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Medicinal Warning Conditionals: A study of the language and structure of contraindication information in medicine packaging

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Medicinal Warning Conditionals

A study of the language and structure of contraindication information in medicine packaging

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MA Thesis: Translation in Theory and Practice

University of Leiden

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1. Introduction and Theoretical Framework

1.1 Topic Description

My research question relates to the use of conditionals in the warning paragraph of medicinal contraindications in a patient information leaflet (PIL), which is also called the Package Leaflet (PL), and whether aspects of the language used can be identified as a potential likely source of anxiety for patients with prescription medicines.

This study will therefore focus on paragraph 2 of Dutch PILs (each PIL paragraph number has a predefined content as required by the European Medicines Agency (EMA)) which relates to contraindications and the conditions under which the patient should *not* take the medicine or *be extra careful* with it. The PIL paragraph 2 contains information which is intended as a warning to the patient as to when to be *especially careful* and when not to use the medicine. In further limiting the research to that subsection of paragraph 2 of a PIL which deals exclusively with *when not to take the medicine* the research focuses not only on the structure and content of the conditionals, but also on their use in an entirely negative context.

The language of PILs in medicines placed on the market in Europe (and authorized by the EMA) has been widely studied from the point of view of readability (Askehave and Zethsen, 2000; Nisbeth Jensen et al., 2012; Lentz and Maat, 2010). The specialized medical and pharmaceutical information from the Summary of Product Characteristics (SmPC) document needs to be reformulated for use in the PIL. The reformulated information of the SmPC is made understandable for the patient and other healthcare professionals in the PIL.

It is possible to consider a PIL as being similar to an operating or instruction manual for a piece of electronic or mechanical equipment: it can be read from beginning to end, but it can also be read an arbitrary section at a time without the need to know or have read a preceding section. Each paragraph of the PIL contains specific information and instructions about a particular point, for example, on what the medicine is and how it is to be used, warnings, possible side-effects, and who the producer is. Some researchers have noted that PILs should be considered as a separate genre altogether (García & Ruiz, n.d.) (Hill-Madsen, 2019) (Grön et al., 2018).

An EU-funded study NIVEL (2014) was influential in raising awareness of the problems pointed out in the literature (Ge-Bu, 2017; MEB, 2021) and providing drafting guidance for future improvement of patient information leaflets.

1.2 Description of the Problem and the Research Question

Certain PIL information has been reported to cause *fear and anxiety* in patients and this has subsequently affected their adherence intentions (Herber et al., 2014). Herber et al. (2014) concluded that "PILs contained too much risk information which was conveyed in a way that led to reduced patient compliance" (p. 5) and they also concluded that "PILs need to convey potential risk information in a language that is less frightening" (p7). In a further participant-based study it was found that the *use of negations* in Dutch PILs was detrimental to patient actual and subjective comprehension as well as their medical adherence intentions (Burgers et al., 2015); the authors concluded that "PIL designers should refrain from using negations as much as possible."

The use of conditionals is a known source of difficulty in text comprehension (Wason, 1968). This has been attributed (Braine & O'Brien, 1991) to the misinterpretation of a conditional statement: people often interpret a conditional as including the biconditional of that statement (i.e., "*if P then Q*" also includes "*if Q then P*"). This is made even more difficult if the initial conditional statement is of the form "*if P then possibly Q*" (Johnson-Laird & Byrne, 2002) as is often the case in the wording of PILs regarding side-effects. The reasons why people make incorrect conditional inferences, however, is a topic of ongoing research (Rader & Sloutsky, 2002; Howarth et al., 2016).

1.3 Theoretical and Societal Relevance of Answering the Question

This study seeks to contribute to an understanding of a potential source of the attested anxiety when reading PILs, which may lie in the use of conditionals, either alone or together with negations in PILs. I investigate the structure and linguistic content of conditional phrases in PILs to determine lexical characteristics and those characteristics which may be a source of confusion or comprehension difficulty (and therefore also contributing to anxiety). The layout of a Package Leaflet (i.e., the PIL) is prescribed by the EMA and paragraphs 2 and 4 relate to the contraindications and potential side-effects respectively (EMA, 2022, pp 24-27). Whilst the use of conditional constructions is not necessarily limited to paragraph 2 of the PIL, we know by the EMA defined descriptive content which is required of this paragraph (i.e. entitled "What you

need to know before you receive/are given X" with the first subparagraph entitled "You must not receive/be given X" where X refers to the medicine), that it must contain the use of at least one conditional and quite possibly more than one. In the case of all medicines, there are a number of conditions of which the patient must be informed prior to the medicine being considered safe to take. These conditions in a PIL are structured in the form of a conditional phrase and are of particular interest due to their importance: these conditional constructions give arguably the most important information in the PIL about the medicine in terms of its danger and risk to the patient under certain circumstances.

The theoretical relevance of an insight here is that this could lead to further research into the anxiety producing aspects of similar type conditional constructions. The societal relevance of insight here would be to provide an impetus for healthcare professionals to assist in raising patient awareness of the problematic aspect of presentation of contraindications. It may also provide motivation to drug companies and national healthcare administrators to modify the language and structure of these conditional constructions.

1.4 Description of the Structure of the Thesis

My thesis uses a corpus-based approach to determine linguistic aspects within the structure and content of medicinal warning conditionals that are likely to result in anxiety-producing comprehension difficulties. After determining these linguistic aspects, I check for the use of similar type PIL paragraph 2 conditionals on Dutch websites to compare these with the use in general language.

1.4.1 Investigation of the Linguistic Aspects

I set out to investigate three aspects of medicinal warning conditionals:

(1) Clause order

The order of antecedent (protasis, *P*) and consequent (apodosis, *Q*) in a conditional phrase has been previously investigated (Dancygier & Sweetser, 2009; Diessel, 2005) and observations made by these authors appear relevant in assessing any variations to standard formulations. Diessel (2005) has noted that semantic forces indicate that conditional adverbial clauses (antecedents) occur sentence–initially: using

the "*if P then Q"* form. This tendency is so strong that sentence-final adverbial clauses in a conditional require "a particular explanation", since the reader or hearer may be inclined to interpret the initial main clause "as a factual statement", which was intended as an hypothesis. Intonation or other linguistic means are used in the main clause to signal the occurrence of a sentence-final adverbial clause.

At first sight, the clause order used in PIL paragraph 2 appears to be that of multiple unrelated independent sentence antecedents with ellipses of the consequents. In this case the antecedents appear to qualify as either free-standing (Dancygier & Sweetser, 2005, pp. 263-266), stacked-P (Declerck & Reed, 2012, pp. 372-374), covert-Q (Declerck & Reed, 2012, pp. 383-386) or insubordinate (Evans, 2007). This presents an obstacle to reliably classifying or annotating the conditionals as it would appear, for the large part, that the consequent is missing, due to the use of ellipses.

It seems that these (mainly) disjunctive antecedent *if*-clauses use an OR functionality, which is marked by sequential listing of multiple conditions using a semicolon or a new line without punctuation or a full stop. This type of clause order would lead to an imbalance or asymmetry between the main and *if*-clause in terms of numbers of words and this might appear to disproportionately emphasize or overcomplicate the *if*-clause part of the conditional phrase. The ratio of antecedent content to consequent content is of interest here as this may also indicate as source or comprehension difficulty leading to anxiety, even more so if the main clauses are elided.

(2) Type of Language Used

The lexical diversity of the conditional phrase is investigated where unique or multiple occurrences of the same word (type-token ratio (TTR)) in the conditional phrase is determined; higher TTR values have been shown to correspond to more difficulty in reading and longer reading times. I also investigate the characteristics of the language of paragraph 2 with respect to the other paragraphs of the same PIL and whether it was possible to identify any lexical aspects which are key to this paragraph.

(3) Negation in the Conditional

I investigate the presence of negation in the main or *if*-clauses, (Burgers et al., 2015). In addition to the presence of any explicit lexical negation in the PIL, the presence of a counterfactual condition in the antecedent is also investigated. Counterfactual conditionals (CTFs) refer to conditional constructions, in which the antecedent "is interpreted to be 'contrary to fact'" (Declerck and Reed 2001, p. 13). This is important, because the PIL conditionals at first sight also appear to be constructed to use CTFs.

1.4.2 A Check for the Use of Similar Type Conditionals

Here I set out to check the use of conditional constructions on the internet; where they were formulated in a similar way to those found in PIL paragraph 2. I do this by looking for similar conditional constructions in Dutch websites using the Sketch Engine corpus analysis tool; using a database derived from Dutch website content (Kilgarriff et al., 2014). I focus on the aspect of clause order during this search.

1.5 Related Research

In research related to the interpretation of conditionals, the literature mentions two models: that of Possible Worlds (PW) and that of Mental Spaces (MS). Appreciation of the context in which conditionals arise is vital for any comment as to impact and meaning. Here, I focus on the use of Mental Spaces Theory (MST) (Dancygier & Sweetser, 2009) to investigate the semantics of the conditionals and causal or predictive constructions of the conjunctions. The use of MST is preferred since the semantics of Possible Worlds has been evaluated as psychologically implausible (Johnson-Laird & Ragni, 2019).

In a corpus-based study related to the use of conditionals in English in medical research articles, journal editorials, and doctor-patient consultations (Ferguson, 2001). Ferguson (2001) found that regarding surveys in the editorials "(…) there is a frequent use of conditional protases to qualify the scope of recommendations, to modulate predictions or prognostications, and to present cautious generalisations" (Ferguson, 2001, p. 80).

In contrast to lexical diversity, readability has been studied in a medical corpus of patient radiography information by examining the use of lexical bundles (Richards Golini, 2022). Similarly, collocation frequencies have been used as a readability measure (Anagnostou & Weir, 2006) in a general context. This approach to readability (i.e. the use of collocation frequencies or

lexical bundles) appears to resemble the determination of keyness values. The researchers appear to use a keyness criterion (related to the frequency of collocations) to establish a general readability criterion which might well be applicable to PILs.

1.6 Summary

In this chapter I introduced the topic of my research question and that finding a solution is relevant since it would provide an insight into the linguistic aspects of contraindication information in a PIL which are particularly troubling or difficult to process for a patient. I mentioned that I solve the question by investigating the aspects of clause order, type of language used, and negation in paragraph 2 of Dutch PILs. Finally I mention that my study included the search for similar conditional constructions on Dutch internet websites.

2. Methodology

2.1 Initial Considerations

In order to answer the question of which aspects of the conditionals used in Dutch PILs can be seen as a potential source of anxiety for patients with prescription medicines, I analyzed the language and structure of the conditionals occurring in a particular section of paragraph 2 of Dutch PILs. I used a sampled selection of the PIL documents from the currently authorized medicines in The Netherlands to perform the analysis. I broke the research question down into three subsections related to the PIL conditionals:

1. **aspects of clause order**
2. **aspects of language type**
3. **aspects of negation**

By linking the language and structure of these conditionals to known psychological responses I developed an insight into aspects that are likely to produce anxiety for a patient.

2.1.1 Guidelines for the Content and Structure of the PIL

According to the guidelines EMA (2022), paragraph 2 of the PIL should contain all appropriate warnings as to the following categories:

- Contraindications
- Appropriate precautions for use; special warnings
- Interactions with other medicines
- Interactions with food and drink
- Use by pregnant or breast-feeding women, information on fertility
- Effects on the ability to drive or to use machines
- Excipients warnings

The general observable structure of paragraph 2 in Dutch PILs is shown in the table below (emphasis added):

Table 1

An example of the structure of paragraph 2 of a Dutch PIL

2.	WANNEER MAG U DIT MIDDEL **NIET** GEBRUIKEN OF MOET U **ER EXTRA VOORZICHTIG** MEE ZIJN?	

	Wanneer mag u dit medicijn/middel **niet** gebruiken/innemen?	
	als u..., als u...heeft, wanneer u... u bent.. u heeft..	
	Wanneer moet u **extra voorzichtig** zijn met dit medicijn/middel?	
	als u...., als u... wanneer u...	
	Gebruikt u nog andere geneesmiddelen?	
	... Als … wordt gebruikt samen met geneesmiddelen die...	
	Zwangerschap, borstvoeding en vruchtbaarheid	
	... Als u een vrouw bent...	
	Rijvaardigheid en het gebruik van machines	
	... Rij niet en gebruik geen machines als u last heeft...	

Within paragraph 2 of each PIL, the subparagraph related to negation (when not to take or be given the medicine) was selected for analysis. This section corresponds to the top part of paragraph 2, as indicated by the left and right arrows in the above table. This section is highlighted here as part of the methodology as the selection of this part of the paragraph ensures that the focus is directed towards all aspects of the research question.

2.2 The Selected Texts

The URLs for the random sample of 17 PILs selected are provided in the list of Appendix B and the PIL number and medicine name is shown in the table below:

Table 2

The selected PIL numbers, medicine names and indication of use

	PIL number	Name in The Netherlands	Use
1	H128830.pdf	Nalador-500 (sulproston)	to induce a medical abortion
2	H123401.pdf	Dostinex (cabergoline)	to treat overproduction of hormone prolactin
3	H127621.pdf	Vesanoid (tretinoïne)	to treat acute promyelocytic leukemia
4	H118758.pdf	Bendamustine HCl Glenmark	to treat certain types of cancer

		(Bendamustinehydrochloride)	
5	H118136.pdf	Metoprololtartraat Aurobindo (metoprololtartraat)	to treat high blood pressure, cardiac cramp, arrhythmia and migraine
6	H116661.pdf	TRANYLCYPROMINE MILSTEIN (Tranylcyprominesulfaat)	to treat depression
7	H115752.pdf	Tracydal (Tranylcypromine)	to treat depression
8	H115266.pdf	Pulentia (budesonide/formoterolfumaraatdihydraat	inhaler to treat adult asthma
9	H114885.pdf	Selokeen ZOC 100 (metoprololsuccinaat)	as a selective beta-blocker
10	H109939.pdf	Drospirenon/Ethinylestradiol (ethinylestradiol/drospirenon)	as a contraceptive
11	H09355.pdf	Parlodel (bromocriptinemesilaat)	to lower the hormone Prolactin, also used for Parkinson's disease
12	H57689.pdf	AdreView, iobenguane injection (jobenguaan)	in body scan to diagnose/identify disease, tumors and heart function
13	H34406.pdf	Fluvastatine Sandoz (fluvastatine)	to treat high blood cholesterol levels in adults
14	H30130.pdf	Metoprololsuccinaat 1A Pharma (metoprololsuccinaat)	as a beta-blocker
15	H18718.pdf	Geïnactiveerd Rabiësvaccin Mérieux HDCV (geïnactiveerd rabiësvirus)	to vaccinate against rabies
16	H26283.pdf	Gemfibrozil Aurobindo (gemfibrozil)	to lower the level of fat (lipids) in blood
17	H28924.pdf	Paroxetine Mylan (paroxetine)	antidepressant (SSRI) for adults

2.3 Problematic Aspects of Annotation

Since conditionals are difficult to reliably classify in general (e.g. given the temporal and/or conditional use of the connectives used (see paragraph 2.3.1 below on “als” and “wanneer”)), but even more so if the syntactic structure uses ellipses, I considered it too onerous to use annotation and opted for manual analysis. Thus, I considered that it was not appropriate for the purposes of corpus exploration or identification of conditionals to use tokenization, lemmatization or tagging.

