning or not.

Finally, with the exception of (3), none provides any information related to the symptoms of liver problems, as in: 'In overdose cases, symptoms generally appear within the first 24 hours and comprise: nausea, vomiting, anorexia, pallor, abdominal pain and a risk of liver injury (F)'. Given that very few readers know the symptoms of a liver disease, the absence of this type of information reveals the weakness of the other warnings. Consequently, the readers may either stop giving the medicine to their children, ignore the message or, even worse, may fail to recognize an overdose, which can result in very serious consequences.

Dixon-Woods (2001) notes that one goal of PILs is that of patient empowerment, that is, providing the reader with information so that s/he is able to act when faced with a problem. Moreover, as mentioned in section 4.1, the goal of PILs is to "enable users to act appropriately" (MHRA). Nonetheless, the analysis of the mandatory warnings reveals that the information provided is inefficient due to vagueness and lack of information about overdose symptoms, despite apparently providing all the necessary information. For this reason, the warnings might be considered open to prosecution in litigations.

4.2.2 The Doctor's Responsibility

In the second section, it is pointed out what should be done before giving/taking the medicine, and the consumer is warned to either talk to a doctor/pharmacist or to check with them before using the medicine if the person who will take it has some other diseases or makes use of the medicines of others. But, given that the medicine has the status of an 'over the counter medicine' (OTC), it means that it can be bought without a doctor's prescription, so it seems a contradiction to warn the consumers to talk to a doctor before taking the medicine. It is interesting that 'doctor' is the second most frequent content word in the English corpus, with 1,494 entries in a corpus composed of 87 files with 150,214 word tokens. This result is similar to the one reported by Hegedüs (2008), where 'doctor' was the most frequent content word in her corpus. (See table 4.5 below).

	CONTENT WORD	ENTRIES
1	Medicine	1675
2	Doctor	1494
3	Take	1449
4	Are	1424
5	Have	1313
6	Is	1251
7	Tablets	1112
8	May	1068
9	Effect	1066
10	Side	1046

Table 4.5: English most frequent content words

Interestingly, ‘your’ co-occurs with ‘doctor’ 1,165 times, implying that every consumer has a doctor. The table below shows the process that most co-occurs with ‘your doctor(s)’. As can be seen, they express obligation, given that they are in the imperative. This finding corroborates Grabowski’s (2013) in that his study revealed a high number of patterns for ‘verb + your doctor’, where the most frequent verbs are: ‘tell’ and ‘ask’.

		Your doctor	1,165
1	Tell		297
2	Talk to		230
3	Ask		111
4	Check with		59
5	Contact		48
6	Consult		20

Table 4.6: doctor's co-ocurrences

As can be seen from the examples below, the processes 'tell', 'contact' and 'consult' are generally employed to refer to the consequences of taking the medicines or to the symptoms the consumers want to relieve when taking the medicine:

You must **tell** your doctor if you experience any unusual bleeding (D4).

Contact your doctor immediately if you: (list of problems) (F4)

If symptoms persist for more than 3 days or get worse, **consult** your doctor or pharmacist. (A 4).

Whereas the processes 'talk', 'ask' and 'check with' are frequently employed to refer to action that should be taking before the medicine.

Talk to your doctor or pharmacist before taking Micropirin (D9).

If you have any further question **ask** your doctor or pharmacist (F2). Take special care and **check with** your doctor before taking paracetamol if: (list of diseases) (A13)

However, despite directing the consumers to get into contact with their doctors, what else do the PILs warn the consumers to do if the consequences were not avoided? The most reasonable action, 'stop taking it', which occurs 182 times. As can be seen, the direction is clear, furthermore, the term 'immediate' strengthens the message.

Stop taking Brufen and seek immediate medical help if you experience: (list of side effects) (C2).

Interestingly, the combination 'stop taking' also occurs in two other different contexts, (see below). In (B1) the consumer is advised to not stop taking it, but this only occurs twice in the whole corpus.

Whereas (E3) is typical of codeine, due to the characteristics of the medicine.

Do not stop taking it without talking to your doctor. (B1)
When you stop taking it, you may get withdrawal symptoms. (E3)

4.2.3 Alcohol, Driving and Using Machines, Pregnancy and Breastfeeding

Knowledge about how actual consumers approach the PILs is fundamental, because it shows whether the consumers read the PILs, which information they need and their difficulties. Silva et al. (2006) conducted an investigation in Brazil that addresses these topics, which reveals that 80% of the 1,829 respondents reported that they read the PILs, although only 22.75% claimed to read the entire PIL. Most of them reported reading the PILs to look for specific information, such as: indication, contraindications, instructions for use and side effects. This result confirms my beliefs that consumers read the PILs to look for specific information, such as: the use of alcohol, driving and using machines, pregnancy and breast-feeding. For this reason, I will address these topics.

Information regarding the ingestion of alcohol is one reason the consumers consult the PILs. But the investigation of the entry 'alcohol', which occurs 95 times in the corpus, leads to two different results. It is sometimes part of the ingredients as in (B7): 'The active substances (…) polyvinyl alcohol partially hydrolysed (…)'. Whereas most occurences of alcohol are in warnings, which either provides information about the concomitant use of the medicine and alcohol or/and give the directions to avoid a risk (see below).

If **adults** take this medicine: the following additional warnings are included in case an adult takes this product. If you drink large amounts of alcohol, you may be more open to the side effects of paracetamol. (A12)

Can adults take this medicine?

This product is intended for use by children under 6 years old. However, the following additional warnings are included in case an adult is taking this medicine. This medicine may be harmful if you have alcoholic liver disease. (A16)

Information for adults intending to take this medicine

This medicine may be harmful if you are dependent on alcohol or have alcoholic liver disease. Do not drink alcohol (wine, beer, spirits) whilst taking this medicine. (A5)

Warnings (A12, A16 and A5) stress that the medicine is for children, but still provide information for adults who intend to take it. The warnings are hypothetical, formed by two parts, a condition and a consequence, following the structure 'if X, then Y' and tend to be more efficient than categorical warnings for at least two reasons: they are easily recognized and are perceived as stronger (Dumas, 1992). On the other hand, some factors weaken the warnings. First, the use of the modal operator 'may' in the consequence 'this medicine may be harmful if you (…)' weakens the warning because it refers to a possibility. Second, the condition of the warnings addresses just some of the readers, in that both (A16 and A5) refer to readers who '(…) have alcoholic liver disease.' and (A12) refer to those who '(…) drink large amount of alcohol (…)'. The problem that results from this is twofold: (1) the addressees, people who are alcohol dependent, may not recognize that the warning is for them, because they do not actually see themselves as alcohol dependent. (2) The warnings allow people to infer that they can drink alcohol, given that the problem is only linked to dependence.

Some warnings also fail to inform consumers how to avoid the risks. While (A5) is clear in relation to how to prevent the risk, 'Do not drink alcohol (wine, beer, spirits) whilst taking this medicine', (A16) and (A12) are obscure, in that the consumers need to infer the actions based on the hazard, which for (A12) is 'If you drink large amounts of alcohol, you may be more open to the side effects of paracetamol'. As can be seen, it fails to effectively inform the risk for at least three reasons: first, the expression 'large amounts' is not specific and can confuse the reader; second, the modal operator 'may' combined with 'be more open' renders imprecision and fails to catch the reader's attention, who will probably ignore it; finally, it is unlikely that the reader is aware of the side effects of paracetamol, and very few readers will be willing to look for the side effects. So, for the reasons just mentioned, it is possible to say that this warning is ineffective.

Warnings (D3, E5 and A13) below also fail to provide exact information about the risks of alcohol. Possibly, most consumers do not know the effects of the medicine, moreover, the processes 'enhanced' and 'increases' are vague.

Alcohol: some of the effects of aspirin are enhanced (D3)
Alcohol: increases the risks of side effects occurring and may make you feel more drowsy (E 5)

Those warnings that aim at directing the consumers' action also range from very vague (A13) to more specific (E19), that states clearly the prohibition. Possibly, the vague warning will be ignored, because it gives no idea about what to do.

Take special care (…) if you suffer from liver disease, severe kidney disease or from alcohol abuse. (A13).
Do not drink alcohol (wine, beers, spirits) whilst taking this medicine (E19)

Surprisingly, A1 warns 'do not give alcohol to your children – while they are being given these suppositories', allowing the reader to infer that her/his child can ingest alcohol when they are not taking the drug. So, the linking word 'while' is not a good choice in this case.
Do not give your child alcohol, or any medicines containing alcohol, while they are being given these suppositories. (A1)

The warnings that refer to alcohol consumption fail to inform clearly about the risks. I know that the organism of each person can react differently, but the risks related to liver and kidneys seem to be common in the case of paracetamol. The analysis above shows that the risk is only linked when the consumers are alcohol dependent or already have liver disease. But they fail to state clearly that the combination of paracetamol and alcohol can seriously damage the liver and the kidneys. The warning (A17) below differs from others for two main reasons: it first provides the instruction to avoid the risks; then it justifies why alcohol should be avoided, which is the consequence. Certainly, the chances of compliance tend to be greater in this case, although it would be more efficient if it informed about the level of severity of the risk.

Paracetamol Oral Solution with food and drink

Do not drink alcohol whilst taking Paracetamol Oral Solution. This is because taking alcohol and paracetamol together can increase the risk of liver damage (A17)

Information regarding driving and using machines appears in most PILs. The entry 'drive' occurs 147 times in the corpus, and more than half of the warnings are under the heading 'driving and using machines (machinery)', which occurs 56 times in the corpus. Interestingly, the analysis shows that some entries are part of an address, as below:

Booth Drive Park Farm South Wellingborough Northamptonshire NN8 6GT, UK (A6)

The entries that refer to the ability to drive, which are most of them, either inform about the influence of the medicine on this ability or instruct the consumers how to act, or even both, which would render it more efficient. The warnings (A14 and C1) below inform about the influence.

Driving and using machines

Paracetamol tablets has no influence on the ability to drive and operate machinery (A14)

Driving and using machinery

Using this product is not known to affect your ability to drive or use machinery. (C1)

As can be seen, these warnings allow the consumers to drive. The way the warnings above provide this information called my attention. Whereas A14 employs a declarative clause, which is clear, C1 uses a passive clause to inform the uncertainty about the influence. I wonder how this warning would be treated in a lawsuit.

Some warnings provide both pieces of information, but, as already pointed out, this is not guarantee of efficiency. The information regarding the effect on driving is vague in B3 and F6. This is because they employ the modal operators 'can' and 'may' that weaken the proposition. Then, they transfer to the consumers the responsibility to check if they are affected. It would not be a problem if the warnings provided more information about it, such as: how long after taking the medicine do the symptoms appear? Finally, the warnings give the direction to avoid the risk, which is clear in B3, but only suggestive in F6.

Driving and using machines - These capsules can cause some people to feel dizzy or giddy, drowsy or sleepy, tired or have problems with their vision. If you are affected, <u>do NOT drive or operate machinery</u>. (B3)

Driving and using machines: This medicine may make you feel dizzy, depressed, sleepy, tired, or make it difficult to sleep. It may also affect your vision. <u>You should not drive or use machines until you are sure you are not affected</u>. (F6)

Warning D15 exemplifies that informing more than necessary can affect the efficacy, which certainly violates the Gricean Maxim of Quantity (1975). Moreover, some consumers may not understand it due to the complexity of the clauses. The use of the passive voice and the length of the sentences are just some characteristics that render the warning complex.

Driving and using machines:

This medicine can affect your ability to drive or use machines as it may make you feel sleepy or dizzy. Do not drive or use machines while taking this medicine until you are sure you are not affected. It is an offence to drive if this medicine affects your ability to drive. However, you would not be committing an offence if: The medicine has been prescribed to treat a medical or dental problem and you have taken it according to the instructions given by the prescriber or in the information provided with the medicine and it was not affecting you ability to drive safely. Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine. (D15)

Pregnancy and breast-feeding is addressed in almost all PILs. Entries related to these terms are: pregnancy with 183 occurrences, pregnant with 193 occurrences, breast-feeding with 122 occurrences and breastfeeding with 67 occurrences. The warnings reveal differences related to the topics that are probably influenced by the medicine itself, given that pregnant/nursing women can use some medicines. Some warnings are clearer not only in relation to the risks (1), but also to the actions (2) and to the addresse.

Breastfeeding:

(2) Do not take codeine while (3) you are breastfeeding. (1) Codeine and morphine passes into breast milk. (D15)

Some others provide different guidance depending on the stage of pregnancy, which can represent a great problem, (see B1 below):

"Take special care with Volsaid and always tell your doctor if:

- you are in the first six months of your pregnancyYour are planning to become pregnant or if you have problems becoming pregnant. Volsaid may make it more difficult to become pregnant" (B1)

"Do not take Volsaid

- if you are in the last trimester of your pregnancy" (B1)

pregnancy and breastfeeding:

"If you are pregnant or breastfeeding, or could become pregnant, talk to your doctor before taking your tablets" (B1)

The warnings above may lead the consumers to adopt an inadequate action, despite offering some pieces of information. All of them are from the same medicine (B1) and are under section 2. The problem lies in the fact that they are separated, that is, under the title 'take special care (...)' the consumer is somehow allowed to use the medicine. Then, after many other warnings and under the title 'do not take (…)' the consumer is now forbidden from using the medicine. Finally, at the end of the section, and under the title 'pregnancy and

breastfeeding' the consumers are adviced to talk to their doctors. If the consumer reads the whole section attentively, s/he will know when the medicines are allowed or forbidden. But, if s/he scans the PILs in order to have specific information, s/he will find it at the beginning of the text, then s/he might stop reading, and consequently, lose the important information about the prohibition of the medicine.

This situation demonstrates two problems that occur in most PILs, separation of information and hierarchy. Shuy (1990) and Wogalter (2006) note that more serious risks should be presented earlier. In this vein, it is possible to assume that 'prohibition' should be presented before 'permission'.

The following warnings address women that are planning to become pregnant or of childbearing age (C5 and D15). But some women may believe that the warnings do not apply to them, because they either do not intend to become pregnant or are abstinents.

Women of childbearing age: If you take this medicine, it may reduce your ability to become pregnant. This effect will be reversed when you stop the medicine. (C5)

"are you pregnant or planning to become pregnant? Although not common, abnormalities have been reported in babies whose mothers have taken NSAIDs during pregnancy. You should not take Voltarol Dispersible Tablets during the last 3 months of pregnancy as it may affect the baby's circulation: (D15)

However, as Morris (2006: 760) notes, "they may not remain abstinents if they meet an appeling male partner". This situation reveals that sometimes consumers may have difficulties to accept that the warnings are in fact for them, which demonstrates that "Convincing patients that they are at risk can be extremely difficult" (Ibid: 760).

Finally, it is also important to note that no information is provided to women that have just discovered they are pregnant and have been taking the medicine.

4.2.4 Brazilian Pils

Interestingly, the Paracetamol warnings of the Brazilian PILs present more shared similarities than the British ones. The analysis reveals that the first warnings of the subsection 4, 'What should I know before taking this medicine?[27]', are phrased equally (see below), but (A22-P).

[27] 'O que devo saber antes de tomar este medicamento?'

Você não deve tomar mais que a dose recomendada (superdose) para provocar maior alívio. Pois pode causar sérios problemas de saúde. Você deve consultar seu médico se a dor ou febre continuarem, pois estes simtomas podem ser sinais dedoenças graves.

As can be seen, the warning alerts the patient about an intentional overdose, that is, if the patient decided to take more than the recommended dose to relieve the pain. The warning is composed of two parts: one that gives the direction to avoid the hazard, as in 'you must not take more than the recommended dose (overdose) in order to try to achieve greater relief' (*Você não deve tomar mais que a dose recomendada (superdose) para provocar maior alívio)*; and another that provides the reason (hazards) for avoiding an overdose 'since it can cause serious health problems' (*pois pode causar sérios problemas de saúde*). The first part of the sentence is direct and employs the modal operator 'must', which is a combination that strengthens the warning. On the other hand, the second part is doubly imprecise. The modal operator 'can' followed by the verb 'cause' leads to uncertainty in relation to when the health problems may occur. Furthermore, it gives no idea about what the health problems are. The last part tells the patient what actions should be taken if the symptoms do not stop.

Advertências de superdosagem: tomar *mais do que a dose recomendada* ***pode causar*** *sérios problemas de saúde.*

Em caso de superdosagem, procure socorro médico imediatamente. O rápido atendimento médico é crítico para adultos e crianças até mesmo se você não notar quaisquer sinais ou sintomas. (A22-P)

The warning (A22-P**)** employs the same verbs '*tomar*' and '*pode causar'***,** but it is weakened for not using the pronoun 'you', which approximates the reader. Moreover, the warning seems to inform rather than give directions, leading consumers to infer the actions to be taken. On the other hand, the warning has some gains, in that it not only offers some information about what to do in the case of an overdose, but also because it uses the alert word 'warnings', which clearly attracts the consumers' attention.

The most important warnings about overdose are in subsection 9, titled 'What to do if someone uses a higher dose than indicated of this medicine?' (*O que fazer se alguém ingerir uma dose maior deste medicamento?*). Most PILs phrase them equally, as can be seen below.

A) O uso de doses excessivas, acima das doses recomendadas (superdose) pode causar danos ao fígado.

B) Em caso de superdose, procure ajuda médica ou um centro de

intoxicação imediatamente.

C) O apoio médico imediato é fundamental para adultos e crianças, mesmo se os sinais e sintomas de intoxicação não estiverem presentes.

D) Os sinais e sintomas iniciais que se seguem a uma dose potencialmente hepatotóxica de paracetamol são: anorexia, náusea, vômito, sudorese intensa, palidez e mal-estar geral.

The warning is composed of '4 chunks' of information. The first informs about the health problem and why it can occur. As usual in all PILs, the structure can + cause is used to talk about the problem. The second is about the actions that should be taken if the risk is not avoided. The word 'immediately' (*imediatamente*) alerts the patient about the urgency of looking for assistance, calling the patient's attention. The third reinforces the need for medical assistance. Finally, the last one describes the symptoms of an overdose. However, the technical vocabulary of the sentence may confuse the patient. For instance, the patient may not know what 'potentially hepatotoxic dose' means and might fail to link it to 'overdose', which is the expression used in A and B.

The warnings in A12-P and A23-P are composed of 3 'chunks', whose order is also different from the one described above, in that it first tells the patient what should be done. Moreover, it adds additional information by directing the patient to provoke vomitting in order to eliminate the medicine (A). Then, it points out the consequences and the need for a doctor (B). Finally, it informs about the symptoms of an overdose (C).

A) Se você tomar uma dose muito grande deste medicamento acidentalmente, ou se alguma outra pessoa tomar dose excessiva intencionalmente deve-se imediatamente provocar o vômito para eliminar o medicamento do estômago e em seguida procurar um médico ou um centro de intoxicação.

B) O apoio médico imediato é fundamental para adultos e crianças, mesmo se não houver sinais e sintomas de intoxicação, pois a dose excessiva de paracetamol pode causar danos ao fígado.

*C) Os sinais e sintomas iniciais de superdose são: náusea, vômito, sudorese intensa, mal-estar geral, ansiedade leve, taquicardia e/*ou *hipertensão leve.*

The Brazilian warnings on overdose present all the information together, in this way; the consumers do not need to look for the different pieces of information spread through the text, which definitely strengthens the warnings. Moreover, they present the symptoms of an

overdose, which is essential to consumers. On the other hand, the technical terms employed to describe the symptoms (*sudorese intensa, taquicardia e hipertensão*) weaken the safety messages, because consumers will not be able to identify unknown symptoms. The word '*anorexia*' called my attention, because I believe that I would not be able to recognize it.

Os sinais e sintomas iniciais que se seguem a uma dose potencialmente hepatotóxica de paracetamol são: anorexia, náusea, vômito, sudorese intensa, palidez e mal-estar geral.

Enabling patients to recognize an overdose and providing information about how to act if an overdose occurs is paramount. However, the analysis shows that there is a disagreement about what is an overdose. Whereas some Brazilian PILs describe it as '*uma grande quantidade de paracetamol*', '*uma dose muito grande deste medicamento*' or '*O uso de doses excessivas, acima das doses recomendadas*', the British PILs adopt a different posture 'if you take too much' 'if you take more than you should'. However, neither is really helpful to consumers.

4.2.5 Alcohol, Driving and Using Machines, Pregnancy and Breastfeeding

Brazilian warnings about alcohol consumption have the same problems of vagueness as the British ones, whose use of the expression 'abusive doses' (*doses abusivas*) leads patients to interpret it in many different ways, and possibly differently from the writer's intended meaning. In the on-line dictionary Collins Cobuild, the term 'excessive' means 'too great in amount or degree'. So, it allows the reader to interpret that moderate consumption of alcohol is safe. But, how many doses would be moderate? Certainly, readers will have disagreements about this.

Uso com álcool: *consumidores de doses abusivas de álcool devem consultar seu médico para saber se podem tomar o paracetamol gotas ou qualquer outro analgésico. (A1-P)*

On the other hand, the warnings in A12-P and A23-P point out to the exact quantity of alcohol consumption that can cause liver problems 'if you take 3 or more doses' (*Se você toma 3 ou mais doses de bebidas alcoólicas*), which prevent readers from misinterpreting. However, the same warning fails for not offering the patient a clear description of 'an increased risk of liver disease' (*risco aumentado de doenças do fígado*), and therefore s/he needs to infer both the severity and the frequency of

the risk.

Se você toma 3 ou mais doses de bebidas alcoólicas, deve consultar seu médico para saber se pode tomar paracetamol + cloridrato pseudoefedrina ou qualquer outro analgésico. Usuários crônicos de bebidas alcoólicas podem apresentar um risco aumentado de doenças do fígado caso seja ingerida uma dose maior que a recomendada (superdose) de paracetamol + cloridrato pseudoefedrina. (A12-P and A23-P)

The ways in which consumers are addressed also influence their understanding and their compliance. It is not clear whether the warning above is addressing the same person when talking about the risk and how to avoid it, which can generate misunderstanding. That is, are the recipients of 'if you take 3 or more doses of drinks' (*Se você toma 3 ou mais doses de bebidas alcoólicas)* and 'chronic users of drinks' (*Usuários crônicos de bebidas alcoólicas*) the same? They only would be similar if the first were 'if you take 3 or more doses of drinks daily', which could be inferred as chronic. And what about a patient that drinks moderately or socially? Would the warning apply to him/her?

Finally, although the warning in A22-P makes use of the signal word 'warnings' (*advertências*), it fails for using complex language (see below).

Advertências referente ao uso do álcool: *o consumo de álcool afeta negativamente a função hepática e pode aumentar o risco de toxicidade no fígado com o uso de produtos que contenham paracetamol, especialmente após overdose. (A22-P)*

The terms 'hepatic function' (função hepática) and 'liver toxicity' (toxidade do fígado) are technical and may confuse the reader who will probably ignore the warning due to lack of understanding. The structures 'affect negatively the hepatic function' (*afeta negativamente a função hepática*) and 'can raise the risk of liver toxicity' (*pode aumentar o risco de toxicidade no fígado*) appear to mask the risk once the readers cannot understand it.

Besides information about alcohol, patients also seek for information about driving and using machines and whether women who are pregnant or breast-feeding can use the medicine. Data shows that fewer Brazilian PILs inform about driving and using machines as compared to the UK PILs. Such warnings were only presented in the PILs of the following medicines: aspirin, naproxen, diclofenac and codeine. The analysis reveals that the entry 'drive' (*dirigir*) occurred 54 times in the Brazilian corpus, and 'operate machines' (*operar máquinas*) 51 times. Interestingly, some warnings are employed to allow the

consumers to drive, see A3-P, B3-P and B9-P.

Efeitos sobre a capacidade para dirigir veículos e operar máquinas

Aspirina C não afeta a capacidade de dirigir veículos ou operar máquinas. *(A3-P)*

Dirigir e operar máquinas *É improvável que o uso deste medicamento afete a capacidade de dirigir, operar máquinas ou fazer outras atividades que requeiram de atenção especial. (B3-P)*

Influência na habilidade de dirigir ou utilizar máquinas

O diclofenaco dietilamônio não influencia a habilidade de dirigir ou operar máquinas. (B9-P)

Given that warnings are about future bad events, which are uttered with the aim of preventing these events, it is possible to say that the warnings above are not in fact warnings, because they would not prevent any danger.

On the other hand, the warnings below F2-P, F1-P and E1-P present some symptoms, such as 'drowsiness, insomnia, dizziness, vertigo and depression', which could lead to a dangerous situation. However, the warnings F1-P and F2-P demand some effort from the consumers, not only related to the understanding of the message but also to figure out the safety behavior. That is, the consumers are warned to self-evaluate in order to check if the symptoms are present. But, how long after taking the medicine should this evaluation be done? If we assume that the consumers should wait for 30 minutes, it would represent too much time for some consumers, in other words, it would demand too much effort to avoid a danger that is not explicit.

-Capacidade para dirigir veículos e operar máquinas

Alguns pacientes podem sentir sonolência, tontura, vertigens, insônia ou depressão com o uso deste medicamento. Se forem observados estes ou outros efeitos adversos semelhantes, recomenda-se cuidado ao exercer atividades que exijam atenção. (F2-P)

Capacidade para dirigir veículos e operar máquinas

Não existem estudos sobre os efeitos do naproxeno sobre a capacidade para dirigir ou operar máquinas. Entretanto, foram observados efeitos adversos como sonolência, tontura, vertigens e insônia no tratamento com naproxeno sódico. Observe atentamente suas reações ao uso do medicamento antes de dirigir ou operar máquinas. (F1-P)

Efeitos sobre a capacidade de dirigir veículos e operar máquinas.

Durante o tratamento, o paciente não deve dirigir veículos ou operar máquinas, pois sua habilidade e atenção podem estar prejudicadas. (E1-P)

As already observed in some UK warnings, the Brazilian ones also transfer to the readers the responsibility of evaluating whether their capability of driving and using machinery is affected by the medicine. One goal of the PILs is that of providing patients with information in order to give them the power to use the medicines safely. To serve this purpose, the information should be clear and unambiguous. However, as pointed out, the warnings above also fail for not offering adequate information, mainly related to the duration of the symptoms. On the other hand, E1-P it is clearer in relation to the action.

Information regarding pregnancy and breast-feeding appear to be present in all Brazilian warning leaflets. The corpus analysis reveals that the entries 'pregnancy' (*gravidez*) occurs 279 times, and 'pregnant' (*grávida*) 72 times, whereas the entries 'breast-feeding' (*amamentação*) occurs 92 times, 'breastfeeding' (*amamentando*) 73, and breastfeed (*amamentar*), 19.

The analysis shows that the PILs provide the consumers with different guidance, which is, of course, influenced by the type of medicine. So, the warning either forbids the use by women who are pregnant or breast-feeding B1-P or transfers the responsibility to their doctors D3-P and A3-P.

Se você estiver grávida ou amamentando, consulte o seu medico (B1-P)

Você não pode tomar este medicamento se:

- você está nos últimos três meses de gravidez.

Este medicamento não deve ser utilizado por mulheres grávidas sem orientação médica ou do cirurgião- dentista (D3-P)

Aspirina C não dever ser utilizado nas seguintes situações:

último trimestre de gravidez (veja item "4. O que devo saber antes de usar este medicamento?", Gravidez). "Este medicamento não deve ser utilizado por mulheres grávidas sem orientação médica. Informe imediatamente seu médico em caso de suspeita de gravidez." (A3-P)

I have been pointing out throughout this dissertation that many warnings fail for not clearly informing about the risks. However, the warning below E1-P explains precisely the effects of the medicines. But I have to confess that I am not able to understand it, due to the mis-use of technical terms. Even though, it lacks an explicit prohibition, I would infer, based on the underlined terms, that it is dangerous, mainly because

'heart attack' (*infarto*) is a very serious risk.

Gravidez e amamentação

Não há estudos clínicos adequados e bem controlados da combinação de codeína e paracetamol em gestantes ou lactantes.

Gravidez

Codeína

A codeína atravessa a placenta. Recém-nascidos que foram expostos à codeína no útero podem desenvolver síndrome de abstinência (síndrome de abstinência neonatal) após o parto. Infarto cerebral foi relatado neste contexto.

Paracetamol

Quando administrado à mãe em doses recomendadas, o paracetamol atravessa a placenta e alcança a circulação fetal em 30 minutos após a ingestão e é efetivamente metabolizado por conjugação com sulfato fetal (E1-P)

4.2.6 Summary of The Section

The analysis reveals that the components of an efficient warning (ANSI) are present in comparatively few warnings. Most warnings are directions that forbid the use of the medicine due to some diseases or problems; however, very few warnings inform about the consequences of disregarding the directions, which would strengthen the warnings. On the other hand, when some warnings do provide such information, the warning is obscured by the use of weak modal operators, lack of information regarding the symptoms and frequency, and vagueness. In addition, the use of technical terms and the passive voice rendered the warnings more complex, which affects comprehension.

The literature on warnings points out that the consumer tends to give up reading the labels when they demand too much effort. Wogalter (2006) notes that longer warnings require more effort because individuals' attention is easily drawn to something else. Likewise, texts that require the consumers to look elsewhere for information may be easily ignored. Moreover, consumers tend to believe that if the information were important it would be displayed together and not broken into pieces and spread around the text. Consumers also tend to infer that the most important information is at the beginning of the texts, which means that 'prohibition' should appear before 'permission'. Thus, long warnings, information broken into pieces, and inadequate sequencing might weaken the warning.

It is interesting to note that despite the fact that the guidelines do not suggest the use of the signal words *warning* and *precaution*, a few leaflets do employ them. These words are acknowledged by the organizations responsible for the standardization of warnings, such as ANSI (American National Standard Institute) and ISO (International Organization for Standardization). Moreover, most readers know that they are used to introduce a warning and for this reason they will probably pay more attention when reading.

Convincing consumers that the risks apply to them is a problem that writers have to face. In order to solve this problem and others mentioned above, writers need to start from the "patient's point of view" (van der Waarde, 2008: 45), which presupposes knowledge about the consumers. Thus, consumers and their needs should be the departing point in the writing of PILs, instead of the SPC.

