Descriptive Abstract

The EU has issued three directives for patient package leaflets (PPLs) for drugs distributed within the EU: the directives 92/27/EEC, 2001/83/EEC and 2004/27/EEC. These directives were to aid the establishment of an internal market with free movement of goods and to protect consumer interests. All directives are mainly concerned with the type of information needed and the order in which it has to be presented. Only some of the directives’ articles state that the leaflets have to be legible and clearly comprehensible. A additional non-mandatory guideline is concerned with the way in which the information has to be formulated, however, the detail of information needed is left open. Aiming at the unification of the internal European market, cultural differences between the countries were ignored. However, these differences do exist (cf. Hofstede, 2001, Schwartz 1994, Claes & Gerritsen, 2002) and they were shown to have an influence on document design (cf. Hoeken et al., 2003). The question is whether they also have an impact on PPLs and whether the scope the EU directives leave for the
design of PPLs is used differently in the Netherlands and Germany. Our study based on 5 German and 5 Dutch PPLs for Ibuprofen shows that these differences do exist. It also shows that pregnant women in both countries appreciate the Dutch PPL more than the German one when looking at its content and language use. However, it is the German version that leads to a more adequate drug use in both countries.

**Keywords**: Patient Package Leaflets, Culture, Germany, Netherlands, EU Directives, communicative effectiveness, appreciation, adequate drug use

MARINEL GERRITSEN, born in Haarlem, the Netherlands studied Linguistics at the Université Catholique d'Angers, the University of Leiden and the University of Amsterdam. She received her doctoral degree in Sociolinguistics from the University of Leiden.

She worked for government and multinationals and held positions at a number of universities in Europe and at the Royal Netherlands Academy of Arts and Sciences. She holds the Christine Mohrmann chair at the University of Nijmegen. Her research currently concentrates on differences between cultures in communication and its impact on intercultural communication and on the use of English as an international language in Europe.

ULRIKE NEDERSTIGT, born in Wolfsburg, Germany, studied English and German at the Free University Berlin, the University of Manchester and the Albert-Ludwigs University Freiburg. In 1997, she was awarded a PhD-stipend from the Max-Planck Society. In 2003, she received her doctoral degree in General Linguistics from the
Humboldt University Berlin. In 2003, she joined the Department of Business Communication at the University of Nijmegen. She works on structural differences between different languages and the consequences for these differences in text construction and communication across languages. She also worked on child language acquisition and focus particles.

FABIA ORLANIDINI

Fabia Orlandini was born in Trieste (Italy). Between 1998 and 2003 she studied Dutch at the School of Interpreting and Translation at the University of Trieste. In 2003, she spent five months at the University of Nijmegen to write her Master thesis. Parts of her research, which was supervised by the first two authors, are reported in this article. In July 2003, she graduated “cum laude”. She currently works as a translator in Klagenfurt, Austria.
1. Background

The EU has issued three directives for patient package leaflets (PPLs) for drugs distributed within the EU: the directives 92/27/EEC, 2001/83/EC and 2004/27/EC. The latter is an amendment of the 2001 directive. These directives were to aid the establishment of an internal market with free movement of goods. They were also to protect consumer interests. Although the 2001 and 2004 directives are much more detailed than the 1992 one, all the directives are mainly concerned with the type of information needed and the order in which it is to appear. The later directives sometimes state that PPLs need to be legible and comprehensive as the below examples show:

(1) “The provisions governing the information supplied to users should provide a high degree of consumers protection, in order that medicinal products may be used correctly on the basis of full and comprehensible information” (2001/83/EEC, article 40).

(2) “The particulars (for example warnings, precautions MG, UN, FO) referred to […] shall be legible, clearly comprehensible […]” (2001/83/EEC, article 56).

(3) “For the identification of the medical product: […] (ii) The pharmaco-therapeutic group or type of activity in terms easily comprehensible for the patient” (2001/83/EEC, article 59 1, a, ii).