Another reason not to use annotation in the corpus is that I anticipated certain PILs would contain paragraphs which *do not use* any of the conventional forms of conditional conjunctive but rather reformulate the conditional connective in the PIL by using implicature or other narrative devices (e.g., when should you not use this medicine: you are pregnant, you have high blood pressure, you are taking other medication, etc.). The use of this type of implied conditional (i.e., with omitted conjunctive or other “unconventional” structure) was intended to be part of the conditionals studied here and therefore much more difficult, if not impossible, to detect with the use of annotation.

2.3.1 A Remark About “wanneer” and “als” in Dutch

It is important to note that the conjunctions “wanneer” and “als” (the main ones relevant to this research) can have a temporal significance which is non-conditional depending on how these words are used (Reuneker, 2022, pp. 184-191). It has been pointed out that the use of English “when” and “if” does not entirely correspond to Dutch uses of “wanneer” and “als” on the *temporal-conditional continuum*. Whilst “als” may be used over the entire continuum, that is for a conditional and an entirely temporal meaning, the range of “wanneer” is more restricted, the use being primarily temporal but still extending part ways over the conditional part (Reuneker, 2022, p. 325).

Furthermore, “als” in Dutch, in addition to having a comparative use, can also be used “as a conjunction of manner, a conjunction of qualification (or ‘state of being’), a temporal conjunction, and, finally, a conditional conjunction” (Reuneker, 2022, p. 185). Whilst “wanneer” may be either temporal or conditional, its use as a conditional is deemed to be more formal than that of “als” (if) (Reuneker, 2022, p. 190). Following this, we might expect the use of “wanneer” as a conditional in the warning paragraph of a PIL as this is a formal aspect of information to be

given to the prospective patient. The significance of this information here regarding “als” and “wanneer” is to additionally require that I confirm the use as conditional and not temporal. There are also conjunctions in Dutch such as “tijdens” (during), which are clearly temporal, but which may also have a conditional meaning depending on the context.

2.4 Analysis Methods of the Selected PILs

To be able to carry out the investigation mentioned in the introduction I set out an approach as to how to investigate:

1. clause order (manually)
2. type of language used (computer: lexical diversity, keyness)
3. negation in the conditional (manually)

Initially considered the extent to which it was possible to perform all these tasks by systematic search (of annotated texts) and text manipulation using a corpus analysis tool or computer programming. Whilst the PIL documents themselves and the corresponding paragraph 2 of each PIL could be obtained by computer programming (Python), it was considered inappropriate to automate much of the other investigation aspects:

> Investigating *clause order* required identification of antecedent and consequent of a conditional phrase and this was unduly time-consuming to set up for machine processing and therefore most appropriate to perform manually.
>
> Investigation of the *type of language* used in a PIL paragraph 2 entailed determining a lexical diversity measure of the paragraph (e.g. using the type-token ratio (TTR)) and performing a keyness evaluation both of which are readily done by computer programming.
>
> Investigating aspects of *negation* for the reasons given above with regard to *clause order*, were most appropriately performed manually.

Therefore, two out of the three aspects for this research necessitated manual analysis: clause order and structural aspects and negation (1, 3). Only one of the aspects (2), which was the type of language used, was considered suitable for evaluation by computer web application or programming.

2.5 General Corpus and Data Preparation

The PIL documents of the presently authorized medicines in the Netherlands (with links to each of the SmPC and PIL documents) were available as a datafile list through the website https://www.geneesmiddeleninformatiebank.nl/, which is regularly updated. This database file was downloaded and the URL link to each of the PIL documents (in column M of the datafile) was used to download the documents which were given in PDF format. The Chrome extension program "Simple mass downloader" from the Chrome web store was used for this purpose. The sampled PIL documents were taken from a version downloaded in October 2022. The PILs were converted to a text format using a high-level Python function.

2.5.1 Extraction of Paragraph 2 from the PIL Documents

Then further processing was performed to randomly select 17 text files which were then processed using a Python program to extract paragraph 2 from each PIL text file. The extracted paragraph 2 file was then written to a separate file with the label "just2" appended to the file name. The remainder of the PIL text file (i.e. containing the other paragraphs) was written to a separate file with the label "minus2" appended to the file name. Regarding keyness, the question to be answered was whether the words of the conditionals of paragraph 2 of the Dutch PILs were typical to that paragraph or whether they can also be expected in other parts of the PIL.

This was the general preparation for all aspects. The files containing paragraph 2 of the PILs were further cleaned to remove bibliographic and text conversion artifacts before manual analysis. The cleaned paragraph 2 files were used for manual analysis and for the determination of lexical diversity measures (TTR and MTLD) in aspect 2. The negation section of paragraph 2 was copied and pasted to an internet application which determined the lexical diversity values of that paragraph.

2.5.2 TTR (Token Type Ratio) and MTLD (Measure of Textual Lexical Diversity)

TTR is sensitive to text sample size, which is a known weakness of this measure (Bérubé et al., 2018). Using this measure and by restricting it to paragraph 2 would give a measure of lexical diversity of the paragraph and would appear to be minimally influenced by the overall text sample size, especially if the different paragraphs were of comparable length.

As an alternative MTLD could be considered as this is a measure which is known to be more suitable for shorter texts, such as those of a paragraph like the number of words in a song (Bollinger, n.d.;Reuneker et al., 2017).

2.5.3 Keyness

In order to determine the keyness,: the two sets of text files were used to form the target and reference corpus: the extracted paragraph 2 text files and the text files of the source PIL minus paragraph 2. The extracted paragraph 2 of source PIL was written to a file with the original PIL number and the label “just2” appended and these formed the text files were used for the target corpus. Source PIL text remaining after the extraction of paragraph 2 was written to a file with the original PIL number and the label “minus2” appended and these text files were used for the reference corpus. A Python program was written to perform the keyness value determination.

Following Culpeper (2009), I decided to determine a keyness value using a corpus of the negation parts of paragraph 2 of the PILs as the target corpus and using the same PIL documents minus that part of paragraph 2 to form the reference corpus. This would be akin to viewing the paragraphs of a PIL (or even part paragraphs) as actors in a play where each has a different role to play and a distinct voice in the overall play. The language of the PIL documents minus that negation part of paragraph 2 can also be seen to provide a baseline against which to the language of that negation part of paragraph 2 can be determined. For determining the keyness value of paragraph 2 of the selected PILs, the *odds ratio* (OR) was used as the effective measure (Pojanapunya & Todd, 2018). The authors mention the equation for determining OR as:

(a/c)/(b/d) = ad/bc, where:

a = frequency of a word in the target corpus

b = frequency of a word in the reference corpus

c = frequency of other words in the target corpus (C–a)

d = frequency of other words in the reference corpus (D–b)

This seemed appropriate as I want to look at the language in paragraph 2 with respect to the language of the rest of the PIL paragraphs minus paragraph 2.

2.5.4 Search in Sketch Engine using the Corpus Query Language (CQL)

Having determined the clause order of the PIL paragraph 2 conditionals, I generalize the sentence structure with a CQL statement to search for similar constructions in a database of internet content.

2.6 Some General Difficulties in Processing the PDF Format PIL Files

The PILs are in PDF file format and submitted to the Dutch regulation authorities by companies each using their own structure and layout. This means that there is no system standard and some companies use the available space for raising the profile of the company by including special graphics for the display of the company name or product, which in some cases includes the company name. Due to the difficulties in processing (unrecognized symbols, headers, footers etc.) in the PDFs and the number of files it was decided to perform an analysis by hand of the sections of interest of a random selection of 17 PIL documents (i.e. paragraph 2). Some of the problems are shown below:

2.6.1 Example 1, enumeration

In the extraction of paragraph 2 there was a need for detecting the paragraph between enumeration “2.” and “3.” However there was text in one of the horizontal text boxes in the PDF which showed the enumeration “1.3.1” in the area being extracted and this prematurely stopped the extraction process. The is shown in the Image 1 below:

Image 1

Screenshot of bibliographic data defeating the paragraph extraction program

2. WANNEER MAG U DIT MIDDEL NIET GEBRUIKEN OF MOET U ER EXTRA VOORZICHTIG MEE ZIJN?

Wanneer mag u dit middel niet gebruiken?

- als u allergisch bent voor één van de stoffen in dit geneesmiddel. Deze stoffen kunt u vinden in rubriek 6. Of als u allergisch bent voor andere soortgelijke geneesmiddelen (bètablokkers)
- als u onvoldoende pompkracht van het hart (hartfalen) heeft die niet behandeld is
- als u ernstige hartblok (blokkade van de hartprikkel) en/of een zeer trage hartslag heeft
- als u een zeer lage bloeddruk heeft.

This is an example of the PDF structure of a paragraph 2, which spans two pages where each page has a header box with paratextual information. After much trial and error, I decided to retain the text in headers or footers and pay special attention to the occurrence of the "3." in the body of a text. In the code which was extracting a paragraph 2, I used a regular expression (i.e. a "regex" in the code) which looked for text which was bounded by "2." and "3." It is not straightforward to spot a possible extraction error which could occur with the reference numeral 1.3.1 as in the phrase of the above PDF "1.3.1. Bijsluiter".

Below is the regular expression originally used which was not suitable due to the occurrence of "3." at an unexpected location.

```
section_regex = r'(?<=\n2\.)[\s\S]*?(?=\n3\.)'
```

Below is a screenshot of the text file section showing the corresponding extracted text to the PDF screenshot above.

Image 2

Screenshot of text file corresponding to image 1

WANNEER MAG U DIT MIDDEL NIET GEBRUIKEN OF MOET U ER EXTRA
VOORZICHTIG MEE ZIJN?
Wanneer mag u dit middel niet gebruiken?
Metoprololtartraat Aurobindo 50 en 100 mg, filmomhulde tabletten
RVG 118134 en 118136

Module 1 Administrative information and prescribing information
1.3.1 Bijsluiter
Rev.nr. 2103
Pag. 2 van 7
- als u allergisch bent voor één van de stoffen in dit geneesmiddel. Deze stoffen kunt u vinden in rubriek 6.

Of als u allergisch bent voor andere soortgelijke geneesmiddelen (bètablokkers)
- als u onvoldoende pompkracht van het hart (hartfalen) heeft die niet behandeld is
- als u ernstige hartblok (blokkade van de hartprikkel) en/of een zeer trage hartslag heeft
- als u een zeer lage bloeddruk heeft.

The regex will be defeated by cases where the “3.” occurs at an unexpected location in the file like "doseringsinformatie bij kinderen en jongeren ouder dan 9 jaar, zie hoofdstuk 3."(PDF screenshot not shown). It is therefore necessary to have a regex modification. The regular expression is modified to be:

section_regex = r"(?m)2\.(.*?)^3\.\s+",

which uses (?m) to enable multiline mode. Then, the symbol ^ ensures that the start of a line is detected, ensuring that the "3." marker is at the beginning of a line.

2.6.2 Example 2, scrambling

In the extraction of paragraph 2 there was a need to check whether the text extracted was part of a table since the extraction program would not recognise the alignment of text in different columns and thus scramble (i.e. lose the alignment of) the text during extraction. The information contained in tabular boxes (see h109939 (hormonal contraceptive)) of Image 3 are shown misaligned (i.e. scrambled) in Image 4. In comparing the two images it is important to note the heading of each column in Image 3 and where these headings occur in the extracted text of Image 4. Note that each heading of the table in Image 3 is in the form of a question and therefore that the occurrence of the question mark in the extracted text of Image 4 is readily spotted.

Image 3

Screenshot of tabular information in PIL paragraph 2

Krijgt u een van deze klachten of symptomen?	Waar kunt u aan lijden?

• zwelling van een been of langs een ader in een been of voet, vooral als dit gepaard gaat met:
  • pijn of gevoeligheid van het been, die u mogelijk alleen voelt bij het staan of lopen
  • verhoogde temperatuur in het aangedane been
  • kleurverandering van de huid van het been, bijvoorbeeld bleek, rood of blauw worden
	diepe veneuze trombose

• plotselinge onverklaarde ademnood of snelle ademhaling • plotseling hoesten zonder duidelijke oorzaak, waarbij u bloed kunt ophoesten • scherpe pijn in de borst, die erger kan worden als u diep ademhaalt • ernstig licht gevoel in het hoofd of duizeligheid • snelle of onregelmatige hartslag • ernstige pijn in uw maag Als u twijfelt, neem dan contact op met een arts, want sommige van deze symptomen, zoals hoesten of kortademigheid, kunnen ten onrechte worden aangezien voor een lichtere aandoening, zoals een luchtweginfectie (bijv. verkoudheid).	longembolie

Image 4

Screenshot of text file corresponding to extracted information of Image 3

```
Krijgt u een van deze klachten of symptomen?
• zwelling van een been of langs een ader in een been of
voet, vooral als dit gepaard gaat met:
•  pijn of gevoeligheid van het been, die u mogelijk alleen

Waar kunt u aan lijden?
diepe veneuze trombose
voelt bij het staan of lopen
•  verhoogde temperatuur in het aangedane been
•  kleurverandering van de huid van het been,
bijvoorbeeld bleek, rood of blauw worden
•  plotselinge onverklaarde ademnood of snelle ademhaling
```

In Image 4 we see that the text data is retrieved, but in the incorrect order as the conversion code is taking data in sentence form from horizontal lines.

In the example of Image 4, the line ending in “alleen” (the third line down in the left hand column) is followed by the question “Waar kunt u aan lijden?” and “diep veneuze trombose” from the right hand column and subsequently followed by the rest of the information from the left hand column.

2.7 Summary

I started this chapter with the research question, which was divided into three subsections, and I outlined the data and the methods which I proposed to use to answer the research question subsections and the further search for similar conditionals in a database of internet content. I mentioned the reasons for not using annotation in the preparation of the files and some of the processing difficulties encountered during preparation of the documents.

3. Results and Analysis

This chapter deals with the presentation of the results of the investigation of clause order, language type and negation of the conditionals in the PILs selected.

3.1 Overview

Regarding clause order, all the PILs were found to contain ellipses of the consequent (i.e. the main clause) in paragraph 2. This type of clause structure has been called insubordinate (Evans, 2007) in the literature, meaning that the subordinate clause (the antecedent) serves as a main clause and that there is an ellipsis of the consequent clause.

Regarding language type, it was found that the lexical diversity of this part of paragraph 2 was not abnormally different to the rest of the PIL. There was a higher instance of personal ("U" and "u") and possessive ("uw") pronouns as well as connectives ("als", "dat", "die", "om"), nouns ("arts, "behandeling", "middel") and verbs of ownership and obligation ("heeft", "moet", "kan"), all of which could be considered consistent with *unambivalent* medical advice, warning and instruction.