4.3 MODALITY

I have pointed out earlier in this thesis that the manufacturers manipulate the information of these safety texts in order to avoid litigation. That is, they have to inform the readers about the risks, but at the same time, they seem to convey this information in a way that does not prevent the customers from buying and using the products. As could be seen, lack of information, sequencing, vague language and technical terms are some strategies employed by the writer, intentionally or not, to confuse the reader.

Additionally, modality also seems to influence the process of interpretation. Hegedüs (2008: 132) conducted a study about the use of modality in PILs and found out that modality is employed with the aim of changing "the truth conditions of information provided by instances of this genre by avoiding explicitness and providing vague information, thereby hindering the process of interpretation of drug information leaflets". Her analysis identified both types of modality: modalisation, which was more frequently employed, and modulation. Both sub-categories of modalisation were observed: probability, mainly through the use of the modal operators 'can' and 'may', which were used to present the side effects of the medicines; and usuality, which was generally manifested by frequency adverbs. Modulation indicating obligation was expressed through the modal operators 'must' and 'should'; whereas inclination, indicating willingness to help, was expressed with the modal operator 'will'. However, obligation was

mainly realized by the imperative, which increases the distance between the participants, but at the same time, provides clearer instructions.

Guiradelli and Santos (2010) investigation of 33 Brazilian PILs reveal that the genre motivates the employment of modulation, in which the clauses express obligation, permission and prohibition. The modal operators '*dever*' and '*poder*' are the most frequent ones in their analysis, whereas '*preciso*', '*necessário*', '*obrigatório*' and '*proibido*' are the most frequent modal adjuncts. The authors point out that this type of modality implies acceptance, in other words, consumers should accept the values in order to act according to the proposal. The characteristics that can influence this acceptance, although not mentioned in their analysis, are fundamental, if the aim is warning compliance.

Thus, it seems that modality plays an important role in the process of PILs' interpretation, because it can either distract from or attract the reader's attention to important information. Moreover, the writers' evaluation of the risks can also influence the readers' intention of compliance. That is, if a low value modal operator, as may, might and can, is employed to give a direction to avoid a risk, consumers may interpret it as unimportant, which enhances the chances of non-compliance.

Modality can be expressed in the finite element, by the use of modal operators, or in other parts of the clause, with the use of modal adjuncts, for example. The results obtained from the corpus analysis (AntConc) reveal the most frequently used modal operators (see table below) in the English corpus:

MODAL MARKERS	OCCURRENCES
MAY	1.068
CAN	709
SHOULD	664
WILL	233
MUST	104
MIGHT	81
COULD	47
TOTAL	2.729

Table 4.7: English modal operators

'May' is the most frequently occurring modal operator with 1.068 occurrences, and it occupies the 22nd position in the list of the most frequent lexical items, whereas 'can', which is the 2nd most frequent occurring modal operator with 709 occurences, only occupies the 37th position. Hegedüs (2008) results from the corpus analysis (Wordsmith) containing 100 PILs from the UK also finds that 'may' and 'can' are the most frequent modal operators, in which 'can' is the 29th most frequent lexical item, with 418 occurrences, and 'may' is the 30th most frequent lexical item, with 401 occurences. A comparison between her study and the present one shows that 'may' and 'can' reverse position, but are still the most frequent modal operators in both studies.

The Brazilian corpus, which is composed of 64 PILs, reveals that the modal operators derived from '*dever*' and '*poder*' are the most frequent. It is important to note that due to the verbal and nominal agreement of Portuguese, the same modal operator can vary, for instance: '*deve*', '*devo*' or '*devem*', but they still express the same meaning.

MODAL MARKERS	OCCURRENCES	
DEVE	851	1257
DEVO	303	
DEVEM	103	
PODE	636	941
PODEM	305	
PODERÁ	91	91
PRECISAR	85	109
PRECISA	24	

Table 4.8: Portuguese modal operators

A comparison between the Brazilian and the English corpora reveals that the frequency listing of the modal operators '*poder*' and '*dever*' is reversed, in that '*deve*', which is more commonly used to give a command, is more frequent in the Brazilian PILs. For example: '*deve*' occurs 1257 times in the Brazilian corpus whereas the corresponding English terms 'should' and 'must' occur 758 times; '*pode*' occurs 941 times in the Brazilian corpus whereas the corresponding English terms 'can', 'may' and 'might' occurs 1858 times.

This result suggests that in the Brazilian PILs, modality occurs more frequently in modulation, that is, in commands. Thus it is possible to assume that the risks are less modalized. On the other hand, in the English PILs, weak modal operators are used twice as frequently, and are generally employed in clauses that offer information, and possibly, information about risks and side effects. Only a closer analysis can show which is more (in)efficient, although the data suggest that due to the high occurrence of weak modal operators, the English PILs tends to be communicatively less efficient.

In order to better present the analysis of modality in the warnings, the sections below are organized based on the kind of information conveyed. In this way, I will first discuss the analysis about the indication of the medicine, followed by warnings, then how to take the medicine and finally the side effects. This distribution was mainly due to the fact that each section has a purpose, which can influence the lexical-grammatical choices made by the writers.

4.3.1 Indication of The Medicine

As already mentioned, Section 1 of the English PIL, under the heading 'What is and what is used for' presents the main ingredient(s) of the medicine and also provides information about its indications. In this way, the commodity exchanged in this section is that of information. The analysis reveals that there are two distinct ways, in terms of the degree of certainty, in which this information is presented. See examples below.

"Volsaid **relieves** pain, **reduces** swelling and **eases** inflammation in the following conditions." (B1)

"Your medicine **is for effective relief** from: mild to moderate pain including headaches, migraines, sharp nerve pain (nevralgia) (…)" (D1)

The examples above present the indication of the medicines in a clear, objective and un-modalised way. The transparency is due to the use of the present tense that restricts different interpretations. Moreover, the material processes 'relieve', 'reduce' and 'ease' also give the idea that the medicine works. In D1 the writer expresses his/her assessment of the medicine by the use of the adjective 'effective', reinforcing the quality of the medicine.

On the other hand, the examples below C5 and A5 create a degree of uncertainty in relation to the indication of the medicine. The analysis

reveals that the structure 'it can be used' is employed 73 times in the English corpus.

"It can be used to relieve headaches, rheumatic and muscular pain, backache, migraine, period pain, dental pain and neuralgia" (C5)

"It can be used to relieve mild to moderate pain including toothache, headache and other pains. It can also be used to relieve the symptoms of colds and flue and to reduce fever" (A5)

These examples, differently from the previous ones, create uncertainties in relation to the indication of the medicines. The instances show how modalisation can influence on the negotiation of information. That is, the modal operator 'can' expresses a 'permission', which demonstrates the writers' unwillingness to provide exact information in relation to the purpose of the medicine. In this sense, Hegedüs (2008: 109) notes that the use of 'can' in the cases above "may serve as a means of self-defense for drug manufacturers in case the medicine proves to be ineffective" or even harmful. In other words, some people's bodies may not correspond to the treatment and for this reason the drug manufacturer avoids giving exact information aiming at avoiding litigation.

The instance in B1 below employs the adverb 'also', which indicates that it is an additional purpose of the medicine. In this way, it gives the idea that it is not the main purpose and for this reason there are chances of the medicine being ineffective.

"They **are also used to treat** pain and inflammation associated with orthopedic, dental and other minor surgery" (B1)

The analysis of the Portuguese PILs reveals that there is a predominance of the structure 'it is indicated (…)' (*é indicado(a) (...)*), given that most PILs adopt this structure to talk about the indication of the medicine. The heading of the section 'what is it indicated for?' (*Para que este medicamento é indicado?*) might motivate the lexicogrammatical choices. However, the formality characterized by the passive voice leaves the warnings more complex, which can make comprehension more difficult. In the examples below, 'it is indicated' collocates with: 'reduction, relief and pain, inflammatory reaction, adjunct' (*redução, alívio, dores, reações inflamatórias, coadjuvante*). The nominalization helps to raise the complexity of the clause (see C3-P, A3-P) and it is widely used in the Portuguese PIL.

Ibuprofeno é um medicamento indicado para **redução** da febre e para o **alívio** de dores (C3-P)

Este medicamento é indicado em adultos para a **redução** da febre e para o **alívio** temporário de dores leves a moderadas, (A3-P)

O naproxeno sódico é indicado para: **dores** agudas causadas por inflamação como por exemplo, **dor** de garganta; (F1-P)

Paracetamol + fosfato de codeína 30 mg é indicado para o **alívio** de dores de grau moderado a intenso (E2-P)

The warning in B9-P below overuses technical terms that make the comprehension impossible to a layperson. It is possible to say that only the professional would understand the information.

(...) é indicado para diminuir reações inflamatórias do **segmento anterior do globo ocular** (...)3. (B9-P)

The analysis shows very few occurrences of modality in this section of the Portuguese PIL. The modal operator 'can' in the example below, B12-P gives the consumers the permission to use the medicine under the indicated conditions.

O diclofenaco sódico pode ser utilizado no tratamento das seguintes condições: • Dor reumática das articulações (artrite) (B12-P)

Thus, the section about the indication of the medicine, of which readers expect to be clear, proves in some instances to be just the opposite, mainly due to the use of modalisation (as in the case of English PILs), and technical terms and nominalization (as in the Brazilian PILs). The passive voice employed in both PILs helps to increase the complexity of the clauses. Clearly, the writers sometimes avoid stating the purpose of the medicine overtly.

4.3.2 Warnings

The second section of the English PILs and the third and fourth sections of the Brazilian PILs provide readers with important information they should know before taking the medicine and the behavior that they should adopt in order to avoid risks. Consequently, both types of modality are employed in these sections, modalization and modulation.

As previously noted, these sections are mainly concerned with warnings which are not signaled as such, and for this reason, consumers may have difficulty in perceiving them. Unfortunately, it is a serious problem that can bring severe consequences if the readers fail to understand the warnings. As expected, the clauses that express obligation are generally realized by the imperative, which corroborates Hegedüs' results (2008).

The high occurrence is mainly because the second section of the English PILs has a subsection headed "Do not take (…) if:" in all medicines, and some of them have the headings "Take special care if:"

and/or “Talk to your doctor before taking (…) if:”, which are followed by a bullet point list of health problems, such as: diseases, allergies and intolerances. There is also a subsection headed “Tell your doctor (or pharmacist) if you are taking:”, which is followed by a bullet point list of medicines. As already pointed out in section 4.2, the employment of technical terms is the main problem of these sections, which weakens the warnings, despite the explicitness of the command that is a typical characteristic of the imperative.

The examples of modulation are mainly realized by the modal operator ‘should’. As can be seen in the examples below, some of them express obligation (D3 and F9), whereas some present prohibition (D12, E6, B13, B3, A17 and F1). The analysis shows that from the 605 occurrences of the modal operator ‘should’, 229 are in the negative.

You should let your doctor you are taking aspirin, particularly if you are going to have an operation, as you may need to stop taking your tablets several days before the operation. (D3)

Naproxen may make it more difficult to become pregnant. You should inform your doctor if you are planning to become pregnant or if you have problems becoming pregnant (F9)

This medicine is for you only and should never be given to anyone else, even if they appear to have the same symptoms as you (B3)

This medicine should not be given to children or adolescents under the age of 16 years (A17)

If you use an antacid (something to reduce acid in the stomach) you should avoid antacids with magnesium in them as these may make Diarrhoea worse. (F1)

The use of ‘should’ is inefficient in some instances above because they are not strong enough to influence consumers’ behaviour. It is widely known that the use of aspirin is forbidden before an operation, given that it prevents blood from clotting. Thus, a modal verb with a stronger illocutionary force must be used.

Obligation and prohibition are also expressed with the use of the modal operator ‘must’, which signals “a higher degree of pressure on the other person to carry out a command” (Thompson, 2002: 59), and for this reason, strengthens the warnings. Nevertheless, the modal operator ‘should’, which has a weaker illocutionary force, was employed almost six times more frequently than the modal operator ‘must’.

Motifene 75 mg Capsules **must** be swallowed whole with a drink of water (about half a glass).

Motifene **must not** be taken during the last three months of pregnancy (see “Do not take the capsules” above) (B3)

You **must not** take any other medicines that contain paracetamol while you are taking this medicine (A3)

Interestingly, the modal operator "can' is also used in modulation, but this time it signals permission (see A9). However, there are only two occurrences of 'can' in the active, as can be seen in C5.

PARACETAMOL MACOPHARMA **can** be used if you are pregnant, but the doctor should then assess whether this treatment is appropriate. (A9)

Breastfeeding: You **can** use this medicine. (C5)

Some PILs in this investigation are taken from medicines for children, and this is clearly pointed out in the name of the medicine, as *Boots (6 months plus)* and *Care Infant Paracetamol*. But, even so, some PILs provide warnings to address this indication (see C 17 below).

"This medicine **can be given** to children from the age of 3 months. However, some children **should not be given** this or you **should seek** the advice of their pharmacist or doctor first" (C17)

It is intriguing that the information about age is modalised by the use of the modal operator 'can', which expresses the idea of permission. It would be simpler and clearer if it were 'this medicine is for children from the age of 3 months', given that it was primarily made for them. On the other hand, a modal operator that has a stronger illocutionary force is successfully employed in the next warning 'should not be given'. However, no reason is presented for such a contra indication, which combined with the use of the indefinite term 'some' to refer to the children that should not be given the medicine, raises doubts and concerns in the consumers. Moreover, it is very odd to imply that children have a pharmacist.

Clearly, the problem of address can confuse the consumers, and unfortunately, it also occurs in other warnings (see B15 below), which also employ the term 'some' to designate the consumers who should not take the medicine.

"Some people **MUST NOT** take Voltarol Dispersible Tablets. Talk to your doctor if: - **you think you might** be allergic to Diclofenac sodium, aspirin, ibuprofen or any other NSAIDs " (B15)

If the consumers read the entire warning, they will perceive that it gives some clues about who are those 'some': 'people who think they are allergic to some medicines'. However, the consumer needs to infer the connection between the first and the second warning, given that this connection is not made explicitly. Unfortunately, due to the employment of the term 'some', the addressee may find difficulties to recognize whether the warning is for her/ him.

Modality is not only expressed in the finite, but also in other parts of the clause, such as the Modal Adjuncts, which also express meanings associated with "polarity, modality, temporality and mood" (Halliday, 1994: 82). The warning in D7 below shows the writer's unwillingness to provide exact information about the association of the medicine and the disease. It gives the impression that the association is not yet proved.

"There is a **possible** association between aspirin and Reye's syndrome when given to children under 16 years. Reye's syndrome is a very rare disease which affects the brain and the liver and can be fatal" (D7)

Uncertainty is also seen in (C17) below:

"**Do not give**: If your child is taking aspirin with a daily dose above 75 mg, or other non-steroidal anti-inflammatory medicines (aspirin **should not generally be given** to children under 16, but doctors **may occasionally** prescribe it)" (C17)

The warning is clear about both the directions 'Do not give' and the addressee 'child that takes aspirin with a daily dose above 75 mg', which minimizes wrong inferences. On the other hand, the warning in parenthesis, which is about the use of aspirin by children under 16, may raise confusion. Although it uses the modal operator 'should' that puts pressure on the reader to follow the message, the level of pressure is lowered by the employment of the mood adjunct 'generally'. Afterwards, the message 'doctors may occasionally prescribe it', that combines the modal operator 'may' and the mood adjunct 'occasionally', clearly shows that the writer is refusing to take responsibility for the proposition. It appears that the purpose is that of justifying the prescription of aspirin to children under 16.

Strangely, some warnings provide information about the doctor's conduct (see B1 below), even though the PIL is addressed to the consumers. The provision of this information demonstrates a lack of writer involvement and the transfer of the responsibility for any side effects to the doctor.

"If you are **elderly**, suffer from kidney, liver or heart problems or have been taking this medicine or similar NSAIDs for a long time, your doctor **may want** to perform regular tests to monitor your condition and **may need** to carry out blood tests from time to time." (B1).

The warning in B15 below follows a bullet point list of 11 questions, such as: 'are you breast-feeding? Do you have kidney or liver problems, or are you elderly?'. This design strategy makes the warnings more conspicuous and easier to understand. However, the problem of

addressing emerges again due to the fact that it lacks a definition of 'elderly', which can also be seen in B1 above.

"If the answer to of any of these questions is YES, discuss your treatment with your doctor or pharmacist because Voltarol dispersible Tablets **might not be** the right medicine for you". (B15)

Both types of modalization occur in this section. However, probability appears more often, motivated, of course, by the main purpose of the sections: informing the consumers about the risks and their consequences. I expect that usuality will appear more often in the sections that describe 'how to take the medicine' and 'the side effects'.

The modal operators 'may' and 'can' are used to express the probability of the risks, although 'may' is more frequently used.

"Use in children with breathing problems: Codeine is not recommended in children with breathing problems, since the symptoms of morphine toxicity **may** be worse in these children". (E6)

"Regular or high dose aspirin therapy during late pregnancy **can** cause serious complications in the mother or baby". (D4)

Information about the concomitant use of two or more drugs appears in all PILs, and there should be information regarding the drugs, the relation between them, the consequences of the concomitant use and the frequency of these consequences. The analysis shows that there are two ways in which this information in conveyed, as a proposition or as a proposal.

In propositions, the modal operators 'may' and 'can' refer to the probability that drug interaction will affect the success of the treatment. The modal operators are the only information regarding the probability that consumers' can rely on, given that the warnings fail to give more precise information about it. As they pursue a low value, consumers' are invited to infer that the probability of the event occuring is low.

"(Mifeprinstone) If taken with aspirin this medicine **may** not be as effective". (D3)

"Also, some other medicines **can** affect the way Solpadol works". (E7)

The vagueness in relation to the probability conveyed by 'may' is enhanced in the following warning B1 because the 'supposed' association is linked to the vague expression 'small increased risk'.

"Medicines such as Volsaid **may be** associated with a **small increased risk** of heart attack or stroke." (B1)

In some warnings, the probability of medicine interaction is expressed by the modal adjuncts, as in C1 below. As a reader, I can perfectly well infer that the interaction is nearly non-existent, by the employment of the modal adjuncts 'possible', 'very' and 'unlikely',

which show the writer's beliefs about the probability of the event. I just wonder why to provide a warning about a risk that is unlikely to occur.
"Interaction between Ibumousse and blood pressure lowering drugs and anticoagulants (medicines that stop blood clotting) is **possible**, in theory, although **very unlikely**." (C1)

In proposals, the modal operator 'should' is generally employed to guide the consumers about what should have been done to minimize the effect of the concomitant use of two drugs (see A9 below).

"This medicine contains paracetamol: this **should be taken** into account if you are taking other paracetamol-based medicines, so that you do not exceed the recommended daily dose (see section below)". (A9)
"A dose reduction **should be considered** for concomitant treatment with probenecid". (A9)

However, the warnings above are not clear for many reasons. Firstly, there is a lack of information in both warnings. The risks of the concomitant use are not mentioned in both warnings. Moreover, the first one gives the direction implicitly, inviting the readers to infer it. Whereas the second one provides vague information regarding the directions, that is, it fails to inform the quantity that should be reduced. Secondly, it is in the passive voice, which is impersonal and more formal, thus, more difficult to be understood by an ordinary reader. Furthermore, the employment of the passive voice in the command seems to disguise it, that is, the consumers may have difficulties in recognizing that the statements are in fact an instruction to avoid a risk. Unfortunately, all these problems undermine the adequate use of the modal operator 'should'.

"This medicine contains paracetamol: this **should be taken** into account if you are taking other paracetamol-based medicines, so that you do not exceed the recommended daily dose (see section below)". (A9)

"A dose reduction **should be considered** for concomitant treatment with probenecid". (A9)

The warnings in the Portuguese PILs also make use of modalisation and modulation, which can affect the way the consumers perceive both the information and instructions. The examples show that whereas some warnings reinforce the illocutionary force of the speech act, others soften it.

The first warning below is in the imperative, which, according to Dumas (1992), is clearer. The imperative is modalised by the modal adjunct 'always' (*sempre*) aiming at reinforcing the command. However, as pointed out by Halliday (1994: 363), even the use of a strong modal adjunct can lower the strength of a proposition, because "I

am admitting an element of doubt". Besides, it also refers to 'other diseases' (*outras doenças*), expanding the number of addressees, which would be an interesting strategy if the aim of the manufacturer were that of avoiding litigation. The second warning below makes proper use of the modal operator 'must' (*deve*) that denotes obligation. But the problem lies in the fact that the consumers may fail to follow the command, given that the expression 'caution' (*cautela*) is vague.

*"Informe **sempre** o médico sobre possíveis doenças do coração, nos rins, no fígado ou outras que você tenha, para receber uma orientação cuidadosa". (C2-P)*

*"Em pacientes com asma ou outras doenças alérgicas, especialmente quando há história de broncoespasmo, o ibuprofeno **deve** ser usado com cautela". (C2-P)*

The following warning also employs the modal operator properly. However, most consumers do not know what '*anti-inflamatórios não esteroidais*' are, and for this reason, it loses its efficacy.

***"Deve**-se evitar o uso de naproxeno juntamente com outros anti-inflamatórios não esteroidais (AINEs)". (F2-P)*

The warnings described below alert the consumers about the restrictions of the medicines, i.e. about who can and cannot use them, and what actions the addressed consumers should take to avoid the risks. As noted, most warnings adopt a modal operator that denotes obligation, like 'must'. Unfortunately, vague information about the directions renders many of the warnings inefficient.

*"Nos casos seguintes Aspirina® Prevent **só deve** ser usada em caso de **absoluta** necessidade e sob cuidados especiais. Consulte um médico se alguma das situações abaixo for o seu caso ou já se aplicou no passado". (D1-P)*

*"Alimentos, antiácidos ou colestiramina: **pode** retardar a absorção de naproxeno, no entanto, não afeta sua ação"; (F2-P)*

"Anti-inflamatórios não esteroides (AINEs) inclusive ácido acetilsalicílico: Aumento do risco de sangramento gastrintestinal"; (F2-P) (no modal)

*"Em geral, é importante tomar a menor dose de diclofenaco potássico que alivia a dor e/ou inchaço e durante o menor tempo **possível,** de modo a manter menor **possível**, o risco de efeitos secundários cardiovasculares"; (B2-P)*

***"Não se recomenda** o uso de medicamentos que contenham ácido acetilsalicílico durante o primeiro e o segundo trimestres de gravidez, **a menos** que seja **realmente necessário"**. (D1)*

The warning section analysed has met my expectations regarding the high occurrences of the imperative, which strengths the warning due to the clarity of its directions. However, this clarity was sometimes obscured by the use of some technical terms that can confuse the consumers and the use of modal adjuncts in some warnings.

4.3.3 How to Take

Section 3 of the UK PILs and section 6 of the Brazilian ones describes the administration of the medicine and for this reason it should be as clear as possible. The imperative is again the most common form of command (see below) and is employed as a prohibition (D9 and B13), obligation regarding the administration (D13, C16 and D10) and also some directions regarding the inefficiency of the medicine (C5).

"Do not take more than the recommended dose". (D9)

"Do not chew or break open the capsules". (B13)

"Always take Nu-seals 75 exactly as your doctor has told you to. (D13)

Give the lowest amount for the shortest possible time to relieve the symptoms". (C16)

"If your symptoms worsen at any time, talk to your pharmacist or doctor". (C5)

"Take two tablets up to four times a day, as required. (…) Take **only** as much as you need to relieve your symptoms and leave at least 4 hours between each dose. Do not take more than 8 tablets in any 24 hours period". (D10)

The warnings C16 and D10 give consumers the power to reduce the doses, but fail to offer more precise information about how to manage the reduction. D10, for example, confuses the reader regarding the number of tablets. First, it allows consumers to take two tablets up to four times a day and stresses that consumers should not exceed 8 tablets a day. But it also allows the consumer to take the medicine every four hours, which would give 12 tablets. Sometimes, when the warning offers too much information, it can reduce its efficiency.

The amount of medicine that the consumers should take can vary according to their individual needs, which may depend on the intensity and frequency of the pain. For this reason, the modal operator 'need' is also employed in the sections related to 'how to take the medicine'.

"Every four hours, if you **need** to, up to four times in 24 hours". (D15)

"The exact amount that you **need** to apply will vary, depending on the extent and severity of your condition, but normally 1 to 2g (1 to 2 golf- ball sized quantities of mousse dispensed into the palm of your hand) should be enough". (C1)

The modal operator 'must' has a strong illocutionary force, meaning obligation, which is closed to additional interpretation. For this reason, it is preferred over 'should', which can be interpreted as a recommendation.

The warnings in B3 and D4 below employ the modal operator 'must', which signals "a higher (...) degree of pressure on the person to carry out a command" (Thompson, 2002: 59). The problem is due to the fact that they are in the passive voice, rendering the warnings more formal.

"Motifene 75 mg Capsules **must** be swallowed whole with a drink of water (about half a glass)". (B3)

"Diclofenac Potassium tablets **must not be taken** long-term, blood tests **should** be carried out if it taken more than a few days". (B7)

The modal operator 'should' is also employed to express a command. The warning in A4 calls the attention because of the employment of a complex sentence. First, it is in the passive voice, then an unusual verb is selected, 'sought', finally the writer implies that the consumer knows what an overdose is. On the other hand, the warning in D4 is clearer if compared to A4, mainly due to the use of active voice.

"IF YOUR OR ANYONE TAKES TOO MUCH: immediate medical advice **should** be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage". (A4)

"If you may be taking this medicine for a long time, you **should** talk to your doctor about it". (D4)

As mentioned before, ordinary consumers are the target audience of PILs, but *doctor* and *doctors* appear 67 times in the British corpus as subjects of the verb when the modal operator is 'may'. It is clear, in the warnings below, the attempt of the manufacturer to transfer the responsibility to the doctor. The preference for the modal operator 'may' gives the idea of a suggestion, as in B15 below. The main problem lies in the fact that warnings are instructions that direct the readers to avoid a risk; but the readers are not directly addressed in the warnings below, the actions are beyond their control. In this way, the consumers may infer different meanings, which may be different from the writer's intended one. They can either lower the dose and take another drug by themselves, or ask the doctor, or even ignore the warnings.

"Your doctor **may advise** you to take a dose that is lower than the unusual adult dose if you are elderly (..)". (B15)

"Your doctor **may** advice you to take a dose that is lower than the usual adult dose if you are elderly. Your doctor **may** want to check closely that the Voltarol Dispersible Tablets are not affecting your stomach". (B2)

The most common modal adjuncts in this section are related to usuality, which can be perfectly explained by the fact that it is related to the frequency that the consumers take the medicine and overdose.

"If you accidentally use too many suppositories or use them too **often**, tell your doctor or go to your nearest casualty department straight away". (B13)

"As you are taking two medicines together there are a lot of side effects listed. Most of these don't happen very **often**, are not serious and will **often** wear off after a while". (F1)

The Portuguese PILs, like the UK ones, sometimes address doctors. Interestingly, the warning below B 16-P is from an over-the-counter medicine, but even so, it warns that the doctor will prescribe the correct dosage.

*"Seu médico dirá a você exatamente quantos comprimidos de diclofenaco sódico você **deverá** tomar. **Dependendo** da resposta do tratamento, seu médico **pode** aumentar ou diminuir a dose". (B16-P)*

The warnings are clear in relation to how B2-P and A5-P and for how long D2-P to take the medicines. The warnings below not only make use of a modal operator that denotes obligation ('must' - *devem/ deve*) and prohibition ('cannot' - não pode), but also present the directions directly.

*"As drágeas de diclofenaco potássico **devem** ser ingeridas inteiras com água ou outro líquido, de **preferência** antes das refeições ou com o estômago vazio". (B2-P)*

*"Este medicamento não **pode** ser partido, aberto ou mastigado. (A5-P)*

*Aspirina não **deve** ser administrada por mais de 3 a 5 dias sem consultar seu médico ou cirurgião-dentista". (D2-P)*

4.3.4 Possible Side Effects

Section 4 of the English PILs and 8 of the Portuguese ones present the side effects and what the consumers should do in order to minimize them. A high degree of modalisation is expected, given that if

the manufacturers present the side effects too clearly, consumers may refuse to use the medicines.

The warning B15 below gives evidence of partiality, that is, on the one hand, it clearly asserts that the medicine is 'suitable for most people', whereas, on the other hand, it lacks the same clarity when presenting the side effects. The combination of the modal operator 'can' and the modal adjunct 'sometimes' suggests that the side effects are unlikely to occur.

"Voltarol dispersible Tablets **are** suitable for most people, but, like all medicines, they **can sometimes cause** side effects." (B15).

The warning in A3 points out the liver and kidney risk, but the analysis reveals that, as occured with other warnings, it resembles a promise, given that it highlights a good event. The vagueness of the expressions 'long time' and short period of time' also helps to weaken the warning.

"If paracetamol is taken for a long time, it **may lead** to liver and kidney problems but if the right amount is taken over a short period of time **there should be no** problems". (A3)

It seems that the modal operator 'may' has been selected to inform about the side effects. The main problem is that there are other features that help to weaken the warnings. The unusual word 'malaise' in A9 is one example, considering that some consumers might not know it. However, the overuse of mood adjuncts in one warning D6, such as 'rarely', 'usually', and 'soon' can confuse the consumers, who need to make an effort, possibly to reread it in order to undertand it.

"In rare cases (more than 1 in 10,000 people but fewer than1 in 1,000 people), malaise, a drop in blood pressure or a change in laboratory values **may occur** (…)". (A 9)

The modal operator 'will' is also employed, although to a lesser extent than 'may' and 'can'. The use of will seems to indicate that the writer is sure about the proposition. Interestingly, it is related to good events, not bad events.

"Most people **will not have** problems, but some **may get** some". (A 7)

Examples of modulation are fewer in these sections. They generally occur when the warnings direct the consumers to deal with the consequences that were not avoided.

"You **should use** appropriate analgesic therapy administered orally as soon as this route of administration **can be used**". (A 9)

The Portuguese PILs also use the modal operator 'may' to present the propositions. Like the English one, they overuse technical and

unusual terms to describe the side effects, which cause problems of comprehension, thereby weakening the warnings.