(4) “The package leaflet must be written in clear and understandable terms for the users and be clearly legible in the official language or languages of the member State where the medicinal product is placed on the market (2001/83/EEC, article 63, 2)

The EU’s growing concern for the actual wording of PPL becomes clear when we look at (4) above and the amendment of this article in (5), the first line in (6) and the article under (7) and (8):
(5) “The package leaflet must be written and designed to be clear and understandable, enabling the users to act appropriately, when necessary with the help of health professionals”. (2004/27/EC, article 48)

(6) “As necessary the Commission shall publish guidelines concerning in particular:
  o the formulation of certain special warnings for certain categories of medicinal products
  o the particular information needs relating to self medication
  o the legibility of particulars on the labeling and package leaflet” (2001/83/EEC, article 65a)

(7) “In consultation with the member States and the parties concerned, the Commission shall draw up and publish detailed guidance concerning in particular […].” (EC 2004/27/ECC, article 49)

(8) The package leaflet shall reflect the results of consultations with target patient groups to ensure that it is legible, clear and easy to use (EEC 2004/27/EC, article 44, 3)

Despite the more rigid formulations, these directives still leave scope for the actual design of PPLs. For example, if you look at article 59 of 2001/83/EEC²

(9) “a list of information which is necessary before taking the medicinal product:
  o contra-indication;
  o appropriate precautions for use;
  o forms of interaction with other medicinal products and other forms of interactions (e.g. alcohol, tobacco, foodstuffs) which may affect the action of the medical product;
  o special warnings;

The list must:
  o take into account the particular condition of certain categories of users (e.g. children, pregnant or breastfeeding women, the elderly, persons with specific pathological conditions)
  o mention, if appropriate, potential effects on the ability to drive vehicles or to operate machinery;
  o detail those excipients, knowledge of which is important for the safe and effective use of the medicinal product and included in the guidelines published pursuant to Article 65”
The direction provides information with respect to the type of information needed, but none on the detail of this information and the way it has to be represented. Is it for example sufficient to say that pregnant women should not take a particular medication or do we also have to state the reasons why; or is it possible to use specialist terminology or not. In 1998, a supplementary EU-guideline (Guideline on the readability of the label and package leaflet of medicinal products for human use) was issued; it concerns the readability of the label and patient package leaflet of medicinal products for human use. This supplementary guideline provides very detailed guidance with respect to the type set, the layout, the format, the content as well as the style of these leaflets, and it provides a model leaflet and a method for testing the readability of PPLs. However, this readability guideline is not mandatory, which means that EU members can interpret it according to their own needs when it comes to the content, style and layout of PPLs as long as they remain within the scope of the above mentioned directives. The question is whether they take the liberty to do so, or whether – in the interest of uniformity within the EU – apply those guidelines.

Based on results of research on differences in cultural values between the EU-countries (Hofstede, 2001, Schwartz 1994, Claes & Gerritsen, 2002) and the impact of these differences on document design (Hoeken, Van den Brandt, Crijns, Domínguez, Hendriks & Planken, 2003, Honold, 1999, Fukuoka, 1999, Le Pair, Crijns & Hoeken, 2000) we would expect that the pharmaceutical companies in the different countries make use of the scope of these directives and come up with different PPLs for the respective countries. Growing competition among the different pharmaceutical companies would support this assumption because the PPL is an important way to meet consumers’ needs and distinguish oneself from competitors. On the other hand, we
would expect that with increasing globalization, pharmaceutical companies try to minimize their costs by selling a uniform product in all the countries they operate in and save the costs for the design of several different PPLs.

In this paper, we investigate whether differences in cultural values between countries in the European Union have an impact on the design of PPLs within the scope of the directive 2001/83/EC and its supplements. Our study concentrates on the Netherlands and Germany. The starting point of our study is work by Claes and Gerritsen (2002), Hall (1976) and Hofstede (2001), Hampden-Turner and Trompenaars (2000) on cultural differences between the two countries. Their work is discussed in section 2, in section 3 we look at the legal aspect of PPLs in the two countries. In section 4, the results of a corpus analysis of German and Dutch PPLs for Ibuprofen 400 tablets are presented. The results of this corpus analysis form the basis for our experimental research on the appreciation and communicative effectiveness of a German and Dutch version of a PPL among potential German and Dutch users of Ibuprofen tablets, which is described in section 5.