There was very little sign of overt negation found. The opening question of paragraph 2 contains the word "*niet"*, (not). There were also rare instances of a full conditional with explicit consequent containing the word *"niet"*. The PIL paragraph 2 ("p2" in the table) token numbers for the negation section and for the entire paragraph and averages are shown in the table below for the 17 selected PILs:

Table 3

A table showing extracted section tokens, total paragraph tokens and percentage ratios

PIL no.	p2 negation section tokens	total p2 tokens	section/total %
1	232	802	29
2	123	992	12
3	105	943	11
4	145	967	15
5	75	680	11
6	144	1905	8
7	183	1818	10

8	40	634	6
9	195	1330	15
10	384	3574	11
11	157	1497	10
12	58	574	10
13	76	1060	7
14	213	1267	17
15	99	648	15
16	134	689	20
17	119	1884	6
sum	2482	21264	---
av	146	1250	12%

This table shows that the total number of tokens in the negation section of the PIL paragraph 2 of the 17 documents is 2482 tokens, which gives an average of 146 tokens per paragraph. The average number of tokens for the entire paragraph 2 of the 17 PILs was 1250, making the negation section on average 12% of the total size of paragraph 2. It is also interesting to note the variation in percentage size of the negation section across the sample: the smallest being 6% and the largest being 29%.

3.1.1 Overview of Structural Features Found in the Sample

In the table below, the column titles show the beginning words of the insubordinate antecedent clause. As shown below, this was mostly U(u) + verb or Als(als) + u. The verbs were consistently drafted in the present tense. Where the antecedent starts with a different connective, this is indicated in column "alternative connective." In the (rare) case that the conditional presents with an explicit consequential clause, it is indicated in the column with the title "Full conditional."

Table 4

A table showing the overview of linguistic aspects of extracted section of the PIL paragraph 2

PIL sample no.	**U(u)+ verb**	**Uw + noun**	**Alternative connective**	**Als(als) + u**	**Wanneer u**	**Full conditional**
1	16		Om (1)			
2	5					

3	1					4
4	5	1	Tijdens/in combinatie met(2)			
5				5		
6	2					
7	10					
8	2					
9			bij (2)	9		
10	11	1				3
11	5		Tijdens (1)	1	1	
12	1					3
13	1			2		1
14	11		Bij (2)			
15				3		1
16	1			5		
17	1				2	2
Totals	72	2	8	25	3	14

3.2 Aspects of Clause Order

3.2.1 The Lack of a Consequent in Most Conditionals

Appendix A shows the sections of paragraph 2 from each of the PIL documents of the random sample of 17 drawn in tabular form. In each table, I have included the text as written in the PIL, which demonstrates aspects of the conditional, namely the leading question and (mostly) the insubordinate antecedents.

Where a consequent is implicit, I have added the Dutch word *Impliciet* as a suggestion together with a probable implied consequent (e.g. see row 1(b) in Appendix A). It is interesting to note that the implied consequent Q may be read as either being located before (*Q if P*) or after (*if P then Q*) the antecedent P. Put another way, the easily retrievable (i.e. implied) negation consequent clause may be located sentence-initially or sentence-finally.

Since most of the conditionals found in the sample were insubordinate, the elided consequent may either be implicitly sentence-initial or sentence-final. Certain traits (punctuation, capitalisation) suggest that one version is preferably indicated: in cases where the insubordinate (antecedent) starts with a non-capital letter (e.g. “als u (...)”, “u heeft (...)”), this suggests that a sentence-initial consequent was intended, alternatively where the insubordinate clause starts with

a capital which might suggest a sentence-final consequent. Full conditionals presented with both sentence-initial and sentence-final forms of the consequent.

I observed that certain antecedents appeared to be formed as complete standalone sentences whereas others required an implicit consequent (e.g. “Gebruik dit medicijn niet (...)”) and conjunctive to make a proper sentence (e.g. “(...) als u (...)”,”(...) indien u (...”)).

Regarding clause order, what can be observed is that both the implied consequent and insubordinate antecedent need to be false for the patient to infer that she may take the medicine.

3.2.2 Discourse Setting By Negative Question

The negation section of paragraph 2 of the selected PILs consistently started with a question of the form:

Wanneer mag u dit medicijn niet gebruiken?

When should you not use(take) this medicine?

A question is often used as an alternative foregrounding strategy as this is considered part of a “spontaneous conversational discourse” and as part of the format “referent + proposition”(Ochs Keenan & Schieffelin, 1976; p. 249; Haiman, 1986). The use of an initial specification of a referent which is then immediately followed by a proposition which is in some way related to the referent. Interestingly Ford & Thompson (1986) have noted that “evaluations and questions” are “particularly associated with non-initial if-clauses ” (p. 370). Furthermore, the use of ellipsis of a conditional clause (either antecedent or consequent) has also been noted for the purposes of “discourse redundancy” (Haiman & Thompson, 2014, p. 512) as well as the insubordinate typological functions mentioned by (Evans, 2007).

In looking at the discourse semantics, we must make a distinction between the speaker and the reader (or hearer) of the warning in paragraph 2 of the PIL. Clearly the speaker is the person who has drafted the words of the PIL and it is from this point of view that we should first analyze the conditionals, although for the purposes of determining any possible anxiety related perception, analysis of the perspective of the reader is necessary. Regarding reader perception briefly, we note that the reader must use a particular form of inferential logic (i.e. to determine that the medicine is safe to take), which is referred to as *denial of an antecedent* and furthermore, that “denial inferences took longer to endorse than affirmative inferences for all the forms of conditionals” (Grosset & Barrouillet, 2003). This would seem to have a significant impact on the

perception of the medical information in the PIL paragraph 2 and possibly also on medical adherence intentions of, and anxiety levels in, the reader.

Furthermore, the patient who is reading the information desires the consequent to be false so that she may be "cleared" to take the medicine. However, all of the antecedents are in the affirmative and contain no negation. Therefore, the patient desires all the antecedents to be false so that she may be "cleared" to take the medicine. This is an important aspect of the structure (i.e. clause order) of the conditional information regarding the contraindications and warnings of the prescribed medicine; it may be that this structure alone provokes worry and anxiety in the patient who is obliged to consider, whilst reading paragraph 2 of the PIL, the *opposite* of what she really desires: she has to read the conditions under which she should *not* take the medicine. She desires the opposite of what is said in the PIL (Espino & Byrne, 2018). She really desires to be cleared to take the medicine. Interesting work on desirability in conditionals Akatsuka (1997;1986) has argued that the preceding context as well as that of the speaker's attitude need to be considered. To this we may add that the desirability of the reader, the patient, must be considered as well as the preceding context.

The semantics of the negative question conditional is further illustrated by means of the Mental Space Theory (MST) diagram below. The type of conditional found in paragraph 2 of a PIL has been called an alternative-based predictive conditional as the conditional predicts a particular future based on the truth of the antecedent *and* an alternative future (i.e. an alternative space structure) based on the falseness of the antecedent. This construction of conditional is conventionally associated with *iff* (if and only if) implicatures and naturally also suited for use with an explicit or implicit conditional *then* (Dancygier & Sweetser, 2005, p. 42).

The diagram below is adapted from Dancygier & Sweetser (2005, p. 47) to show the Mental Space Theory diagram for paragraph 2 of a PIL. Like the example (Dancygier & Sweetser, 2005, 46), the speaker in the PIL commits to a *negative epistemic stance* (left hand side of the diagram below: introduced with the question "when not to take this medicine?") whilst the use of the present tense verbs in the antecedent (i.e. if you are allergic) shows a *neutral stance*. The use of the present tense verbs in the antecedent with future reference is called tense *backshifting* and serves to build "background mental spaces against which the main clause can be used to make a prediction" (Dancygier & Sweetser, 2005, p. 43). I have elected to show the Base space of the conditional in the MST diagram from the point of view of the reader which is clearly

not the same as that of the speaker. I see this anomaly (i.e. in Base space description) as an incoherence between the epistemic stance of the speaker and reader, which I refer to in more detail below.

In PIL paragraph 2, the implied main clause which contains the prediction of being able, or not, to take the medicine (see last box to the bottom left and bottom right of the diagram below) is left to the reader to infer for herself. The reader must infer that the medicine is safe for her to take by denying the (insubordinate) antecedent information. She must say to herself "No, I am not allergic to a substance in this medicine and therefore it is safe for me to take."

The insubordinated antecedent "You are allergic to a substance in this medicine" (U bent allergisch voor één van de stoffen in dit medicijn) is consistently a constituent part of the warnings in the PIL. Indeed, the word *if* in the *if*-clause is also mostly elided: in PIL number 5, 9, and 10, it is explicitly used (i.e. "als u allergisch bent"). In PIL number 15, the word "overgevoelig" (oversensitive) is used instead of allergic in the phrase which relates to a similar warning. The main clause prediction about whether the medicine is safe, or not, for the reader is foregrounded by the question "Wanneer mag u dit medicijn niet gebruiken?" (When should you not take this medicine?). This is resolved by the two possible outcomes: "U mag dit medicijn (niet/wel) gebruiken" (you (should not/ may) take this medicine) and these are shown in the bottom left and right boxes of the MST diagram.

Image 5

An MST depiction of PIL paragraph 2 conditionals

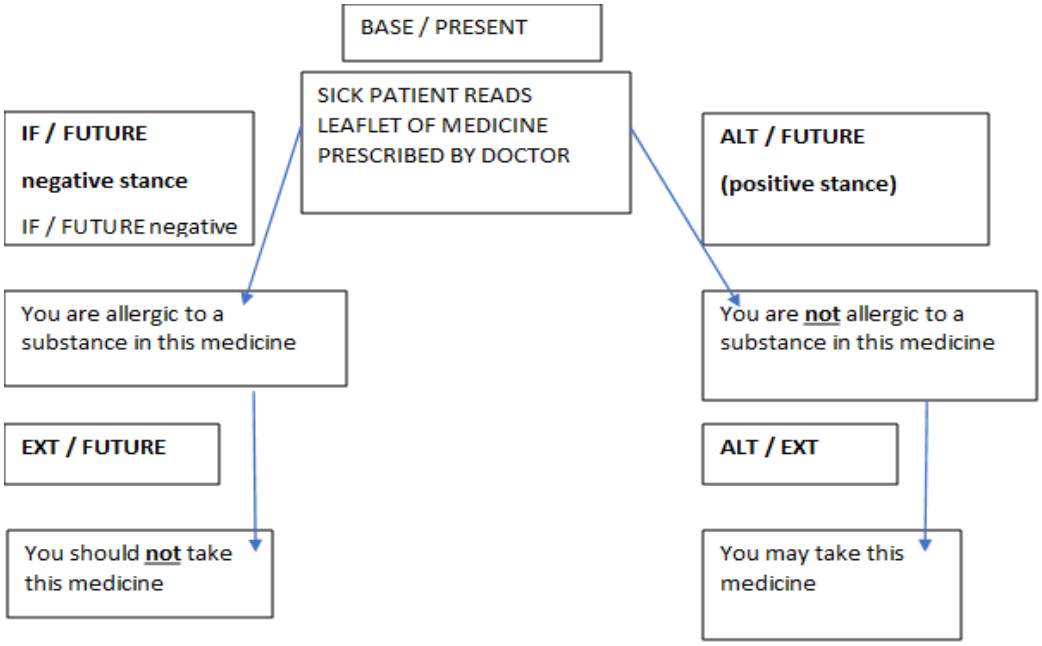


Diagram showing example of negative epistemic stance of the PIL paragraph 2 conditionals with sentence-final consequent: "You are allergic to a substance in this medicine (then) you should not take this medicine" (*if P then Q*) shown on the left-hand side. The alternative future predictive state is on the right-hand side: "You are not allergic to a substance in this medicine (*not P*) (*then*) you may take this medicine (*not Q*)."

Interestingly Dancygier & Sweetser (2005, p. 48) mention the contrasting epistemic stance invoked with the use of *when* and *if*. *When* is used to additionally construct a temporal space alongside a general type of situational (and sometimes alternative) space and produces a positive epistemic stance in relation to the situation of the *when* clause (*when* clauses are identified with positive epistemic stance and presupposed material). *If* clauses produce a neutral stance as they are identified with non-positively viewed material (the speaker does not express a positive stance).

3.2.3 Regarding Coherence of Epistemic Stance

The main clause (*Q*) prediction at the bottom left of the MST diagram in Image 5 ("You should not take this medicine"), which follows directly from the PIL paragraph 2 title question, is a prediction which is set up for a negative *epistemic stance*. When this is placed in the context of the (sick) reader's Base reality space (top center of the Mental Spaces diagram), which is set

up for *positive epistemic stance/status*, there is a problem of coherence. The reader is asked (during reading) to consider the neutral or negative epistemic stance of the speaker of the PIL information.

This is a difficult viewpoint for the patient to ascribe to as she must orientate towards the alternative future state (right-hand side of the Mental Spaces diagram) to arrive at her goal; one that is an alternative to that state predicted implicitly by the negative question of PIL paragraph 2 (i.e. you should not take this medicine). The patient starts reading the information from a *positive epistemic status* (e.g. having visited a doctor and having been prescribed this medicine), but she must read information which is set up for a *negative epistemic stance*.

The inference task is arguably made more difficult since the *negative epistemic stance* marking of the implicit main clause prediction is directed towards the entire multiple (disjunctive) clause construction of the listed antecedents in the PIL paragraph 2. And, for her to infer that the medicine is safe to take, it is not sufficient for just one of the antecedents to be false, they must all be false. The denial inference task is one of multiple denials. Whilst the *if*-clauses themselves are marked for a *neutral* epistemic stance (using present tense verbs), the implicit main clause prediction is marked for *negative epistemic stance* and although the epistemic stance of the speaker in the PIL paragraph 2 cannot be said to be incoherent, it certainly clashes with that of the reader when seen from the viewpoint of her Base reality space.

3.2.4 Alternative Connectives in the Conditionals

Here I say a few words about connectives other than *als* and *wanneer*. I observed different connectives ("om" (in order to), "indien" (in case), "tijdens" (during, while) , "in combinatie met" (when coupled with), "bij" (if/when there is) where there was an implicit consequent. Here, the use of certain connectives (e.g. om, in combinatie met) does not always appear to be conditional, or maybe has a temporal as well as a conditional function, but in the context of the implied consequent clearly sets up a causative conditional. Here are some examples:

From PIL no. 1 (H128830.pdf):

(*Impliciet*) Gebruik dit medicijn niet,...

> Om de geboorte van een levensvatbaar kind in te leiden, omdat nadelige effecten op het kind niet zijn uit te sluiten.

From PIL no. 4 (H118758.pdf):

(*Impliciet*) Gebruik dit medicijn niet,...

Tijdens borstvoeding;(...)

in combinatie met een gele-koortsvaccinatie.

From PIL no. 11 (H09355.pdf):

(*Impliciet*) Gebruik dit medicijn niet,...

- Wanneer u overgevoelig bent voor middelen die op dit middel lijken, de zogenaamde ergotalkaloïden.
- Tijdens of na zwangerschapsvergiftiging.

From PIL no. 14 (H30130.pdf):

(*Impliciet*) Gebruik dit medicijn niet,...

Bij een 'shock' veroorzaakt door onvoldoende pompwerking van het hart.

Bij een ernstig vertraagde hartslag (bradycardie).