*"Baixo nível de elevações de transaminases **pode** ocorrer em alguns pacientes recebendo doses recomendadas de paracetamol; estas elevações não foram acompanhadas de insuficiência hepática e **geralmente** foram resolvidas com o tratamento contínuo ou descontinuação de paracetamol". (E1)*

4.3.5 Summary of The Section

Both types of modality are employed in the PILs, but the purpose of each section certainly motivates the employment of a type of modality. For instance, modalisation is more frequently employed in the sections that describe the purpose of the medicine. Both modalization and modulation are employed in the warning sections, but under different purposes: either giving information or issuing a command. On the other hand, the imperative was largely employed in this section. The sections devoted to how to use the medicine were also marked by commands, with the use of both imperative and modulation. Finally, the sections that describe the side effects also confimed my expectations about the use of modulation expressing possibility.

The analysis reveals that the low value modal operators 'may' and 'can' weaken the warnings. Moreover, a dangerous combination of these modal operators was found, especialy in warnings that express the risks and side effects. For example: Modal operators + Modal Adjuncts; modal operators + vague or technical terms. Clearly, these combinations undermine the strength of the risks, even if explicitly pointed out. Likewise, the use of vague and technical terms in the commands leads consumers to infer important information about quantity and time that if mis-infered, can be dangerous.

The analysis of the proposition shows the writers' unwillingness to present the information about risks and the side effects clearly, given that the degree of validity expressed is generally low. It represents a very serious problem, given that consumers may fail to perceive the risks, and consequently, not comply with the warnings. This is because a weak warning is not able to change the consumers' beliefs, and their beliefs have a great impact on the compliance of the warnings. Possibly, it is a strategy employed by the writers' not to frighten the consumers, otherwise, their sells would decrease.

CHAPTER V
BRAZILIAN PRODUCT LABELS

5 INTRODUCTION

This chapter is organized into three main sections, each one deals with the labels from one product: fireworks, hair dye and food. The sequence is based on the explicitness of the risks, which is strictly linked to the consumers' behaviour. That is, people know that fireworks offer some kind of risk, and for this reason, they adopt some precautions, often inadequate, to protect themselves. Some consumers also tend to adopt some specific precautions when dyeing their hair, but some might be unaware of the real risks of hair dye. Finally, most consumers tend to believe that food can only bring risks to allergic people, but the reality is different. This chapter deals with how different product labels warn people about risks that are known and risks that are unknown.

5.1 FIREWORKS LABELS

Fireworks have allured people throughout the world for approximately two thousand years. The sparkling and the colors fascinate people from an early age and we forget that they are, in fact, explosives. They can cause very serious injuries not only to the people who are handling them, but also to people who are nearby. Hundreds of people get hurt with fireworks in Brazil every year, whose traumas involve burns, amputations and loss of sight and hearing. The number of accidents triples during the months of June and July, mainly due to the traditional Brazilian party '*Festa Junina'*.

The celebration of New Year's Eve also registers an increase in the number of accidents with fireworks. A fatal accident was registered on the last day of 2015[28] with a man who lit a firework and put it in his mouth. The problem is that the shot did not lift into the air, and exploded prematurely in the tube, which was in his mouth. According to his brother, the man was used to playing with fireworks in that way.

[28] Retrieved from: http://g1.globo.com/am/amazonas/noticia/2016/01/homem-morre-ao-tentar-soltar-rojao-com-boca-durante-reveillon-no-am.html

Unfortunately, the media report every year innumerable cases like this, involving fatal accidents with fireworks.

Most people know that fireworks are dangerous artifacts that can cause serious injuries. I know from experience that there is no such thing as a safe firework, even 'sparklers' (*estrelinhas*), which are made specifically for children, can cause second and/or third degrees burn, given that their temperature can reach 1.000 degrees Celsius [29]. Unfortunately, this information is not announced, because if it were, many parents would certainly avoid buying them or handling them near their children.

The question 'what does the person who buys fireworks need to know?' emerges at this point in order to discuss the necessary information that can direct consumers to adopt safe behavior. The answer to this question can be divided into five topics: the risks, the consequences, how to avoid the consequences, how to use and how to store them.

As mentioned above, fireworks are explosives and reach very high temperatures, but the main problem comes from the fact that some people tend to believe that some pyrotechnic materials, such as 'sparkers', are inoffensive. Thus, people need to be informed that **all** types of firework pose **very** serious risks. Then, people need to know not only the consequences but also their severity. Statistics show that 70% of the accidents result in burns, 20% in lacerations, while 10% in amputation[30]. Moreover, according to the Brazilian Ministry of Health, more than 100 people died between 2003 and 2013 due to burns caused by fireworks[31]. People also need to know how to avoid or minimize these risks, that is actions that should be followed and/or avoided. For example, 'what should and should not be done if the firework fails?', 'who can handle the fireworks?'. After that, people need to know 'how to use fireworks', which encompasses information about how to light them, where to use them, and the distance to be kept between places and other people. Finally, information about storage is also essential. For instance, can people store them in a humid place? Or even inside the car? Or close to other fireworks when they are alight?

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[29] Retrieved from: http://saudeinfantil.blog.br/2012/06/cuidado-com-os-fogos-de-artificio/

[30] Retrieved from: http://saudeinfantil.blog.br/2012/06/cuidado-com-os-fogos-de-artificio/

[31] Retrieved from: http://www.ebc.com.br/cultura/2013/06/saiba-como-usar-os-fogos-de-artificio-com-seguranca-nas-festas-juninas

5.1.1 Analysis

In order to address the factors that can influence the adequacy of firework warning labels, I will visit the Brazilian guidelines for fireworks and verify whether the labels are in agreement with them. At the same time, I will briefly analyze the non-verbal information. Then, I will analyze whether the selected warning labels contain the information that the person who buys fireworks needs to know. I will also verify how the information in conveyed, if it is conspicuous, explicit and clear, and how the writers evaluate the risks.

The risks and consequences arising from fireworks are very serious and must be explicitly pointed out. There are various forms to tell the readers that a product offers some kind of risk, such as colors, pictures, symbols, signal words and written messages. Their employment depends on the risk, audience and purpose. For example: symbols and colors are perfect in the case of traffic signs, due to the need for an immediate response, given that there is not time for the audience to process a full written text. The combination of more than one form, which would be ideal, renders the warnings more efficient, given that they will be more conspicuous. In this way, readers will be more willing to read, and depending on the message, on what they understand and on their evaluation, they can choose to comply with the warning.

5.1.2 Guidelines

The Brazilian Army is responsible for the regulation of explosives and fireworks in Brazil. The guidelines R-105[32] establish the norms from the manufacturing to the trading. Information related to the labels is also included in these guidelines, under the Art. 122 (see below):

> *Art. 122. As embalagens contendo substâncias ou artigos explosivos, deverão trazer, obrigatoriamente, em* ***caracteres bem visíveis****:*
> *I - em, pelo menos, uma face ou posição:*
> *a) nome da empresa;*
> *b) nome e endereço da fábrica;*

[32] Retrieved from: http://www.dfpc.eb.mil.br/index.php/component/content/article/2-uncategorised/172-r-105-art-91-ao-159

> *c) identificação genérica do produto e nome comercial;*
> *d) peso bruto e peso líquido;*
> *e) data da fabricação e validade;*
> *f) CNPJ e inscrição: Indústria Brasileira;*
> *II - em, pelo menos, duas faces ou posições:*
> *a) rótulos de risco, de acordo com a NBR 7500;*
> *b) rótulos de segurança, de acordo com a NBR 7500;*
> *c) inscrição de:" EXPLOSIVO – PERIGO ", na mesma cor do rótulo de risco;*
> *d) lote e data de fabricação;*

They are clear in relation to the prominence of the information, by pointing out that they should be written in '*caracteres bem visíveis'*. The labels should also provide the signal word 'EXPLOSIVO – PERIGO'. As can be seen, it focuses mainly on general information about the products, whereas NBR 7500 focuses on the safety information.

NBR 7500 [33] is a document provided by ABNT aiming at 'Identification for transportation, handling, movement and storage of materials', which focuses dangerous and chemical goods (see below):

> NBR 7500
> 4.2 Rótulos de risco
> 4.2.1 O rótulo de risco é dividido em duas metades, sendo a metade superior do rótulo reservada para o símbolo de risco ou para o n. das subclasses 1.4, 1.5 ou 1.6, e a metade inferior para textos indicativos da natureza do risco, o n. da classe e grupo de compatibilidade, quando apropriado.
> 4.2.2 quando constar nos rótulos de risco o texto indicativo da natureza do risco (nome da classe ou da subclasse (5.1 ou 5.2) do produto), ou informação complementar, deve ser colocado na metade inferior do rótulo. Os caracteres devem ter altura mínima de 6% a 8% do comprimento da diagonal do rótulo, escritos simetricamente dentro destes.

[33] Retrieved from: http://licenciadorambiental.com.br/wp-content/uploads/2015/01/NBR-7.500-Simbolos-de-Risco-e-Manuseio-Para-o-Transporte-e-Armazenamento-De-Materiais.pdf

As can be seen, numbers and symbols specify information related to the nature of the risks, which shows clearly that it does not address ordinary people, as it demands some type of specific knowledge. Thus, there is evidence that the norms fail to guide the writers on the task of informing the final consumers, given that information about how to use the product appropriately is not envisage in the documents mentioned above.

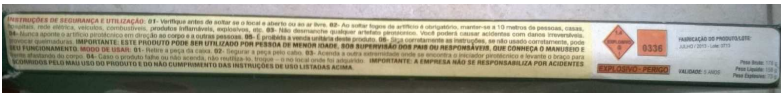
5.1.3 Fireworks Labels

From the four fireworks labels selected, three are visibly in disagreement with the guidelines above (1, 2 and 4), as they fail to provide the information in 'visible characters', given that it is impossible to read the labels '*candela romana*' (picture 5.1) and '*apito com vara*' (picture 5.3). The label '*chuva de prata*' (picture 5.2) is readable, although the font size is still small. As pointed out in chapter 3, despite the font size, the color combination also affects visualization. On the other hand, the label 'Sputinik' (picture 5.3) is more conspicuous due to the font size, color combination, quality of the label and printing, and layout. The headings are highlighted and the instructions are in number list[34].

Product 1

Picture 5.1: Candela Romana

Product 2



Picture 5.2: Chuva de Prata

[34] The transcritpions of the warning labels are in Appendix 2.

Product 3

Picture 5.3: Sputinik

Product 4

Picture 5.4: Apito com vara

The picture below illustrates all the labels; in this way it is possible to visualize the difference between them.

Picture 5.5: 4 Fireworks labels

5.1.4 Symbols

The analyzed warning labels contain symbols, headings and written text aiming at informing about the risks. However, the analysis reveals that all the warning labels fail in not informing about the risks efficiently. In order to justify this assertion, I will present the analysis of each component responsible for informing the risks.

The ABNT regulation specifies the use of an orange 'diamond' with the word 'explosive' (*explosivo).* As can be seen below, there are numbers above and below the word, 1.4 and 1. According to the document provided by ABNT NBR 7500, number 1 represents explosive, whereas numbers 1.4 represent "substances and items that do not present significant risks" (p. 40). Clearly, the information of the 'symbol' addresses those involved in the transportation of the product, given that the transportation of fireworks might represent a minor risk if compared to other explosive substances. But, as mentioned before, ordinary readers have no idea of the meaning of these numbers, neither that they refer to transportation. Besides, for this kind of reader, fireworks are supposed to be dangerous. Thus it seems that the analysed

warning labels are addressed to more than one audience, the consumers and the person who is in charge of transportation.

Figure 5.1: Explosive

On the other hand, even being addressed to the person in charge of transportation, the 'symbol' might call the reader's attention, due to the word and colour. 'Explosive' is a strong word, and 'orange' is the color associated with the second highest risk value, according to ANSI. The main problem lies in the fact that the symbols are small and the printings are of poor quality. At this point, the issue of design emerges given that a warning label that is poorly designed can reduce considerably the appeal and even worse, the readability of the message.

5.1.5 Headings

The headings are important warning components that guide the readers to the content of the 'section'. They also serve as 'alert words' or 'signal words', as named by standards making organizations, which have the function of attracting the readers' attention to the risks by indicating the level of the hazard. These words are widely used and mandatory for many different products. For example: the signal words 'CAUTION! DANGEROUS' (*CUIDADO! PERIGOSO*) are used in the labels of Fly Insecticide, whereas the signal word 'PRECAUTIONS' (*PRECAUÇÕES*) is employed in the labels of cleaning products. But, the headings of the fireworks labels analyzed are inadequate given that they not only fail to guide the readers to the content, but also confuse the reader.

There are two sections common in all fireworks labels. The first section is titled '*instruções de segurança e utilização*' in all labels, which is followed by the second section that is variously titled: '*instruções de uso*' (label 1), '*modo de usar*' (label 2), '*modo de soltar'* (label 3) and '*instruções de uso'* (label 4). The terms '*utilização',* employed in the first section, and '*uso',* employed in the second section (labels 1 and 4) have the same meaning and for this reason the reader might infer that the information in both sections is repeated and consequently avoid reading it. In order to solve this problem, the first section should be rephrased as follows: '*instruções de segurança*' or '*advertências*', which would be much more attractive and avoid misinterpretation.

The heading in 1 called my attention because of the addition of the warning '*Caso contrário você poderá sofrer queimaduras*' in parenthesis beside the title '*Instruções de Segurança*'. It tells the consumers explicitly that if the instructions are not followed, they can suffer burns. Unfortunately, the consumer needs to infer the condition to avoid burns. Despite this fact, it is the only warning label that informs the consumers about the overall risk of the fireworks. This is because, as will be shown in the analysis, the few risks mentioned are always linked to an instruction direction, leading the consumers to ignore the instructions directions that do not mention risks.

The analysis shows that the warning labels employ the signal words with parsimony, as can be seen below:

	ATTENTION	IMPORTANT	WARNING
1	1		1
2		2	
3	2		
4			

Table 5.1: Fireworks headings

There is evidence, based on the table above, that there is not a specific regulation about the signal words that should anticipate the 'warning message', given that each product uses a different one.

The first brand uses the signal word 'warning' (*advertência)* once*,* which according to ANSI, should be used to refer to a situation that "could result in death or serious risks" (Kundinger, 2008:13). However*,* as can be seen below, the use of the signal word is totally

inadequate, given that the message is neither related to accident prevention, nor to risks, but it clearly sets out to transfer the responsibility of hazard prevention to the consumer.

ADVERTÊNCIA A empresa isenta-se de quaisquer responsabilidade por acidentes ocorridos do mau uso do produto e do não comprimento das instruções citadas na embalagem. (1A)

The question of the difference between a warning and a threat arises here. As we saw in chapter 2 many authors point out (Fraser, 1998; Shuy, 1993; Dumas, 1992) that the boundaries between these speech acts are not clear-cut. Issues such as context, writers' intention and reader's perceptions are crucial to determining the speech act. Fraser (1998) notes that a warning does not benefit the speaker but that it is uttered to the addressee's benefit.

It is possible to infer that the message above would benefit the writer due to the fact that it would help the manufacturer to avoid litigation. Consequently, it would be detrimental to the addressee. In this way, the just mentioned speech act resembles a 'threat', in that it seems to be uttered for the writer's benefit and to the reader's detriment (Shuy, 1993).

Moreover, a warning is an alert message proffered to warn the reader about a hazardous event. To accomplish it, the message should inform about both the hazard and how to avoid it. Both elements are not present in the above speech act, which is about a risk that is not explicit. Readers are not informed about what kind of accidents they are exposed to, neither if it is related to personal injury of material damages. Thus, for the reasons exposed above, it is possible to assert that, despite the signal word 'warning', the consumers may have difficulty in recognizing 1A as a warning.

The second and third brands also 'threaten' the reader about their responsibility for accident prevention, but this time it is correctly placed under the heading 'IMPORTANT' (*IMPORTANTE*). It is interesting to note that the instruction is in upper case (2 A below) aiming at attracting the readers' attention.

IMPORTANTE: A EMPRESA NÃO SE RESPONSABILIZA POR ACIDENTES OCORRIDOS PELO MAU USO DO PRODUTO E DO NÃO CUMPRIMENTO DAS INSTRUÇÕES DE USO LISTADAS ACIMA. (2A)

IMPORTANTE: A empresa não se responsabiliza pelo uso incorreto do produto. (3A)

The example above, in 1A illustrates the indiscriminate use of the signal words, which can affect the readers' faith in them. That is, if a warning that conveys a message about a minor risk adopts the signal words 'danger' or 'warning', the appealing effect will be weakened, even when the risks are significant. This can explain why some consumers ignore warnings and even avoid reading them.

The opposite is equally problematic. That is, when the product label employs a 'weak' signal word to warn about a serious risk, which occurs in 1B below, where the word 'attention' actually anticipates information about the risk of burns. The problem lies in the fact that the signal word *per se* does not convey a message of a situation that can bring serious injuries, as is the case of the signal words 'danger' and 'warning'. As noted by Shuy (1990) the signal words 'attention' and 'important' can be used to anticipate both good and bad events. The Collins on-line dictionary defines the word 'attention' as 'great interest that is shown in someone or something'[35], which is not necessarily about a negative event.

ATENÇÃO

Após acendimento, sempre direcionar para o alto. Sendo assim não haverá queimaduras. (1B)

Interestingly, the warning in 1B above is different from most warnings analyzed in this study. The difference lies in the fact that it employs the modal operator 'will' in the negative, which expresses a prediction. The use of 'will' in the negative is uncommon in warnings, although it is common to express a promise. However, since the writer cannot control the outcome (Fraser, 1998), it is not a promise.

The third brand also uses the signal word 'attention' inadequately, given that it alerts about a serious injury (see below).

ATENÇÃO! DESMANCHAR FOGOS PODE CAUSAR QUEIMADURAS (3B)

As can be seen, it explicitly warns about burns, which consequently raises the readers' perception of the risk. But it employs the modal operator 'may' combined with the verb 'cause', which gives the idea of possibility. It clearly moderates the illocutionary force, reducing the strength of the word 'burns'. Besides, this warning is inappropriately placed at the end of the instruction section, which confuses the reader and reduces the strength. Readers may perceive it as part of the instruction and may not give enough attention to it. It would

[35] Retrieved from: https://www.collinsdictionary.com/dictionary/english-cobuild-learners/attention

be better if it were earlier, because readers expect to have the most important information at the beginning of the text (Shuy, 1990).

The following warnings are used to inform who can safely handle the fireworks, which have their use restricted according to the age of the user. As can be seen, each one adopts a different heading. The first uses the term '*classe B*', which is unknown to most people[36]. The second adopts the term 'important', whereas the third uses the term 'attention'. Finally, the fourth employs the heading '*uso permitido*', which can bring problems of interpretation. That is, some readers may judge it positive because the heading is allowing them to use, then they can give up reading the message. In order to avoid such misinterpretation, the heading should restraint the use, which would cause more effect.

CLASSE "B"

este produto só pode ser utilizado por pessoa de 16 anos, supervisionada por um maior de idade que não esteja EMBRIAGADO e que conheça o manuseio e o seu funcionamento. (1C)

IMPORTANTE, ESTE PRODUTO PODE SER UTILIZADO POR PESSOA DE MENOR IDADE, SOB SUPERVISÃO DOS PAIS OU RESPONSÁVEIS, QUE CONHEÇA (sic) O MANUSEIO E SEU FUNCIONAMENTO (2B)

ATENÇÃO ACONSELHÁVEL PARA MAIORES DE 12 ANOS SOB SUPERVISÃO DOS PAIS OU RESPONSÁVEIS (3C)

USO PERMITIDO

Este produto pode ser utilizado por pessoa maior de 18 anos que não esteja embriagado (sic) e que conheça o manuseio e seu funcionamento. (4A)

The signal word 'important' (*importante*) and 'attention' (*atenção*) seem to be correct at first sight, given that the warnings do not give the idea of a negative event, on the contrary; it allows children to use the product. For this reason, the readers may have difficulties in recognizing them as warnings because they do not have the characteristics of warnings: they do not mention a risk nor the consequences. Moreover, as was mentioned before, it is allowing children to handle the product. There is a restriction, but it is not clearly emphasized. A 'BUT ONLY warning', as in (1), would be more adequate and could solve part of the problem, see below an example.

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[36] R-105 § 3º "The fireworks included in **category B** can be sold to any person, including minors" (*Os fogos incluídos na Classe B podem ser vendidos a quaisquer pessoas, inclusive menores*)

"IMPORTANTE: Este produto pode ser utilizado por pessoa menor de idade, mas somente sob supervisão dos pais ou responsáveis, que conheçam o manuseio e seu funcionamento".

Nevertheless, information regarding the risks and their consequences is still missing and readers may have difficulties to infer them properly. Consequently, the message may not be followed and the results of non-compliance can be very serious.

Departing from the point that readers avoid reading the full text, but instead they scan the text and select what they are going to read based on the headings, it is possible to say that the careless use of headings may affect the readers' willingness to read the warning. That is, they might avoid reading them, mainly because the headings fail to convey the severity of the risks. Besides, some warnings are not clear and can be easily confused with other speech acts, such as threats and promises.

5.1.6 Risks and Their Consequences

As we noted in Chapter 2 both risk identification and the consequences are essential components in any warning label. Leonard and Wogalter (2000:383) note that "the extent to which one perceives the risk in a hazard is based on understanding its consequences". There are many factors that contribute to the construction of this understanding. In the case of fireworks, national campaigns promoted by both public entities, like the fire department, and private entities, like the Brazilian Society of Pediatrics, help to disseminate the consequences of handling fireworks carelessly. Besides, some people have an acquaintance who has suffered an accident with fireworks. The main problem lies in the fact that both the information and the stories tend to be forgotten over time. It is exactly at this point that warnings are required to inform and remind the readers about both the consequences and the risks.

The analysis has revealed so far that all four fireworks labels fail for not informing about the risks and the consequences properly, even though the risks arising from the fireworks are particularly dangerous. Studies show that when both the risks and the level of hazardousness are directly pointed out, users tend to comply more often. But, at the same time, when these risks are directly pointed out, consumers may avoid buying the products. For this reason, it is possible to say that the manufacturers adopt a strategy that renders the risks and consequences less threatening. Certainly, some consumers would refuse to buy a

product that clearly points out that it could cause lacerations and amputations.

There is evidence that the four labels warn about both the risks and their consequences inefficiently, given that they would not lead consumers to infer the actual severity of the consequences. That is, they fail to inform that the consequences are potentially serious such as severe burns, dilacerations, and even death. When the risks are indicated they are related to an action and not the product, giving the idea that the problem is tied to the consumer's behavior and not the product itself. Of course the consumer's behavior can largely influence the safety, and it is for this reason that warnings are extremely important, given that they can guide this behavior.

The first brand informs about the risks twice (see below), which are correctly tied to a direction. In this way, the readers do not need to infer the necessary actions to avoid the risk.

"Se o produto falhar, é obrigatório manter-se afastado por no mínimo 20 minutos. Aproxime-se com cautela e jogue água com abundância para que não haja perigo de explosão. Não tente reacendê-lo. Troque-o no local onde foi adquirido". (1D)

"ATENÇÃO

Após acendimento, sempre direcionar para o alto. Sendo assim não haverá queimaduras". (1E)

Explosion tends to be perceived as a severe risk that can bring very serious consequences, and for this reason readers' willingness to comply with the warning tends to be higher. The warning adopts the structure 'if X, then Y', which, as noted by Tiersma (2002), is largely employed in this kind of speech act. The condition 'if it fails' is clear and objective. The main problem lies in the action 'it is mandatory to keep away for at least 20 minutes', whose cost of compliance is unreasonable (Lehto, 1992). That is, it is highly unlikely that users will wait 20 minutes to approach the firework. Furthermore, it is unclear if the users should throw water after 20 minutes or right after the firework fails.

Although the warning in 1D points out the risk of burning, which is the most common consequence of handling fireworks, it is strange that it, like 1D, presents the consequence in the negative. Lehto (1992), when discussing about designing of warning labels, recommends that negations should be avoided because they can "create comprehension problems" (Wright, 1982; as cited in Lehto, 1992: 131). For example, readers may sometimes fail to perceive that the sentence is in the

negative and will understand exactly the contrary, 'sendo assim, haverá queimaduras'.

A further problem is linked to the fact that the warning label does not inform about the overall risks and consequences, instead it informs about them in the middle of the text, which is always attached to a direction. In this way, the readers can erroneously infer that the risks are only linked to that specific direction. That is, the risk of an explosion can only occur if the firework fails, and following the same reasoning, the risk of burns is nonexistent if the consumer directs the firework upwards.

The second warning label informs about the consequences twice (see 2C and 2D below). However, the lack of specificity in relation to the consequence in (2C) weakens the warning. First, because the readers have to infer the consequences, which can be different from the writer's intended list of consequences. Second, readers can reasonably perfectly suppose that if the consequences were really serious, the warning label would inform them. Finally, it does not make explicit what kind of damage will occur, personal or material.

"Não desmanche qualquer artefato pirotécnico. Você poderá causar acidentes com danos irreversíveis". (2C)

The word 'damage' (*danos*) seems to refer to property. However, a search in the BNC- Lancaster [37] demonstrates that 'damage' is frequently used in the judicial context. Thus, it is inadequate to warn about the fireworks' hazards and their consequences.

[37] Retrieved from: http://bncweb.lancs.ac.uk/cgibinbncXML/BNCquery.pl?theQuery=search&urlTest=yes

Your query "damages" returned 2259 hits in 417 different texts (98,313,429 words [4,048 texts]; frequency: 22.98 instances per million words) (365 seconds)

|< << >> >| Show Page: 1 Show KWIC View Show in random order New Query Go!

No	Filename	Hits 1 to 50 Page 1 / 46
1	A0U 2472	Eleanor used to say that she inherited her father's nose and she would one day sue him for **damages**.
2	A17 1458	My veterinary colleagues tell me one of the main dangers with such large dogs is not that they injure themselves (through overexercising before their skeletons can carry their weight) but that their diets are over-supplemented, particularly with excessive calcium, which **damages** bone growth and hinders development.
3	A1E 62	The insurance cover is designed to protect intermediaries against suits for **damages** brought by irate customers.
4	A1J 33	In working out the percentage deduction from the **damages** of successful claimants, comparison should be made with trade union funded personal injury litigation where costs were paid to winning defendants.
5	A1T 348	Letter: Excessive **damages** for libel
6	A1T 358	Letter: Excessive **damages** for libel
7	A1T 360	Sir: Marcel Berlins's instructive and provocative article (29 September) on juries and libel **damages** prompts supplementary comment on two points.
8	A1T 363	What is remarkable — and, I think, indefensible -about English libel trials is that the judge gives directions and guidance on the measure of **damages** as part and parcel of a single summing-up on the substantive issue.
9	A1T 364	For example, the last four pages of Sir Bernard Caulfield's summing-up to the jury in the Archer case is concerned with **damages**, and heavily stresses the aggravating factors.
10	A1T 369	It is worth pointing out — as did Dr Akena Adoko in his book on the Jeffrey Archer trial — that there may have been an additional development in the folkways of the juryroom: the frequent practice of the rich (the typical plaintiffs) to pass on their **damages** to charity, as did Mr Archer, might act as an additional, and self-legitimating, incentive to take awards through the ceiling.
11	A2A 231	The International Bar Association conference: Punitive **damages** awards 'necessary to protect public'
12	A2A 233	CIVIL and criminal courts should have a new power to impose punitive **damages** awards on companies which demonstrate wanton or reckless disregard for human life, a lawyer said yesterday.
13	A2A 234	Rodger Pannone, a solicitor involved in the Piper Alpha, King's Cross and M1 air disasters, told the International Bar Association conference in Strasbourg: 'Unless there are **damages** awards — which must be uninsurable - of hundreds of thousands, if not millions, of pounds in certain circumstances, bad companies have no threat or incentive to make products and services safer.'
14	A2A 238	Mr Pannone's comments reflect the philosophy of the American courts, where juries are able to award punitive **damages**.
15	A2A 239	'I find it difficult to justify enormous punitive **damages** being paid to victims on a first-past-the-post system.
16	A2A 241	David McIntosh, a leading insurance company defence solicitor, who opposed Mr Pannone in the Opren drug case, attacked claims that British levels of **damages** were 'miserly'.
17	A2A 242	'Others, including myself, believe that non-punitive but truly compensatory **damages** awarded by the courts of the United Kingdom are preferable to the exorbitance of emotionally-driven jury awards,' he said.

Table 5.2: BNC Lancaster (damages)

The same warning label also warns about ‘burnings’ under the structure, if X then Y (see 2D below). Although the structure is adequate, the employment of the modal operator reduces the efficacy. *“Siga corretamente as instruções, se não usado corretamente, pode provocar queimaduras”. (2D)*

The third warning label warns about the consequences of fireworks only once, and it is attached to the action ‘take apart the fireworks’. As a reader I can perfectly infer that burning is only associated with taking apart the fireworks, given that there is not a general warning that says that the product can burn.

“ATENÇÃO! DESMANCHAR FOGOS PODE CAUSAR QUEIMADURAS”. (3D)

At the beginning of this section, I pointed out the most common consequences of fireworks, namely: burnings, amputations, dilacerations and hearing and sight loss. On the other hand, the discussion above showed that burning is the only consequence listed in the 4 warning labels analyzed. Moreover, there is no reference regarding the severity of the burnings, which can be very serious. Besides, the consequences, with the exception of 2B, are linked to a specific direction, which can lead the readers to infer that the risks are only associated with that specific ‘event’.

Thus, there is evidence that these warning labels are inefficient in informing about the risks and their consequences.

5.1.7 How to Avoid the Consequences and How to Use

The person that buys fireworks also needs to know how to avoid the risks that they are exposed to when handling the fireworks. Moreover, s/he also has to be informed about how to use these artifacts.

The heading '*instruções de segurança e utilização*' addresses the first topic mentioned above. The table below shows the headings and the warnings of the four product labels.