2. Differences in cultural values between Germany and the Netherlands and their possible impact on the design of PPLs

One of the key notions in the research on cultural differences is the notion of values. Values are defined as broad tendencies to prefer a certain state of affair over others, whether, for example, one believes that it is normal to obey the rules of a society at all costs. Up to now cultural specialists distinguish about fifteen different values centered on 6 basic values (Kluckhohn & Strodtbeck, 1961, Claes & Gerritsen, 2002):
1. the character of human nature
2. the relationship of people to other people (individualism versus collectivism, power distance, universalism versus particularism, neutral versus emotional, achieved versus ascribed status)
3. what motivates people (masculinity versus femininity, uncertainty avoidance)
4. the relationship of people to space (personal space, territory, specific versus diffuse),
5. the relationship of people to time (monochrony versus polychrony, relationship past, present, future, short versus long term orientation)
6. the relationship of people to nature

Those values are learned implicitly. By the age of ten most children have acquired the values of their own culture. The values of one culture or nation are never absolute, not all the people of one culture have exactly the same values, but in most cases the differences within one culture or nation are much smaller than those between different cultures or nations.

The question is in how far cultural values can have an influence on the document design or more precisely on the design of PPLs. Following Hofstede (2001) there is no single aspect of our lives that is not influenced by culture. We would therefore expect the way in which PPLs are written is also influenced by the culture in which the leaflets are used, and that they also reflect the values of this particular culture. The communicative function of PPLs is threefold: It needs to inform a patient about illnesses and symptoms and their remedies, it needs to instruct a patient in the proper dosage and use of the drug, and it needs to persuade patients that the medication is the right one for
their illness or symptom, and that the patient’s use of the product is in compliance with the use intended by the pharmaceutical company. Research on persuasive and instructive texts has shown that culture plays an important role in the design of these text types (cf. e.g. Albers-Miller & Gelb, 1996, de Mooij, 1998, Le Pair et al., 2000, Hoeken et al., 2003, Hoeken, 1998, Jansen, 1999). The two text types appeal to the values of the target group.

The cultural values of Germany and the Netherlands have been relatively well researched. There are studies on almost all of the 15 values that have been described so far (Claes & Gerritsen 2002, p. 168). These studies have shown that the two cultures differ considerably in 3 of the 15 values, namely masculinity, individualism and uncertainty avoidance. The latter seems to be particularly interesting with respect to PPLs. In cultures with high uncertainty avoidance unpredictability is seen as a constant threat that needs to be avoided and controlled. In order to do so, people from highly uncertainty avoiding cultures try to create rigid structures and formulate everything as explicitly and precisely as possible; nothing is left to chance. On a scale of 0 (low uncertainty avoidance) to 100 (high uncertainty avoidance) the Netherlands score 53 and Germany 64 (Hofstede, 2001, p. 500). Even though this difference is not very large, we expect that the difference in uncertainty avoidance is reflected in the interpretation of the EU directives and consequently in the design of PPLs because for an important part these texts contain information on risks: contra-indication, precautions and interactions. We expect that these risk are verbalized differently in German and Dutch PPLs.

Though research on the relation between culture and communication is still in its infancy and it is difficult to directly relate culture to communication, we attempt to do
so. Given that the EU directives leave scope for the culture specific design of PPLs, and the fact that Germany scores higher on uncertainty avoidance that the Netherlands, we expect to find the following:

1. **German PPLs contain more elaborate and detailed information than their Dutch equivalents**

   A lot of detailed information minimizes unpredictability.

2. **German PPLs are more structured than their Dutch equivalents**

   In order to be able to access a lot of information a text needs more structure, especially on a secondary level, than a text containing less information.

3. **German PPLs make use of specific – medical and pharmaceutical – terminology more often than their Dutch equivalents**

   Specialist terminology increases accuracy.

4. **German PPLs contain more information on risks than their Dutch equivalents**

   Naming risks reduces the unpredictability concerning one’s health.