In the examples above I considered the conditional use of "om" (in order to), "tijdens" (during, while), "in combinatie met" (in combination with) and "bij" (in case(s) of) to be conditional. In the context of the PIL document where it is used, "om" is equivalent to "if." Similarly, "tijdens" can be seen as equivalent to "if" (i.e. "if breastfeeding"). Also, similarly "in combinatie met" is equivalent to a conditional "when" in ("when coupled with"). Again similarly "bij" can be seen as equivalent to "if" ("if there is").

In PIL no. 15 (H18718.pdf) we observe (last sentence):

Daarom is het bovenstaande niet van toepassing na contact met materialen of dieren die met rabiës besmet kunnen zijn.

The conjunctive "na" (after) in the above conditional phrase is also equivalent to "if" ("if there is"). Here again, the conditional clause order is of the form *Q if P*.

From PIL no. 17 (H28924.pdf) in the sentence:

Uw arts zal u adviseren hoe u moet beginnen met het innemen van paroxetine, nadat u met het gebruik van de MAO-remmer bent gestopt.

Here similarly the conjunction “nadat” (after) is used in a conditional phrase (which nevertheless also has a temporal aspect to it) where this is also equivalent to “if” in the clause order of *Q if P*.

3.3 Aspects of Language Type

3.3.1 Lexical Diversity

The MTLD measure was used to determine a value for lexical diversity of each selected PIL and first part of paragraph 2. The $MTLD_1$ and TTR_1 evaluated by copy and paste measure on the website *Lexical Diversity Measurements* (https://www.reuneker.nl/files/ld) (Reuneker, 2017). whereas the TTR_2 and ARI_2 were evaluated on the website Stylene (https://stylene.uantwerpen.be/) developed by the Center for CLiPS (Computational Linguistics and Psycholinguistics, University of Antwerpen.

Table 5

A table of lexical diversity values for the paragraph 2 section of the selected PILs

	$MTLD_1$	TTR_1	TTR_2	Automated Readability Index: ARI_2
1. H128830	54.53	0.39	0.4	niveau 15-16 jaar
2. H123401	54.26	0.33	0.34	niveau 16-17 jaar
3. H127621	60.21	0.32	0.33	niveau 14-15 jaar
4. H118758	63.94	0.32	0.34	niveau 14-15 jaar
5. H118136	57.26	0.38	0.44	niveau 17-18 jaar
6. H116661	66	0.3	0.32	niveau 18-22 jaar (univ/hogesch)
7. H115752	54.59	0.29	0.31	niveau 18-22 jaar (univ/hogesch)
8. H115266	46.07	0.37	0.38	niveau 15-16 jaar
9. H114885	61.54	0.31	0.33	niveau 17-18 jaar
10. H109939	49.79	0.21	0.22	niveau 15-16 jaar
11. H09355	59.51	0.3	0.31	niveau 15-16 jaar
12. H57689	60.22	0.4	0.42	niveau 15-16 jaar
13. H34406	57.07	0.32	0.34	niveau 15-16 jaar
14. H30130	61.65	0.3	0.31	niveau 16-17 jaar
15. H18718	82.63	0.36	0.38	niveau 14-15 jaar
16. H26283	45.19	0.34	0.35	niveau 15-16 jaar
17. H28924	64.22	0.3	0.31	niveau 17-18 jaar

A slight difference was noted between the TTR scores from website 1 and 2 (see subscripts of columns for TTR) which can most probably be associated with the tokenization rules of the application used. I noticed for example that in number 5 the word count from the tokenization rules of website 1 was 925, whilst that from website 2 was indicated as 683 words. Because it was possible to visualize the tokenization on website 1, I could see that the bullet points, of which there are many, were also included in the tokenization of the paragraph. I also note with interest (although not part of the general focus here) how the MTLD measure does not seem to correlate with the ARI scores: a higher lexical density does not necessarily indicate a more difficult text to read.

3.3.2 Keyness

For determining the keyness value of paragraph 2 of the selected PILs, the *odds ratio* was used as the preferred effective measure. This seemed appropriate as we look at the language in paragraph 2 with respect to the rest of the PIL paragraphs minus paragraph 2. Below are the keyness values for the selected files with the paragraph 2 PIL files forming the target corpus and the PILs minus paragraph 2 forming the reference corpus.

Table 6

Keyness values and word rankings of the PIL paragraph 2 sections

	word	**keyness**
1	heeft	3.34
2	andere	3.25
3	U	3.10
4	dat	2.71
5	als	2.12
6	behandeling	2.12
7	u	1.87
8	Als	1.79

9	of	1.71
10	arts	1.45
11	kan	1.44
12	uw	1.43
13	moet	1.41
14	een	1.38
15	die	1.32
16	om	1.27
17	middel	1.23
18	-	1.20
19	•	1.14
20	met	1.13

It is interesting to note that “U” and “u” and “Als” and “als” appear in the keyness list of top values. This suggests that in any further processing (e.g. for word embeddings analysis) of the PIL documents that a cased model should be used.

It is perhaps surprising to note that the word “niet” does not appear in the keyness list of PIL paragraph 2 as this is a warning and related to conditions under which the medication is not to be taken. However, we know that this is due to the use of the insubordinate clause structure and the ellipsis of the main clause containing the word “niet.”

3.4 Aspects of Negation

3.4.1 Ellipsis of the Consequent

The negation contained in the implicit consequent (i.e. “Do not take this medicine if (...)”) was a constituent part of the ellipsis. Therefore the chosen clause order for the PIL paragraph 2 conditionals (i.e. insubordination) had apparently concealed the presence of negation. Or rather the choice of clause structure has made the negation implicit. Because of this the negation aspect overlapped with that of clause order mentioned above.

3.4.2 Presupposed Counterfactual

Because of the structure of the antecedents as counterfactual (i.e. assumed at least to be not true), there is already a structural aspect of negation in the semantics of the PIL paragraph 2 conditional. Here again, the negation aspect overlaps with that of clause order. The patient desires all the insubordinate antecedents to be false so that the implied consequent can be false and that she may therefore be clear to take the medicine. This concealing purpose with the use of an insubordinate structure has been noted in terms of a face threatening act (FTA) and the use of ellipsis to place this FTA (i.e. the negation) "off the record" (Evans, 2007). This strategy of being indirect (Evans, 2007, p. 387) and this concealing function has been noted in Brown & Levinson (1987) where the authors mention a strategy entitled "Be incomplete, use ellipsis" (p. 227).

The combination of insubordinate clauses with presuppositional force together with the negation of an implicit main clause ("You should not take this medicine") can function as an implication of the affirmative of that main clause (Evans, 2007, p. 410).

The use of verb phrase negation (VPN) in the opening question of the PIL paragraph 2, from a discourse pragmatics viewpoint, presupposes the corresponding affirmative as a shared knowledge:

> Negative assertions are, it seems, made on the tacit assumption that the hearer either has heard about, believes in, is likely to take for granted, or is at least familiar with the corresponding affirmative. (Givón, 2018)

Following this, I conclude that there is a particularly striking effect of the negative assertion of the implicit main clause (i.e. "you should not take this medicine (...)") in paragraph 2 of the PIL. The reader of the PIL paragraph 2 is presented with the tacit assumption that she "is likely to take for granted … the corresponding affirmative" (Givón, 2018) of the implicit main clause (i.e. "you may take the medicine (...)"). In other literature this has been called the pragmatic-inference hypothesis (Levine & Hagaman, 2008, p. 475) which is important here since the negative assertion implied in the paragraph opening question asserts that there are indeed situations under which "you should not take this medicine." Thus, not only the insubordinate clause structure, but also the introductory main clause negative assertion both contribute to the presuppositional nature of PIL paragraph 2. Regarding the presence of negation in the implied assertion, this produces an inferential process, due to the pragmatic-inference hypothesis, where the reader searches for a presupposition which can be canceled or denied. The fact that in a PIL

these presuppositions are the antecedents which follow directly on from the opening question allows an *easy* identification of the presupposed material. However, this is complicated by the number of antecedents and the lack of a main clause (due to the insubordinate clause structure). If the assertion and presupposition to be denied are presented in a single sentence then the context-dependent function of the negation is readily understood; if however, the presuppositions are somehow "difficult to find or infer" (e.g. due to the use of an insubordinate structure) then further mental processes yield the effect of retaining the negative assertion and not being able to suppress it (Levine & Hagaman, 2008, p. 492).

3.5 Comparison with similar lexical formulations on Dutch Websites

In this part of the research, I wanted to compare the type of PIL paragraph 2 conditionals to the use of conditionals in general language. To accomplish this, I made a search for the most commonly occurring conditionals of this type in a corpus of website information. For this I used the Dutch Web 2020 corpus, available on the Sketch Engine website and performed the searches using CQL within the Concordance tool of Sketch Engine (Kilgarriff et al., 2014). This corpus, also called nlTenTen20, contains almost six billion tokens: the download between June and July of 2020 contains texts from a variety of topics, genres and website sources and the corpus is promoted as being "for both general use and also specialized language" (https://www.sketchengine.eu/nltenten-dutch-corpus/), which was ideal for my purpose. The genre types included only discussion, blog, legal or none. The entries with genre type "none" made up 99.1% of the corpus.

In the examples below searches were made in the corpus for different types of start to the sentence following the question mark: "A(a)ls", "U(u)+verb". Here is a CQL query, using the structure of the most prevalent PIL structure which is an independent sentence (which itself follows a question mark) starting with capitalized "U" or an uncapitalized "u" followed by the verb forms "bent/heeft/lijdt" where the following sentence is itself not another question.

Image 6

A screenshot of the CQL query and the hits retrieved for "(...) ? U(u) + verb (...)"

CQL [word=="?"]</s>(<s>[word="U|u"][tag="verb.*"] []* [word!="?"]</s> within <s/>)

Number of hits	64,319
Number of hits per million tokens	9.41
Percent of whole corpus	0.0009408%
Corpus size (tokens)	6,836,979,371

Limiting the above search from Image 6 to only search for an uncapitalized "u" (which is also evidenced in the PIL wording) gives result in Image 7:

Image 7
A screenshot of the CQL query and results of the Image 6 search limited to an uncapitalized "u"

CQL [word=="?"]</s>(<s>[word="u"][tag="verb.*"] []* [word!="?"]</s> within <s/>)

Number of hits	160
Number of hits per million tokens	0.02
Percent of whole corpus	0.000002340%
Corpus size (tokens)	6,836,979,371

An example of a retrieved hit from the Image 7 search is:
<s>Wat gebeurt er als u iets niet (op tijd) meldt ?</s><s>u krijgt minder subsidie </s>.

Therefore, the difference when only the capitalized "U" was used is shown in Image 8:

Image 8
A screenshot of the CQL query and results of the Image 6 search limited to a capitalized "U"

CQL [word=="?"]</s>(<s>[word="U"][tag="verb.*"] []* [word!="?"]</s> within <s/>)

Number of hits	64,159
Number of hits per million tokens	9.38
Percent of whole corpus	0.0009384%
Corpus size (tokens)	6,836,979,371

From this I can confirm the correct retrieval of information from the corpus since the number of hits shown in Image 8 and 7 sum to the hits shown in Image 6 namely 64,159 + 160 = 64, 319 hits.
This further shows, unsurprisingly, that the uncapitalised "u" to start a sentence after a question mark is much rarer in Dutch than the capitalized "U"start to a sentence following a question mark.

Below, the query is modified by inserting the word “A(a)ls” (if) with either capitalized or uncapitalized first letter before the “U(u)” in the query of Image 6. This is also a formulation which is seen in paragraph 2 of the PILs (e.g. 3(d), 5(a-e), 9(a-d, f, h-k), 11(h), 12(c, d), 13(b,c), 15(b-d), 16(b-f)) and the results are shown :

Image 9

A screenshot of the CQL query and the hits retrieved for “(...) ? Als(als) U(u) + verb (...)”

Below, I wanted to check the results with the capital letter start for capitalized “Als” against the uncapitalised results. The query of Image 9 was modified to use only capitalized “Als” (Image 10) and thereafter using only uncapitalized “als” (Image 11):

Image 10

A screenshot of CQL query with Image 9 query using only capitalized “Als”

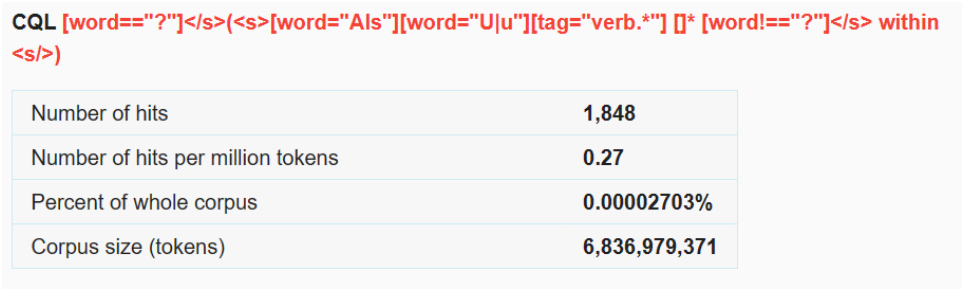
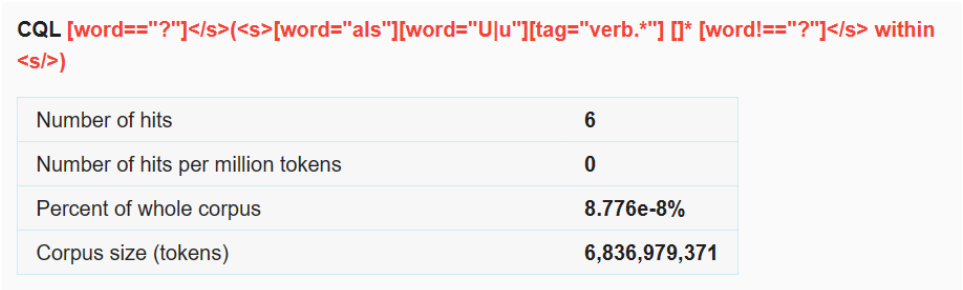


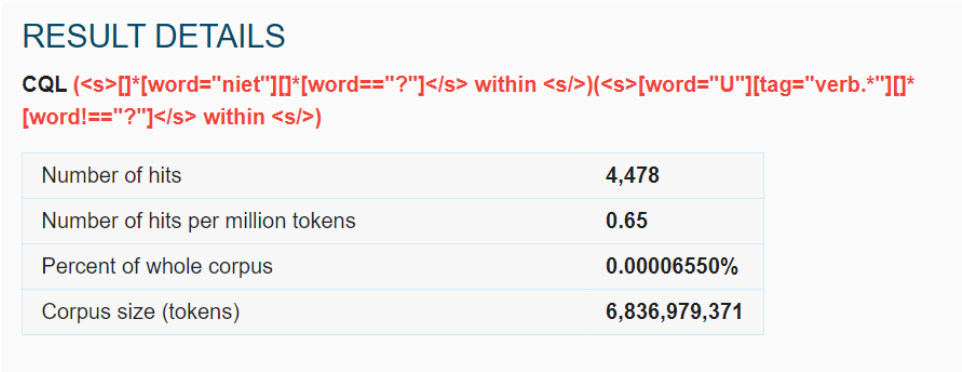
Image 11

A screenshot of CQL query with Image 9 query using only uncapitalized “als”



Indeed, the search results show that the “Als” or “als” search gave six more hits than the capital-only search. This shows that the small letter “als” is much rarer than the capitalized “Als” as a starting word in a sentence following a question mark.
Below is a screenshot of the CQL, which is modified to look for a question sentence with “niet” (not) in it, as occurs in all the PIL paragraphs 2, and with the following sentence starting with capitalized “U”.