	1 Instruções de segurança e utilização	*2 INSTRUÇÕES DE SEGURANÇA E UTILIZAÇÃO*	*3 INSTRUÇÕES DE SEGURANÇA E UTILIZAÇÃO*	*4 INSTRUÇÕES DE SEGURANÇA E UTILIZAÇÃO*
A	É proibido soltar fogos em lugares fechados ou próximos a produtos inflamáveis ou explosivos.	Verifique antes de soltar se o local é aberto ou ao ar livre.	É proibido soltar em locais fechados, cobertos ou próximo a produtos inflamáveis ou explosivos.	Verifique se o local é adequado, sendo ao ar livre, não tendo fios elétricos, marquises ou arvores que impeçam a livre trajetória do produto.
B		Ao soltar fogos de artifício é obrigatório, manter-se a 10 metros de pessoas, casas, hospitais, rede elétrica, veículos, combustíveis, produtos inflamáveis, explosivos, etc.	É obrigatório soltar fogos a 50 m de distancia de pessoas, casas, veículos e rede elétrica.	Proibido soltar próximos aos produtos inflamáveis, residenciais, veículos e hospitais.

C		Não desmanche qualquer artefato pirotécnico. Você poderá causar acidentes com danos irreversíveis.		
D	Se o produto falhar, é obrigatório manter-se afastado por no mínimo 20 minutos. Aproxime-se com cautela e jogue água com abundância para que não haja perigo de explosão. Não tente reacende-lo. Troque-o no local onde foi adquirido.		Se o produto falhar, mantenha-se distante por no mínimo 120 segundos. Não tente reutilizá-la. Troque-o no local onde foi adquirido.	Caso o produto falhar ou não acender, aguarde 30 segundos e não tente reutilizá-lo. Troque-o no local adquirido.
E		Nunca aponte o artifício pirotécnico em direção ao corpo ou a outras pessoas.		Nunca se posicione sobre o produto depois de acender.

F		Siga corretamente as instruções, se não usado corretamente, pode provocar queimaduras.		
G				Venda proibida a pessoas alcoolizadas e menores de 18 anos.
H		É proibida a venda unitária deste produto.	É proibida a venda unitária deste produto.	

Table 5.3: Safety instructions

As can be seen, all four labels warn about where to use/and not to use the fireworks. The warnings A1 and A3 adopt the structure 'it is forbidden to use…' (*é proibido soltar...*), in which the word 'forbidden' strengthens the warning, given that it is clear and it closes the readers' possible inferences. On the other hand, warnings A2 and A4 use the verb 'check' (*verifique*), which transfers to the readers the responsibility of judging if the place is adequate. At least, A4 provides some examples that can help the readers to decide if the place is appropriate 'No electrical cables, marquee or trees' (*Não tendo fios elétricos, marquises ou árvore*), but A2 just mentions 'if the place is open and outdoors' (*é aberto ou ao ar livre*). Finally, no warnings inform about the risks of non-compliance, which would certainly influence the adherence, given that knowledge about the risks can trigger the decision.

At this point, Lehto and Miller's definition arises (1986, as cited in Lehto, 1992: 116), in that "warnings are specific stimuli which alert a user to the presence of a hazard, thereby triggering the processing of additional information regarding the nature, probability, and magnitude of the hazard". The warning discussed above fails to inform about the presence of a hazard, which has to be inferred. The main problem in this case is that the readers' inference may be totally different from the real hazard. For example, they can legitimately infer that the warning is to prevent material damage, not personal injury. Lack of information regarding the risks and/or consequences also occurs in B (2, 3 and 4), D (3 and 4), E (2), F (4), H (4) and I (2 and 3), which can reduce the

reader's compliance due to the non-recognition of the risk. On the other hand, D (1 and 4) provide exact information about how long should the users wait if the fireworks fail. Strangely, while D (1) suggests 20 minutes, D (4) suggests 30 seconds. The difference is huge, and I doubt that users will wait 20 minutes after firework fails. Given that the firework is made in China, it might be a translation mistake.

The multiple addressees in the same section can also weaken the warning. For example G4 (*Venda proibida a pessoas alcoolizadas e menores de 18 anos*) and H2 and H3 (*é proibida a venda unitária deste produto*) clearly address the seller. But the problem is that these warnings are under the heading (*Instruções de segurança e utilização*), which is supposed to be addressed to the consumers. In this sense, Coulthard (1994: 05) notes that "the writer has not clear picture of the imagined reader", which explains the problems observed in the analysis.

Moreover, what seems to be more problematic to the reader is the fact that there is more than one speech act in each move, that is, there is a mix of instruction, warning and threat, which may confuse the reader, for instance: A, B, C, D and E are instructions; F, G, I and J are warnings; while H is a threat (see the table below). This mixture represents a further barrier to the reader, given that the boundaries between these speech acts are not clear-cut. Dumas (1992: 267) notes that "the uncertainty of the definition of the term 'warning' derives largely from its being confused with such activities as instruction, persuading and advising". So, warnings may go unnoticed by readers. The table below illustrates the speech acts, which are differentiated by colors, in this way, blue is used for instructions, red for warnings and green for threats.

	1 Instruções de uso:	2 Modo de usar:	3 Modo de soltar	4 Instruções de uso
A	Retire o produto da embalagem;	Retire a peça da caixa.		Retire o apito da embalagem;
B			Colocar o produto em superfície plana e lisa.	Coloque o produto dentro de uma garrafa de vidro;
C	Segure na extremidade inferior;	Segure a peça pelo cabo.		
D	Acenda o iniciador pirotécnico e direcione para o alto;	Acenda a outra extremidade onde se encontra o incinerador pirotécnico e levante o braço para frente afastando do corpo.	Acender o estopim e afastar-se rapidamente do local.	Acenda o iniciador pirotécnico (estopim) e afaste-se rapidamente do local;
E				Repita o procedimento com os outros apitos (veja o desenho ao lado)
F	É proibido colocar qualquer parte do corpo em frente ao produto após acendimento.		É proibido colocar o corpo sobre o produto depois de aceso.	

G	Solte esse produto no mínimo 50 metros de animais, edificações, veículos, marquises, explosivos ou inflamáveis;			
H			A empresa não se responsabiliza pelo uso incorreto do produto	
I		Caso o produto falhe ou não acenda, não reutilize-o, troque-o no local onde foi adquirido.		
J	Solte somente ao ar livre;			

Table 5.4: Speech acts

5.1.8 Modality

The data has 73 clauses: 23 in A, 19 in B, 15 in C and 16 in D. As was expected, most clauses are commands (57 clauses), given that the analysis has shown higher occurrences of both safety instructions and instructions for use. But the consumers need to have good reasons to follow these instructions; otherwise, they can ignore them. Information about the risks and consequences can be a good reason for consumers to follow the instructions. I am not suggesting that the consumers should be frightened with very serious consequences, which would lead them to avoid buying the products, I am just proposing that the consequences should be shown clearly.

Most commands are realized by imperative clauses, of which there are 42 occurrences. They are issued to give the consumers directions on how to handle the fireworks (see below):

***"Retire** o produto da embalagem; **segure** na extremidade inferior; **acenda** o incinerador pirotécnico e **direcione** para o alto"; (1F)*

***"Segure** a peça pelo cabo"; (2E)*

***"Acenda** o estopim e **afaste**-se rapidamente do local"; (3E)*

***"Coloque** o produto dentro de uma garrafa de vidro", (4B)*

Or to instruct consumers on how to avoid risks, despite the fact that the risks are not mentioned in most clauses (see below):

***"Solte** esse produto no mínimo 50 metros de animais, edificações, veículos, marquises, explosivos ou inflamáveis";(1G)*

"Não desmanche qualquer artefato pirotécnico";(2F)

"Se o produto falhar, mantenha-se distante por no mínimo 120 segundos. Não tente reutilizá-la. Troque-o no local onde foi adquirido"; (3F)

"Nunca se posicione sobre o produto depois de acender"; (4C)

Interestingly, of the 57 commands, 12 are declarative in form (see below). It is important to point out that they are impersonal, which increases the distance between the participants. If compared to the imperative, the distance between the participants is even greater, given that the subject 'you' is implicit in imperative clauses (Halliday, 1994).

"É proibido soltar fogos em lugares fechados ou próximos a produtos inflamáveis ou explosivos".(A3)

"É obrigatório soltar fogos a 50 m de distancia de pessoas, casas, veículos e rede elétrica".(B3)

The writers, who issue the commands, have the power over the interactions, which increase the distance between the participants.

There are also 3 clauses in the imperative where the command is modulated by the employment of the mood adjunct 'never' and 'always' (see below). Modal adjuncts "are those which express the speakers' judgment regarding the relevance of the message" (Halliday, 1994:49). In the clause below, 'never' carries the writers' evaluation about the level of compliance of the proposal, which have a high value.

"Nunca aponte o artifício pirotécnico em direção ao corpo ou a outras pessoas". (E2)

There are three declarative clauses where the modal operators indicate obligation, in which 'can' is used to allow the consumers to handle the fireworks (see below). However, it has a low value, which weakens the illocutionary force of the proposal. The adjunct of mood

'only' in (1) expresses explicitly the writer's position regarding the person that can handle the artefact.

"Este produto só pode ser utilizado por pessoa maior de 16 anos"; (1)

"ESTE PRODUTO PODE SER UTILIZADO POR PESSOA DE MENOR IDADE, SOB SUPERVISÃO DOS PAIS OU RESPONSÁVEIS, QUE CONHEÇA O MANUSEIO E SEU FUNCIONAMENTO". (2)

"Este produto pode ser utilizado por pessoa maior de 18 anos que não esteja embriagado (sic) e que conheça o manuseio e seu funcionamento". (4)

Finally, 6 declarative clauses are modalised (see below). As can be seen, these clauses point out the risks of misuse. The modal operator 'will' (*poderá*) in (1) is used to indicate a bad future event, which is the consequence of non-compliance. Whereas 'won't' (*não haja*) in 2 indicates an ideal future event.

"Caso contrario você poderá sofrer queimaduras". (1)

"Para que não haja perigo de explosão". (2)

The modal operator (*pode*) in 2 and 3 is employed to indicate probability, which based on the value of the modal operator, conveys the idea that the probability of the risk occurring is low.

"DESMANCHAR FOGOS PODE CAUSAR QUEIMADURAS"; (3)

"Se não usado corretamente, pode provocar queimaduras". (2)

In the examples above, the writer's belief about the probability of the risk, which is low, can influence the consumers' decision to comply with the warning. In such cases, the employment of a stronger modal operator would strengthen the warning and consequently the chances of compliance.

5.1.9 Summary of the Section

The analysis revealed that the fireworks warning labels are inefficient for many reasons. First, the poor design affects the readability due to the use of small font on labels (1, 2 and 4) and the low quality printing on labels (1 and 4). The inappropriate use of the signal words and the sequencing of information bring to light the inattention of the writers to elements that are fundamental to attract the consumers' attention to the risks. These facts allow me to assert that there is either disagreement in relation to the guidelines, or inefficient supervision, or even lack of regulation.

Second, warning labels are safety information designed to address consumers, but the analysis shows two other addressees: the person in charge of the transportation and the seller. Third, the warnings fail to inform about the risks as well as their severity of them. Burning is the only risk pointed out, but as mentioned in the introduction of this section, the risks of dilacerations, loss of sight and hearing and even death are also present. Clearly, it violates the Maxim of quantity (Grice,1975), in that it provides less information than necessary. Consequently, consumers may infer the wrong information. Finally, the analysis of Mood and Modality shows high occurrence of commands, especially imperatives, which is a characteristic of the genre. There are few instances of modalization, and most of them have a low value, which weaken the warnings.

5.2 HAIR DYE LABELS

In a survey conducted by Target Group Index, it was revealed that more than a quarter of the Brazilian population use hair dye. Women represent 85% of this number (INMETRO, 2012). At the same time, hair dye color is responsible for a great number of complaints at INMETRO[38] for countless reasons: allergic reaction, hair loss and the inadequacy of the warning (due to the size of the letters). The case of Ann-Marie Hyde, a British woman who had a severe allergic reaction after having her hair dyed, became well known all over the world in 2015. The British newspaper Mail Online[39] reported that "she had gone temporarily blind" because "her eyes puffed up to the size of golf balls" (see pictures below). Mrs. Hyde asserted that she used the same hair dye for ten years and had done the patch test before the incident, which should have prevented the risks. Cases like Ann-Marie are frequently reported in the media in Brazil, and for this reason, this chapter will examine the adequacy of some of the warning labels of hair dye sold in Brazil.

I will first report four lawsuits from Brazil in order to have a better view of not only the problems related to hair dye, but also to verify how the cases are conducted, more precisely, if there is any

[38] INMETRO - Instituto Nacional de Metrologia, Qualidade e Tecnologia. National Institute of Metrology, Quality and Technology.

[39] Retrieved from: http://www.dailymail.co.uk/health/article-3210029/Mother-30-left-temporarily-blind-looking-like-Nutty-Professor-horrific-allergic-reaction-hair-dye-used-10-YEARS.html

linguistic analysis that supports the defense. The analysis will depart from these finding, that is, whether the selected warning labels informed adequately about the potential injuries actually suffered by the plaintiffs. After that, I will verify if the warning labels are in agreement with ANVISA's guidelines. Then, I will investigate whether the warnings have all the necessary information to direct safe behavior, which will be based on the literature of Ergonomics. I will analyze the texts' characteristics, in terms of readability and intelligibility. Finally, I will investigate whether the warnings are written in a way that encourages the consumers' compliance. In order to accomplish this, I will focus on modality (Halliday, 1994; Thompson, 1996).

5.2.1 Liability Cases

The analysis departs from some judicial cases in which the plaintiff suffered some kind of damage after using hair dye. The table below illustrates some judicial cases, collected from the site http://www.jusbrasil.com.br/jurisprudencia/ in 2013. As can be seen, the damage identified was either hair loss or an allergic reaction.

CASE	PRODUCT	HAZARD	ARGUMENT	RESULT
1) Deise Torres Vs UNILEVER[40]	Hair dye	Hair loss	She used a 'progressive' dye	Warning was inadequate (lack of information about the risk of hair loss)
2) Valdecir Martins Vs PROCOSA[41]	Hair dye (Garnier Nutrisse)	Allergic Reaction	She didn't do the test	She didn't follow the instruction
3) Maria Costa Vs Biofitogenia Laboratorial[42]	Hair dye (Cor e Tom)	Hair Loss	She used a 'progressive' dye	She didn't follow the instruction
4) Daniela Cristina Prado de Almeida Leandro Vs Procter & Gamble Do Brasil S/A E Belfam Indústria Cosmética Ltda[43]	Hair dye (Koleston Tintura creme)	Severe allergic reaction and damaged hair		Warning was inadequate (Lack of information about the severity of the risk)

Table 5.5: Four Liability cases

[40] Apelação no 0028876- 24.2007.8.26.0000. Retrieved from: http://tj-sp.jusbrasil.com.br/jurisprudencia/20681682/apelacao-apl-288762420078260000-sp-0028876-2420078260000-tjsp/inteiro-teor-110063322

[41] Apelação no 0201821- 34.2009.8.26.0004. Retrieved from: http://tj-sp.jusbrasil.com.br/jurisprudencia/23024210/apelacao-apl-20182134200982600004-sp-0201821-3420098260004-tjsp/inteiro-teor-111204300

[42] Apelação no 9146799-15.2007.8.26.0000. Retrieved from: http://tj-sp.jusbrasil.com.br/jurisprudencia/18742039/apelacao-apl-9146799152007826-sp-9146799-1520078260000/inteiro-teor-104107759

[43] Apelação no 0065491-59.2007.8.26.0114. Retrieved from: http://tj-sp.jusbrasil.com.br/jurisprudencia/117595509/apelacao-apl-65491592007826011 4-sp-0065491-5920078260114/inteiro-teor-117595518

Case 1 – In this case the plaintiff did not have an allergic reaction, but she suffered hair loss. The defendant alleged that the plaintiff had previously dyed her hair with a progressive dye and for this reason she had disregarded the instruction on the package. However, she denied that she had ever used a progressive dye. The expert report reveals that she might have had problems due to the constant use of hair dye and other procedures that can reduce the acid mantle, which is the protective layer. Given that there were no warnings about the constant use of hair dye, the responsibility of the event was not transferred to the plaintiff, who won the case.

Case 2 – The plaintiff suffered an allergic reaction and was found negligent for not observing the warning "always do the patch test 48 hours before each time you use the product". The plaintiff stated that she knew about the patch test, but thought that the fact of always dealing with dyes could free her from the task.

Case 3 – This is another case where the plaintiff suffered hair loss. However, in this particular case, the plaintiff was deemed responsible for not attending to the information on the warning label, which stated "do not use the product on hair that had been dyed with any kind of henna, progressive dyes or dyes based on metallic salts or caustic soda, because it can break the hair fiber". The expert attested that the plaintiff had previously used a progressive dye and that the problem was due to the interaction between the products.

Case 4 – RISK - The plaintiff suffered severe allergic reaction 12 days after applying the product to her hair, with red spots on the body and swelling. She was even admitted to the ICU. The treatment lasted four months and she had to shave her hair. The defendant argued that the plaintiff did not follow the safety instruction, that is the 'Patch Test', although the plaintiff stated she had done it. In the end, she admitted that she didn't do the 'Patch Test' because she thought it was a test to verify the color and not the allergic reaction. The defendant was found guilty for not offering information about the severity of the risks. Unfortunately, I did not have access to the data, which would allow me to verify the warnings.

In all the cases described above, the defendants argued that the consumers had failed to follow the instructions. They first interrogated whether the plaintiff had done the 'patch test', which could prevent the customer having an allergic reaction to any of the hair dye components. However, as can be seen, in half of the cases, the customers had suffered hair loss. So, the 'Patch Test' would not have prevented that.

Moreover, the defendants also claimed that the users who had hair loss had disregarded the warning that states: 'do not use on hair previously dyed with henna or metallic dye' or the statement 'do not use if your hair was dyed with henna, progressive dyes or colorant based on metallic salts', since the use under these circumstances could result in hair loss. As mentioned earlier, I did not have access to the data, which impedes me to analyze the efficacy of the warnings. But, by the discussion provided in the case files, it was possible to see that the linguistic aspects were not explored, that is, the issues of readability and legibility were not raised.

The defendants clearly used the warnings as an instrument of self-protection and transferred the responsibility for any risk onto the plaintiff, which would be unfair if the warnings were unclear, illegible or complex.

The negative consequences suffered by most people who use hair dye are hair loss and/or an allergic reaction. For this reason, the following question emerges: Do the products warn efficiently and effectively about hair loss and allergic reactions? These consequences can be triggered by many causes; however, determining these causes is not the focus of this investigation. As Shuy (2008) notes, the linguistic task "has to do with the text of warning messages" rather than the "foreseeability of any misuses of the product".

The defendants in the cases summarized in the table above based their arguments on two points: the 'patch test' and the use of two types of dye (metallic and henna). For this reason, this analysis will first focus on warnings related to these topics. Then, I will verify whether the warnings have the components of efficient warnings, as proposed by the guidelines (ANSI[44] and ABNT[45]) and endorsed by authors in the areas of linguistics and ergonomics. But I will first present the analysis of ANVISA's mandatory warnings.

5.2.2 Anvisa

ANVISA requires the employment of six warnings (see table 2 below; bold and capitalization in the original has been reproduced). The first column has ANVISA's wordings, the second the warnings of product A, the third product B and the fourth product C. Note that

[44] ANSI – American National Standard Institute.
[45] ABNT – *Associação Brasileira de Normas Técnicas* (Brazilian Association of Technical Norms).

ANVISA requires the exact wording to be reproduced only for the sixth warning.

	ANVISA	A	B	C
1	*Pode causar reação alérgica. Fazer a Prova de Toque (descrever);*	*"Antes de usar, faça a prova do toque". (art. 107 - decreto 79094/77). Aplicar uma pequena quantidade do produto preparado na pele de trás da orelha ou do antebraço. Aguardar o tempo de ação e enxaguar. Se após 48 horas não existirem sinais de irritação ou vermelhidão, o produto poderá ser aplicado;*	***Advertências**: Os corantes capilares podem provocar reações alérgicas graves. Recomenda-se uma prova preliminar de sensibilidade/ prova de toque. (...) Ver folheto explicativo.*	*IMPORTANTE: AS COLORAÇÕES PODEM PROVOCAR UMA REAÇÃO ALERGICA QUE, EM ALGUNS CASOS, AINDA QUE RAROS, PODE SER GRAVE. É OBRIGATÓRIO EM TODOS OS CASOS FAZER UMA PROVA DE TOQUE (TESTE DE ALERGIA CUTÂNEA), IMPRETERIVELMENT E 48HORAS ANTES DE CADA UTILIZAÇÃO DESTRE PRODUCTO (VER FOLHETO EXPLICATIVO).*
2	*Não usar nos cílios e sobrancelhas ;*	*Não utilizar para pintar cílios ou sobrancelhas;*	*Não usar para pintar cílios ou sobrancelhas*	*Evitar o contato do produto com a pele e os olhos, não utilizar para a coloração de cílios e sobrancelhas. Não seguir estas instruções pode levar à cegueira*
3	*Não aplicar se o couro cabeludo estiver irritado ou lesionado;*	*Não aplicar se o couro cabeludo estiver irritado ou lesionado;*	*Não aplicar se tive erupção cutânea na face ou apresentar o couro*	*NÃO UTILIZE SE:* *- Já apresentou alguma reação alérgica a um produto de coloração.* *- Seu couro cabeludo está irritado ou lesionado.*

			cabeludo sensível, irritado ou lesionado;	
4	*Em caso de contato com os olhos, lavar com água em abundância;*	*Evitar o contato com os olhos. Se isto acontecer, enxaguar com água em abundância imediatamente .*	*Em caso de contato com os olhos lavar imediatamente com água em abundância e procurar um médico;*	*Se o produto entrar em contato com os olhos lave com água em abundância*
5	*Manter fora do alcance das crianças;*	*Mantenha fora do alcance das crianças;*	*Manter fora do alcance das crianças*	*Manter fora do alcance das crianças. Não utilizar em crianças*
6	*CUIDADO. Contém substâncias passíveis de causar irritação na pele de determinadas pessoas. Antes de usar, faça a prova de toque. (Art.107- Decreto 79.094/77).*	*"CUIDADO. Contém substâncias passíveis de causar irritação na pele de determinadas pessoas. Antes de usar, faça a prova de toque" (Art.107- Decreto 79.094/77).*	*CUIDADO. Contém substâncias passíveis de causar irritação na pele de determinadas pessoas. Antes de usar, faça a prova de toque.*	*CUIDADO. Contém substâncias passíveis de causar irritação na pele de determinadas pessoas.*

Table 5.6: Hair dyes Mandatory warnings

The manufacturers followed the requirements of ANVISA concerning the content of the warnings, and included all the six topics. Two of them inform about hazard identification (1 and 6), three give directions about how to avoid a hazard (2, 3 and 5), and one gives instructions about what to do if the hazard was not avoided (4). As can be seen in Table 5.6, 7 warnings use identical wording, 2 warnings simply rephrase the ANVISA wording, whereas 9 warnings add new information. Note that in some warnings there is no information about

the hazard, although there is information about how to avoid it (see below the content of each warning).

1. Risk (allergic reaction) and directions.
2. Directions to avoid the risk. Only C refers to the risk (blindness).
3. Directions to avoid the risk, which is not clear.
4. Directions if the risk was not avoided.
5. Directions to avoid the risk, which is not clear.
6. Risk (allergic reaction) and directions to avoid the risk.

At this point, the model of a warning proposed Laughery and Wogalter (2014) can serve to illustrate the consumers' reasoning when reading a warning. First, the consumer must decide to read it. There are many factors that can influence this decision, for example, the story of a friend who suffered some hair damage recently can trigger in the consumer the interest to use the product with far more care. Let's assume that s/he can understand it. But even so, s/he needs to believe that the directions are important to avoid a risk. If the directions demand effort and time and if the risk is not mentioned, the warning may be ignored. This is because the reader may believe that if it were a serious risk it would be mentioned. For this reason, pointing out the risk explicitly is paramount.

Apparently, the three brands contain all the required information. But a closer analysis reveals that brand C failed to reproduce the whole text of the sixth topic "*Antes de usar, faça a prova de toque*". But there is evidence that all warnings, even the ANVISA requirements, are incomplete. In order to better evaluate them and answer the query: Do the warning labels warn about the risks: hair loss and allergic reaction? I will address two topics that can lead me to the answer, 'henna' and 'patch test'. Then I will analyze the non-textual information and explore the topics (components of warnings) separately. Finally I will analyze mood and modality in order to check how the interpersonal meaning is construed.

5.2.2.1 Henna

The warnings make reference to henna in two different ways: black henna tattoos and hair dye. The table below shows the warnings about black henna tattoo in the three brands.

BRAND	WARNING STATEMENT
A	*Tatuagens temporárias de "hena preta" (com adição de PPD – parafenilenodiamina) podem aumentar o risco de alergia.*
A	*Não aplicar no cabelo se: Você já teve reação após aplicação de tatuagem temporária de "henna preta".*
B	*As tatuagens temporárias de hena negra podem aumentar o risco de alergias;*
B	*Não aplicar no cabelo se: Você já teve reação após aplicação de tatuagem temporária de "hena preta".*
C	*TATUAGEM HENA PRETA:* *Se você já fez, mesmo que uma única vez, uma tatuagem de hena preta, provavelmente você corre o risco de ter se tornado alérgico sem saber. Não use este produto sem fazer a prova de toque (teste de alergia cutânea) 48 horas antes de cada aplicação deste produto.*

Table 5.7: Warning about henna tattoo.

A's warning is explicit about the type of henna that can increase the risk of allergies. However, this information is meaningless to an average person, who does not know what 'parafenilenodiamina' is. It is a technical term that is likely to be unknown to most people. Moreover, if the user has ever made this kind of tattoo, it is unlikely that s/he remembers, if she ever knew, the substances contained in the henna. Generally, this kind of information is not given to customers, at least in Brazil.

Lack of explicitness is evident in the following warning in A, because the relationship between the allergies caused by a henna tattoo and the product is not stated. I have to confess that I am not able to infer this relationship, maybe they have the same components, although I have always believed that henna is a 'natural ink', which is totally different from the hair dye. Certainly, the warnings should provide more information not only about this relation but also about the severity and the frequency of the risks. This lack of information allied to the modal operator 'can', which expresses possibility, makes me infer that the warnings are not important and for this reason I would ignore them.

The same problem occurs in B, which is aggravated by the use of two terms to refer to the same substance, '*henna negra*' and '*henna preta*'. It is likely that some consumers may get confused. But the main problem in my view is the fact that many parents believe that this kind of tattoo will not cause allergies and this cannot be ignored. Many parents allow their children to tattoo their bodies with henna, especially at the beach. Thus, a warning that deals with a product that has the status of being harmless should be carefully phrased; otherwise it has the risk of being ignored.

A more attentive reader will read the following information chunk to remove any doubt before deciding what to do. But the information given is:

"Instruções de uso: Não aplicar no cabelo se: você possuir erupções ou inflamações na pele do rosto, ou se o couro cabeludo estiver sensibilizado, irritado ou danificado • Você já teve alguma reação após tingir seu cabelo • Você já teve reação após aplicação da tatuagem temporária de "henna preta". (A)

"Não aplicar se tive erupção cutânea na face ou apresentar o couro cabeludo sensível, irritado ou lesionado; Não aplicar se alguma vez apresentou alguma reação alérgica após pintar os cabelos ou após fazer uma tatuagem com hena negra". (A)

As can be seen, the information about what to do to avoid the hazard, which is not explicit, is only presented after some statements, which can dilute the information and weaken the warning. Besides, the way the sentences are structured in A can create confusion, because there is no connection between the first part of the clause '*não aplicar se*' and the three subsequent clauses. Moreover, the first letter of these clauses is in upper case, which gives the idea of a new sentence. The structure below would avoid a possible confusion.

"Não aplicar no cabelo se:

- *você possuir erupções ou inflamações na pele do rosto, ou se o couro cabeludo estiver sensibilizado, irritado ou danificado;*
- *você já teve alguma reação após tingir seu cabelo;*
- *você já teve reação após aplicação da tatuagem temporária de "henna preta". (A)*

Although the warnings in A and B inform about the hazard and what to do to avoid it, it is still weak for at least three reasons: first, the relation between the henna tattoo and the product (hair dye) is still missing; second, it fails to inform about the hazard explicitly; and finally, the discourse sequencing of points within the warning statements (Shuy, 2008) is not appropriate, that is, the information about the hazard

is distant from the information about how to avoid the hazard, truncating the warning message. Thus, just providing the information is not enough to guarantee comprehension.

On the other hand, C's warning clearly associates henna tattoo and allergy, but it fails to associate this with the product.

"TATUAGEM HENA PRETA:

Se você já fez, mesmo que uma única vez, uma tatuagem de hena preta, provavelmente você corre o risco de ter se tornado alérgico sem saber. Não use este produto sem fazer a prova de toque (teste de alergia cutânea) 48 horas antes de cada aplicação deste produto". (B)

At least to my knowledge, it seems that the henna's substances are not the same as those of the hair dye, so is there any relation between being allergic to henna and to the hair dye? The warning does not mention this relation and forces the reader to infer not only about this relation, which would be the hazard, but also about the consequences, which are omitted. The warning also instructs the users to do the 'patch test', but again, it fails to inform about the reasons for doing this test. Thus, all warnings fail to inform about 'henna tattoo'. And what about dyeing the hair with henna or metallic dyes?

A's warning advises the consumers not to dye their hair if it has been dyed with henna or metallic salts dyes.