The Netherlands and Germany differ with respect to another aspect that is not related to cultural values, but is very important to communication: context. Hall (1976) argues that human beings are confronted with many perceptual stimuli and that it is impossible to pay attention to all of them at the same time. He argues that cultures differ in the extent to which they use contextual and situational information for the interpretation of a message. There is a continuum that ranges from high- to low-context cultures. In high-context cultures, for example Asian cultures, the meaning of a message cannot be deduced from the meaning of the words, but has to be deduced from the context and the
situation. In low-context cultures, for example Germany, the meaning of a message can be deduced from the meaning of the words; here context and situation play only a minor role. Contexts in high-context cultures are implicit. In low-context cultures, they are explicit; every detail is mentioned and preferably put down in writing.

Hall’s (1976) theory on the differences in context is based on observations rather than experimental research. He did not observe the Netherlands, but grouped it together with the Scandinavian’ countries. He argues that Scandinavian cultures are less explicit than the German culture. The differences in context lead to similar expectations as those mentioned in relation to uncertainty avoidance (cf. 1-4) because cultures with a low-context prefer detailed and accurate information.

3. The impact of culture on the legislation

Before we have a look at the corpus analysis to see whether the results of the analysis come up to our expectation formulated in 1 to 4, we first look at the legislation concerning PPLs in Germany and the Netherlands, the integration of EU-regulation in particular³. Differences in national legislation could also reflect cultural differences between the two countries and consequently have an influence on the design of PPLs.

The Netherlands ratified the European directive 92/27/EEC and incorporated it in the Besluit etikettering en bijsluiter farmaceutische producten (29.06.1994) ‘Decree labeling and patient package leaflets pharmaceutical products’. The 2001 directive was ratified in 2004. The directive as well as the supplement form part of the Dutch Bijslui ter van farmaceutische produkten MEB 5-3.0 (22.01.2004) ‘Patient package leaflets for pharmaceutical products’ issued by the College ter Beoordeling van
Geneesmiddelen ‘Medicines Evaluation Board’. This Dutch directive also contains a translation of the model PPL provided by the European guideline and a list of easy-to-understand terms to be used in PPLs. Any PPL not written according to this model has to be tested with respect to its readability before it can enter the market.

Germany also ratified the European directive 92/27/EEC and integrated the directive into their own Gesetz über den Verkehr mit Arzneimitteln (AMG) ‘law governing the manufacture and prescription of drugs’ in 1994 (Fünftes Gesetz zur Änderung des Arzneimittelgesetzes (09.08.1994) ‘5th law to change the law governing the manufacture and prescription of drugs’). In 2002, they issued the Empfehlung zur Gestaltung von Packungsbeilagen ‘Recommendations for the design of patient package leaflets’ which is based on the ‘Guideline on the Readability of the Label and the Package Leaflet of Medicinal Products for Human Use’, and in 2004 the directive 2001/83/EEC was integrated in the AMG (Zwölftes Gesetz zur Änderung des Arzneimittelgesetzes (30.07.2004) ‘12th law to change the law governing the manufacture and prescription of drugs’). But other than the Dutch, the Germans authorities had their own directive before the European one was introduced. The later Gesetz über den Verkehr mit Arzneimitteln combines German and EU directives. The German authorities did not only translate the European directive, but added detailed comments. They also added a model PPL for all medicinal products available on the German market, and determined header and sub-header that have to appear in the PPL. Summarizing, it can be said that the German directives leaves far less scope to the writers of PPLs and make more suggestions concerning the structure of the text than the Dutch one (expectation 2).
4. The Corpus analysis

4.1. The Corpus

In order to determine the differences between Dutch and German PPLs, we collected
PPLs in both countries in May 2003. Following Schuldt (1992, p. 30) we took a
convenience sample of PPLs for tablet containing only one active substance, namely
400mg Ibuprofen. Our choice was determined by the following three factors:

a) The composition of tablet containing the active substance Ibuprofen hardly varies in
the two countries which means that differences in the PPL can not be attributed to
differences in the composition of the tablets.