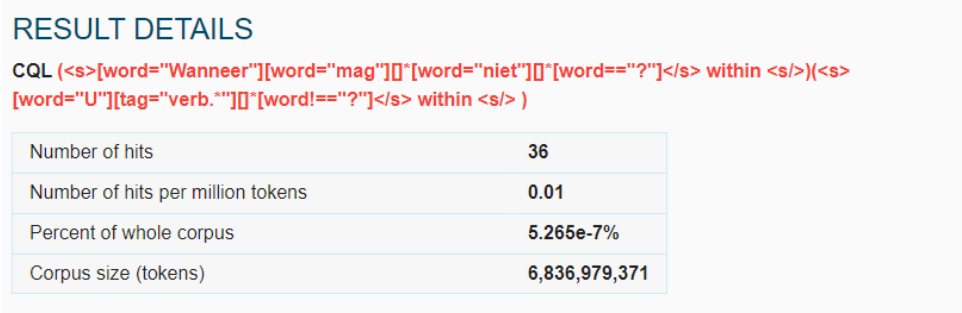
Image 12
A screenshot of CQL query looking for “niet” anywhere in a question followed by a sentence starting with capitalized “U”



Then I modified the search to include “Wanneer mag”(when should) as a further limitation to the initial question used in Image 12. The results are shown below.

(<s>[word="Wanneer"][word="mag"][]*[word="niet"][]*[word=="?"]</s> within <s/>)(<s>[word="U"][tag="verb.*"][]*[word!=="?"]</s> within <s/>)

Image 13
A screenshot of CQL query modified from Image 12 to further include “Wanneer mag” at the start of the question sentence



Of the 36 entries found, there were only two (shown below) not related to PIL information (from the websites avrotros.nl and consuwijser.nl):

- <s> Wanneer mag een rijexaminator (niet) ingrijpen? </s><s> U beschikt vast over voorschriften en richtlijnen voor rijexamens en gedrag van rijexaminatoren. </s>

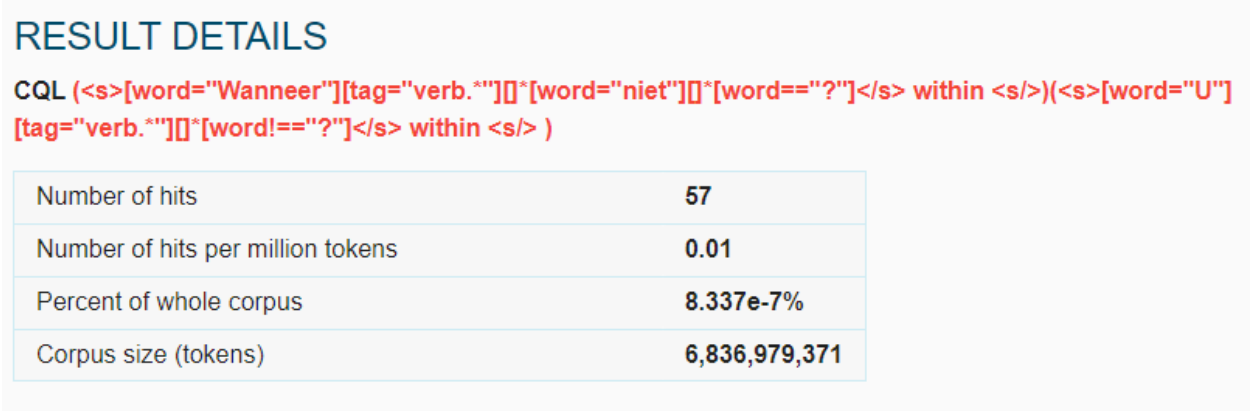
- <s> Wanneer mag ik mijn abonnement niet opzeggen? </s> <s> U mag uw abonnement niet opzeggen in de volgende gevallen: </s>

All other 34 entries related to medicinal warnings contained in PILs. Then, I modified the search of Image 13 to look for a less restrictive verb than "mag" to follow the initial "Wanneer." The results shown below used a verb tag (i.e. looking for any word which is tagged as a verb) following "Wanneer" in the question). The CQL query used was:

(<s>[word="Wanneer"][tag="verb.*"][]*[word="niet"][]*[word=="?"]</s> within <s/>)(<s>[word="U"][tag="verb.*"][]*[word!=="?"]</s> within <s/>)

Image 14

A screenshot of CQL query modified from Image 13 to be less restrictive with the verb following "Wanneer"


RESULT DETAILS

CQL (<s>[word="Wanneer"][tag="verb.*"][]*[word="niet"][]*[word=="?"]</s> within <s/>)(<s>[word="U"][tag="verb.*"][]*[word!=="?"]</s> within <s/>)

Number of hits	57
Number of hits per million tokens	0.01
Percent of whole corpus	8.337e-7%
Corpus size (tokens)	6,836,979,371

Here, I found 57 entries, but the vast majority of these were related to PIls. So when I subtract the known PIL formulations from Image 13 (i.e. 36-2) then I have the number of hits which are not PIL related, namely 57 – 34 = 23 hits. These are shown in detail below.

Interestingly however, of the remaining 23 instances, 15 do not make use of insubordinate clause formulations. These 15 explicitly (re)state the question clause (whether antecedent or consequent) in the sentence which follows the initial question (as opposed to PILs where there is

an ellipsis of the main clause). See the remaining entries below where the question clause is highlighted in bold underline. The sixteen underlined question clause statements show that a full conditional is used. Then six of the remaining seven instances use insubordinate formulations (*****) where there is an ellipsis of the main clause (one clearly relates to a medical procedure). One of the instances is temporal. So, I conclude that 7 of the 57 instances use an insubordinate clause formulation in a negation setting which is not related to PILs. This corresponds to just over 10% of the small number found. When interpreting the results, we need to be mindful of the varying temporal and conditional uses of "wanneer" (as mentioned above under main heading 2). The 23 hit results from the Image 14 search which were not PIL related are listed below:

1. Wanneer komt u niet in aanmerking? </s><s> U komt niet in aanmerking voor een operatie als u een ernstige eetstoornis (zoals boulimie), psychiatrische aandoening of alcohol- of drugsverslaving heeft.
2. Wanneer meld ik niet? </s><s> U maakt geen melding bij de gemeente.
3. Wanneer komt u niet in aanmerking voor de NIPT als screeningstest? </s><s> U bent zwanger van (in aanleg) een tweeling, waarbij één kindje is overleden. (*****)
4. Wanneer kunt u niet naar de diëtist komen? </s><s> U kunt niet naar het spreekuur van de diëtist komen, wanneer u een verwijzing heeft van de huisarts of wanneer u een dieet heeft wat niet binnen de doelgroepen valt.
5. Wanneer komt u in niet aanmerking? </s><s> U hebt een arbeidsverplichting. (*****)
6. Wanneer komt u niet aanmerking? </s><s> U voldoet niet of onvoldoende aan de arbeidsverplichtingen. (*****)
7. Wanneer mag een rijexaminator (niet) ingrijpen? </s><s> U beschikt vast over voorschriften en richtlijnen voor rijexamens en gedrag van rijexaminatoren.(*****)
8. Wanneer zijn de feestdagen in Europese landen en is het een Nationale Feestdag of niet? </s><s> U vindt op onze website een zo compleet mogelijk overzicht. (*temporal*)
9. Wanneer stopt u toch niet met het opbouwen van pensioen bij SPH? </s><s> U blijft nog deelnemen aan de pensioenregeling in de volgende situaties:
10. Wanneer kunt u niet naar de dagbesteding of ontmoetingsplek? </s><s> U komt niet wanneer u verkoudheidsklachten heeft.
11. Wanneer kan digitaal melden niet? </s><s> U kunt niet digitaal melding maken van uw huwelijk of partnerschap als één van u in het buitenland is geboren, in het buitenland woont, of niet de Nederlandse nationaliteit bezit.
12. Wanneer is duidelijk dat niet permanent in een recreatieverblijf wordt gewoond? </s><s> U beschikt over een aantoonbaar hoofdverblijf elders in Nederland. (*****)
13. Wanneer gebruikt u dit formulier niet? </s><s> U hoeft dit formulier niet te gebruiken als: de lening niet verplicht afgelost hoeft te worden om renteaftrek te krijgen.
14. Wanneer kan ik niet kosteloos annuleren? </s><s> U kunt niet zomaar annuleren bij dienstverleners die iets nieuws voor u maken, of iets repareren, verbouwen of aanpassen.

15. Wanneer kunt u niet in behandeling bij ons? </s><s> U hebt last van actieve suïcidaliteit (uw wens om niet te leven is zo sterk dat u het omzet in plannen en acties). (*)
16. Wanneer bent u niet verzekerd? </s><s> U bent niet verzekerd als u tijdens het beoefenen van kitesurfen, windsurfen, golfsurfen en kite-buggyen (expres) willens en wetens een verbod of waarschuwing negeert.
17. Wanneer is geheimhouding van uw gegevens niet mogelijk? </s><s> U kunt uw gegevens nooit geheim houden voor overheidsinstellingen (andere gemeenten, de Belastingdienst, de Sociale Verzekeringsbank, de Rijksdienst voor het Wegverkeer e.d.), notarissen en gerechtsdeurwaarders.
18. Wanneer hoeft u niet te rapporteren? </s><s> U produceert energie met een opgesteld vermogen van maximaal 10 MW (elektriciteit) of 20 MW (gas). (*)
19. Wanneer ben ik als werknemer niet betrokken bij een vervoerscontract? </s><s> U bent niet betrokken bij een vervoerscontract als uw arbeidsovereenkomst afloopt voor de aanvangsdatum van het vervoer.
20. Wanneer wordt u niet behandeld? </s><s> U kunt voor veel klachten bij de Osteopaat terecht maar niet met alles. (temporal)
21. Wanneer mag ik mijn abonnement niet opzeggen? </s><s> U mag uw abonnement niet opzeggen in de volgende gevallen:
22. Wanneer hebben jullie vakantie (en wordt er niet geleverd en is het afhaalmagazijn gesloten? </s><s> U kunt bij Beplatingswinkel.nl betalen via iDeal of via een vooruitbetaling, als u komt afhalen kunt met PIN betalen (CreditCard is niet mogelijk).
23. Wanneer is de watertoets verplicht en wanneer niet? </s><s> U kunt zelf via het watertoetsloket controleren of de watertoets op uw plan van toepassing is en welke procedure geldt.

Subsequent to this I replaced the personal pronoun with the uncapitalized “U” with a tag to search for any personal pronoun and this gave 270 results (shown below). The CQL query used was:

(<s>[word="Wanneer"][tag="verb.*"][]*[word="niet"][]*[word=="?"]</s> within <s/>)(<s>[tag="pronpers.*"][tag="verb.*"][]*[word!="?"]</s> within <s/>)

Image 15

A screenshot of CQL query modified from Image 14 to be less restrictive with the personal pronoun after the question mark

RESULT DETAILS

CQL (<s>[word="Wanneer"][tag="verb.*"][]*[word="niet"][]*[word=="?"]</s> within <s/>)(<s>[tag="pronpers.*"][tag="verb.*"][]*[word!=="?"]</s> within <s/>)

Number of hits	270
Number of hits per million tokens	0.04
Percent of whole corpus	0.000003949%
Corpus size (tokens)	6,836,979,371

This gave many fewer interesting results since the results contained many more conversational type sentences as might occur in emails or social media chat. As before, I observed the foregrounding questionification of part of the conditional, related to either the consequent or the antecedent, also with the repetition of content of the question, often in the affirmative, in the following sentence.

3.5.1 The Use of Questionification in Conditionals

I have noticed that conditionals in the PILs investigated are structured as questions and that these are used to set up the antecedents P which are mainly constructed as a list of conditions. The question structure in the PIL documents is rather the (re)formulation of the consequent Q as a question: the conditionals with *implicit consequent Q* can be of the form *Q if P* or indeed *if P then Q* depending on the reader, but the content is easily recoverable from the context of the question. The consequent is left away or implied as an ellipsis. However, the intended consequent which is elided is easily recoverable from the context as mentioned by (Evans, 2007). Interestingly the implied consequent could be either positioned before (sentence-initially) or after the antecedent (sentence-finally).

In the PIL paragraph 2, the implied consequent in each of the antecedents is set up by means of a question. I noted from a supplemental Sketch Engine investigation that either the consequent or antecedent of a conditional can be formulated as a question. From this, it is possible to say something about the different questionification (i.e. the act of making a "question") of the consequent and antecedent that takes place in Dutch. It seems these formulations are frequently used in Dutch media and societal life.

From the Sketch Engine search, I can conclude that outside the PIL documents the use of negation in the questionification of the consequent together with an insubordinate clause structure is rather rare. However, the foregrounding of either consequent or antecedent with questionification together with a repetition of the questionified material in a propositional sentence that follows the question is more widespread.

3.6 Summary

In the results chapter, I presented the analysis of the three subsections of my research question. I mentioned that the clause order found was insubordinate and that this allowed for the ellipsis of the main clause which contained the negation. I showed that there was an incoherence in epistemic stance between the writer of the PIL paragraph 2 and the patient reader. In a CQL search in Sketch Engine for similar conditionals to those found in the PILs analyzed, I managed to determine that the use of conditionals that contained a negation and an insubordinate clause structure is quite rare in general language use. I mention that the questionification of both consequent and antecedent as a communicative device for instruction and conveying information is commonplace in Dutch media and societal life although the use of “niet” in the question is largely confined to the language of PILs.

4. Discussion

4.1 Linguistic Aspects of PIL Warning Conditionals

This research sets out to investigate whether there were aspects of the conditionals used in paragraph 2 of PILs which could serve as a source of anxiety in the reader/hearer/patient. I looked at three aspects of conditionals:

1. clause order
2. language type
3. negation

From the Results section in 3, we see that the aspects of language type do not indicate anything surprising: the type of language used (keyness) and the lexical diversity of this section of PIL paragraph 2 were consistent with an informational/instructional text. The surprising aspects were seen in those of "clause order" and "negation", numbers 1 and 3 in the list above. These two aspects of the conditionals investigated were found to be interrelated, because the structure chosen for the conditionals was of an insubordinate format where a subordinate clause (antecedent) was used as a single (main) clause and the reader was left to infer the consequent clause, which was the clause containing the negation. Put another way, it is because of the aspect of "clause order" that the aspect of "negation" is made implicit. The negation aspect has disappeared into the ellipsis of the consequent, which arises on account of the insubordinate structure chosen for the conditionals of paragraph 2. Nevertheless, the reader/hearer/patient must infer the instructional content of PIL herself by using just such a negation. Furthermore, it has been shown that people interpret conditionals of the *if p then q* type in a probabilistic manner; making judgements about the probability of the antecedent and consequent being true.