"Não utilizar em cabelos previamente pintados com hena ou tintas metálicas";(A)

Likewise C's warning says that:

"Não utilizar se os seus cabelos foram pintados com henê ou com uma coloração progressiva ou à base de sais metálicos"; (B)

However, there is still a lack of information in both warnings. First, there are technical terms that are probably unknown by an ordinary person, such as 'metallic salts dyes' and 'progressive dyes'. Second, the term 'previously' is too vague. How long afterwards should a person have to wait to have her/his hair dyed? And finally, it fails, again, to inform explicitly about the negative consequences. Based on an empirical investigation, Dumas (1992) classified as weak warnings that are characterized by: the use of technical terminology and lack of explicit information about the negative consequences of a hazard. As the warnings above have these characteristics, it seems that they are inadequate in warning the consumers about the hazards resulting from the chemical reaction of these different dyes (permanent, progressive and henna).

5.2.2.2 'Patch Test'

The 'patch test' is an important safety action that can show whether the user has any allergic reaction to the hair dye. A's warning is an example of incompleteness. The first direction informs: 'apply a small amount of the prepared product on a small patch of skin behind the ear'. Nonetheless, it does not inform how to prepare the product. Then, it says: 'wait the reaction time and rinse'. Again, it does not inform the action time. Thus, the warnings permit the reader to do the test in a wrong way, which can influence on the result.

"PROVA DE TOQUE: Aplicar uma pequena quantidade do produto preparado na pele de trás da orelha ou do antebraço. Aguardar o tempo de ação e enxaguar. Se após 48 horas não existirem sinais de irritação ou vermelhidão, o produto poderá ser aplicado; (side of the package)". (A)

However, the information about the 'patch test' on the leaflet is slightly different. In fact, the warning diverges on two points, since it states that the product should not be mixed and the user should not rinse the hair, which would solve, the uncompleted points mentioned above.

"Teste de sensibilidade: aplicar uma pequena quantidade do produto (não misturado) em uma pequena porção de pele atrás da orelha (não enxágue). Se depois de 48 horas não houver sinal de irritação ou manchas vermelhas, o produto dever ser aplicado. (leaflet)". (A)

Although B is more specific about the reaction time, 20 minutes, it is not as informative as it needs to be for the user to prepare the product, since the quantity is not mentioned.

***"Prova de toque**: Limpar bem com álcool uma parte da pele na dobra do braço. Aplicar na área preparada uma pequena quantidade de Evolution of the Color misturado com Alfaparf água oxigenada. Após aproximadamente 20 minutos, retirar o excesso e cobrir a pele com esparadrapo ou bandaid. Aguardar 48 horas sem lavar. Se após este período não apresentar irritação, vermelhidão, coceira, inchaço ou queimação na área onde o produto foi aplicado, ou em outras áreas do corpo, o produto poderá ser utilizado. Só para uso profissional". (B)*

On the other hand, C's warning is more explicit about the preparation and the action time.

"Retire os brincos, aplicar atrás da orelha com o auxílio de um cotonete o suficiente do produto colorante não misturado, para cobrir uma área de 1cm². Reaplicar duas ou três vezes, deixando secar a cada intervalo. Fechar cuidadosamente o produto colorante. Espere 48h sem

lavar ou cobrir o local. Se no decorrer deste período você constatar reações anormais tais como coceira, vermelhidão ou inchaço na zona testada ou em volta dela, NÃO FAÇA A SUA COLORAÇÃO". (B)

However, the three warnings above say that the user should apply the product to the skin, either behind the ear or on the arm, to test whether the person has any allergic reaction. But, what about hair loss? Since the product is not applied on the hair, it is not possible to verify risks associated with hair health. Neither the warnings related to the use of henna and other dyes nor the 'patch test' mention the risk of hair loss. Thus, the warnings seem to be inefficient.

But, in order to evaluate whether the warning labels are efficient, it is necessary to take into account all the information included on the labels, as well as the non-textual information. For this reason, the following sections will present an analysis regarding these topics.

5.2.3 Non-Textual Information

Visual and graphic presentations are an essential feature of warnings for at least two reasons: the text has to be legible, that is, users need to be able to read them and they need to be displayed in a way that encourages reading. Preview studies have shown that texts written with tiny letters, with a background color that does not contrast with the text, and that do not allow any white space tend to discourage reading since it makes the reading tiring.

The guidelines for cosmetics in Brazil do not prescribe any rules about visual and graphic presentation. As can be seen in the illustrations below, the visual quality of the warning labels of the products vary considerably. It is important to stress that the size of the illustrations is slightly smaller than the original packages.

HAIR DYE A

Picture 5.6: Hair dye A[46]

HAIR DYE B

Picture 5.7: Hair dye B

[46] The pictures are not legible because I wanted to maintain their originality in order to illustrate the difficulties the consumers have when reading them. Their transcriptions are in the appedixes.

HAIR DYE C

Picture 5.8: Hair dye C

It is difficult to read the warnings of products A and B due to the size of their font. Moreover, in A, the low quality of the printing impairs the reading of some sentences. As noted in chapter 2 Wogalter (2006) observes that warnings "should take into account the lowest ability levels of the target population" (p. 07), the ability can be related to cognitive aspects and sensory-perceptual difficulties. Besides, the color combination of the background and the letters makes the reading difficult and tiring. Probably, the users would abandon the reading since the warnings, especially A, require too much effort, even for a person with normal vision.

On the other hand, C is much more readable. It uses different colors, font sizes, capital letters, underlined sentences, and bold to draw the attention of the consumer to the most important points. The disposition of the text, organized into a bulleted list and justified only on the left, facilitates reading.

5.2.4 Topics

According to Shuy (2008: 72), warnings "should identify and describe the nature and danger of the risk. Then they should tell the reader how to avoid it. Finally they should communicate in clear and understandable language". Moreover, a warning should also inform the user what s/he has to do if the hazard was not avoided. In this way, this analysis will verify whether the warnings have this information. In order to organize the presentation of the data as well as the discussion, I will present the analysis of each topic separately, namely: signal word, hazard identification, instructions on how to avoid hazards, consequences and what to do if the hazard was not avoided. The table below shows the occurrences of each topic on the warning labels of the three brands. The numbers refers to informational chunks (Shuy, 1990) and the asterisks show the quantity that was counted, that is, when hazards and the consequences are presented in the same warning, only one informational chunk was counted, as in: '*Tatuagens temporárias de 'henna preta'* [hazard] *podem aumentar o risco de alergias* [consequences]*'*.

	PRODUCT			
TOPICS	A	B	C	TOTAL
Signal word	4	4	7	15
Hazard identification	7	8	7	22
Instructions on how to avoid hazards	57	34	56	147
Consequences	11 (5*)	6 (0*)	9 (4*)	26 (9)
What to do if the hazard was not avoided	15	5	10	30
Total	94 (88)	57 (51)	89 (84)	240 (223)

Table 5.8: Warning components

5.2.4.1 Signal Words

The inclusion of signal words is recommended by many guidelines, such as ANSI and ISO. These words are employed to alert

users to the presence of a hazard and to indicate the level of danger involved (Wogalter, Jarrard & Simpson, 1994).

The warnings of the three brands show the careless use of signal words. All three warnings refer to the same risk, but under a different heading:

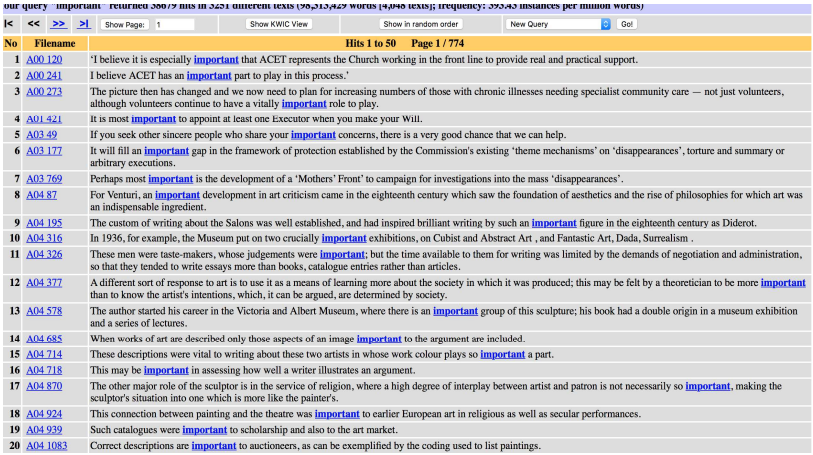
***"Cuidado**: Contém substâncias passíveis de causar inflamação na pele de determinadas pessoas". (A)*

***"Advertência**: Os corantes capilares podem provocar reações alérgicas graves". (B)*

***"Importante**: as colorações podem provocar uma reação alérgica que, em alguns casos, ainda que raros, pode ser grave". (C)*

Both *caution* and *warning* should refer to an event, which if not avoided, can result in some kind of injury. The main difference between them lies in the degree of severity, whereas *caution* results in a minor injury, *warning* results in a severe injury. In Brazil, the product influences the choice of the signal word, for example NBR 14725, which is a Brazilian regulation for safety signaling, adopts '*perigo*', and '*cuidado*', where '*perigo*' refers to more dangerous risks. But, in the case of hair dyes, the guidelines dictate the use of '*advertência*' and '*cuidado*' before the mandatory warnings. On the other hand, the signal word 'important' can indicate not only bad but also good events. A search at the BNC [47] web from Lancaster shows that the word 'important' (see below) is generally related to appointments, developments, exhibitions, groups, arguments and so on.

[47] Retrieved from: http://bncweb.lancs.ac.uk/cgibinbncXML/processQuery.pl?theData=important&chunk=1&queryType=CQL&qMode=Simple+query+%28ignore+case%29&inst=50&max=INIT&qname=INIT&thMode=INIT&thin=0&qtype=0&view=list&theAction=Start+Query&urlTest=yes



Our query "important" returned 38879 hits in 3251 different texts (98,313,429 words [4,046 texts]; frequency: 395.43 instances per million words)

|< << >> >| Show Page: 1 Show KWIC View Show in random order New Query Go!

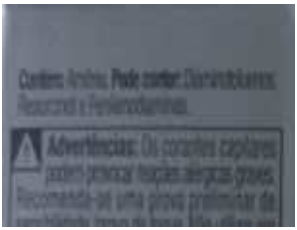
No	Filename	Hits 1 to 50 Page 1 / 774
1	A00 120	'I believe it is especially **important** that ACET represents the Church working in the front line to provide real and practical support.
2	A00 241	I believe ACET has an **important** part to play in this process.'
3	A00 273	The picture then has changed and we now need to plan for increasing numbers of those with chronic illnesses needing specialist community care — not just volunteers, although volunteers continue to have a vitally **important** role to play.
4	A01 421	It is most **important** to appoint at least one Executor when you make your Will.
5	A03 49	If you seek other sincere people who share your **important** concerns, there is a very good chance that we can help.
6	A03 177	It will fill an **important** gap in the framework of protection established by the Commission's existing 'theme mechanisms' on 'disappearances', torture and summary or arbitrary executions.
7	A03 769	Perhaps most **important** is the development of a 'Mothers' Front' to campaign for investigations into the mass 'disappearances'.
8	A04 87	For Venturi, an **important** development in art criticism came in the eighteenth century which saw the foundation of aesthetics and the rise of philosophies for which art was an indispensable ingredient.
9	A04 195	The custom of writing about the Salons was well established, and had inspired brilliant writing by such an **important** figure in the eighteenth century as Diderot.
10	A04 316	In 1936, for example, the Museum put on two crucially **important** exhibitions, on Cubist and Abstract Art , and Fantastic Art, Dada, Surrealism .
11	A04 326	These men were taste-makers, whose judgements were **important**; but the time available to them for writing was limited by the demands of negotiation and administration, so that they tended to write essays more than books, catalogue entries rather than articles.
12	A04 377	A different sort of response to art is to use it as a means of learning more about the society in which it was produced; this may be felt by a theoretician to be more **important** than to know the artist's intentions, which, it can be argued, are determined by society.
13	A04 578	The author started his career in the Victoria and Albert Museum, where there is an **important** group of this sculpture; his book had a double origin in a museum exhibition and a series of lectures.
14	A04 685	When works of art are described only those aspects of an image **important** to the argument are included.
15	A04 714	These descriptions were vital to writing about these two artists in whose work colour plays so **important** a part.
16	A04 718	This may be **important** in assessing how well a writer illustrates an argument.
17	A04 870	The other major role of the sculptor is in the service of religion, where a high degree of interplay between artist and patron is not necessarily so **important**, making the sculptor's situation into one which is more like the painter's.
18	A04 924	This connection between painting and the theatre was **important** to earlier European art in religious as well as secular performances.
19	A04 939	Such catalogues were **important** to scholarship and also to the art market.
20	A04 1083	Correct descriptions are **important** to auctioneers, as can be exemplified by the coding used to list paintings.

Picture 5.9: BNC -Lancaster 'important'

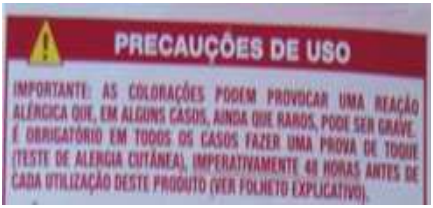
As can be seen in the picture above, no example relates the word 'important' to a bad event. Although the examples are limited, it can serve as a picture of how the word is employed. Thus, it is not appropriate to use it to anticipate a warning, which is information about a bad situation.

The guidelines for cosmetics (ANVISA) specify neither the signal words nor the use of colors to identify the hazard nor the level of severity. But, despite this, the manufacturers could adopt the conventions, employed by ANSI or ISO for example, to alert consumers, in this way, their attention would be attracted and they could choose to read the text, especially if these components convey the idea of a more serious hazard.

It is interesting to note how color can highlight the text. The warnings of products B and C (see pictures below) adopt the alert symbol, but they employ different colors. Whereas the first uses two shades of gray, the second uses yellow and red, attracting more attention.



Picture 5.10: alert symbol B



Picture 5.11: alert symbol C

Most international guidelines (ANSI and ISO) argue that **yellow** should be used to identify 'warnings', and so does ABNT. As can be seen, it catches the readers' attention, besides indicating the level of severity of hazards. Even so, some consumers are unable to relate the color to this level of warning.

5.2.4.2 Hazard Identification

Providing information about the hazard is crucial if the aim is the consumers' compliance, given that readers are more willing to read when they perceive that the hazard can be severe (Otsubo, 1988; as cited in Azevedo, 2006). However, the nature of the hazard needs to be made explicit, without technical terms that can impede comprehension; otherwise, the warning may lose its efficacy, which might be the case of warnings A and B (see below), since the information provided by them is unclear to most consumers, who do not know the substances and their reaction.

"A) Contém: Fenilenodiaminas, resorcinol, amoníaco, 1-naphilol, Diamindenois";

"B) Contém amônia. Pode conter: Diaminotoluenos, rersocinol, e Fenilenodiaminas";

Although I am not an expert in Chemistry, it seems to me that there is not an explanation for the terms above. But the identification of the possible reactions of such substances and the clear relation between the product and the reaction could solve the problem. Warning A, for example, is followed by the statement: '*CUIDADO: Contém substâncias passíveis de causar inflamação na pele de determinadas pessoas*'; and B is followed by the statement: '*Advertências: Os corantes capilares podem provocar reações alérgicas graves*'. In this way, they fail to relate the substances to the specific hazards: 'skin inflammation' and 'allergic reactions', leaving the consumer with the task of making this relation. This problem would be solved if the warning informed:

"Contém: Fenilenodiaminas, resorcinol, amoníaco, 1-naphilol, Diamindenois";

"CUIDADO: ***estas*** *substâncias podem provocar reações alérgicas graves";*

Moreover, warning C appears to be even less explicit regarding the hazard. As can be seen below, the participants are '*o revelador*' and '*o produto colorante*', which may cause confusion. That is, the consumer may fail to infer that these terms are synonyms of the product itself.

*"*O Revelador *contém peróxido de hidrogênio (água oxigenada)";*

"O produto colorante contém amônia, Fenilenodiaminas e resorcinol";

Besides, there is no reference to any consequence after stating the substances in C, such as: allergic reaction'. Instead, there is the instruction: '*Evitar o contato do produto com a pele e os olhos*', which tells the consumer that the product may pose some kind of risk, but only, implicitly. The fact that the hazards are not explicitly related to the consequences is intriguing. Maybe the manufacturers believe that if this relation were clearly pointed out, the consumers would avoid buying the products.

5.2.4.3 Instructions on How to Avoid Hazards

The majority of the information conveyed by the warnings refers to instructions on how to avoid hazards, totalizing 147 information chunks. With a few exceptions, these instructions were written in the imperative, with 105 occurrences, while 38 were declarative clauses. The low number of clauses where the finite signals modality, called my attention – there are only 4 occurrences.

The imperative warning statements were evenly distributed between negative and affirmative. The table below shows the occurrences of each choice. As can be seen, the use of affirmative warning statements is slightly greater than the use of negative warning statements.

TYPE	A (imperative)	B	C	TOTAL
AFFIRMATIVE	18	14	20	56
NEGATIVE	22	10	16	49
TOTAL	40	24	36	105

Table 5.9: Imperative warnings

The affirmative imperative clauses were mainly employed to direct consumers on how to use the dye:

"Utilize a pintura diretamente"; (A)

"Utilize luvas apropriadas"; (A)

"Enxague bem o cabelo depois da aplicação"; (A)

On how to do the patch test:

"Retire os brincos, aplicar atrás da orelha com o auxílio de um cotonete o suficiente do produto colorante não misturado (tubo de creme colorante C), para cobrir uma área de 1cm². Reaplicar duas ou três vezes, Fechar cuidadosamente o produto colorante. Espere 48h sem lavar, nem cobrir ou tocar o local". (B)

And on what to do to avoid some risks.

"Manter fora do alcance das crianças". (B)

"Aplicar a mistura preferencialmente em um ambiente arejado". (C)

"Preparar a mistura preferencialmente em um ambiente arejado". (C)

"Para questões relativas à sua sensibilidade, consulte o seu médico". (C)

The negative imperative clauses are mainly related to actions, that if avoided, can prevent risks.

"Evitar o contato com os olhos". (A)

"Não utilizar para pintar cílios ou sobrancelhas". (A)

"Não aplicar se tiver erupção cutânea na face". (B)

"Não utilize em cabelos defrisados *ou imediatamente após uma descoloração ou permanente". (C)*

"Não utilizar em cabelos previamente pintados com hena ou tintas metálicas"; (A)

The main problem is that consumers may not understand some of the warnings above due to technical terms, such as '*defrisados*' and '*erupção cutânea'*. Vagueness also leads to misunderstandings, the imprecision related to time is evident due to the terms '*previamente*' and '*imediatamente*'. For example, the time that the customer who had the hair dyed with henna needs to wait before dying the hair again is not mentioned. The plaintiff (in the third case mentioned in section 5.5.2) used the hair dye three months after dying the hair with progressive dye and this time delay was apparently insufficient, since she had unpleasant consequences. Likewise, 'immediately' is imprecise and can be interpreted differently. Vagueness also occurs in some positive imperative clauses. As can be seen below, '*ambiente arejado'* is too general and its meaning depends on many variables that are out of the authors' control. That is, the consumers will rely on their beliefs, which is different from person to person. Moreover, the adverb '*preferencialmente*' leaves space for the consumer to interpret that non-compliance would not result in risk.

"Aplicar a mistura preferencialmente em um ambiente arejado". (C)

"Preparar a mistura preferencialmente em um ambiente arejado". (C)

The high occurrence of negative warning statement leads us to question their efficiency. Are they more effective than affirmative warning statements?

The FDA (Food and Drug Administration) published a note suggesting that affirmative warning statements would be better understood than negative statements (2010). This note explains that:

> The negative and passive parts of the warning are encoded in the working memory of the brain apart from the rest of the words in the warning. Thus, a healthcare provider under stress may fail to process the negative parts of the statement—such as Do Not—and misinterpret the warning as an affirmative action.

Based on this, it is possible to say that an affirmative statement requires less effort than a negative one. Besides, the note exposes one problem of misinterpretation showing that: when a warning occupies two lines and the 'DO NOT' part is separated from the remaining part of

the message, the reader may focus on the second part, ignoring the negative one. Problems of printing can also impair the correct understanding when the 'DO NOT' part is erased or blurred. Two negative statements were separated in two lines in B, as can be seen below.

Picture 5.12: Negative warnings

Declarative clauses are generally employed to describe a health problem that is an impediment to the dye application, such as: 'rash on the face', 'sensitive, irritated or damaged scalp'. They are also employed to talk about allergic reactions triggered by the use of hair dye.

"você possuir erupções ou inflamações na pele do rosto," (A)

"ou se o couro cabeludo estiver sensibilizado, irritado ou danificado". (A)

"alguma vez apresentou alguma reação alérgica após pintar os cabelos ou após fazer uma tatuagem temporária com "hena negra"; (B)

"Se no decorrer deste período você constatar reações anormais tais como coceira, vermelhidão ou inchaço na zona testada ou em volta dela", (C)

As mentioned before, the finite signals modality in only four clauses and indicates obligation. The modal operator 'must' employed in

the warnings below represents a higher level of pressure on the consumer.

"Para segurança, um teste de sensibilidade deve ser realizado 48 horas antes de seu uso". (A)

"Se depois de 48 horas não houver sinal de irritação ou manchas vermelhas, o produto deve ser aplicado". (A)

Whereas the modal operator 'will' (see below) is used to allow the consumer to use the hair dye if the symptoms of allergy are not present.

"Se após este período não apresentar irritação, vermelhidão, coceira, inchaço ou queimação na área onde o produto foi aplicado, ou em outras áreas do corpo, o produto poderá ser utilizado". (B)

Although the imperative increases the distance between the participants, given that "in interpersonal terms, an imperative is presented as not open to negotiation" (Thompson, 1996: 48), it's use is endorsed by authors like Tiersma (2002) and Dumas (1992). These authors point out that the imperative is clearer in relation to what should or should not be done to avoid a risk. Moreover, readers tend to perceive the warnings more easily when they are in the imperative form (Dumas, 1992). However, Thompson (1996) also recognizes that despite being closed to negotiation, there is no guarantee that the command will be obeyed. But I believe that some textual characteristics can influence the consumers' decision to comply with the warnings, which is the goal of the dissertation. The explicit presentation of the risk might be one of them.

It was verified that many warning statements give instructions without stating the hazard, given that there are 22 warning statement that identify the hazards and 147 warning statements that instruct on how to avoid the hazards. In these cases, where the information about the hazard is not offered, the reader needs to infer it and based on this inference, s/he will adopt a behavior, which can comply with the warning, or not. Compliance is influenced by many factors, such as hazard perception (Wogalter Desaulniers and Brelsford, 1986). The question of whether users perceive the hazard by reading this kind of instruction emerges now. Is the reader able to infer that the warning statement '*não usar para pintar os cílios e sobrancelhas*' is concerned with a potentially very serious hazard, such as 'blindness'? If the answer is no, there is a risk of non-compliance.

5.2.4.4 Consequences

The consequences of interacting with the product or of non-compliance with the warning should be stated in an explicit form to guarantee a better understanding. Many authors note that warnings with explicit consequences lead more users to comply with the instructions (Borade, Bansod & Gandhewar, 2008). The examples below are very similar, since they are mandatory. But, as can be seen, the structure '*contém substâncias passíveis de causar*' may confuse the reader since it is unusual and complex. The term 'likely' (*passíveis*) modalizes the clause indicating possibility, whose value is low. The consequences, although similar, are not the same, given that they differ with respect to the level of severity. The term '*inflamação'* appears to be stronger than '*irritação*'. But it is important to point out, that B and C adopt ANVISA's wordings.

"Contém substâncias passíveis de causar inflamação na pele de determinadas pessoas".(A)

"Contém substâncias passíveis de causar irritação na pele de determinadas pessoas". (B)

"Contém substâncias passíveis de causar irritação na pele de determinadas pessoas".(C)

Moreover, some authors point out that willingness to comply is greater when the warning informs about the gravity of the hazard, instead of the frequency of it. In addition, Dumas (1992) conducted an empirical investigation and concluded that the use of strong words, like poison, strengthen the warnings. But, unfortunately, they are rarely used. Only a few examples are found.

Warnings B and C use the adjective '*grave*', which exposes the gravity of the hazard, catching the reader's attention.

"Os corantes capilares podem provocar reações alérgicas graves". (B)

"AS COLORAÇÕES PODEM PROVOCAR UMA REAÇÃO ALERGICA QUE, EM ALGUNS CASOS, AINDA QUE RAROS, PODE SER GRAVE". (C)

Besides the use of adjectives, there are also some nouns that can strengthen the message, such as '*explosão*', '*cegueira*'. Although I have never heard that the mixture of hair dye could explode.

"Risco de explosão ou rachadura". (A)

"Não seguir estas instruções pode levar à cegueira". (C)

5.2.4.5 Sequence

The sequence of information of the warnings can make understanding more difficult and lead consumers to misinterpret. The analysis revealed that the topics are mixed, for instance, one text warns that a henna tattoo can increase the risk of allergy but it only warns about how to avoid it four sentences later.

"Tatuagens temporárias de "hena preta" (com adição de PPD – parafenilenodiamina) podem aumentar o risco de alergia. Instruções de uso: Não aplicar no cabelo se: você possuir erupções ou inflamações na pele do rosto, ou se o couro cabeludo estiver sensibilizado, irritado ou danificado. Você já teve alguma reação após tingir seu cabelo. Você já teve reação após aplicação de tatuagem temporária de "henna preta". (A)

The warnings would be more efficient if they were organized according to topics, that is, if the warning statement is about 'metallic dyes', the hazard, how to avoid it, as well as the consequences should be in a sequence, as can be seen in this warning in C, which informs about the hazard resulting from contact with eyes.

"Evitar o contato do produto com a pele e os olhos, não utilizar para a coloração de cílios e sobrancelhas. Não seguir estas instruções pode levar à cegueira"; (C)

Shuy (2008 s/p) notes that readers "normally expect the most important points of a discourse to be made first and the less important ones to follow". Importance can be evaluated by the level of severity or by the most frequent hazards. However, the warning labels analyzed here seem not to follow this rule. The warning statements below offer instructions about how to avoid a risk that has to be inferred by the reader, because the risk is only stated at the beginning of the text. In relation to the sequences, my intuition would say that informing about the dangers of using the hair dye after having dyed the hair with progressive dyes is more important than informing about the need to rinse the hair after application. Furthermore, it is a lesser known risk.

"Usar as luvas apropriadas fornecidas na embalagem;

Enxaguar bem os cabelos após a aplicação;

Não utilizar em cabelos defrisados ou imediatamente após uma descoloração ou permanente;

Não utilizar se os seus cabelos foram pintados com henê ou com uma coloração progressiva ou à base de sais metálicos"; (C)

4.2.5 Writer X Consumers' Relationship

The identity of the writer is not indicated anywhere in the text, given that the use of 'I' and 'me' was not in any warnings. This lack of identity increases the distance between the participants. The audience, on the other hand, range from the hair professional (brands A and B) to the general public (brand C). However, as already stated here, the warnings should address those members of the audience who have the lowest level of knowledge. The fact that brands A and B address the hair professional does not mean that s/he has the same level of knowledge as the writer. Sometimes the hair professional lacks formal education.

The audience is addressed in different ways, even in the same brand. For example, brand A is for professional use, which is explicitly indicated at the beginning and at the end of the document '*ADVERTÊNCIAS: Somente para uso profissional'* as well as the last one *'Produto de uso exclusivamente profissional'*, which seems to be designed to catch the customer's attention given the prominence they receive. It sounds as if this warning is highlighted to protect the manufacturer in case of a lawsuit, instead of to protect the consumer. Otherwise the risks would receive the same treatment.

However, the pronoun 'you' is mistakenly used (see below)

"*Instruções de uso: Não aplicar no cabelo se: <u>você</u> possuir erupções ou inflamações na pele do rosto, ou se o couro cabeludo estiver sensibilizado, irritado ou danificado. <u>Você</u> já teve alguma reação após tingir seu cabelo". (A)*

There are some instances, which a hair professional is correctly addressed (see below):

"*Se durante a coloração <u>a cliente</u> apresentar:*

Irritação ou queimação e/ou erupções, enxágue imediatamente e pare de usar o produto, pois isto pode indicar uma reação mais grave. Não aplicar a coloração novamente e aconselhe <u>a cliente</u> a buscar ajuda médica." (A)

However, the majority of the time, the addressee is not marked, as in:

"Não utilizar para pintar cílios ou sobrancelhas; Evitar o contato com os olhos. Se isto acontecer, enxaguar com água em abundância imediatamente";(A)

These warnings, which are in the imperative, are different from the warnings below, even though they are also in the imperative. The main difference lies in the fact that the reader is explicitly addressed in the second.

"*Use luvas adequadas para a manipulação e aplicação do produto; Enxágue bem o cabelo após a aplicação*". (A)

Although the third brand is intended for the general customer, there are few warnings where the consumer is directly addressed, as in the example below.

"*Se <u>você</u> já fez, mesmo que uma única vez, uma tatuagem de hena preta, provavelmente <u>você</u> corre o risco de ter se tornado alérgico sem saber".(C)*

The subject is 'hidden' in some warnings, as in:

"• NÃO UTILIZE SE:

- <u>Já apresentou</u> alguma reação alérgica a um produto de coloração".(C)

The pronoun 'your' indicates the consumers:

- <u>Seu</u> couro cabeludo está irritado ou lesionado".(C)

5.2.6 Summary of the Section

The three warning labels analyzed are not adequate to warn about the hazards mentioned in the judicial cases, namely: hair loss and allergic reaction. In fact, hair loss is not even mentioned in the warnings. The warning labels dedicate their attention to the risk of allergic reaction, which is the only risk that is pointed out in the guidelines. However, they fail to inform about it in an explicit form. The warnings permit the readers to infer the hazard since they have to connect the relation between the stated hazard and the product. Likewise, the consequences are not explicitly stated. Shuy (1990) and Tiersma (2002) note that warnings should be explicit in order to avoid wrong inferences. On the other hand, there is plenty of information about how to avoid the hazards, which are explicitly stated. However, studies have shown that willingness to read and compliance are closely associated with the perceived hazard (Wogalter, 2006; Wogalter Desaulniers & Brelsford, 1986). Thus, if the warnings fail to state clearly the hazards as well their consequences, it is likely that the users may not comply with the warnings.