b) The majority of tablets containing 400 mg Ibuprofen are non-prescription drugs in
Germany and the Netherlands. For this type of drug PPLs are particularly important
(cf. Schuldt 1992, p. 51) because patients have to make a decision with respect to the
use of the drug. Therefore it is important that patient package leaflets are readable
and comprehensible and fit in with the patient’s culture in terms of form and contents
of the leaflet. In our study we only used PPLs of non-prescription tablets containing
400mg Ibuprofen.

c) Ibuprofen is not only available as brand name drug, but also as generic drug which
means that there are several different products with the same active ingredients on
the market. Consequently, there are several PPLs.
For each country we were able to find 5 different PPLs. All PPLs were –at the moment of collection available- on the Internet (see references). Table 1 gives an overview of the leaflets we used:

<table>
<thead>
<tr>
<th>Name of the product</th>
<th>Pharmaceutical concern</th>
<th>Date PPL was issued</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dutch PPLs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Advil 400</td>
<td>Whitehall Laboratoria B.V.</td>
<td>April 1998</td>
</tr>
<tr>
<td>Ibuprofen 400 Kring</td>
<td>Vereniging Kring-apothekers</td>
<td>May 2000</td>
</tr>
<tr>
<td>Ibuprofen 400 PCH</td>
<td>Pharmacemie BV</td>
<td>November 2001</td>
</tr>
<tr>
<td>MP Ibuprofen</td>
<td>Multipharma B.V.</td>
<td>August 2002</td>
</tr>
<tr>
<td>Ibuprofen 400 Huismerk</td>
<td></td>
<td>May 1999</td>
</tr>
<tr>
<td>German PPLs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Advel</td>
<td>Hexal AG</td>
<td>May 2000</td>
</tr>
<tr>
<td>Aktren Forte</td>
<td>Bayer Vital GmbH</td>
<td>February 2001</td>
</tr>
<tr>
<td>Ibuhexal Akut 400</td>
<td>Hexal AG</td>
<td>July 2000</td>
</tr>
<tr>
<td>Ibu-rathiopharm 400</td>
<td>Ratiopharm GmbH</td>
<td>February 2000</td>
</tr>
<tr>
<td>Vivimed Migräne</td>
<td>Dr. Gerhard Mann GmbH</td>
<td>May 2003</td>
</tr>
</tbody>
</table>

Table 1. PPLs from non-prescription tablets containing 400mg Ibuprofen used in the study

4.2. Research Methodology

We determine the elaborateness and the detail of the information in PPLs (expectation 1) by counting the total number of words used in the PPL assuming that the elaborateness and detail of information increases with the number of words. Given the nature of the document, we did not expect patients to be presented with superfluous information. Since German and Dutch are both Germanic languages and have a similar morphology we did not expect differences to be caused by the nature of the two languages. We used the word count option of Word 2000 to count the total number of words of all the German and the Dutch PPLs.

For the expectations 2, 3 and 4, we concentrated our analysis to the section ‘list of information necessary to know before taking the medicinal product’ (cf. 9) because this
part of text offers the larger scope for culture specific interpretations than sections such as ‘identification of the medicinal product’, ‘therapeutic indications’. We did not look at the subsection ‘forms of interactions with other medicines and other forms of interaction’ because we expected long lists with complicated names.

The degree of structure (expectation 2) was determined by counting the number of headings and subheadings. We also looked for other means that provide structure, e.g. the use of bullets or separate paragraphs. We counted the numbers of specialist terms to determine the degree of specialist terminology usage (expectation 3). The amount of information on risks (expectation 4) was determined by the number of risks mentioned.

The first two authors performed the counts independently. Comparing and discussing the results led to the results as reproduced in tables 2 to 5.

4.3. Results

Elaborateness and detail of information

The differences between Dutch and German PPLs for Ibuprofen become clear by simply looking at them: The German versions are much longer and their font size is much smaller than that of their Dutch equivalent. The results in table 2 confirm this impression.