In addition to this, since the clause structure used sets up antecedents in the affirmative, the reader is required to *deny the antecedent* (a phrase used in formal logic) in each case to be able to infer that the medicine is safe to take. The conditional instruction "You should <u>not</u> take the medicine if you are allergic to a substance in it" is met with the patient's own thought process (using an *if p then q* format and logic inference), which runs along the lines of "I am <u>not</u> allergic to the substance(s) of the medicine therefore I may take it." The antecedent (p) "You are allergic to a substance in the medicine" is consistently one of the insubordinate clauses which follow the foregrounding question "When should you not take this medicine?" Interestingly from a psychological and philosophical perspective, this type of inference is termed *denial of the*

antecedent (DA) and is recognised as being fallacious with respect to conditional reasoning (Grosset & Barrouillet, 2003, p. 289).

4.1.1 Inference Processing Characteristics

Table 7
The four types of formal logic inferences from a premise of the type "if p then q "

Inference	Minor premise	conclusion	Logic validity
MP: Modus Ponens	p	q	correct
AC: Affirmation of Consequent	q	p	fallacy
DA: Denial of Antecedent	not p	not q	fallacy
MT: Modus Tollens	not q	not p	correct

The table above shows the logic of conditional reasoning given the major premise *if p then q* where the four minor premises arise from either the negation or affirmation of the antecedent or consequent (Grosset & Barrouillet, 2003).

When testing reaction times for forward and backward inferences for the different modes of conditionals which necessarily included affirmative and negative inference tasks, it was found that "negative inferences *take significantly longer* to endorse than affirmative inferences for all the conditional forms" (Grosset & Barrouillet, 2003, p. 304, emphasis added). The negative inference modes were DA and MT and the affirmative modes were MP and AC. MP and AC are forward inferences (i.e. from consequent to antecedent) and DA and MT are backward inferences (i.e. from antecedent to consequent).

Elsewhere, researchers found that when processing the uncertain logical forms of DA and AC "(...)if reasoners manage to retrieve at least one potential alternative, they will tend to produce an *uncertainty response*" (Quinn & Markovits, 2002, p. 190, emphasis added) even if the antecedent is relatively unlikely .

Other research shows that the number of alternative antecedents has an impact on processing. Apparently, when making judgements, we are systematically affected by the number of alternative causes or disabling conditions. The conclusions in conditionals are more

acceptable when they are derived from fewer alternative causes (Cummins et al., 1991, [abstract]). The researchers also found that a discounting principle applied in this situation and that ultimately the reasoner experiences a disinclination "(...) to accept the conclusions of arguments based on conditional scenarios with *many* alternatives**"** (Cummins et al., 1991, p. 281, emphasis added).

Further to this, the presence of two antecedents, which must be denied during the processing, can be seen to require syllogistic reasoning where the conclusion (the consequent) follows from the truth or falseness of multiple premises (disjunctive antecedents). This type of reasoning is known to be influenced by the form of argument and prior beliefs and furthermore, the belief bias effect is known to be "(...) more marked on invalid than on valid forms." (Cummins et al., 1991, p. 281). Here the word "form" refers to the syllogistic form which is a restricted form of the logical conditional forms shown in the table above. Whilst this is not identical to the DA inference task it does show that when people reason deductively, they are sensitive to syntactic form.

Research into context-based approaches to inference shows that interpretations can be determined by such common inferential situations as permission, causation, and obligation (Thompson, 1994, p. 744). The research mentions that *perceived necessity* can be a more influential determining factor than permission in the interpretation of causal relationships. Following this, if the reader/hearer/patient of the PIL paragraph 2 views the information as an assessment of permission, she might choose not to favor interpretations based on permission and instead be inclined to favor those based on perceived necessity (i.e. her thought process might include a thought like, " I really need this medicine to get well"). When seen this way, we can conclude that pragmatic goals are used in the inference process. A permission schema is seen as one of the pragmatic reasoning schemas and seems to facilitate understanding of the inference process in the PIL since it "(...) describes a type of regulation in which taking a particular action requires satisfaction of a certain precondition" (Cheng & Holyoak, 1985, p. 396). The logic of the context-free *p* and *q* of the *if p then q* conditionals is replaced by concepts of "possibility, necessity, an action to be taken, and a precondition to be satisfied," (Cheng & Holyoak, 1985, p. 396) which is considered context-sensitive with regard to a particular purpose. However, this is also not quite appropriate here as there is no regulatory authority where permission is to be

acquired. The PIL paragraph 2 conditionals fall somewhere between a causal and a permission schema.

Returning to the observed probabilistic nature in processing of conditionals, it has been observed that a large proportion of people (50%) when faced with interpreting an *if p then q* conditional which holds also think about the model *if p then ¬q* which does not hold (Evans et al., 2003, p. 335). The *if p then ¬q* model is not part of normal inference logic for the interpretation of conditionals and the authors identified this as a new paradigm regarding how a reasoner evaluates the probability of conditional statements. In context of my research question, this means that this type of reader of the PIL paragraph 2 considers the two possibilities of *if p then q* and if *p then ¬q* where in the medicinal context:

p = you have and an allergy to a constituent in the medicine (antecedent)

q = you should not take this medicine (consequent)

¬q = you may take the medicine (negation of the consequent)

Following this, it is important to remember that the reader is using probabilistic criteria to evaluate the truth of conditional statements. Nevertheless, it is an important insight that a large proportion of PIL paragraph 2 readers also consider the possibility (n.b. that is probability-dependent) of taking the medicine (*¬q:* you may take the medicine) *even if* they have an allergy to it (p: you have and an allergy to a constituent in the medicine). Whatever other thoughts are going through the mind of the patient, this must surely conjure up a degree of anxiety.

Espino & Byrne (2020) have shown that inferences are suppressed in certain types of conditionals, especially counterfactuals which contain additional (i.e. multiple) conditions as in the case for paragraph 2 PIL conditions. The authors mention that "knowledge of alternative conditions suppresses inferences such as denial of the antecedent" (Espino & Byrne, 2020, p. 3/4) and furthermore, that people tend to no longer make this type of inference in the face of these alternatives. This attested behavior can have a destabilizing effect for the PIL reader as mostly there are at least a few disjoint alternatives in the antecedents of the warning. It seems that because of the existence of more than one antecedent, the reader tends to not complete the inference or suppress it. The authors also mention a switch-suppression effect which occurs with counterfactuals with a negation. Instead of viewing the counterfactuals conjunctively (in AND combination), they are viewed disjunctively (in OR combination). This was found to also occur

in negated conditionals as well as negated counterfactuals (Espino & Byrne, 2020, p. 26). See PIL entry 1(h) for an example of negated antecedent.

From Oaksford et al. (2000, p. 897), it appears almost certain (supported by the many theorists on probabilistic conditional inference) that one of the main reasons patients have anxiety when reading medicinal warning conditionals is due to their own probabilistic inferences during the decision-making process. If there is a condition (antecedent, p) for which the patient thinks this has a probability of only 50% to hold in their situation then conflict and anxiety is set up in trying to evaluate the probability of the conditional P(*if p then q*) = P(q|p), by DA (denial of the antecedent) inferential logic.

Other research also shows that moderate P(q|p) probability ratings are likely to give rise to a "neither true nor false" evaluation (Wang & Zhu, 2019, p. 6). The same research suggests that even when there is high but less than 100% probability rating in the warning conditional of PIL paragraph 2, this will be overruled by the patient's own assessment: even when they are not allergic to a substance (¬p), they will still view the conditional *if p then q* as true (instead of inferring ¬p & ¬q), meaning that they will not take the medicine when they should really make the inference that the consequent is also false and that they may take the medicine (i.e. that they correctly infer ¬p & ¬q)). (Wang & Zhu, 2019, p. 17). This appears to be supported in other research (Frosch & Byrne, 2012), which shows the suppression of the DA inference when a counterfactual is involved.

It seems that pragmatic reasoning schemas together with probabilistic inferential reasoning can explain the anxiety in the interpretation processes of a patient reading PIL warnings. The patient having been prescribed a medicine by a doctor or healthcare professional is already predisposed to a positive emotional stance about receiving medication and a strong critical attitude when reading the PIL warnings. "These warnings will probably not apply to me," the patient might say. So, already with a moderate probability rating for the warning advice the patient is put into a state of openness when evaluating the conditional as neither false nor true.

4.1.2 Processing Insubordinate Clauses

Due to the ellipsis of the consequent, the reader only has part of the conditional statement presented. It has been argued that a critical aspect affecting the reasoner of an inferential conditional is the lack of ability to make a unified mental representation of the information

(Wason & Green, 1984, p. 608). The authors explored this with the reduced array selection task (RAST) where the lack of unified mental representation presented a difficulty in the selection task. When considering the use of an insubordinate clause structure in the PIL paragraph 2, where the ellipsis of the consequent is repeatedly used, this lack of unified mental representation is most likely to translate into longer processing time for the patient reader.

The research on probability rating tasks (PRT) suggests that when a negated categorical premise (i.e. the conditional sentence) is presented in implicit form, there is a tendency not to draw a conclusion (Oaksford et al., 2000, p. 897). Following this, the reader of the PIL paragraph 2 with implicit negation consequent (i.e. "You should not take this medicine") is likely to hesitate and avoid drawing conclusions, which would certainly lead to an amount of anxiety and insecurity.

4.2 Discourse Effect of the Observed Clause Order

I have argued that it is possible to call the PIL paragraph 2 counterfactual conditionals (CTFs) since they are conditional constructions, in which the antecedent "is interpreted to be 'contrary to fact'" (Declerck & Reed 2001, p. 13). I have regarded these CTFs as hoped-for assumptions or presuppositions. Thus, perhaps the medicine marketer, in using a structure and language of assumption, that the listed conditions are false (i.e. contrary to the fact) for the patient reading the PIL and that there is no condition which can prevent the medicine being taken. This appears to follow the use of counterfactual conditionals (CTFs) in legal reasoning in Dutch (Nivelle, 2022) where antecedents are used to mention those facts which are beyond dispute or not to be questioned.

Following this, I conclude that the pragmatic force of such CTF conditional formulations in a Dutch PIL paragraph 2 similarly (echoing the language of the courts) presupposes that the negation of antecedents cannot be put into question.

4.3 Freestanding, Stacked-P, Covert-Q or Insubordinate

Dancygier & Sweetser (2005) mention that parts of conditionals may be "freestanding" (pp. 263-266). The authors refer to other earlier work (Haiman 1978, 1986) on these types of conditionals, which is still valid today.

Declerck & Reed (2012) refer to a similar structure as stacked-P conditionals where the different antecedents may also show an interdependence also called entailment. This seems a more sophisticated type of category that rarely occurs with simpler disjunctive antecedents which generally form the structure of paragraph 2 of a PIL. However, as noted in point 3 above, there were times when I did observe a more complicated antecedent such as in PIL entry 9(k). The authors also mention Covert-Q conditionals, which are intended as those Q-clauses which have been "deleted to avoid repetition", but also for "presupposition" and "manipulation" (Declerck & Reed, 2012, pp. 383-386), which appears to go some way to outlining the typology of functions for insubordination.

Evans (2007) introduced the concept of insubordination, which when applied to conditionals is taken to mean the ellipsis of the consequent. This is particularly interesting here as Evans (2007) also mentions the functions of the use of insubordination which relate to the concealing of uncomfortable material or facts. The use of "*als"* in Dutch insubordinate conditionals has a particular politeness function in requesting that an action be carried out, but the authors also note that it can function as a threat, pressing desire or "signaling presupposed information" (Boogaart et al., 2013, pp. 15, 17, 19). I argue, following (Nivelle, 2022) mentioned in the previous paragraph, that the presupposition signaled in a PIL paragraph 2 is that of a counterfactual, namely that you do not have any of the conditions which prohibit you from taking the medicine. The ellipses of consequence result clauses are also recognised to function in the formulation of indirect requests where only the insubordinate reason clause is left explicit (Evans, 2007, p. 410). More importantly however, is the function of the insubordinate in signaling a high level of presupposition (Evans, 2007, p. 410). This can only cause increased anxiety levels in a patient where at some stage she must disagree with the presupposed material. It seems, however, that the presentation of at-issue material through a method of presupposition rather than one of assertion can reduce the frequency of that material being challenged (Lorson et al., n.d.). The researchers found that across the spectrum of participants there was a "(...) dispreference for objecting to presupposed content" (Lorson et al., n.d., p. 4). This again would appear to support the conclusion that it is this aspect of clause order (i.e. the presuppositional nature of insubordination) that provides a main contribution to the complexity and the anxiety of patients when reading paragraph 2 of a PIL.

4.4 Problematic Aspects of the Analysis

The fact that the Mental Spaces theory does not appear to account for the different viewpoints of the medicine provider and the patient (who is sick and has been prescribed the medicine). The medicine provider seeks to fulfill the legal and professional and ethical requirements of informing a patient of the risks and dangers in taking the medicine. The language of the PIL should arguably not set up a tone or epistemic stance that presupposes the drug is safe. What needs further investigation is the extent to which syntactic structures like insubordination in PIL conditionals obscure instructions or present medicinal warning instructions about the safety of a medicine in the form of presuppositions. The patient merely seeks to check that the medicine is safe for her to take given her knowledge of her own medical history.

Most of the research cited for the pragmatic inference logic is based on English and it is possible that these views do not correspond with the inference logic used pragmatically in Dutch or other Germanic languages.

In future work, research could be expanded to include investigations of conditionals in the remainder of paragraph 2 of the PIL as this section appears to have a similar structure to the initial section which was the subject of the present research. From the annotation point of view, further work must be done to identify conditionals using tokenization, lemmatization and tagging. This would be beneficial to a wider community of researchers and deserves more attention in future research.

4.5 Summary

In this chapter, I concluded that the chosen structure of the conditionals (i.e. the use of an insubordinate clause format) appears to contribute to the complexity of processing the information of paragraph 2 of the PIL and therefore is likely to produce anxiety in the patient reader/hearer. Further to this, it appears that the construction which uses denial of the antecedent (DA) as a means of inference logic to determine that the medicine is safe also contributes to the complexity of processing conditional information. In addition to this the number of antecedents has been shown to cause difficulty which is further increased by the fact that people use a probability criterion when assessing whether the antecedent medical condition is true or not in their case. Pragmatic aspects have also been shown to influence processing outcomes and

therefore PIL paragraph 2 warnings will certainly have an anxiety producing effect which is context-dependent. I mention that the presuppositional effect of the insubordinate clause structure together with the implied negative assertion must also cause hesitation and anxiety in cases where the patient, in all probability, has to agree with a condition (drafted as counterfactual) stated in the warning paragraph. Because of the drafting choice of using an implicit main clause assertion which contains a negation (i.e. "You should not take this medicine"), all the conditions in a PIL paragraph 2 need to be denied for the patient to infer that the medicine is safe. I also mention the incoherent discourse effect of PIL paragraph 2 medicinal warnings which is problematic since the PIL must indeed contain contraindication information in one form or another.