5.3 FOOD LABELLING

So far I have been discussing the characteristics that strengthen or weaken a warning, which is the main topic of this investigation. In this section, I will continue, but first, I would like to talk about the relationship of trust between the consumer and the manufacturer. I will

use the Volkswagen (VW) scandal on emissions that exploded last year to exemplify this relationship. We know that air pollution causes massive problems, even thousands of premature deaths annually. In order to attract new consumers, VW promoted a massive campaign claiming that their cars had 'low emission'. But the scandal (BBC)[48] revealed that not only had VW cheated on the emission tests, but also the government tests were known to be faulty. Many consumers bought VW cars because they trusted the 'non-polluting' claims. But, as shown on the news, these cars "emitted nitrogen oxide pollutants up to 40 times above what is allowed in the U.S." (ibid).

Likewise, most consumers trust 'food claims', without knowing whether they are in fact true healthier. The media are responsible for the popularization of many *'diet', 'light'* and *'health'* products. However, some strategies employed by both the media and the producers to influence consumers' food choices are deceptive. For example, the sentence 'lactose free' (*sem lactose*) stamped on a bottle of soy juice is considered an infraction based on RDC 259/ 2002 since the product is naturally free of the substance anyway, but this strategy is still employed by some manufactures (Camara, 2007). According to the guidelines, the manufacturers should state that these products are 'naturally' free from lactose.

The concern for adopting a healthy diet and consuming products that have a lower impact on the environment is increasing every day, likewise so are the products that exploit these attributes. However, as pointed out by Rodrigues and Rodrigues (2002: 1), these products "are complex and specific, and they demand additional information to be fully understood". Moreover, some manufacturers exploit this market niche by conveying messages that are sometimes misleading. In this sense, Celeste (2001: 218) notes that these messages "can lead to the belief that certain products have medicinal properties, which may delay the customer from searching for an adequate therapeutic care".

Supermarket shelves are full of products claiming to be 'fat free', low carb', 'sugar free', 'rich in fiber', 'rich in protein', 'lactose free' and gluten free' aiming at attracting the consumers. The aggressive marketing implies that these products are healthier, and some consumers include them in their diet, without knowing, in fact, what they are eating. But, at the same time, the WHO (World Health Organization)[49] is concerned about the growth of obesity in the world. A survey made in

[48] Retrieved from: http://www.bbc.com/news/business-34324772 04/02/2016.
[49] Retrived from: http://www.who.int/mediacentre/factsheets/fs311/en/ 04/02/2016.

2014 revealed that "1.9 billion adults were overweight, of these over 600 million were obese". The same organization also asserts that obesity is linked to several diseases, such as cardiovascular diseases, diabetes and some cancers. It seems that we are living an 'alimentary epidemic', even despite the wider availability of 'healthier food' and the spreading of knowledge about a 'healthy diet', given that there has never been so much talk about a 'health diet' as there is now.

Interestingly, the number of people that need a specific diet has also increased. According to the WHO[50], it is estimated that 9% of the adult population have diabetes. Unfortunately, about "1,5 million deaths were directly caused by diabetes" in the whole world in 2012 and this number is rising, because the projection made by WHO, predicts that diabetes "will be the 7th leading cause of death" by 2030. Besides, the number of people that suffer some kind of allergy from food components, such as lactose and gluten, is also rising. The special products mentioned above can help these special consumers, but their great variety, the complexity of the nutritional facts and also the nutritional claims can confuse consumers. That is, the food industry has developed new products, which are unknown to most people, and reading the nutrition labels can be a complicated task that demands specific knowledge.

At this point, food labelling is an important source of nutritional information that can help the consumer to choose the most appropriate food for her/his nutrition. Camara (2007) notes that food labelling has the status of an activity that promotes health and it can be seen as a link between the industry and the consumer. Besides, food labelling is a fundamental tool for food safety, especially for consumers that have some kind of food restriction, as mentioned above. The Brazilian Statute 986/69 defines food labelling as "every description, legend, picture or any graphic or descriptive material, written, printed, stamped, engraved, embossed or lithographed or pasted on the food package".

Given the number of individuals who suffer from diabetes, and particularly because one of my family members has diabetes, my focus will be on the information about diabetics' needs when buying food. This is because diabetes control is mainly achieved through diet and the insulin. Thus, I will first analyze the guidelines for food labeling provided by ANVISA focusing on two main questions: Are the guidelines adequate? Are the food labels in agreement with these guidelines? Then I will verify the efficacy of the nutrition labels in order

[50] Retrieved from: http://www.who.int/mediacentre/factsheets/fs312/en/ 04/02/2016.

to see whether the information is successfully conveyed and whether these labels provide all the information necessary for diabetics.

5.3.1 Guidelines

The first Brazilian guidelines for food labelling were approved in 1969 (986/MS) and they are still in force (in an expanded version). According to these guidelines, food labels should have information related to registration and batch numbers and expiry date. They also state that the information should be legible. RDC 259/2002 is a fundamental law that aims to protect the consumer since it prohibits expressions or pictures that can deceive the consumer. For example, the expression in a bottle of a grape (picture below) "*Produto saudável! O coração agradece! Redutor do mau cholesterol*!" that suggests that the product has some medicinal properties is not allowed, not even if true.

Picture 5.13: Grape juice

The terms 'reduced'/'raised' or 'low'/'high' can also confuse consumers given that they can be open to different interpretations. Which product has less sodium, one that informs that sodium is reduced or one that claims that has low sodium? ANVISA allows both terms, but they have different definition rules. RDC 54/ 2012[51], which regulates the Complementary Nutrition Information (*Informação Nutricional Complementar*), presents the term *Reduced,* which is used to refer to a product that has at least 25% reduction in calories or any component, such as: sugar, fat, sodium and cholesterol, whereas the term *raised* is employed to refer to a product that has an increment of 25% in any nutrient, such as fiber, protein, calcium, vitamins.

[51] Retrieved from: http://portal.anvisa.gov.br/wps/wcm/connect/630a98804d7065b981f1e1c116238c3b/Resolucao+RDC+n.+54_2012.pdf?MOD=AJPERES

The term ‘low’ has different values:

- 3 gr of fat in100 gr/ml of the product;
- 1,5 gr of saturate or trans fat in 100 gr/ml of the product;
- 20 mg of cholesterol in 100 gr/ml of the product;
- 80 mg of sodium in 100 gr/ml of the product;
- 40 Cal of energy in100 gr/ml of the product;
- 5gr of sugar in 100 gr/ml of the product;

Thus, it is difficult for an ordinary person to evaluate which product would be better for his/her diet, those products that claim to have ‘reduced’/‘raised’ components or those that describe the components as low/high, especially when the consumers do not know what is normal or non-low. Furthermore, some knowledge of mathematics is necessary, given that reduced/raised are defined in terms of percentages, while low/high are defined in terms of the quantity (gr, mg, cal) that is reduced or increased. Obviously, it also demands some effort, which consumers may not be willing to make. Interestingly, RDC 54/2012 points out that “Complementary Nutrition Information will facilitate the consumer’s knowledge about the food’s nutritional properties, contributing to the adequate selection of food” (pp. 02). However, the terms ‘*baixo, não contém, alto conteúdo, fonte, muito baixo, sem adição, reduzido, aumentado*’ generate different interpretation from what they actually mean and possibly confuse consumers. A study conducted by Reid and Hendricks in Canada (1994; as cited in Celeste, 2001) explores the consumers’ interpretation of two terms “low fat” and “reduced fat”. Their results revealed that the distinction between them is not clear. In this vein, a distinction between the ‘eight’ terms just mentioned above would certainly be unclear.

Thus, despite the fact that the Brazilian Constitution, the Consumer Defense Code (CDC) and the Guidelines provided by ANVISA and MAPA assert that consumers have the right to receive clear and correct information about the ingredients of the products they buy, this right seems to be disrespected due to many problems we face when reading a label, and it seems that the guidelines themselves fail to provide adequate guiding.

360/2003 is considered an important step to the access of information since it made nutrition labeling mandatory. Labels are required to inform about the quantities of calories, carbohydrates, proteins, total fat, saturated fat, trans fat and sodium. However, they should be better detailed. For example, the kind of carbohydrate is not specified, that is, sugar, which is a carbohydrate, is not listed, neither the

kind of carbohydrate, which can be either simple (monosaccharides) or complex (polysaccharides).

Portarias 27 and 29 /1998 regulate diet and light products. The criteria established for these terms are based on the Codex Alimentarius (see section 3.2.1.3.2). In this way, dietary products are: "*Alguns alimentos com modificações no conteúdo de proteínas, carboidratos e outros nutrientes ou valor energético para atender às necessidades de pessoas em condições fisiológicas e metabólicas específicas*", whereas light products are defined as: "*Alimentos que apresentam a quantidade de algum nutriente ou de valor energético baixa ou reduzida (quando comparado a outro alimento*)". Nowadays, despite many campaign about the difference between diet and light, many consumers still confuse them. For example, what is the difference between the two types of Coca Cola: light and diet? Based on the definition provided above, Coca Cola diet has no sugar and it is recommended for people who need a diet with sugar restriction. Coca Cola light presents a reduction of at least 25% of calories and is indicated for people who want to reduce the ingestion of calories.

The Normative Instruction (*Instrução Normativa*) SDA 30/1999 establishes the identity and quality patterns for 'diet' and 'low calorie' drinks. It allows the use of the term 'diet' for drinks that substitute all the added sugar by low-calorie sweeteners whose sugar level is lower than 0.5 g per 100 ml; whereas 'light' is adopted for drinks that substitute all the added sugar by low-calorie sweeteners, but that have up to 20 calories per 100 ml. Thus, both substitute sugar, but the diet version uses sweeteners with lower calories. To give a better idea of the amount of sugar, there are 85 calories in 200ml of full Coca Cola (full), whereas zero calories in 200 ml of Coca Cola (light and diet). Contrary to other **light** products, Coca Cola light has zero calories.

Providing specialized information for ordinary consumers is a difficult task, and the regulative agencies should act in order to minimize the knowledge gap by demanding clearer and more detailed information. However, based on what has been discussed above, it seems that the regulations in force are not adequate, mainly because they generate confusion and doubts.

5.3.2 Food Labels

The food labels were selected during the month of September 2015. The selection of the products was based on doubts related to the counting of carbohydrates. The diabetic depends on glycemic control

that can only be achieved by carbohydrate counting, that is, the quantity of carbohydrate that an individual ingests will determine the insulin dosage required. This task can be complex, because there are many factors that can influence the counting, such as fibers and sugar alcohols (Polyols). Hall (2013) explains that diabetics should "subtract one-half of the fiber grams from the total carbohydrate grams". For this reason, information about fibers should be clearly indicated, otherwise the diabetic may overdose.

Sugar alcohols also affect this counting, but more studies need to be developed in order to determine the quantity that should be subtracted, given that there are many variables that can affect it, such as the type of sugar alcohol [Lactitol, Maltitol, Mannitol, Sorbitol, Xylitol, Isomalt] and "on the nature of the food into which it is incorporated" (Wolever et al., 2002: 360). The main concern related to sugar alcohols is hypoglycemia, that is, when blood sugar drops below normal levels. The concern emerges when the consumers base their insulin calculation on simply the amount of carbohydrate and then "eat a meal containing predominantly sugar alcohols" and do not factor the sugar alcohols into the calculation (Woelever et al, 2002: 360), which can result in an episode of hypoglycemia. This is because sugar alcohols are partially absorbed (ibid) which means that they "do not provide carbohydrate to the body for metabolism" (ibid: 357), for example, only 50% of the sugar alcohols 'Xylitol' and 'Mannitol' are absorbed from the human body, which suggests that they provide only 50% of what might be assumed and therefore calculated.

Unfortunately, as noted by Freman and Hayes (2004: 137) "the current marketplace can be a source of a great deal of misinformation, cause considerable confusion, and possibly affect glycemic control". For this reason, the nutrition labeling must be as clear and informative as possible, allowing the diabetics to successfully calculate the quantity of carbohydrate ingested in order to adjust the insulin dosage. Woelever et al. (2002: 360) note that "food labels of products containing sugar alcohol can be confusing" and "a lack of consistent labeling, both nationally [Canada] and internationally" can intensify this confusion (ibid: 361). Thus, given that fibers and Polyols (sugar alcohol) can affect diabetes control, I will focus on products that contain such substances.

5.3.2.1 Fibers

The first doubts emerge during the purchase, and both the advertisement and the nutrition claims can interfere in the choice by

influencing consumers to select a product that is not what had been expected. Portaria 27/ 1998 regulates the quantities and the terms. In order to illustrate this, we will analyze the fiber claims of a whole grain rice label. The terms allowed by ANVISA are 'source' (*fonte*) with 3 g of fiber in 100 g of food, and 'high' (*alto teor*) with 6 g of fiber in 100 g of food. There are many products that disrespect this instruction by employing the terms without having the minimum quantity of fiber. The picture below illustrates this, since the label claims that the product has 'high content of fiber and nutrients'. According to the guidelines the product should have 6 g of fiber in 100 g, but the nutrition facts reveal that the product has only 1 g of fiber in 50 g, which corresponds to 2 g of fiber in 100 g. Thus, the claims are incorrect and totally misleading. Moreover, the labels also claim 'high content of nutrients', which are not specified declared in the nutritional facts.

Picture 5.14: Whole rice (front)

Picture 5.15: Whole rice (nutrition label)

Most people are unaware of these guidelines and for this reason they are not able to evaluate, based on the labels or claims, which products would be suitable for their dietary needs. Although 'high content of fiber' may not lead to miscomprehension, the term 'source' certainly can. According to the Merriam Webster dictionary source means "someone or something that provides what is wanted or needed". A Brazilian dictionary (*Aurélio*) provides the following meaning

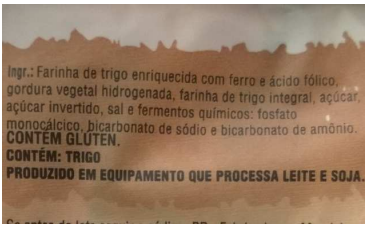
'origin'. Thus, the term may be inadequate since the word does not express the quantity, in the way that high and low do.

Moreover, the food market knowing the benefits of fibers, explores this niche by adding 'whole cereals' in their products, which brings many benefits to the consumers. At the same time, the manufacturers widely advertise that their products are made with 'whole cereals' (see picture 5.16 below) or even add the term 'integral' to the brand (see picture 5.17 below). The list of ingredients reveals that they are made with 'whole cereals'. On the other hand, there are some products that add the term 'integral' to the brand and the claim that '*cereais integrais contribuem para uma alimentação equilibrada*' (see picture 5.18 below), whose list of ingredients shows that the main ingredient is '*farinha branca enriquecida com ferro e ácido fólico*' (see picture 5.19), in other words, 'white flour'. Unfortunately, some consumers might believe that they are consuming 'whole biscuits', but are in fact consuming normal biscuits with a small addition of 'whole flour'.

Picture 5.16: Cereal

Picture 5.17: Cookies

Picture 5.18: Biscuits



Picture 5.19: Ingredients (biscuits)

It seems that the biscuit complies with the regulations, given that it does not use the terms 'high content of fiber' and 'source of fiber'. The claim '*cereais integrais contribuem para uma alimentação*

equilibrada' may lead the consumers to infer that the product can contribute to a balanced diet, but it does violate RDC 259/2002, given that it does not assert that the product contributes to a balanced diet.

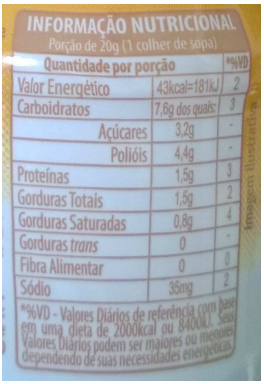
5.3.2.2 Sugar Alcohols

Reading the food labels is a difficult task for two main reasons: readability and comprehensibility. The first occurs when consumers are not able to read the labels due to font size, blurred text or even the colour combination of the font and the background. The second occurs when consumers cannot understand the information in the tables mainly due to the use of technical terms or lack of information, which can lead diabetics to select an inadequate product that can cause long-term problems.

Unfortunately, technical terms are still largely employed in many different product labels, as could be seen throughout this dissertation. But it seems that the use of them on food labels is greater. I believe that space constraints might be used to justify their employment. On the other hand, the space destined to the brand and the claim is much bigger.

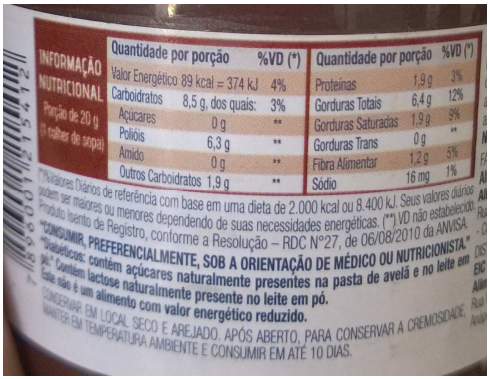
The labels below (pictures 5.20 and 5.21) are from diet products and for this reason the type of carbohydrate is specified. As can be seen, 'sugar' (*açúcar*) is a type of carbohydrate, as well as a 'starch' (*amido*), 'polyol' (*polióis*) and "others carbohydrates' (*outros carboidratos*). Although all terms are technical, the term 'polyol' attracts attention, because it is an unusual term.

PRODUCT A



Picture 5.20: *Doce de leite* (nutrition label)

PRODUCT B



Picture 5.21: Hazelnut cream A (nutrition label)

I decided to read the whole labels in order to have more information, but I found nothing related to Polyol. However, a warning (product A) called my attention: 'Diabetic: this product can cause laxative effect' (*Diabético: este produto pode causar efeito laxativo*). An investigation led me to Polyol. In order to explain it I first need to define Polyol.

A brief search of the term led me to the site: http://polyol.org that states: "Polyols serve as useful sugar replacers in a wide range of products as part of a sugar free diet. (…) With a low glycemic response, they can also reduce insulin response, helping reduce risk for diabetes". The site also explains that Polyol (or sugar alcohols) "are neither sugars nor alcohols. Instead, they are a group of low-digestible carbohydrates used as sugar replacers". The site also informs that "laxative effects are common for all non-digestible carbohydrates and foods rich in them". Thus, it seems that polyol has a laxative effect, but this information was not explicitly conveyed in the warning. Moreover, B also contains polyol and didn't have the warning.

I also consulted the ANVISA guidelines in order to check if the warning was mandatory and I found in RDC 18 (24 de março de 2008) the following information: (a*) Todos os alimentos e as bebidas contendo polióis deverão obedecer aos requisitos de rotulagem referentes a efeitos laxativos*). As can be seen, all products that contain polyol should inform about the laxative effect. So, B is not in agreement with the guidelines.

Moreover, as was mentioned earlier in this section, Polyols can also influence the carbohydrate count, and if consumed in excess

without adjusting the insulin dose, it can cause an episode of hypoglycemia. However, ordinary consumers may well not know this. I know that it is advisable that a nutritionist should orient the diabetic's diet, but some people cannot afford it. Moreover, the manufacturer should inform consumers about the most important factors of an ingredient. A warning would be appropriate in this case.

Another technical term that called my attention is *EDULCORANTES*. I have always read it on food labels, even in 'normal products', and I wrongly inferred that it was a type of 'coloring'. I only realized the real meaning when I was writing this chapter and I needed to translate it into English. To my surprise *EDULCORANTES* are 'sweeteners'. The question 'why is the term so simple in English? Immediately emerged in my mind. The problem with the Portuguese term is that it not only very different from the real meaning, but also is liable to lead consumers to infer the wrong meaning, due to the similarity with the word 'coloring' (*corantes*).

Technical terms are also present on the list of ingredients and reading the list from the product below raises many doubts, and now I question whether the information I have learned about 'sweeteners' is wrong. I am not an expert in the area, which can explain my doubts. But I am a consumer, and I believe that most consumers would have similar doubts when reading the food labels.

I have learned that the ingredients are sequenced according to their quantity. So, in the picture 5.22 below, 'vegetable oil' (*óleo vegetal*) is the main ingredient, followed by Maltitol.

PRODUCT C

Picture 5.22: Hazelnut cream B (front)

Picture 5.23: Hazelnut cream B (nutrition label)

My doubts come from the term Maltitol. According to the site http://polyol.org (see below), Maltitol is a Polyol. So, why is it not pointed out in the food label under carbohydrates? The only carbohydrate listed is sugar (see above). Then, at the end of the ingredient list we see: 'sweeteners: sucralose (*edulcorante: sucralose*). But Maltitol is not there. The ame lack of information was observed on Hazelnut cream A. Finally, being a Polyol, the label should also bring the warning about the laxative effect.

This fact reveals a great problem that frequently occurs in food labels: the use of technical terms that are not explained. It is quite possible for an ordinary consumer to consume an ingredient that s/he did not intend to. This is because the ingredients are well disguised, intentionally or not, behind an obscure term. Sugar is one of them, which unfortunately represents an immense risk not only to diabetics, but also to all consumers, given that the excessive ingestion of 'sugar' has a damaging effect on health.

The ingredients list below (E) is from a cereal, commonly called Corn Flakes, which means that it does not have the sugar covering the flakes. But, even so, it contains more than one type of sugar: sugar (*açúcar*), sugar syrup (*xarope de açúcar*), malt extract (*extrato de malte*). It is important to point out that these sugars are chemically different and have differing effects on our health.

Picture 5.24: Corn flakes (ingredients)

5.3.4 Summary of the Section

The facts mentioned above show just some of the problems related to 'food labels' and they reveal that the consumers' right is being doubly violated. First, the information is obscure; second, there is a lack of information. Consequently the message will not be understood, or even worse, it will be mis-understood. I have already noted that inference is the main outcome when there is obscure or total lack of information, and as pointed out by Tiersma (2002) the chances of being 'mis-inferred' are great. The problem is increased when a term appears to be related to another one, as '*edulcurantes*'. This resembles 'false cognates', which are words that appear to be related but have different meanings.

The food labels also violate at least 3 of Grice's Maxims (1975). The 'Maxim of Quantity', which requires the writer's contribution to be "as informative as required" can be observed in several ways. There is lack of information related to the kinds of carbohydrate on the labels of general products, which forces the consumers to read the ingredients list to verify whether there is sugar, of what kind and how much. Information regarding Polyol and its role in the counting of carbohydrates should be pointed out, at least in 'diet' products. The 'Maxim of Manner' requires that information given be 'perspicuous', without ambiguity. To be perspicuous, technical terms should be explained, or at least should be categorized, as sweeteners, preservatives, and so on. The 'Maxim of Relation' requires the information to be relevant. In this respect, Shuy (1990: 296) notes that the writer should not expect 'the reader to make the needed connections between the separate bits of information provided". But as discussed above, the consumers need to connect the information from the nutrition label and the list of ingredients in order to infer the correct information.

5.4 FINAL REMARKS

Although this section analyzes very different products, the results are somehow similar, in that all fail to inform the consumers adequately. The most explicit problem is the lack of information, about either the risks or how to avoid them, especially in the case of fireworks and hair dyes. In food labels, lack of information was observed in the nutrition tables, which could display more detailed information. It was also demonstrated that Products B and C did not provide the warning related to the laxative effect. Furthermore, some substances, such as Polyols, can affect the insulin dosage and for this reason, the labels should carry a warning about it. Thus, the regulative organs should take this into account and review their norms. Obviously, this could create not only worries in the consumers, but also linked profit problems for the manufacturers, given that consumers could well avoid buying products with polyols.

A closer analysis reveals that when the warnings do provide all the necessary information (i.e. risks and how to avoid them), they may be weakened by the use of technical terms, vagueness, modality and complex clauses that can hinder comprehension. Moreover, some warnings also fail by not relating the risks to the guidance explicitly. But it seems that these problems are not taken into account by the regulative organs, given that they seem to be concerned only with the presence of the information, instead of how it is conveyed.

The manufacturers exploit this gap by providing warnings which include the information specified in the guidelines, but which at the same time do not truly communicate the risks. In this way, they avoid litigation and protect their profits.

CHAPTER SIX
SUGGESTIONS

6 INTRODUCTION

In this section, I will present some suggestions to improve PILs and product warning labels. Differently from chapters four and five, in which the items were analyzed separately, each one in a discrete chapter/section, here the suggestions will be presented jointly, with the exception of food labels, as the PILs but also product warning labels had almost the same communicative problems.

As emphasized above a warning requires much more than a single sentence to warn about a possible bad event, since it needs not only to catch the consumers' attention, but also to be readable and comprehensible. These characteristics are essential for at least four reasons, where each one influences a different stage of warnings: first, consumers need to be able to read the warnings, so, the text should be presented in a readable font size, with a contrasting color combination to facilitate the reading. Second, based on the evidence that consumers tend not to read labels and when they do, they rarely read the entire label, especially when it is a long text (as are PILs), the text should have some characteristics to catch attention. Third, the writer should bear in mind that the warning label is addressed to an ordinary person, whose level of knowledge and linguistic competence is unknown and many times basic, and for these reasons, the text should be written in simple syntax and using ordinary vocabulary. Finally, the consumers should comply with the safety messages. Empirical studies showed that compliance is greater when the risks are explicitly pointed out as well as their severity. Thus, the way the writers evaluate them is paramount to compliance.

The analysis identified many characteristics that can weaken the warnings on different stages (see chapter 2.2.5 for C-HIP model, developed by Laughery and Wogalter (2014)). Based on these findings we will present some suggestions to improve the quality of the PILs and the product warnings labels. The suggestions will focus first on readability, then on the characteristics that can attract the consumer's attention and affect comprehensibility, and finally on food labels.

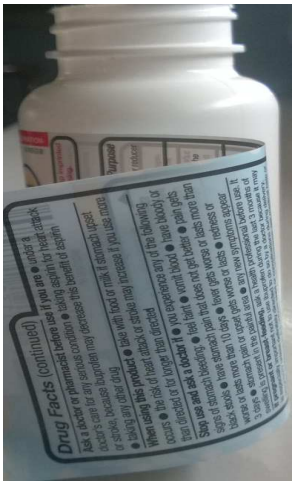
6.1 READABILITY

Many studies reported that PILs are difficult texts to read due to design, in which the font size, organization of the text, color combination, paper and printing quality impair reading. However, many of these important characteristics were necessarily disregarded in this study, given that the data were collected in electronic form. Notwithstanding, the suggestions presented in this section can also be applied to PILs.

I experienced difficulties in reading some warnings due to the font size, which led me to ask for some help in order to transcribe them. The print quality and color combination also contributed to decrease the legibility of the warnings. Thus, based on the difficulties I experienced and on the findings of some empirical investigation (Fujita, 2004) readability can be improved if:

- Texts use a font size bigger than 8 (1.8 mm);
- More space between lines are allowed;
- Text are left aligned;
- Contrasting color combination is employed;
- Texts are printed using a good quality paper/ink;

Clearly, more space should be provided for warnings and very probably manufacturers rely on space constraints in order to justify their inadequacies. An interesting strategy to overcome space constraints is adopted in the medicine label below (picture 6.1).



Picture 6.1: Medicine label

As can be seen, the label has information on both sides, allowing more writing to be produced on the same size of label. Fireworks and some food labels could take advantage of this strategy, especially those that have very limited space (see below).

Picture 6.2: Fireworks Label

6.1.1 Attracting The Consumers' Attention

Signal words and headings, when successfully employed, are able to attract the consumers' attention to important information, such as risks, and at the same time, to inform about their level of severity. PILs should definitely use the signal word 'warnings' (*advertências*) to facilitate their recognition. The signal words 'attention' (*atenção*) and 'important' (*importante*) should be avoided when the risks are severe and the signal words 'danger' (perigo) and 'warning' (advertência) should be employed instead. Finally, "color to codify the level of the hazard" should be employed in the signal words (Wogalter et al., 2006: 163) and an alert symbol should be added to "switch attention towards" the warnings (Ibid: 160) (see the revised text below).

⚠ *PERIGO! ~~ATENÇÃO!~~ DESMANCHAR FOGOS ~~PODE CAUSAR~~ CAUSA QUEIMADURAS (fireworks) (R1)*

⚠ ***Advertência*: ~~Importante~~**: *as colorações podem provocar uma reação alérgica que, ~~em alguns casos, ainda que raros~~, pode ser grave (hair dye) (R2)*

When texts are comparatively long, as are PILs, important information should be highlighted to facilitate searching. Separating the corresponding items of texts into groups, which are headed according to their topics, is an interesting strategy. At this point, empirical researches and testing are paramount in order to verify the consumers' most frequent doubts and subsequently reorganize the distribution of information based on the research. The results demonstrated that the unlabeled 'warning sections' are the longest due to the amount of information. It would be more efficient if the sections were sub-divided, in this way, section 2 (English) and sections 3 and 4 (Brazilian) could

have the following sub-sections, which are organized in terms of importance:

WARNINGS

- Do not take it if (diseases):
- Do not take if you are taking the following medicine:
- Talk to your doctor before taking it if:
- Stop taking it if (symptom):
- If you are pregnant and breast-feeding:
- Driving and operating machines
- Do not drink alcohol

Results also showed that warnings related to the same topics were often distributed over more than one sub-section (as can be seen below) creating confusion.

"Take special care with Volsaid and always tell your doctor if:

- you are in the first six months of your pregnancy
- Your are planning to become pregnant or if you have problems becoming pregnant. Volsaid may make it more difficult to become pregnant

(…)

Do not take Volsaid

- if you are in the last trimester of your pregnancy

(…)

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding, or could become pregnant, talk to your doctor before taking your tablets" (O3)

The reorganization below has not only grouped the warnings, but also ranked them in terms of seriousness. Moreover, repeated warnings were deleted. Finally, the word 'trimester' was substituted by 'three months', which is not only easier but also follows the same pattern employed in the subsequent warning 'first six months'.