<table>
<thead>
<tr>
<th>Dutch PPLs</th>
<th>Number of words</th>
<th>German PPLs</th>
<th>Number of words</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advil 400</td>
<td>761</td>
<td>Advel</td>
<td>2039</td>
</tr>
<tr>
<td>Ibuprofen 400 Kring</td>
<td>1050</td>
<td>Aktren Forte</td>
<td>1769</td>
</tr>
<tr>
<td>Ibuprofen 400 PCH</td>
<td>1019</td>
<td>Ibuhexal Akut 400</td>
<td>2350</td>
</tr>
<tr>
<td>MP Ibuprofen</td>
<td>972</td>
<td>Ibu-rathiofhar 400</td>
<td>2003</td>
</tr>
<tr>
<td>Ibuprofen 400 Huismerk</td>
<td>996</td>
<td>Vivimed Migrâne</td>
<td>2370</td>
</tr>
<tr>
<td>mean</td>
<td><strong>959</strong></td>
<td></td>
<td><strong>1706,5</strong></td>
</tr>
</tbody>
</table>

Table 2. Number of words in Dutch and German PPLs
On average the German PPL for Ibuprofen is nearly twice as long as its Dutch equivalent. Though there is quite some variation among the figures for the German as well as the Dutch leaflets with differences of 601 and 289 words respectively, the shortest German PPL is still more than 1.5 times as long as the longest Dutch PPL.

**Structure**

Table 3 shows that the structural differences between the PPLs of the two countries are large. In the Dutch versions, the information is mainly given in four subsections with each one heading. This is more or less the same for all Dutch PPLs. In the leaflet for MP-Ibuprofen we find the headings *Niet gebruiken* ‘Do not use’, *Gebruik tijdens zwangerschap en boerstvoeding* ‘Use during pregnancy and while breastfeeding’, *Invloed op de rijvaardigheid en de bekwaamheid om machines te gebruiken* ‘Influence on the driving ability and the ability to use machines’ and *Waarschuwingen en voorzorgsmaatregelen*. ‘Warnings and precautions’. Further structuring is achieved by means of bullets or separate paragraphs, but hardly by the use subheadings. The structure of the German PPLs is quite different. The German versions make less use of headings, but use more sub-headings. Versions with two headings typically have a heading *Gegenanzeigen* ‘Contra-indications’ and one called *Vorsichtsmaßnahmen für die Anwendung* ‘Precaution for use’, versions with only one heading combine the two under a heading like *Was müssen vor der Einnahme von Aktren® Forte beachten?* ‘What do you need to keep in mind before taking Aktren® Forte’, but use more subsections such as *Kinder* ‘children’, *Schwangerschaft* ‘pregnancy’ or *Worauf müssen Sie noch achten?* ‘What else do you have to keep in mind?’ to provide the necessary
structure. The German PPLs also make use of bullets. The structure of German PPLs is more complex than that of the Dutch ones.

<table>
<thead>
<tr>
<th>Dutch PPLs</th>
<th>Number of headings</th>
<th>Number of sub-headings</th>
<th>German PPLs</th>
<th>Number of headings</th>
<th>Number of sub-headings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advil 400</td>
<td>4</td>
<td>0</td>
<td>Advel</td>
<td>2</td>
<td>7</td>
</tr>
<tr>
<td>Ibuprofen</td>
<td>4</td>
<td>0</td>
<td>Aktren Forte</td>
<td>1</td>
<td>8</td>
</tr>
<tr>
<td>400 Kring</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ibuprofen</td>
<td>3</td>
<td>3</td>
<td>Ibuhexal</td>
<td>2</td>
<td>7</td>
</tr>
<tr>
<td>400 PCH</td>
<td></td>
<td></td>
<td>Akut 400</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MP Ibuprofen</td>
<td>4</td>
<td>0</td>
<td>Ibu-rathiopharm 400</td>
<td>2</td>
<td>8</td>
</tr>
<tr>
<td>Ibuprofen 400</td>
<td>3</td>
<td>2</td>
<td>Vivimed Migräne</td>
<td>1</td>
<td>9</td>
</tr>
<tr>
<td>Huismerk</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>total/mean</td>
<td>18/3.6</td>
<td>5/1.0</td>
<td>8/1.6</td>
<td>39/7.8</td>
<td></td>
</tr>
</tbody>
</table>