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Appendices

Appendix A

The negation part of paragraph 2 of the sample selection of Dutch PILs together with some remarks

1. H128830.pdf: Nalador-500, poeder voor oplossing voor infusie 500 mcg (sulproston)

	Wanneer mag u dit medicijn niet gebruiken?	
a		U bent allergisch voor één van de stoffen in dit medicijn.
b	***Impliciet***: (Gebruik dit middel niet (als):)	Om de geboorte van een levensvatbaar kind in te leiden, omdat nadelige effecten op het kind niet zijn uit te sluiten.
c		U lijdt aan aandoeningen van de luchtwegen zoals aanvalsgewijs optredende benauwheid (astma) of ontsteking van de luchtwegen welke gepaard gaat met hoesten en opgeven van slijm (bronchitis).
d		U heeft reeds bestaande hartafwijkingen, ook zonder verschijnselen van hartfalen (onvoldoende pompkracht van het hart oftewel decompensatio cordis).
e		U heeft vaataandoeningen gehad, in het bijzonder van de bloedvaten van de hartspier (kransvaten).
f		U heeft ernstig verhoogde bloeddruk (hypertensie).
g		U heeft ernstige lever- of nieraandoeningen.
h		U heeft niet ingestelde of ontregelde suikerziekte (diabetes mellitus).
i		U heeft een neiging tot toevallen/stuipen (convulsies).
j		U heeft verhoogde oogboldruk (groene staar oftewel glaucoom).
k		Uw schildklier produceert te veel schildklierhormonen (thyreotoxicose).
l		U heeft een acute besmetting van uw geslachtsorganen (gynaecologische infecties).
m		U heeft een terugkerende (ernstige) ontsteking van de dikke darm (colitis ulcerosa).
n		U heeft een acute maagzweer (ulcus ventriculi).
o		U heeft een bepaalde vorm van bloedarmoede (sikkelcelanemie).

p		U heeft een aandoening van uw rode bloedkleurstof (hemoglobine), genaamd thalassemie.
q		U lijdt in het algemeen aan (een) ernstige ziekte(n).
r		U heeft een baarmoederoperatie gehad.

In PIL 1 we can observe all the right column antecedents are phrased as stand-alone sentences which start with a capital letter and end with a full stop. Whilst these antecedent sentences are stand-alone, they are part of narrative and must be read in context. That narrative relates to the question asked by the title: When should you not take this medicine. Phrase 1(b) is the only sentence which is clearly part of the sentence as it starts with the conjunctive word "om", in order to, (somewhat confusingly also with a capital letter as if appearing to be stand-alone). This is clearly part of a sentence, and therefore it must be inferred that there is a clause which precedes it. This is why I put the Dutch word "Impliciet" before a probable consequent, so the conditional takes the form Q if P, where the if corresponds to "om" in order to.

All the other antecedent sentences (apart from 1(a) which uses "U bent" and 1(c), 1(q) which use "U lijdt") take the verb form "U heeft". It seems possible to view these sentences in two ways: the first is that there is a consequent that precedes the antecedent in a similar fashion to that of 1(b) (with the verb of the antecedent being moved to the other side of the adjective of that clause) and second possibility is that the consequent follows the antecedent in an if P then Q form.

The first possibility also requires the addition of the conjunctive als in addition to the displacement of the verb to the other side of the adjective:

> Gebruik dit middel niet als
>
> (~~U bent~~) *u* allergisch *bent* voor één van de stoffen in dit medicijn.

The native speaker effortlessly makes the adjustment of the verb pronoun inversion in the antecedent. The important point here is that there is a possibility of the consequent to precede the antecedent.

I see the second possibility as an internal reader response to the antecedent made into a question by the reader. So, for example the reader makes the antecedent 1(a) into a question by simply putting a question mark at the end of the sentence and makes the (internal) reply depending on personal knowledge:

> U bent allergisch voor een van de stoffen in dit geneesmiddel(?)
>
> (Dan?) Gebruik dit medicijn dan niet/wel.

In this example the consequent naturally follows in an if P then Q format for the conditional. A similar remark appears regarding the second possibility to all the antecedents of the right-hand

column apart from that of 1(b). Another possibility is that the reader reads the question back to herself in the first person:

> Ben ik allergisch voor een van de stoffen in dit geneesmiddel(?)
>
> Dan mag ik dit medicijn niet/wel gebruiken.

This example is very similar to the previous one except for the use of the first person (the reader is addressing the question to herself) and the verb-pronoun inversion to form the question syntactically as opposed to using intonation.

I have offered ways of interpreting the information which is given in this paragraph. It is not possible to say here how any particular person would interpret the structure of the conditional phrase. This would have to be a topic for further study.

2. H123401.pdf: Dostinex 0,5 mg, tabletten (cabergoline)

	Wanneer mag u dit middel niet gebruiken?	
a		U bent allergisch voor een van de stoffen in dit geneesmiddel.
b		U bent allergisch voor bepaalde migrainemiddelen zoals ergotamine.
c		U bent allergisch voor andere middelen voor onderdrukking van de melkproductie, voor behandeling van aandoeningen die gepaard gaan met hyperprolactinemie (zie rubriek 2) of voor bepaalde middelen die gebruikt worden bij de ziekte van Parkinson zoals bromocriptine, pergolide en lisuride.
d		U heeft in het verleden fibrotische reacties (vorming van littekenweefsel) gehad die uw hartzakje, longen of buik hebben aangetast.
e		U wordt behandeld met Dostinex voor een lange periode en u heeft of heeft fibrotische reacties (vorming van littekenweefsel) gehad die uw hart hebben aangetast.

In PIL 2 again we observe multiple stand-alone sentences of the form “U bent” 2(a)(b(c), “U heeft” 2(d) and “U wordt” 2(e). Here too similar remarks apply to those made above regarding PIL 1.

3. H127621.pdf: Vesanoid, zachte capsules 10 mg (Tretinoïne)

	Wanneer mag u dit middel niet gebruiken?	
a		U bent allergisch voor: • tretinoïne of één van de andere stoffen die in dit geneesmiddel zitten (zie rubriek 6) • andere 'retinoïde'-geneesmiddelen, waaronder isotretinoïne, acitretine en tazarotene • pinda's of soja. Vesanoid bevat namelijk soja-olie
b	Gebruik dit middel niet:	• als u zwanger bent, zwanger wilt worden of borstvoeding geeft (zie rubriek 2, Zwangerschap, borstvoeding en vruchtbaarheid)
c		• als u vitamine A, tetracyclinen of retinoïden gebruikt.
d	Gebruik dit middel niet	als een van de bovenstaande punten op u van toepassing is.
f	Als u twijfelt,	neem dan contact op met u arts of apotheker voordat u Vesanoid gebruikt.

Similar remarks to those made above apply here to the information in the antecedents of 3(a): the consequent could either precede or follow to form the conditional. In 3(b) and 3(c) however the consequent is explicitly positioned to precede the antecedent in a Q if P form.

4. H118758.pdf: Bendamustine HCl Glenmark 2,5 mg/ml poeder voor concentraat voor oplossing voor infusie (Bendamustinehydrochloride)

	Wanneer mag u dit middel niet gebruiken?	
a		• U bent allergisch voor een van de stoffen in dit geneesmiddel.
b	Impliciet: (Gebruik dit middel niet:)	• Tijdens borstvoeding; als de behandeling met Bendamustine HCl Glenmark noodzakelijk is gedurende deze periode, moet u stoppen met de borstvoeding (zie onder "Borstvoeding" in de rubriek "Wanneer moet u extra voorzichtig zijn met dit middel?").
c		• U hebt ernstige leverproblemen (schade aan de functionele [werkende] cellen van de lever).
d		• Uw huid of oogwit wordt geel vanwege lever- of bloedproblemen (geelzucht).

e		• U hebt een ernstig verstoorde beenmergfunctie (beenmergdepressie) en ernstige veranderingen in het aantal witte bloedcellen en bloedplaatjes.
f		• U hebt een grote operatie gehad in de afgelopen 30 dagen voordat de behandeling start.
g		• U hebt een infectie, vooral wanneer dit samengaat met een vermindering van witte bloedcellen (leukocytopenie).
h	Impliciet: (Gebruik dit middel niet:)	• In combinatie met een gele-koortsvaccinatie.

Here in PIL 4 it is the use of the "Tijdens" in 4(b) and "In combinatie met" in 4(h) which strongly imply that the consequent precedes the antecedent. Again, it is somewhat confusing that both these antecedents begin with a capital appearing to signify that these sentences can be considered stand-alone which they clearly cannot. Both these sentences begin with a conjunctive signifying that they are part of a larger sentence where the missing part (the consequent) precedes those conjunctions.

5. H118136.pdf: Metoprololtartraat Aurobindo 50 mg, filmomhulde tabletten (metoprololtartraat)

	Wanneer mag u dit middel niet gebruiken?	
a	Impliciet: (Gebruik dit middel niet:)	• als u allergisch bent voor één van de stoffen in dit geneesmiddel.
b		Of als u allergisch bent voor andere soortgelijke geneesmiddelen (bètablokkers)
c		• als u onvoldoende pompkracht van het hart (hartfalen) heeft die niet behandeld is
d		• als u ernstige hartblok (blokkade van de hartprikkel) en/of een zeer trage hartslag heeft
e		• als u een zeer lage bloeddruk heeft.

All the antecedents listed in the right-hand column of PIL 5 are clearly part of a conditional sentence where (due to the "als u" construction) the consequent precedes the antecedent in a Q if P form.

6. H116661.pdf: TRANYLCYPROMINE MILSTEIN 10 mg OMHULDE TABLETTEN (Tranylcyprominesulfaat)

	Wanneer mag u dit middel niet gebruiken?	
a		U bent allergisch voor één van de stoffen in dit geneesmiddel.
b		U lijdt aan de volgende aandoeningen: - porfyrie (een stoornis bij de aanmaak van bloed)
c		- een bepaalde vorm van kanker van de bijnieren of in het maag-darmkanaal
d		- ongecontroleerde verhoogde werking van de schildklier (hyperthyroidïsm)
e		- problemen met hart en de bloedvaten, zoals een recente beroerte (CVA)
f		- zwelling en verzwakking van een bloedvat (aneurysma)
g		- hoge bloeddruk
h		- problemen met de lever
i		- diabetes insipidus
j		- maligne hyperthermie, een erfelijke aandoening die bij anesthesie tot een levensgevaarlijke stijging van de lichaamstemperatuur kan leiden
k		- problemen met de nieren
l		- delirium, een acute toestand van verwardheid
m		- acute vergiftiging met middelen die werken op het centrale zenuwstelsel zoals slaappillen, pijnstillers en middelen tegen psychische aandoeningen en alcohol

In PIL 6 all the antecedents begin with “U bent” 6(a) or “U lijdt” 6(b).

7. H115752.pdf: Tracydal 20 mg filmomhulde tabletten (Tranylcypromine)

	Wanneer mag u dit medicijn niet gebruiken?	
a		U bent allergisch voor een van de stoffen in dit medicijn.
b		U heeft een bepaalde vorm van kanker van de bijnieren of in het maag-darmkanaal (uw arts zal bepalen of u dit medicijn mag gebruiken).
c		U heeft problemen met hart en bloedvaten, zoals een recente beroerte (CVA), een verwijding van de slagaders (aneurysma), of hoge bloeddruk.
d		U heeft problemen met de lever.
e		U heeft ernstige problemen met de nieren.
f		U lijdt aan porfyrie, een stoornis bij de aanmaak van bloed.
g		U lijdt aan diabetes insipidus, een ziekte waarbij u veel drinkt omdat u veel dorst heeft en veel moet plassen.
h		U heeft een delirium, een acute toestand van verwardheid.
i		U heeft een acute vergiftiging doordat u te veel slaappillen, pijnstillers en medicijnen tegen psychische aandoeningen heeft gebruikt en doordat u mogelijk ook te veel alcohol heeft gebruikt.
j		U lijdt aan maligne hyperthermie (een zeldzame erfelijke ziekte die bij anesthesie tot een levensgevaarlijke stijging van de lichaamstemperatuur kan leiden).

In PIL 7 only “U bent” and “U lijdt” are used to introduce the antecedents.

8. H115266.pdf: Pulentia 200 microgram/6 microgram/dosis inhalatiepoeder, voorverdeeld (budesonide / formoterolfumaraatdihydraat)

	Wanneer mag u dit middel niet gebruiken?	
a		u bent allergisch voor budesonide, formoterol of één van de stoffen in dit geneesmiddel.
b		u bent allergisch voor lactosemonohydraat (dat kleine hoeveelheden melkeiwit bevat).

In PIL 8 only “u bent” is used to introduce the antecedents. Interesting to note here is that the head letter “u” is not a capital which gives the strong suggestion that the consequent should precede the antecedents.

9. H114885.pdf: Selokeen ZOC 100, tabletten met gereguleerde afgifte 95 mg (metoprololsuccinaat)

	Wanneer mag u dit middel niet gebruiken?	
a	Impliciet: (Gebruik dit middel niet:)	Als u allergisch bent voor een van de stoffen die in dit geneesmiddel zitten.
b		Als u overgevoelig bent voor andere bloeddrukverlagende middelen van hetzelfde type als Selokeen, zgn. bètablokkers;
c		Als u stoornissen heeft in de prikkelgeleiding van het hart (2e- en 3e-graads AV-blok);
d		Als u acuut hartfalen of hartfalen heeft dat niet onder controle is met vocht in de longen (longoedeem) of een verlaagde bloeddruk (hypotensie);
e		Bij een 'shock' veroorzaakt door onvoldoende pompwerking van het hart;
f		Als u lijdt aan ernstige doorbloedingsstoornissen;
g		Bij ernstig vertraagde hartslag (bradycardie);
h		Als u continu of met tussenpozen behandeld wordt met bepaalde middelen die de pompkracht van het hart beïnvloeden (zgn. bèta-agonisten);
i		Als u een bepaalde stoornis in het hartritme (sick-sinussyndroom) heeft en u heeft hiervoor geen pacemaker gekregen;
j		Als u een hartinfarct (myocardinfarct) heeft in combinatie met een trage hartslag, een lage bloeddruk of gedecompenseerd bent;
k		Als u het middel verapamil per injectie in de aderen krijgt toegediend, omdat de bloeddruk daardoor kan dalen, omdat hartgeleidingsstoornissen kunnen optreden en omdat hartfalen kan ontstaan.

PIL 9 is rather confusing since each of the antecedent sentences start with a capitol letter giving the impression that they can be considered stand-alone. However, this is not the case since, apart from 9(e) and 9(g) which use "Bij een", all the antecedents start with "Als u". Because of the use of the conjunction als and bij a clear indication of preceding consequent is given. Therefore, all the conditionals are in a *Q if P* form.

I see in 9(k) that here further antecedents appear to be added and also entailed, the one entails the other.