"IF YOU ARE PREGNANT OR BREASTFEEDING:

- DO NOT TAKE Volsaid if you are in the **last three months** ~~**trimester**~~ of your pregnancy

- Tell your doctor if you are in the **first six months** of your pregnancy

- You are planning to become pregnant or if you have problems becoming pregnant. Volsaid may make it more difficult to become pregnant" (R3)

The fireworks warnings (presented in a revised form below) would attract more attention if it were headed 'WARNING' (ADVERTÊNCIA). Besides, I have changed the sequence, so that the original Warning (3) has been placed before (2), given that it is related to (1). Finally, item (4) was deleted given it is not a warning.

⚠ *ADVERTÊNCIA!*

1. É proibido soltar em locais fechados, cobertos ou próximo a produtos inflamáveis ou explosivos.

2. É obrigatório soltar fogos a 50 m de distancia de pessoas, casas, veículos e rede elétrica

3. ~~2~~. Se o produto falhar, mantenha-se distante por no mínimo 120 segundos. Não tente reutilizá-la. Troque-o no local onde foi adquirido.

~~*3. É obrigatório soltar fogos a 50 m de distancia de pessoas, casas, veículos e rede elétrica.*~~

~~*4.É proibida a venda unitária deste produto.*~~ *(R4)*

Preventing hazards is the goal of warnings, so it seems reasonable to inform the consumer explicitly about these hazards. In the fireworks label (3), which was analyzed in section 5.3, the hazards are presented at the end of the text and are related to the action: 'take apart the fireworks' (*demanchar fogos*). It should first be moved to the beginning of the text, right after the word 'warning'. Furthermore, as the risk was weakened by the modal operator and there was no reference to the level of severity, it was rewritten. Finally, the restriction was substituted by 'fireworks' (*fogos de artifícios*) (see below).

ATENÇÃO! DESMANCHAR FOGOS PODE CAUSAR QUEIMADURAS (O5)

⚠ *ADVERTÊNCIA! FOGOS DE ARTIFÍCIO CAUSAM QUEIMADURAS* ***GRAVES*** *(R5)*

The English mandatory warning would be more efficient if it provided more clear information about the quantity of the dosage that is harmful, as '**too much'** is vague. The risks '**serious liver damage'** was placed before the directions, and the symptoms of an overdose were added at the end of the warning.

"If you give too much

Talk to a doctor at once if your child takes too much of this medicine even if they seem well. This is because too much paracetamol can cause delayed, serious liver damage". (O6)

⚠ **WARNING! If you give more than the recommended dose** (see 'how to take section', because the correct dose depends on your child's weight)

Dose higher than the recommended can cause **serious liver damage**. Take your child to the nearest healthcare center even if s/he seems well. This is because the symptoms of paracetamol only appear 12-48 hours after taking Paracetamol. The symptoms include: pallor, nausea, vomiting and abdominal pain. (R6)

The warnings below address only consumers who are alcohol dependent or who have alcoholic liver disease. But close reading shows that all consumers should avoid the combination of Paracetamol and alcohol. Thus, the use of two warnings, each addressing a different group, would be more appropriate. Moreover, clear information related to the risk (liver damage) and the level of severity (serious) has been included in the rewritten version.

"Information for adults intending to take this medicine

This medicine may be harmful if you are dependent on alcohol or have alcoholic liver disease. Do not drink alcohol (wine, beer, spirits) whilst taking this medicine". (O7)

Information for adults intending to take this medicine

Do not take this medicine if you are dependent on alcohol or have alcoholic liver disease. ~~This medicine may be harmful for you.~~ This medicine can seriously damage your liver.

Do not drink alcohol (wine, beer, spirits) whilst taking this medicine. The combination of Paracetamol and alcohol can cause serious liver damage. (R7)

6.1.2 Comprehensibility

There are many linguistic features that can influence the understanding of warnings, such as lack of information related to the risks and directions, the use of technical and unusual terms, complex clauses and vagueness. As already pointed out, they lead consumers to make inferences, which may be different from the writers' intended message. Consequently, consumers may adopt the wrong behavior. The warnings below suffered at least one of these characteristics.

Clearly, compliance would be greater if the warning below pointed out the risks. Furthermore, the modal operator 'may' gives the impression that stopping taking the medicine is optional. However, aspirin decreases the capacity for blood clotting, which is a very serious

risk. Information about the risk would certainly lead consumers to tell their doctors that they are taking aspirin.

"You should let your doctor know you are taking aspirin, particularly if you are going to have an operation, as you **may** need to stop taking your tablets several days before the operation". (O8)

Aspirin decreases the capacity of blood to clot. You **must** tell your doctor if you are taking aspirin, particularly if you are going to have an operation. You **will** need to stop taking it several days before the operation. (R8)

"The technical term 'metallic dyes' (*tintas metálica*s) is not known to most consumers, who will probably have difficulties in understanding the warning. *Não utilizar em cabelos* ***previamente*** *pintados com hena ou tintas metálicas".* (O9)

Não use se ***ainda há*** *tinta metálica ou hena em seus cabelos,* ***pois isso pode danificar seus cabelos****. Tintas metálicas* ***são feitas à partir de sais metálicos, chumbo ou prata, e tingem os cabelos aos poucos****. Se você tem dúvidas a respeito dos tipos de tintura, consulte sua/seu cabeleireira/o.(R9)*

As can be seen, the revised text includes the explanation of metallic dyes. It is also more specific about the how long the consumers should wait if they have previously use metallic dyes. Lastly, the risk is informed.

The warning below has an interesting combination, as it is not only vague and complex but also fails for not offering enough information.

"If paracetamol is taken for a **long** time, it **may lead** to liver and kidney problems but if the **right** amount is taken over a **short** period of time **there should be no** problems" (O12)

In order to supplement the gaps I consulted the SPC to have more reliable information, but I found nothing related to the length of the period of safe use. In relation to the right amount, the PILs warn consumers' to take a 'maximum of 8 tablets in 24 hours. But they also allow consumers to take 2 tablets every 4 hours, resulting in a petential maximum of 12 tablets, which is confusing. Thus, due to the impossibility of offering more exact information, this warning (O12) should be deleted, given that the information is unnecessary.

6.1.3 Food Labels

The ingredients are listed in decreasing order according to quantity, that is, 'vegetable oil', which appears first in the list, has the

largest quantity, ‘maltitol’ is the second ingredient in terms of quantity, and so on. This sequence is extremely important and any change would result in information loss. Nonetheless, understanding it is still problematic, mainly due to the excessive use of technical terms. As can be seen, ‘emulsifiers’ (*emulsificantes*) and ‘sweeteners’ (*edulcorantes*) are described at the end. It is an interesting strategy, which helps consumers to identify what emulsifiers and sweeteners are, but it prevents them from knowing the quantities included. It seems that the rating ends at ‘calcium’ (*cálcio*). Furthermore, as noted in chapter 5.3, ‘maltitol’ is also a sweetener and it is not listed as such.

INGREDIENTES: ÓLEO VEGETAL,
MALTITOL, PASTA DE AVELÃ, CACAU
EM PÓ, POLIDEXTROSE (FIBRA SOLÚVEL),
LEITE DESNATADO, SORO DE LEITO EM PÓ,
GORDURA VEGETAL E CÁLCIO.
EMULSIFICANTE: POLIRICINOLEATO
DE POLIGLICEROL E LETICINA DE
SOJA, AROMA SINTÉTICO IDÊNTICO
AO NATURAL DE BAUNILHA,
EDULCORANTE: SUCRALOSE.
NÃO CONTÉM GLUTEN (O13)

The list of ingredients was then reviewed based on the discussion above (see below). First, uppercase letters were only used in the topics, which facilitates reading and also renders the topics more conspicuous. Then the technical term ‘*edulcorantes*’ was substituted by ‘*adoçantes*’. Maltitol was included in the sweeteners list, and the information related to the aroma was placed at the end. Given that I do not know the quantity of sucralose, I did not include it in the decreasing list, but it should be in the list.

INGREDIENTES: óleo vegetal,
maltitol, pasta de avelã, cacau
em pó, polidextrose (fibra solúvel),
leite desnatado, soro de leito em pó,
gordura vegetal e cálcio.
EMULSIFICANTES: poliricinoleato
de poliglicerol e lecitina de soja.
ADOÇANTES: Maltitol e sucralose.
Aroma sintético idêntico
ao natural de baunilha.
NÃO CONTÉM GLUTEN (R14)

As noted in section 5.3, fibers and Polyols should be taken into account in the carbohydrate counting. Thus, a warning should be provided to alert the consumers.

Advertência para diabéticos: Este produto contém (fibras/ Polióis) que interferem na contagem de carboidratos. Para melhor orientação, consulte um/a nutricionista. (R15)

Finally, as many consumers use the Internet to look for information about products and medicines, manufactures could take advantages of it, and provide information in digital format. Consumers can also take advantages of apps on smartphones, which could meet individual's needs. The combination of digital and analogue information is already used in different domains, such as: banking system and invoicing system (van der Waarde, 2014). However, the regulatory agencies do not allow these different sources of information (Ibid).

Although both the guidelines for PILs (English and Brazilian) and consumer products are inefficient, manufacturers could still improve the efficiency of the safety information. Some problems pointed out in this analysis, especially those related to comprehension and modality are not guidelines based, but possibly problems derived from the writers' lack of knowledge regarding the process of text production. "As linguists we have the tools to analyze the problems and improve the communicability of PILs" and warning labels as well (Hagemeyer and Coulthard, 2015: 66). Thus, regulative organs and manufacturers should consult linguists if they really aim to improve their documents.

CHAPTER SEVEN
FINAL REMARKS

7 INTRODUCTION

This study aimed to investigate the (in)efficiency of warnings employed in different consumer products, namely: medicines, fireworks, hair dyes and food. Although they differ in terms of content, structure, and length, the strategies employed by manufacturers to either present or conceal the risks are similar. The results of this study will be presented below by revisiting the research questions that were presented in Chapter One.

Are both the PILs and the warnings adequate to warn the consumers about the potential risks of the products?

which unpacks into five specific ones:

1) Are the PILs and the warnings written according to the guidelines?

1 A - The analysis of the PILs shows that the documents are partially in agreement with the guidelines. That is, the structure, which comprises the elements as **headings, sequencing, content** and the **wording of some warnings** was written according to the guidelines. However, both guidelines prescribe that the PILs need to be written in 'clear and understandable' language, and the findings reveal that they fail in this aspect. As can be seen is section 4.2, the use of technical terms that describe the symptoms (i.e. **lethargy**), vagueness in relation to the frequency (i.e. **occasionally** the blood does not clot well), quantity (i.e. If you drink **large amounts** of alcohol, you may be more open to the side effects of paracetamol), time (i.e. this is because too much paracetamol can cause **delayed**, (…)) and complex clauses (i.e. Immediate medical advice should be sought in the event of an overdose) render the warnings obscure and difficult to understand. At this point, it is important to note that according to the UK guidelines, a PIL must "enable the users to act appropriately" (van der Waarde, 2008: 41). However, it was verified that the consumers' need more information in order to be able to act properly. This result corroborates van der Waarde's (2014: 134) argument when he notes that most information about medicines for patients in Europe fails these [clear, understandable and enable the user to act properly] criteria".

1 B - The findings demonstrated that the fireworks warning labels partially disregarded the guidelines. They presented information regarding the symbol, the risk number '1.4' and the signal words '*Perigo – explosivo*'. Nevertheless three out four failed for not presenting the information legibly. The analysis revealed that it was difficult to read the warning labels of products 2 and 4, due to the font size, color combination and poor printing quality, whereas, the tiny font size employed in the warning label of product number 1 made reading impossible.

The analyzed hair dye labels apparently followed the requirements of ANVISA, but a closer analysis revealed that in brand C the text of the sixth topic was incomplete.

Some analyzed food labels also failed to follow the requirements of ANVISA. Claiming a 'high content' of fiber in the rice labels disrespects Portaria 27/ 1998 which determines that 'high content' (*alto teor*) can only be used if the product contains 6 g or more of fiber in 100 g of food. However, the nutrition label reveals that in fact the product contains only 2 gr per 100 g of food.

The hazelnut creams) and 2 fail for not providing the mandatory warning about the laxative effect. Moreover, product 2 did not provide the necessary information about Polyols in the nutrition facts, and both fail to inform that 'Maltitol' is a sweetener.

2) Are the guidelines (ANVISA, MHRA, ABNT) adequate to ensure that good quality PILs are produced?

The standardization brings many benefits in relation to the quality of the PILs. It guarantees uniformity not only in relation to the structure, which helps consumers to build a prior knowledge about the genre and therefore where to search for information, but also in relation to the content, which assures that all PILs have the necessary information to enable consumers to use medicines appropriately. On the other hand, through the analysis of the structure, it was found that the headings and sequencing create problems of **findability**, mainly in relation to the 'ingredients', 'warnings', 'medicine interaction' and 'side effects'. Moreover, the signal word '**warning**' was excluded from both PILs, reducing the appeal and possibly the recognition. Some problems related to the UK PILs emerge from the fact that they are written based on the SPC, in this way, information that are not in the SPC, should not be included on the PIL (van der Waarde, 2008). The main problem appears when the consumers' needs are not envisaged in the SPC, because then the PILs cannot include them. Given that the success of any informative text depends on how the writer conceptualizes the 'imagined readers' to

further write their texts based on this conceptualization (Coulthard, 1994), it is possible to assert that creating the text by starting from and adapting the SPC, rather than from the consumers' perceived needs, is one reason for the inefficiency of the PILs.

1 B – The guidelines of all the three types of products analyzed in Chapter Five presented some problems. However, the guideline for fireworks is the most inefficient, despite fireworks offering very serious risks. First, it clearly does not focus on the consumers, which is the main reason for such inefficiency. As could be seen in the analysis, the risks are informed through numbers and symbols, probably unknown to most consumers. The severity is ranked in terms of class (A, B, C and D), which determines who can handle the fireworks (age and professional use), and it is highly unlikely that ordinary consumers know about this. The textual messages are incomplete, as they fail to inform explicitly about the risks and their consequences. Thus, the firework guidelines need to be reviewed urgently, and they need to depart from the doubts that consumers have when handling fireworks.

The ANVISA guidelines for hair dye provide instructions for only one consequence, **allergies**. And as noted in the liability cases, there is a great number of consumers that had their hair damaged, a consequence that is not even considered in the guidelines.

The guidelines for food labels, especially those that regulate '**diabetes**' and '**complementary nutritional information**' allow '**nutrition claims**' that on the one hand help the diabetics to select more adequate products, but on the other hand, give space for confusion. This is because there are many terms that can be used to advertise the benefits of products, section (5.3.1) pointed out at least eight terms but there might be more. The problem is that consumers can misinterpret these terms and assume a wrong meaning. At the same time, manufacturers overuse '**nutrition claims**' to catch the consumers' attention, and sometimes use them incorrectly, as with the 'whole rice' presented in section (5.3.2). Thus, the consumer's right to receive adequate information is being violated.

Finally, the food labels are not adequate to inform diabetics who make use of 'carbohydrate counting', given that there is lack of information related to the substances and their quantity. This lack of knowledge can lead consumers to miscalculate the insulin dosage, which can cause an overdose.

3) What are the similarities and differences between the Brazilian and UK PILs?

The most striking difference between them lies in the structure. The analysis revealed that they differ in the organization of the information, the titles of the headings and some of the sequencing. It seems that the structure of the Brazilian PILs is preferable to that the English ones, as it presents the ingredients in only one section and has more sections. Moreover, the Brazilian PILs are organized into questions/answers, which tend to facilitate comprehension. In relation to modality, the findings revealed that they employed both types, modalization and modulation, but the Brazilian PILs made more use of modulation, while the English ones made more use of modalization. The examples of modulation employed in the Brazilian PILs had media value, and the examples of modalization employed in the English PILs had low value. Thus, there is evidence that the Brazilian PILs are communicatively preferable, given that modulation with higher value can motivate compliance.

Similarities are also present in all levels, such as: the content, which is presented in a similar sequencing; the grammatical choices with both using imperative and conditional clauses to direct the consumers; the lexical choices, the frequency listing revealing some similarities in relation to the content words, in which *medicine* is the most frequent content word, followed by *doctor*; the strategies to disguise the risks and side effects, both overusing vagueness, modality and technical terms.

4) Which characteristics make the warnings stronger or weaker?

As already noted, efficiency of warnings depends on a large array of factors that influence the different stages of warnings, **attention**, **comprehension**, **attitudes/beliefs**, **motivation** and **behavior (compliance)** (see chapter 2.2.5 for C-HIP model, developed by Laughery and Wogalter (2014)). As the characteristics of each stage influence the other stages, a fault in the first stage, that is, a weak characteristic in the first stage may undermine the entire process. In this way, warnings should first catch the consumers' **attention**. The factors that influence this stage are mostly related to design. The analysis demonstrated that the use of a small font size, upper-case letter used in the entire message, justified alignment, non-contrasting color-combination (background/font) and low printing quality fail to catch the consumers' attention and might discourage reading. On the other hand, the use of a readable font size (at least 8), signal words, alert signs, contrasting color-combination, left alignment, headings with different

colors (red, orange and yellow), different font size or/and upper-case letters, all catch the consumers' attention and encourage reading.

The characteristics that influence the second stage are those that influence **comprehension**. The content of warning labels and PILs is specialized and motivates the use of technical and unusual terms, passive voice, complex clauses and vagueness which weaken the warnings given that they hinder comprehension. The analysis also revealed that the consumers have to read the entire text in order to have complete information. This is because information about the same topic was spread throughout different sections/sub-sections, forcing the consumers to make connections between the separated parts. In contrast, the use of imperative and declarative clauses rendered the warnings stronger mainly because they present the directions explicitly. Long texts organized into bullet point list also help comprehension and information identification.

As noted earlier, some consumers' may understand the warnings and even so decide to disobey them. This is because consumers underestimate the risks, that is, they **believe** that the risks are minimal. The analyses demonstrated that most warnings were not able to change this belief, mainly because the risks were not explicit. The overuse of modalization, which was sometimes employed in the modal operator and modal adjunct together, weakened the warnings. This result corroborates Hegedüs' findings (2008) as she noted that modality seems to be employed to conceal the medicines' risks. On the other hand, the explicit presentation of risks and their consequences as well as their severity rendered warnings stronger. Clear instructions and explicit risks can influence consumers' **motivation** to **comply** with warnings and PILs, but as pointed out above, earlier stages might be affected, undermining the whole process.

5) Which characteristics can increase the likelihood of reader compliance?

Compliance is closely linked to the consumers' beliefs (Wogalter, 2006) in that if they believe that the product can offer some types of risks, chances of compliance are greater. Thus, the way the risks are presented can largely influence the compliance, for example: when risks as explicitly pointed out or when writers' evaluate the risks as serious, by the use of strong words (*severe, serious*), the adherence to the warnings tend to be higher. Adherence tends to be higher when writer's emphasize the urgency of the action, as in "Talk to a doctor **at once** if your child takes too much of this medicine even if they seem well" (paracetamol).

However, the analysis reveals more characteristics that decrease the likelihood of reader compliance, such as: risks are double modalised, (i.e. aspirin **should** not **generally** be given); probability of the risk is low (i.e. Medicines such as Volsaid **may** be associated with a **small increased** risk of heart attack or stroke); modal operators with a weak illocutionary force are used (i.e. Mifeprinstone if taken with aspirin this medicine **may not** be as effective); vague and technical terms that create confusion are also used (i.e *Também é indicado como* ***coadjuvante*** *no tratamento da inflamação na* ***ceratite*** *do* ***estroma corneano*** *por herpes*).

Finally, the analysis of the relationship between the writers and consumers demonstrated that the consumers were constantly addressed, as 'you', 'your child', 'patients'. On the other hand, there was no reference to the writers, increasing the distance between the participants and decreasing the confidence of the 'consumers'.

7.1 CONCLUSION

"Are both the PILs and the warnings adequate to warn the consumers about the potential risks of the products?"

The results mentioned above reveal that the PILs and the warnings are inadequate. I will not point out the characteristics that render them inadequate again, but I would like to raise some reasons that can impede improvements. Based on the premise that the main reason of PILs is to empower consumers to use medicines adequately, we can conclude that any writing must start from the patient's point of view. In this way, "it is necessary to start from observations of current practice to find out how well specific medicines are used at the moment". (van der Waarde, 2012: 45). Given that the medicines analyzed are painkillers, consumers have a similar purpose when taking them and might have similar doubts, which are not contemplated in the PILs. Although this can explain the inefficiency of PILs, I believe that there are others more noticeable reasons.

The findings show that the manufacturers are reluctant to inform about risks, which can be explained by the fact that efficient warnings can impact "on their [manufacturers] ability to make a profit" (Bohme & Egilman: 2006: 635). This is because some consumers would avoid buying products that offer serious risks. Moreover, "other companies might use this information [risks] against them" (ibid: 636). But at the same time, manufacturers need to be in agreement with the requirements imposed by regulatory agencies, under the risk of having their licenses

to sell withdrawn, or even facing litigation due to 'failure to warn'. Thus, manufacturers developed strategies to cope with these problems: anti-warnings (ibid). The analysis has shown many strategies of anti-warnings to make the warnings weaker, which are used not only in warning labels but also in PILs (both English and Brazilian). The strategies are employed in all levels, such as the structure and organization of the text, the lexicogrammatical choices and semantics. Some studies point out that part of this problem could be solved if the warnings were empirically tested before entering into force (Boheme & Egilman, 2006). Of course that it would depend on the government and regulators' willingness.

7.2 SUGGESTIONS FOR FURTHER RESEARCH

This study provides a panorama of the (in)efficiency of warnings labels and PILs, which demonstrate that the consumers' right to receive **clear** and **understandable** information is being violated, which consequently leads them to adopt an unsafe behavior. Chapter 6 provided some suggestion to improve the warnings; however, investigating the readers' comprehension, acceptability and opinions about both warnings in force and their modified versions would bring relevant data that help us to increase our understanding of the warnings' reception, which is paramount for their improvement.

Furthermore, further studies are necessary in order to better understand how writers evaluate the risk and how their position can influence consumers' compliance. Thompson (2002:65) notes that evaluation "can be simply defined as the indication of whether the speaker thinks that something (a person, thing, action, event, situation, idea, etc.) is good or bad". In this vein, appraisal theory (Martin & White, 2005) can offer important insight as it enable us to explore the writer's postion, which if low, can create problems of compliance, given that readers will probably ignore warnings that have low risks.

Coulthard and Johnson (forthcoming) discuss on the how forensic linguists can express their opinions semantically. Coulthard notes that he used a scale of opinions in a case he participated, which is adapted from a scale used by the International Association of Forensic Phoneticians. Coulthard's scale range from 5, which means that the expert witness is "Personally satisfied that X is the author" (ibid, 197) to -5, which means that the expert witness is "Personally satisfied that X is not the authors" (ibid, 198). Following his criteria, a scale of warnings effectiveness can be built in order to express the warnings' evaluation in court.

Finally, the main concern of this study is not pedagogical, but given the important social issues raised throughout this dissertation, it is possible to adapt some points discussed here to a pedagogical context. Heberle (2005: 210) stresses that "recent studies in applied linguistics (AL) discuss broader sociocultural issues (not only gramatical/formal issues or linked to the teaching of communicative function)". Likewise, the Curricular Guidelines for Secondary School (OCEM – *Orientações Curriculares para o Ensino Médio*) from Brazil points out that the teaching of reading should encompass issues relates to "values, ideologies, discourse and world perspective" (OCEM, 2006, p.98). Thus, the genres **warning labels** and **PILs** and the **neo liberal capitalism** issues linked to them, where warnings are seen as a strategy to avoid litigation, can be perfectly explored in the classroom, contributing to students' critical thinking.

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APPENDIX 1 – ENGLISH AND PORTUGUESE PILS

PARACETAMOL (A)		
	NAME	**TYPE**
1	Alvedon	Suppositories 125 mg
2	Anadin	Tablets
3	Paracetamol	Oral suspension 120 mg/ 5 ml
4	Paracetamol	Caplets 500 mg
5	Boots (6 years plus)	Oral suspension 225 mg/ 5 ml
6	Boots Soluble	Tablets 500 mg
7	Boots (6 years old plus)	Oral suspension 500 mg
8	Boots (3 months plus)	Sachets 120 mg/ 5m oral
9	Paracetamol Macopharma	Solution for infusion 10 mg/ ml
10	Paracetamol 500	Tablets 500mg
11	Perfalgan	Solution for infusion 10 mg/ ml
12	Calpot six plus past melts	Tablets 250 mg
13	Hedex Paracetamol	
14	Care infant paracetamol	Suspension 120 mg/ 5ml
15	Paracetamol 500mg	Oral suspension 500 mg/ 5 ml
16	Paracetamol 100mg/ ml	Suspension for Infusion 10 mg/ ml
17	Paracetamol 500 mg	Soluble Tablets 500 mg

Table A1: Paracetamol (English)

DICLOFENAC (B)		
	NAME	**TYPE**
1	Volsaid Retard 75 mg e 100 mg	Tablets (diclofenac sodium)
2	Reumatac Retard 75	Diclofenac sodium - Modified released tablets
3	Motifene 75 mg	Capsules Diclofenac sodium
4	Double action pain relief 125 mg	Tablets
5	Diclofex 75 mg SR and Diclofex Retard 100 mg	Prolonged released tablets
6	Diclofex 25 mg and 50 mg	Gastro-resistant tablets
7	Diclofenac Potassium 25 and 50 mg	Tablets
8	Joint pain relief 12.5 mg	Tablets – Diclofenac Potassium
9	Arthrotec 50	Modified released tablets - diclofenac sodium, misoprostol
10	Voltarol ophtha	Diclofenac sodium
11	Voltarol rapid tablets 25 and 50 mg	Tablets - Diclofenac sodium
12	Voltarol 75 mg RS and Voltarol retard tablets 100mg	Tablets - Diclofenac sodium
13	Voltarol suppositories 12.5, 25, 50, 100 mg	Suppositories -Diclofenac sodium
14	Voltarol ampoules	Ampoules - Diclofenac sodium
15	Voltarol dispersible tablets 50 mg	Tablets - Diclofenac sodium

Table A2: Diclofenac (English)

IBUPROFEN (C)		
	NAME	**TYPE**
1	Ibumousse	5% w/w
2	Brufen	Granules 600 mg
3	Brufen	Syrup 100 mg% 5 ml
4	Anadin	200 mg Tablets
5	Boots Long Lasting	200 mg capsules
6	Alamus 3 months plus	100 mg/ 5ml strawberry
7	Alamus 3 months plus	100 mg/ 5ml orange
8	Boots Maximum strength	10% gel
9	Boots 3 months plus	100 mg/ 5ml strawberry
10	Boots 3 months plus	100 mg/ 5 ml ????