Table 3. Structure of Dutch and German PPLs

Use of specific terminology

We distinguished two types of uses of specific terminology: terms that were used as explanation or specification as in (10) and terms that were used as normal words as in (11):

(10) Sie dürfen ADVEL® nicht anwenden bei

- Blutungen im Magen-Darmtrakt (gastrointestinale Blutung)
  ‘You should not use ADVEL® in case of
  - bleedings in the gastro-intestinal tract (gastro-intestinal bleedings)’

(11) … bei Überempfindlichkeit gegen Schmerz- und Rheumamittel aus der Gruppe der nicht-steriodalen Antiphlogistika

  ‘… in case of hypersensitivity to painkillers and medication for rheumatism from the non-steroid antiphlogistics groep’
Table 4 shows that German PPLs make much more use of specific terminology than their Dutch equivalents.

<table>
<thead>
<tr>
<th>Dutch PPLs</th>
<th>simple use</th>
<th>explanatory</th>
<th>German PPLs</th>
<th>simple use</th>
<th>explanatory</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advil 400</td>
<td>0</td>
<td>0</td>
<td>Advel</td>
<td>1</td>
<td>17</td>
</tr>
<tr>
<td>Ibuprofen 400 Kring</td>
<td>1</td>
<td>0</td>
<td>Aktren Forte</td>
<td>7</td>
<td>3</td>
</tr>
<tr>
<td>Ibuprofen 400 PCH</td>
<td>0</td>
<td>0</td>
<td>Ibuhexal Akut 400</td>
<td>17</td>
<td>2</td>
</tr>
<tr>
<td>MP Ibuprofen</td>
<td>1</td>
<td>1</td>
<td>Ibu-rathiopharm 400</td>
<td>14</td>
<td>2</td>
</tr>
<tr>
<td>Ibuprofen 400 Huismerk</td>
<td>1</td>
<td>1</td>
<td>Vivimed Migräne</td>
<td>7</td>
<td>5</td>
</tr>
<tr>
<td><strong>total/mean</strong></td>
<td><strong>3/0,6</strong></td>
<td><strong>2/0,4</strong></td>
<td><strong>62/12,4</strong></td>
<td><strong>12/2,4</strong></td>
<td></td>
</tr>
</tbody>
</table>

Table 4. Use of specific terms in Dutch and German PPLs

**Information on risks**

In a similar way we distinguished between three different types of risks: Risks that are directly mentioned as in (12), those that mentioned indirectly as in (13) and risks that appear in relation to particular circumstances and prevent you from taking Ibuprofen as in (14):

(12) … kann … zur dauerhaften Nierenschädigung führen.

‘… can lead to long term kidney damage’

(13) Sollte von ärztlicher Seite eine langfristige Therapie mit ibu-vivimed®400 gegen Schmerzen für erforderlich gehalten werden, sind regelmäßig Leberwerte, die Nierenfunktion sowie das Blutbild zu kontrollieren.

‘In case of medical indications for a long term treatment with ibu-vivimed®400 the liver – and kidney function and blood counts need to be controlled regularly’

(14) Sie dürfen ibuhexal ® akut 400 nicht anwenden bei ungeklärten Blutbildstörungen.

‘Do not take ibuhexal ® akut 400 in case of unsolved blood count disorders’
As table 5 shows German PPLs mention all three types of risks more often than their Dutch equivalents.