10. H109939.pdf: Drospirenon/Ethinylestradiol 3/0,02 mg 24+4 Sandoz®, filmomhulde tabletten (ethinylestradiol/drospirenon)

	Wanneer mag u dit middel niet gebruiken?	
a	U mag dit middel niet gebruiken	als u een van de hieronder vermelde aandoeningen heeft.
b	Als u een of meer van de hieronder vermelde aandoeningen heeft,	vertel dit dan aan uw arts.
c		• U heeft een bloedstolsel in een bloedvat van de benen (diepe veneuze trombose, DVT), de longen (longembolie, PE) of een ander orgaan, of u heeft dit in het verleden gehad.
d		• U weet dat u een stoornis heeft die uw bloedstolling beïnvloedt – bijvoorbeeld proteïne C-deficiëntie, proteïne S-deficiëntie, antitrombine-III-deficiëntie, factor V-Leiden of antistoffen tegen fosfolipiden.
e		• U moet worden geopereerd of u bent gedurende lange tijd niet op de been (zie rubriek Bloedstolsels (trombose)).
f		• U heeft ooit een hartaanval of beroerte gehad.
g		• U heeft angina pectoris (een aandoening die hevige pijn in de borst veroorzaakt en een eersteverschijnsel van een hartaanval kan zijn) of een transiënte ischemische aanval (TIA – voorbijgaande symptomen van een beroerte), of u heeft dit ooit gehad.
h		• U heeft een van de volgende ziektes, die het risico op een bloedstolsel in uw slagaders kunnen verhogen:
i		- ernstige diabetes met beschadiging van bloedvaten;
j		- ernstig verhoogde bloeddruk;
k		- een ernstig verhoogd vetgehalte in uw bloed (cholesterol of triglyceriden);
l		- een aandoening die hyperhomocysteïnemie wordt genoemd.

m		• U heeft een type migraine dat "migraine met aura" wordt genoemd, of u heeft dit gehad.
n		• U heeft een leveraandoening (of u heeft er ooit een gehad) en de werking van uw lever is nog niet normaal.
o		• Uw nieren werken niet goed (nierfalen).
p		• U heeft een tumor in uw lever (of u heeft dit ooit gehad).
q		• U heeft borstkanker of kanker van de geslachtsorganen (of u heeft dit ooit gehad) of er bestaat een vermoeden dat u dat heeft.
r		• U heeft bloedverlies uit uw vagina waarvan de oorzaak niet duidelijk is.
s		• U bent allergisch voor ethinylestradiol of drospirenon, of voor een van de andere stoffen die in dit middel zitten.
t	Gebruik dit medicijn niet	als u hepatitis C heeft en medicijnen gebruikt die ombitasvir/paritaprevir/ritonavir en dasabuvir, glecaprevir/pibrentasvir of sofosbuvir/velpatasvir/voxilaprevir bevatten (zie rubriek 2 “gebruikt u nog andere medicijnen”).

PIL 10 shows an unusual trait in that before the medical information of the antecedents is given at 10(c), two different general “interpretational” conditional phrases are presented, one in a Q if P form 10(a) and the other in an if P then Q form 10(b).

All the antecedents from 10(c) to 10(s) start with either “U heeft”, “U weet”, “U moet”, “Uw” and “U bent”. This suggests, as before, that either of the two conditional forms observed may be used Q if P or if P then Q. In 10(t) because of the explicit imperative consequent only the Q if P form is presented.

11. H09355.pdf: Parlodel 2,5 mg tabletten, 5 mg capsules (Bromocriptinemesilaat)

	Wanneer mag u dit middel niet gebruiken?	
a		• U bent allergisch voor één van de stoffen in dit geneesmiddel.
b	Impliciet: (Gebruik dit middel niet:)	• Wanneer u overgevoelig bent voor middelen die op dit middel lijken, de zogenaamde ergotalkaloïden.
c		• U heeft een hartaandoening of een andere ernstige aandoening van de bloedvaten of u heeft deze gehad.

d		• U heeft een hoge bloeddruk.
e	Impliciet: (Gebruik dit middel niet:)	• Tijdens of na zwangerschapsvergiftiging.
f		• U heeft ooit bloeddrukproblemen tijdens de zwangerschap of in het kraambed gehad, zoals eclampsie, pre-eclampsie, hoge bloeddruk door de zwangerschap en hoge bloeddruk na de bevalling.
g		• U heeft ernstige psychische stoornissen of u heeft deze gehad.
h	Impliciet: (Gebruik dit middel niet:)	• Als u gedurende lange tijd met dit middel zult worden behandeld en zich bij u fibrotische reacties (vorming van littekenweefsel) voordoen of hebben voorgedaan met aantasting van uw hart als gevolg.

In PIL 11, each antecedent starts with a capital which is only confusing where that word is a conjunctive as in 11(b) “Wanneer”, 11(e) “Tijdens” and 11(h) “Als” where this necessarily implies a preceding consequent. The other antecedents would appear to allow the consideration of a preceding or following consequent as mentioned in similar cases above.

12. H57689.pdf: AdreView, Iobenguane Injection, oplossing voor injectie 74 MBq/ml (jobenguaan)

	Wanneer mag u dit middel niet toegediend krijgen?	
a		• U bent allergisch (overgevoelig) voor jobenguaan of één van de andere bestanddelen (zie rubriek 6).
b	(• *Niet gebruiken...*)	• Niet gebruiken bij te vroeg geboren kinderen of pasgeborenen.
c	Gebruik AdreView niet	als het bovenstaande op u van toepassing is.
d	Overleg met uw nucleaire geneeskunde arts of verpleegkundige	als u niet zeker bent.

PIL 12 is interesting because of the number of explicit consequent first conditionals, 12(b), (c) and (d). Only the antecedent 12 (a) appears to leave open the two possibilities of the consequent preceding or following the antecedent.

13. H34406.pdf: Fluvastatine Sandoz® 40 mg, harde capsules (fluvastatine)

	Wanneer mag u dit middel niet gebruiken?	
a		• U bent allergisch voor een van de stoffen in dit geneesmiddel.
b	Impliciet: (Gebruik dit middel niet:)	• Als u op dit moment leverproblemen heeft, of onverklaarbare aanhoudend hoge leverwaarden (transaminasen).
c		• Als u zwanger bent of borstvoeding geeft (zie Zwangerschap en borstvoeding).
d	Als één van deze zaken op u van toepassing is,	neem dit middel dan niet in en neem contact op met uw arts.

In PIL 13 the explicit use of the if P then Q form is seen in 13(d). The antecedents of 13(b) and (c) although beginning with a capitalise “Als”, necessarily indicate a preceding consequent as shown in the left-hand column of 13(b).

14. H30130.pdf: Metoprololsuccinaat 1A Pharma® retard 200, tabletten met gereguleerde afgifte 190 mg (metoprololsuccinaat)

	Wanneer mag u dit middel niet gebruiken?	
a		U bent allergisch voor één van de stoffen die in dit geneesmiddel zitten.
b		U bent allergisch voor andere bloeddrukverlagende middelen uit dezelfde groep als dit middel, namelijk de bèta-blokkers.
c		U heeft stoornissen in de prikkelgeleiding van het hart (2e- en 3e-graads AV-blok).
d		U heeft acuut hartfalen of hartfalen dat niet onder controle is, met vocht in de longen (longoedeem) of een verlaagde bloeddruk (hypotensie).
e	Impliciet: (Gebruik dit middel niet:)	Bij een 'shock' veroorzaakt door onvoldoende pompwerking van het hart.
f		U lijdt aan ernstige doorbloedingsstoornissen.
g	Impliciet: (Gebruik dit middel niet:)	Bij een ernstig vertraagde hartslag (bradycardie).

h		U wordt continu of met tussenpozen behandeld met bepaalde middelen die de pompkracht van het hart beïnvloeden (zgn. bèta-agonisten).
i		U heeft een bepaalde stoornis in het hartritme (sick sinus syndroom).
j		U heeft een hartinfarct (myocardinfarct) in combinatie met een trage hartslag, een lage bloeddruk en hartfalen.
k		U krijgt het middel verapamil per injectie in een ader toegediend, omdat daardoor de bloeddruk kan dalen, hartgeleidingsstoornissen kunnen optreden en hartfalen kan ontstaan.
l		U lijdt aan longaandoeningen zoals astma of luchtwegaandoeningen.
m		U heeft een gezwel van het bijniermerg, dat gepaard kan gaan met plotselinge sterke bloeddrukverhoging, heftige hoofdpijn, zweten en versnelde hartslag (feochromocytoom).

(see third last antecedent here: incomprehensible or ambiguous at least)

In PIL 14 we observe most antecedents with stand-alone sentences starting with “U bent”,“U heeft”, “U lijdt”, “U wordt” and “U krijgt” indicating that both preceding and following consequents are possible with each antecedent. Only 14 (e) and (g) use “Bij een” which necessarily implies the use of a preceding consequent.

Although commenting on the content of the PILs is beyond the scope of this research a small word about the syntactic structure of information in 14(k) seems appropriate. The antecedent of 14(k) contains three clauses in total: the first is considered the main antecedent which is followed by a comma and a second clause which starts “omdat” and terminates with a comma before a third clause starts with “hartgeleidingsstoornissen”. The sentence appears to descend into apparently needless complexity after the initial antecedent in an attempt to motivate or clarify the initial antecedent. The second two clauses of this antecedent appear to refer to medical consequences of the combination of the PIL medicine with the injected drug verapamil. However, the warning paragraph should most probably stop after the first clause since this is the condition which should exclude the combination of the two drugs. It is a most confusing antecedent 14(k).

15. H18718.pdf: Geïnactiveerd Rabiësvaccin Mérieux HDCV, poeder voor injectievloeistof 2,5 I.E (Geïnactiveerd rabiësvirus)

	Wanneer mag u dit middel niet gebruiken?	

a	Behandeling voor blootstelling aan het rabiësvirus:	
b	Impliciet: (Gebruik dit middel niet:)	• als u koortsig bent of een andere acute aandoening hebt.
c		• als u overgevoelig bent voor een van de bestanddelen van het vaccin.
d		• als u weet dat u om andere redenen dit vaccin niet verdraagt.
e	Behandeling na blootstelling aan het rabiësvirus:	
f	De mogelijke gevolgen van een besmetting met rabiësvirus zijn bijzonder ernstig. Daarom is het bovenstaande niet van toepassing	na contact met materialen of dieren die met rabiës besmet kunnen zijn.

(really confusing here as the conditional antecedents (and so also the consequent) are restricted to being valid only before contact with a rabies infected animal.) (use of the vaccine is not appropriate after contact (i.e. if there has already been contact) with a rabies animal)

In PIL 15 which relates to a rabies vaccine there is a further piece of warning information which relates to treatment before or after contact with the rabies virus. The antecedents 15(b), (c), (d) all start with non-capitalised “als” and therefore imply a preceding consequent. The conditional of 15(f) explicitly uses a consequent first in a Q if P form where “na” corresponds to “if”.

16. H26283.pdf: Gemfibrozil Aurobindo 900 mg, filmomhulde tabletten (gemfibrozil)

	Wanneer mag u dit middel niet gebruiken?	
a		• U bent allergisch voor een van de stoffen in dit geneesmiddel zitten.
b	Impliciet: (Gebruik dit middel niet:)	• Als u een leverfunctiestoornis heeft;

c		• Als u ernstige nierfunctiestoornissen heeft;
d		• Als u galstenen of een aandoening aan de galwegen of de galblaas heeft of deze heeft gehad
e		• Als u in het verleden een foto-allergische of fototoxische reactie (een allergische reactie door blootstelling aan zonlicht) gehad heeft tijdens een behandeling met fibraten
f		• Als u op dit moment het geneesmiddel repaglinide (een bloedsuikerverlagend middel bij suikerziekte, simvastatine of 40 mg rosuvastatine (cholesterol verlagende geneesmiddelen) of dasabuvir (een geneesmiddel dat wordt gebruikt voor de behandeling van infecties met hepatitis C) of selexipag (een geneesmiddel dat wordt gebruikt voor de behandeling van pulmonale arteriële hypertensie) gebruikt.

PIL 16 uses an antecedent in 16(a) “U bent” which allows the two possibilities mentioned above. The antecedents 16(b) to (f) all start with “Als u” which, although confused by the capitalisation of “Als” implies that a consequent must necessarily precede these antecedents.

17. H28924.pdf: Paroxetine Mylan 30 mg, filmomhulde tablette (paroxetine)

	Wanneer mag u dit middel niet gebruiken?	
a		• U bent allergisch voor één van de stoffen die in dit geneesmiddel zitten.
b	***Impliciet:*** (Gebruik dit middel niet:)	• Wanneer u zogenaamde monoamineoxidaseremmers (MAO-remmers, waaronder moclobemide, linezolid en methylthioninechloride (methyleenblauw)) gebruikt, of één van deze geneesmiddelen op enig moment in de afgelopen twee weken heeft gebruikt.
c	Uw arts zal u adviseren hoe u moet beginnen met het innemen van paroxetine,	nadat u met het gebruik van de MAO-remmer bent gestopt.
d	***Impliciet:*** (Gebruik dit middel niet:)	• Wanneer u antipsychotische geneesmiddelen (middel tegen psychose, ernstige geestesziekte) genaamd thioridazine of pimozide gebruikt.
e	Wanneer één van de bovenstaande punten op u van toepassing is,	vertel dit dan aan uw arts én neem Paroxetine Mylan niet in.

PIL 17 shows the traits seen above. Antecedent 17(a) “U bent” allows the two possibilities for the consequents: before or after the antecedent. The antecedents 17(b), (c) and (d) use preceding consequents where, aside from the confusing capitalisation of the starting word “Wanneer”, a preceding consequent is necessarily indicated. Antecedent 17(c) explicitly uses a preceding consequent in the Q if P form where “nadat” corresponds to “if”. In 17 (b) and (c) “Wanneer” corresponds to “als”. Finally, the if P then Q form is used explicitly in 17(e).

Appendix B

URLs for the selected sample of PIL documents

The internet links to the files of 17 PILs selected are shown below (the wording may differ slightly from the version downloaded in October 2022 for this research):

1. **https://www.geneesmiddeleninformatiebank.nl/bijsluiters/h128830.pdf**
2. **https://www.geneesmiddeleninformatiebank.nl/bijsluiters/h123401.pdf**
3. **https://www.geneesmiddeleninformatiebank.nl/bijsluiters/h127621.pdf**
4. **https://www.geneesmiddeleninformatiebank.nl/bijsluiters/h118758.pdf**
5. **https://www.geneesmiddeleninformatiebank.nl/bijsluiters/h118136.pdf**
6. **https://www.geneesmiddeleninformatiebank.nl/bijsluiters/h116661.pdf**
7. **https://www.geneesmiddeleninformatiebank.nl/bijsluiters/h115752.pdf**
8. **https://www.geneesmiddeleninformatiebank.nl/bijsluiters/h115266.pdf**
9. **https://www.geneesmiddeleninformatiebank.nl/bijsluiters/h114885.pdf**
10. **https://www.geneesmiddeleninformatiebank.nl/bijsluiters/h109939.pdf**
11. **https://www.geneesmiddeleninformatiebank.nl/bijsluiters/h09355.pdf**
12. **https://www.geneesmiddeleninformatiebank.nl/bijsluiters/h57689.pdf**
13. **https://www.geneesmiddeleninformatiebank.nl/bijsluiters/h34406.pdf**
14. **https://www.geneesmiddeleninformatiebank.nl/bijsluiters/h30130.pdf**
15. **https://www.geneesmiddeleninformatiebank.nl/bijsluiters/h18718.pdf**
16. **https://www.geneesmiddeleninformatiebank.nl/bijsluiters/h26283.pdf**
17. **https://www.geneesmiddeleninformatiebank.nl/bijsluiters/h28924.pdf**