Table A3: Ibuprofen (English)

ASPIRIN (D)		
	NAME	**TYPE**
1	Anadin original	Aspirin and Caffeine
2	Aspirin 75mg	Gastro-resistant tablets
3	Aspirin 300 mg	Gastro-resistant tablets
4	MigraMax 900mg/ 10/mg	Powder for oral solution
5	Beechams Powders Aspirin and Caffeine	
6	Anadin Extra soluble tablets contains aspirin, paracetamol and caffeine	Soluble tablets
7	Micropirin 75 mg	Gastro-resistant tablets (aspirin)
8	Anadin extra contains aspirin, paracetamol and caffeine	
9	Asasantin retard	Dipyridamole and aspirin
10	Nu-seals 75	Aspirin
11	Nu-seals 300	Aspirin
12	Dispersible co-codaprin tablets	Codeine phosphate and aspirin. 8/400mg
13	Aspirin and codeine tablets BP	Tablets
14	Aspirin extra tablets aspirin, codeine and paracetamol	Tablets

Table A4: Aspirin (English)

CODEINE (E)		
	NAME	**TYPE**
1	Codeine Phosphate	Tablets 8/400mg
2	Dispersible Co-codaparin	
3	Paradocol	Capsules 500mg/8mg
4	Paradocol	Tablets
5	Boots Aspirin and Codeine	Tablets
6	Aspirin and Codeine	Capsules 500mg
7	Solpadol	Capsules 500mg/30mg
8	Solpadol	Tablets 500mg/30mg
9	Paracetamol and Codeine	Caplets
10	Ibuprofen and Codeine	Tablets 12.8 mg
11	Paracetamol and Codeine Extra	Capsules
12	Migraleve Pink	Tablets
13	Migraleve Yellow	Tablets
14	Codipar	Effervescent Tablets 500mg/15mg
15	Solpadeine Plus	Tablets
16	Solpadeine Plus	Tablets
17	Solpadeine Plus	Capsules
18	Kapake	Tablets 500mg/15mg
19	Paracetamol and Codeine	Tablets
20	Codis 500	Tablets
21	Nurofen Plus	Tablets
22	Panadol Ultra	Tablets
23	Ibuprofen and Codeine	Tablets 200mg/ 12.8
24	Ibuprofen and Codeine	Tablets 12.8 mg

Table A5: Codeine (English)

NAPROXEN (F)		
	NAME	**TYPE**
1	Napratec	Tablets 500mg (Naproxen) 20mcg (Cytotec)
2	Naprozyn	Tablets 250mg/ 500mg
3	Naproxen	Tablets 250mg/ 500 mg
4	Naproxen Gastro-Resistant	Tablets 250mg/ 375mg/ 500mg
5	Feminax Ultra gstro-resistant	Tablets 250 mg
6	Period Pain Relief (Naproxen)	Tablets 250mg
7	Vimoxo (naproxen e esomeprazole)	Tablets 250mg (Naproxen) 20 mg esomeprazole

Table A6: Naproxen (English)

PARACETAMOL (A)		
	NAME	**TYPE**
1	Paracetamol	Solução Oral 200mg/ml
2	Paracetamol	Tablets 750mg
3	Paracetamol	Tablets 750mg
4	Paracetamol + Cafeína	Tablets 500mg/ 65mg
5	Paracetamol	Tablets 500mg/ 750mg
6	Paracetamol	Solução Oral 200mg/ml
7	Paracetamol	Solução Oral 200mg/ml
8	Paracetamol	Tablets 750mg
9	Paracetamol	Solução Oral 200mg/ml
10	Paracetamol	Solução Oral 200mg/ml
11	Paracetamol	Tablets 750mg
12	Paracetamol + Cloridrato de Pseudoefedrina	Tablets 500mg/30mg
13	Paracetamol	Tablets 750mg
14	Paracetamol	Solução Oral 200mg/ml
15	Paracetamol	Solução Oral 200mg/ml
16	Paracetamol	
17	Paracetamol	Solução Oral 200mg/ml
18	Paracetamol	Solução Oral 200mg/ml
19	Paracetamol	Tablets 750mg
20	Paracetamol	Solução Oral 200mg/ml
21	Paracetamol	Solução Oral 200mg/ml
22	Fervex	Pó para preparação extemporânea 500mg
23	Paracetamol + Cloridrato de Pseudoefedrina	Tablets 500mg/30mg

Table A7: Paracetamol (Portuguese)

DICLOFENACO (B)		
	NAME	**TYPE**
1	Cimed	Gel tópico
2	Sandoz	Drágeas
3	Diclofenaco Sódico	Comprimidos revestidos 50 MG
4	Neo Química Diclofenaco Sódico	Comprimidos revestidos 50 MG
5	diclofenaco dietilamônio	Aerosol
6	Neo Química Diclofenaco Sódico	Comprimidos revestidos 50 MG
7	Diclofenaco sódico	Solução injetável 75mg/3mL
8	diclofenaco dietilamônio	Gel dermatológico 11,6 mg/g
9	Still	Solução oftalmológica 5ml
10	Diclonenaco Dietilonômio	Gel Dermatológico 11,6 mg/g
11	Diclofenaco Sódico	100mg de comprimidos de desintegração lenta
12	Still	Solução oftalmológica 5ml (1,0mg/ g)
13	Diclofenaco Sódico	Injetável 75mg/3ml
14	Diclofenaco Sódico	Injetável 25mg/ 3ml
15	Diclofenaco Sódico	Tablets 50mg
16	Diclofenaco Sódico	Tablets 50mg
17	Diclofenaco potássio	Tablets 50mg
18	Diclofenaco Sódico	Tablets 50 mg
19	Diclofenaco Sódico	Ingetável 25mg/ml
20	Diclofenaco potássio	Tablets 50 mg
21	Diclofenaco potássio	Tablets 50 mg
22	Diclofenaco resinado	Suspensão oral 15mg/ml
23	Diclofenaco potássio	Tablets 50mg
24	Still	Solução oftalmológica 5ml

Table A8: Diclofenac (Portuguese)

IBUPROFENO (C)		
	NAME	**TYPE**
1	Ibuprofeno	50mg/ml
2	Ibuprofeno	Gotas 50mg/ ml
3	Ibuprofeno	Gotas 50mg/ ml
4	Ibuprofeno	Tablets 200mg
5	Ibuprofeno	Tablets 200mg
6	Ibuprofeno	Tablets
7	Ibuprofeno	100mg/ml
8	Ibuprofeno	100mg/ml
9	Ibuprofeno	Tablets 200mg

Table A9: Ubuprofen (Portuguese)

ASPIRIN (D)		
1	Aspirina Prevent	Tablets 100mg/ 300mg
2	Aspirina	Tablets 500mg
3	Aspirina C	400 mg AAS 240mg ácido ascorbico
CODEINE (E)		
1	Paracetamo + fosfáto de codeína	500mg + 30mg
2	Paracetamo + fosfáto de codeína	500mg + 30mg
3	Paracetamo + fosfáto de codeína	500mg + 30mg
NAPROXEN (F)		
	BRAND	**TYPE**
1	Naproxeno Sódico	Tablets 500mg
2	Naproxeno	Tablets 250mg/500mg

Table A10: Aspirin, Codeine and Naproxen (Portuguese)

APPENDIX 2 – ENGLISH PIL

Please read right through this leaflet before you start using this medicine.

Keep this leaflet, you may need to read it again.

If you have any questions, or if there is anything you do not understand, ask your pharmacist.

In this leaflet:

1. What Beechams Powder do

Bechams Powders provide relief from cold and flu symptoms, including sore throat pain, headache, feverishness and aches and pains. It also provides relief of mild to moderate pain including migraine, neuralgia, toothache, sore throat, period pain and rheumatic pain.

2. Check before you take Beechams Powders

Do not take:

- if you are allergic to **aspirin** or salicylates, **caffeine,** any other medicines known as **NSAIDs** or to any other ingredient (listed in Section 6).
- if you have had an allergic reaction after taking ibuprofen or aspirin.
- if you have had **asthma** or **shortness of breath** in response to **aspirin** before.
- if you suffer from high blood pressure or heart disease.
- if you have ever had **a stomach ulcer, perforation** or **bleeding of the stomach.**
- if you have **blood clotting disorders** (e.g. haemophilia) or have ever had **gout.**
- if you have **liver** or **kidney disease.**

Do not give to children under 16 years of age unless your doctor tells you to.

Take special care with Beechams Powders

- There is a possible association between aspirin and Reye's syndrome when given to children under 16 years. Reye's syndrome is a very rare disease which affects the brain and liver and can be fatal.
- Aspirin may cause bleeding. You must tell your doctor if you experience any unusual bleeding.
- Drinking alcohol at the same time as taking aspirin increases the risk of bleeding.
- Avoid excessive intake of caffeine (e.g. coffee, tea and some canned drinks) while taking this product.
- If you think you are dehydrated (you may feel thirsty with a dry mouth).

Ask your doctor before you take this medicine:

- if you suffer from **high blood pressure, asthma, allergic disease, kidney** or **liver problems.**
- if you are taking any prescribed medicines; particularly **methotrexate;** blood thinning drugs **(anticoagulants)** or blood pressure lowering treatments **(ACE inhibitors); oral hypoglycaemics** (to lower blood glucose) or medicines for treating **gout** such as **probenecid** or **sulfinpyrazone; ibuprofen** or other painkillers known as **NSAIDs** (e.g. **iclofenac**); **SSRI antidepressants** (such as **fluoxetine**); treatments for **epilepsy** (such as **phenytoin** or **valproate**); **beta-blockers** (e.g. **atenolol**); **acetazolamide**; if you are taking any water tablets **(diuretics)** or steroid hormones **(corticosteroids); antacids;** or have an intolerance to some sugars.

If you are pregnant or breast feeding

Do not take Beechams Powders if you are **pregnant** or **breast feeding,** except on medical advice.

3. How to take Beechams Powders

Mix the powder with a little water and stir before drinking.

Adults and children aged 16 years and over:

One powder every 3 to 4 hours as needed.

Do not take more than 6 powders in 24 hours.

Do not use for more than 10 days for pain relief (or more than 3 days for fever). If symptoms persist **see your doctor.**

If you take more than the recommended dose seek medical advice immediately

4. Possible side effects

Like all medicines, Beechams Powders can cause side effects, although not everybody gets them. **If you experience any of these effects then STOP taking this medicine immediately and contact your doctor or pharmacist:**

• Stomach ulceration or perforation: Symptoms could include severe abdominal pain, nausea and vomiting. People with sensitive stomachs may suffer stomach irritation and may experience bleeding (you may pass blood in your stools, or vomit blood or dark particles that look like coffee grounds).

• Severe allergic reactions: Symptoms could include difficulty breathing, skin rash or swollen facial features, or tightening of the chest or asthma attacks in those sensitive to aspirin.

• Occasionally the blood does not clot well, which may result in bruising or bleeding, or yellowing of the skin and eyes may occur. Other side effects may include lethargy, weakness, shortness of breath, and generalized swelling or water retention, ringing in your ears or temporary hearing loss.

• High caffeine intake can result in nervousness and dizziness.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Beechams Powders

Keep out of the sight and reach of children.

Do not use this medicine after the 'EXP' date shown on the pack. Store below 25°C in a dry place surely wrongly placed

6. Further information;

Active ingredients Each powder contains: Aspirin 600 mg and Caffeine 50 mg. **Other ingredients** Lactose, maize starch, colloidal anhydrous silica, sodium lauryl sulphate, saccharin sodium, sodium cyclamate and spice flavour.

Packs of Beechams Powders contain either 10 or 20 powders.

APPENDIX 3 – FIREWORKS

CANDELA ROMANA (1)

Instruções de segurança e utilização, caso contrário você poderá sofrer queimaduras.

- 1 é proibido soltar fogos em lugares fechados ou próximos a produtos inflamáveis ou explosivos.
- 2 Se o produto falhar, é obrigatório manter-se afastado pro no mínimo 20 minutos. Aproxime-se com cautela e jogue água com abundância para que não haja perigo de explosão. Não tente reacende-lo. Troque-o no local onde foi adquirido.

Instruções de uso:

- Retire o produto da embalagem;
- Segure na extremidade inferior;
- Acenda o iniciador pirotécnico e direcione para o alto;
- Solte esse produto no mínimo 50 metros de animais, edificações, veículos, marquises, explosivos ou inflamáveis;
- Solte somente ao ar livre;
- É proibido colocar qualquer parte do corpo em frente ao produto após acendimento.
- ATENÇÃO
- Após acendimento, sempre direcionar para o alto. Sendo assim não haverá queimaduras.
- ADVERTÊNCIA
- A empresa isenta-se de quaisquer responsabilidade por acidentes ocorridos do mau uso do produto e do não comprimento das instruções citadas na embalagem.

DENOMINAÇÃO GENÉRICA

Candela

EFEITO PRINCIPAL

Lançamento de baladas e/ou bombas aéreas, sem sequência 30 baladas.

ESTOCAGEM

Estocar em local seco, seguro, protegido do calor e fora do alcance das crianças.

CLASSE “B”

este produto só pode ser utilizado por pessoa maior de 16 anos, supervisionada por um maior de idade que não esteja EMBRIAGADO e que conheça o manuseio e o seu funcionamento.

NÃO DESMANCHE QUALQUER ARTEFATO PIROTÉCNICO. VOCÊ PODERÁ CAUSAR ACIDENTES COM SEQUELAS IRREVERSÍVEIS BEM COMO RISCO DE VIDA.

FOGUETE CHUVA DE PRATA (2)

INSTRUÇÕES DE SEGURANÇA E UTILIZAÇÃO: 01 – Verifique antes de soltar se o local e aberto ou ao ar livre. 02 – ao soltar fogos de artifício é obrigatório, manter-se a 10 metros de pessoas, casas, hospitais, rede elétrica, veículos, combustíveis, produtos inflamáveis, explosivos, etc. 03 – Não desmanche qualquer artefato pirotécnico. Você poderá causar acidentes com danos irreversíveis. 04 – Nunca aponte o artifício pirotécnico em direção ao corpo ou a outras pessoas. 05 – é proibida a venda unitária deste produto. 06 – siga corretamente as instruções, se não usado corretamente, pode provocar queimaduras. IMPORTANTE, ESTE PRODUTO PODE SER UTILIZADO POR PESSOA DE MENOR IDADE, SOB SUPERVISÃO DOS PAIS OU RESPONSÁVEIS, QUE CONHEÇA O MANUSEIO E SEU FUNCIONAMENTO. Modo de usar:

Retire a peça da caixa. -2. Segure a peça pelo cabo. 03 – Acenda a outra extremidade onde se encontra o incinerador pirotécnico e levante o braço para frente afastando do corpo. 04 – Caso o produto falhe ou não acenda, não reutilize-o, troque-o no local onde foi adquirido. IMPORTANTE: A EMPRESA NÃO SE RESPONSABILIZA POR ACIDENTES OCORRIDOS PELO MAU USO DO PRODUTO E DO NÃO CUMPRIMENTO DAS INSTRUÇÕES DE USO LISTADAS ACIMA.

1.4 EXPLOSIVO G 1 0336 EXPLOSIVO – PERIGO

FONTE (3)

INSTRUÇÕES DE SEGURANÇA E UTILIZAÇÃO

1. é proibido soltar em locais fechados, cobertos ou próximo a produtos inflamáveis ou explosivos.

2. Se o produto falhar, mantenha-se distante por no mínimo 120 segundos. Não tente reutilizá-la. Troque-o no local onde foi adquirido.
3. É obrigatório soltar fogos a 50 m de distancia de pessoas, casas, veículos e rede elétrica.
4. É proibida a venda unitária deste produto.

MODO DE SOLTAR

1. Colocar o produto em superfície plana e lisa.
2. Acender o estopim e afastar-se rapidamente do local.
3. É proibido colocar o corpo sobre o produto depois de aceso.
4. A empresa não se responsabiliza pelo uso incorreto do produto.

ATENÇÃO

ACONSELHÁVEL PARA MAIORES DE 12 ANOS SOB SUPERVISÃO DOS PAIS OU RESPONSÁVEIS.

EFEITO PRINCIPAL

EMISSÃO DE CENTELHAS E CHAMAS COLORIDAS.

ATENÇÃO! DESMANCHAR FOGOS PODE CAUSAR QUEIMADURAS.

ESTOCAGEM

Em local seco, seguro, protegido do calor, fogo e fora do alcance de crianças.

APITO COM VARA (4)

INSTRUÇÕES DE UTILIZAÇÃO E SEGURANÇA

1 – Verifique se o local é adequado, sendo ao ar livre, não tendo fios elétricos, marquises ou arvores que impeçam a livre trajetória do produto.

2 – Nunca se posicione sobre o produto depois de acender.

3- Caso o produto falhar ou não acender, aguarde 30 segundos e não tente reutilizá-lo. Troque-o no local adquirido.

4 – Proibido soltar próximo aos produtos inflamáveis, residenciais, veículos e hospitais.

5 – Venda proibida a pessoas alcoolizadas e menores de 18 anos.

INSTRUÇÕES DE USO

1 – retire o apito da embalagem;

2 – coloque o produto dentro de uma garrafa de vidro;

3– acenda o iniciador pirotécnico (estopim) e afaste-se rapidamente do local;

4 – repita o procedimento om os outros apitos (veja o desenho ao lado)

USO PERMITIDO

Este produto pode ser utilizado por pessoa maior de 18 anos que não esteja embriagado (sic) e que conheça o manuseio e seu funcionamento.

ESTOCAGEM: EM LOCAL SECO, SEGURO, PROTEGIDO DO CALOR E DO FOGO.

FOGOS DE ARTIFÍCIO – DENOMINAÇÃO GENÉRICA – ROJÃO – CLASSE: D – PAÍS DE ORIGEM: BRASIL

APPENDIX 4A – ANVISA GUIDELINES (HAIR DYES)

ANEXO V

REGULAMENTO TÉCNICO SOBRE ROTULAGEM ESPECÍFICA PARA PRODUTOS DE HIGIENE PESSOAL, COSMÉTICOS E PERFUMES

c) AGENTES CLAREADORES DE CABELOS E TINTURAS CAPILARES:

1 Pode causar reação alérgica. Fazer a Prova de Toque (descrever);

2 Não usar nos cílios e sobrancelhas;

3 Não aplicar se o couro cabeludo estiver irritado ou lesionado;

4 Em caso de contato com os olhos, lavar com água em abundância;

5 Manter fora do alcance das crianças.

d) TINTURAS CAPILARES COM ACETATO DE CHUMBO:

1 Não aplicar se o couro cabeludo estiver irritado ou lesionado;

2 O uso inadequado pode provocar intoxicação por absorção de chumbo;

3 Aplicar somente no couro cabeludo (cabelos);

4 Depois do uso, lavar as mãos com água em abundância para evitar a ingestão acidental;

5 Manter fora do alcance das crianças.

ANEXO VI

OUTRAS OBRIGATORIEDADES EXIGIDAS PELOS DECRETOS 79.094/77 E 83.239/79

7.1 AGENTES CLAREADORES DE CABELOS E TINTURAS CAPILARES: Os rótulos das tinturas e dos agentes clareadores de cabelos que contenham substâncias capazes de produzir intoxicações agudas ou crônicas deverão conter as advertências: "CUIDADO. Contém substâncias passíveis de causar irritação na pele de determinadas pessoas. Antes de usar, faça a prova de toque" (Art.107-Decreto 79.094/77).

APPENDIX 4B – WARNINGS (HAIR DYES)

PRODUCT A

SIDE OF THE PACKAGE

ADVERTÊNCIAS: Somente para uso profissional; Contém: Fenilenodiaminas, resorcinol, amoníaco, 1-naphilol, Diamindenois; "CUIDADO: Contém substâncias passíveis de causar inflamação na pele de determinadas pessoas"; "Antes de usar, faça a prova do toque". (art. 107 –decreto 79094/77). Aplicar uma pequena quantidade do produto preparado na pele de trás da orelha ou do antebraço. Aguardar o tempo de ação e enxaguar. Se após 48 horas não existirem sinais de irritação ou vermelhidão, o produto poderá ser aplicado; Não utilizar para pintar cílios ou sobrancelhas; Utilize luvas apropriadas; Evitar o contato com os olhos. Se isto acontecer, enxaguar com água em abundância imediatamente; Enxague bem o cabelo depois da aplicação; Não utilizar em cabelos previamente pintados com hena ou tintas metálicas; Utilize a pintura diretamente; Não utilizar restos de misturas de tinta, e lave o recipiente imediatamente depois da aplicação; Nunca guarde a mistura em recipientes fechados (risco de explosão ou rachadura). Mantenha fora de alcance das crianças. Não aplicar se o couro cabeludo estiver irritado ou lesionado.

BACK OF THE PACKAGE

Advertência: Os pigmentos de tintura para cabelo podem causar reações alérgicas graves. Leia e siga as instruções: Este produto não é destinado para menores de 16 anos. Tatuagens temporárias de "hena preta" (com adição de PPD – parafenilenodiamina) podem aumentar o risco de alergia. Instruções de uso: Não aplicar no cabelo se: você possuir erupções ou inflamações na pelo do rosto, ou se o couro cabeludo estiver sensibilizado, irritado ou danificado. Você já teve alguma reação após tingir seu cabelo. Você já teve reação após aplicação de tatuagem temporária de "henna preta". Para segurança, um teste de sensibilidade deve ser realizado 48 horas antes de seu uso. Em caso de contato do produto com os olhos, lave-os imediatamente. Use luvas adequadas para manipulação e aplicação do produto. Produto de uso exclusivamente profissional.

LEAFLET

Instruções de segurança

- Advertência: Os pigmentos de coloração para cabelo podem causar reações alérgicas graves.
- Leia e siga as instruções.

• Este produto não é destinado para menores de 16 anos.
•Tatuagens temporárias de “hena preta” (hena com adição de PPD – parafenilenodiamina) podem aumentar o risco de alergia.

Instruções de uso: Não aplicar no cabelo se o cliente:

• Possui erupções ou inflamações na pele do rosto ou se o couro cabeludo estiver sensibilizado, irritado ou danificado.
• Já teve alguma reação alérgica após tingir os cabelos.
• Já teve alguma reação após aplicação da tatuagem de “hena preta”.
• Somente para uso profissional.
• Contém fenilenodiaminas (toluenodiaminas) resorcinol e amônia.
• Um teste de sensibilidade deve ser feito 48 horas antes do uso.
• Teste de sensibilidade: aplicar uma pequena quantidade do produto (não misturado) em uma pequena porção de pele atrás da orelha (não enxágue). Se depois de 48 horas não houver sinal de irritação ou manchas vermelhas, o produto dever ser aplicado.
• Se durante a coloração a cliente apresentar:
- Irritação ou queimação e/ou erupções, enxágue imediatamente e pare de usar o produto, pois isto pode indicar uma reação mais grave. Não aplicar a coloração novamente e aconselhe a cliente a buscar ajuda médica.
- Erupções que se espalham rapidamente, tontura ou desfalecimento, falta de ar ou inchaço nos olhos/ rosto, enxágue imediatamente. Aconselhe a cliente procurar um médico imediatamente e entre em contato com o fabricante.
• Se logo após a coloração ou nos dias seguintes a cliente apresentar coceiras e erupções, bolhas e/ou secreções na pele/ couro cabeludo, inchaço nos olhos/ rosto Aconselhe a cliente procurar um médico imediatamente e entre em contato com o fabricante.
• Use luvas adequadas para a manipulação e aplicação do produto.
• Não aplique a coloração nos cílios e sobrancelhas.
• Mantenha longe dos olhos. Se o produto entrar em contato com os olhos, lave-os imediatamente.
• Enxágue bem o cabelo após a aplicação.
• Não use o produto se o cabelo tiver sido colorido com hena ou com produtos que contenham metal.

- Tire todos os produtos de metal do cabelo. Não use ferramentas de metal.
- Aplique a mistura diretamente. Não reutilize a sobra da mistura, jogue-a fora imediatamente após o uso. Nunca deixe a mistura em uma embalagem fechada (a embalagem pode expandir ou explodir).
- Mantenha fora do alcance das crianças.
- Não uso tons naturais junto com a tinta 7.44.
- Não use tons das séries Special Blonde e Super Ash Blonde em cabelos descoloridos ou brancos.

PRODUCT B
SIDE OF THE PACKAGE

Contém amônia. Pode conter: Diaminotoluenos, rersocinol, e Fenilenodiaminas; Advertências: Os corantes capilares podem provocar reações alérgicas graves. Recomenda-se uma prova preliminar de sensibilidade/ prova de toque. Não utilizar em menores de 16 anos; As tatuagens temporárias de "hena negra" podem aumentar o risco de alergias; Não aplicar se tive erupção cutânea na face ou apresentar o couro cabeludo sensível, irritado ou lesionado; Não aplicar se alguma vez apresentou alguma reação alérgica após pintar os cabelos ou após fazer uma tatuagem temporária com "hena negra"; Não usar para tingir cílios ou sobrancelhas; Em caso de contato com os olhos lavar imediatamente com água em abundância e procurar um médico; Para proporção da mistura seguir as instruções de uso; Utilizar luvas adequadas; Manter fora do alcance das crianças; Não se recomenda o uso em gestantes; Cuidado: Contém substâncias passíveis de causar irritação na pele de determinadas pessoas. Antes de usar fazer a Prova de Toque. Modo de uso, prova de toque e demais informações: Vide verso do cartucho. SÓ PARA USO PROFISSIONAL.

INSIDE THE PACKAGE

Advertências: Os corantes capilares podem provocar reações alérgicas graves. Recomenda-se uma prova preliminar de sensibilidade/ prova de toque.

Não utilizar em menores de 16 anos; As tatuagens temporárias de "hena negra" podem aumentar o risco de alergias; Não aplicar se tive erupção cutânea na face ou apresentar o couro cabeludo sensível, irritado ou lesionado; Não aplicar se alguma vez apresentou alguma reação alérgica após pintar os cabelos ou após fazer uma tatuagem temporária com "hena negra"; Não usar para tingir cílios ou

sobrancelhas; Em caso de contato com os olhos lavar imediatamente com água em abundância e procurar um médico; Para proporção da mistura seguir as instruções de uso; Utilizar luvas adequadas; Manter fora do alcance das crianças; Não se recomenda o uso em gestantes; CUIDADO: Contém substâncias passíveis de causar irritação na pele de determinadas pessoas. Antes de usar fazer a Prova de Toque. Prova de Toque Limpar bem com álcool uma parte da pele na dobra do braço. Aplicar na área preparada uma pequena quantidade de Evolution of the Color misturado com Alfaparf água oxigenada. Após aproximadamente 20 minutos, retirar o excesso e cobrir a pele com esparadrapo ou bandaid. Aguardar 48 horas sem lavar. Se após este período não apresentar irritação, vermelhidão, coceira, inchaço ou queimação na área onde o produto foi aplicado, ou em outras áreas do corpo, o produto poderá ser utilizado. SÓ PARA USO PROFISSIONAL.

PRODUCT C
SIDE OF THE PACKAGE
PRECAUÇÕES DE USO

IMPORTANTE: AS COLORAÇÕES PODEM PROVOCAR UMA REAÇÃO ALERGICA QUE, EM ALGUNS CASOS, AINDA QUE RAROS, PODE SER GRAVE. É OBRIGATÓRIO EM TODOS OS CASOS FAZER UMA PROVA DE TOQUE (TESTE DE ALERGIA CUTÂNEA), IMPRETERIVELMENTE 48HORAS ANTES DE CADA UTILIZAÇÃO DESTRE PRODUCTO (VER FOLHETO EXPLICATIVO).

• NÃO UTILIZE SE:
- Já apresentou alguma reação alérgica a um produto de coloração.
- Seu couro cabeludo está irritado ou lesionado.

• TATUAGEM HENA PRETA:
- Se você já fez, mesmo que uma única vez, uma tatuagem de hena preta, provavelmente você corre o risco de ter se tornado alérgico sem saber. Não use este produto se fazer a prova de toque (teste de alergia cutânea) 48 horas antes de cada aplicação deste produto.

PENSE EM COMPRAR ESTE PRODUTO DE COLORAÇÃO COM ANTECEDÊNCIA PARA FAZER A PROVA DE TOQUE (TESTE DE ALERGIA CUTÂNEA) 48 HORAS ANTES DO USO.

• O Revelador contém peróxido de hidrogênio (água oxigenada);
• O produto colorante contém amônia, Fenilenodiaminas e resorcinol;

- Evitar o contato do produto com a pele e os olhos, não utilizar para a coloração de cílios e sobrancelhas. Não seguir estas instruções pode levar à cegueira;
- Se o produto entrar em contato com os olhos lave com água em abundância;
- Usar as luvas apropriadas fornecidas na embalagem;
- Enxaguar bem os cabelos após a aplicação;
- Não utilizar em cabelos defrisados ou imediatamente após uma descoloração ou permanente;
- Não utilizar se os seus cabelos foram pintados com henê ou com uma coloração progressiva ou à base de sais metálicos;
- Manter fora do alcance das crianças. Não utilizar em crianças;
- CUIDADO: contém substâncias passíveis de causar irritação na pele de determinadas pessoas.

SIGA AS INSTRUÇÕES E PRECAUÇÕES DE USO DO FOLHETO EXPLICATIVO

LEAFLET
PRECAUÇÕES DE USO – LEIA ANTES DE UTILIZAR O PRODUTO

PROVA DE TOQUE (TESTE DE ALERGIA CUTÂNEA): REALIZAR IMPRETERIVELMENTE 48 HORAS ANTES DE CADA APLICAÇÃO. MESMO SE VOCÊ JÁ UTILIZOU ANTERIORMENTE UM PRODUTO DE COLORAÇÃO DE IMÉDIA EXCELLENCE OU DE OUTRA MARCA.

PROVA DE TOQUE (TESTE DE ALERGIA CUTÂNEA)
IMPORTANTE: AS COLORAÇÕES PODEM PROVOCAR UMA REAÇÃO ALERGICA QUE, EM ALGUNS CASOS, AINDA QUE RAROS, PODE SER GRAVE. PARA AJUDAR VOCÊ A PREVENIR O RISO DE REAÇÕES ALÉRGICAS, É INDISPENSÁVEL SEGUIR AS SEGUINTES PRECAUÇÕES:

- NÃO UTILIZE SE:
  - Já apresentou alguma reação alérgica a um produto de coloração.
  - Seu couro cabeludo está irritado ou lesionado.

• TATUAGEM HENA PRETA:
- Se você já fez, mesmo que uma única vez, uma tatuagem de hena preta, provavelmente você corre o risco de ter se tornado alérgico sem saber. Não use este produto se fazer a prova de toque (teste de alergia cutânea) 48 horas antes de cada aplicação deste produto.

FAZER EM TODOS OS CASOS, UMA PROVA DE TOQUE (TESTE DE ALERGIA CUTÂNEA), IMPRETERIVELMENTE 48 HORAS ANTES DE CADA UTILIZAÇÃO DESTE PRODUTO. AS ALERGIAS PODEM APARECER DE REPENTE, MESMO QUE VOCÊ JÁ TENHA USADO ANTERIORMENTE UM PRODUTO DE COLORAÇÃO DESTA OU DE OUTRA MARCA.

REALIZAÇÃO DA PROVA DE TOQUE (TESTE DE ALERGIA CUTÂNEA):

• Retire os brincos, aplicar atrás da orelha com o auxílio de um cotonete o suficiente do produto colorante não misturado (tubo de creme colorante C), para cobrir uma área de 1cm². Reaplicar duas ou três vezes, deixando secar a cada intervalo. Fechar cuidadosamente o produto colorante.
• Espere 48h sem lavar, nem cobrir ou tocar o local. Se no decorrer deste período você constatar reações anormais tais como coceira, vermelhidão ou inchaço na zona testada ou em volta dela, NÃO FAÇA A SUA COLORAÇÃO.

PRECAUÇÕES PARTICULARES

EM CASO DE REAÇÃO DURANTE A APLICAÇÃO tal como formigamentos intensos, irritações, empolamento, sensação de ardência do couro cabeludo, enxágue imediatamente, com água e suspenda o uso. Em caso de dificuldade para respirar, peça imediatamente assistência médica. Antes de refazer uma coloração, consulte um médico.

• Evitar contato do produto com a pele e os olhos, não utilizar para coloração dos cílios e das sobrancelhas. Não seguir estas instruções pode levar à cegueira;
• Enxaguar imediatamente os olhos se o produto entrar em contato com os eles. Se você usa lentes de contato, retire-as antes de enxaguar abundantemente os olhos com água;
• Usar as luvas apropriadas fornecidas na embalagem;
• Enxaguar bem os cabelos após a aplicação;

- Preparar e aplicar a mistura de preferencia em um ambiente bem arejado;
- Não inalar ou ingerir;
- Para questões relativas à sua sensibilidade pessoal, consulte seu médico;
- Não utilizar sobre a barba ou bigode ou para qualquer outro uso que não seja a coloração dos cabelos;
- Espere 15 dias após uma defrisagem ou permanente para aplicar a coloração;
- No caso das nuances 4.6, 6.66, 10 e 10.1: Não utilizar em cabelos defrisados ou imediatamente após a coloração ou permanente. Esperar 15 dias após a descoloração ou permanente para aplicar a coloração;
- Não aplicar se os cabelos foram pintados com henê ou com uma coloração progressiva ou à base de sais metálicos;
- Manter fora do alcance de crianças. Não utilizar em crianças;
- CUIDADO: Contém substâncias passíveis de causar irritação na pele de determinadas pessoas.

PARA A UTILIZAÇÃO, RESPEITAR AS INSTRUÇÕES DE USO.