<table>
<thead>
<tr>
<th>Dutch PPLs</th>
<th>direct</th>
<th>indirect</th>
<th>circumstantial</th>
<th>German PPLs</th>
<th>direct</th>
<th>indirect</th>
<th>circumstantial</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advil 400</td>
<td>3</td>
<td>0</td>
<td>17</td>
<td>Advel</td>
<td>5</td>
<td>4</td>
<td>32</td>
</tr>
<tr>
<td>Ibuprofen 400</td>
<td>3</td>
<td>0</td>
<td>17</td>
<td>Aktren Forte</td>
<td>2</td>
<td>3</td>
<td>28</td>
</tr>
<tr>
<td>Kring</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ibuprofen 400</td>
<td>4</td>
<td>0</td>
<td>18</td>
<td>Ibuhexal 400</td>
<td>5</td>
<td>2</td>
<td>29</td>
</tr>
<tr>
<td>PCH</td>
<td></td>
<td></td>
<td></td>
<td>Akut</td>
<td>2</td>
<td>2</td>
<td>28</td>
</tr>
<tr>
<td>MP Ibuprofen</td>
<td>3</td>
<td>0</td>
<td>17</td>
<td>Ibu-rathiopharm</td>
<td>2</td>
<td>2</td>
<td>28</td>
</tr>
<tr>
<td>Vivimed Migräne</td>
<td>4</td>
<td>0</td>
<td>18</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 5. Number of risks mentioned in Dutch and German PPLs

Summing up, our four expectations (see 2.) that were based on differences in uncertainty avoidance and context between the Netherlands and Germany proved to be correct: German PPLs are much longer and more detailed, they are more structured, use more specific terminology and mention more risks than their Dutch equivalents. However, there is also quite a lot of variation among the different German PPLs which we did not expect given the rather rigid German directives (cf. 3).

5. Appreciation by Dutch and German patients

In the previous section, we were able to show that there are a number of differences between Dutch and German PPLs for the drug Ibuprofen. The question is whether the two different PPLs are appreciated differently in the two countries. Based on previous research on the influence of culture on the appreciation of instructive and persuasive texts we pose the following questions:
1. Do Dutch patients appreciate the PPLs that are typical for the Dutch culture more than those that are typical for the German culture?

2. Do German patients appreciate the PPLs that are typical for the German culture more than those that are typical for the Dutch culture?

3. Are PPLs that are typical for the Dutch culture communicatively more effective in the Netherlands than in Germany?

4. Are PPLs that are typical for the German culture communicatively more effective in Germany than in the Netherlands?

5.1. Research Methodology

5.1.1. Materials

Despite the fact that there was some variation among the different German PPLs as well as the different Dutch PPLs, the differences between Dutch and German leaflets were clear for all version of the PPL. Consequently, we randomly took one version from each country and translated them into the respective other language. In order to guarantee the equivalence between the Dutch and the German versions three native or very proficient speakers of Dutch and German translated the respective translations back into the respective source language, discussed difference in translation and came up with the final version of the document. We ended up with four versions of PPLs for a medicine that we gave the non-existing name Pharmapren 400 to avoid possible influences from experiences with a known product.
a) an original Dutch version (D/D)
b) a German translation of the Dutch version (G/D)
c) an original German version (G/G)
d) a Dutch translation of the German version (D/G)

Versions a) and d) were used in the Netherlands, b) and c) in Germany.

5.1.2. Respondents
For this type of experiment it is important to find respondents that are really interested in such a text because the less interested respondents are in a text the less reliable are the results of the experiment. Following Pander, Maat and Lenz (1994) we decided to carry out the experiment among pregnant women. We expected that most pregnant women are very reluctant to take medication and are consequently more interested in the information PPLs provide. With the restriction to pregnant women, we were also able to ask direct questions with respect to the communicative function of parts of the PPL, parts that concerned pregnancy and breastfeeding. This restriction allowed for a closer approximation of a real life situation where pregnant women have to make a choice.

We had a total of 50 Dutch and 49 German respondents. The Dutch respondents were interviewed in two midwives’ surgeries in Nijmegen, the German respondents were interviewed in two German hospitals (in Goch and Kleve) where they either visited the midwives’ surgeries or took part in an antenatal class.
5.1.3. Measuring instruments

The respondents were presented with one of the four versions of the PPL (see 5.1.1.) and had to fill in a questionnaire with questions concerning the text. After a section of more general questions concerning the PPL, they were asked to concentrate on the sections ‘Therapeutic indications’, ‘Contra-indications’, ‘Use of the drug during pregnancy and while breastfeeding’, ‘Warnings’ and ‘Side effects’. Following the EU guideline on readability those are most problematic sections. The above-mentioned sections were marked at the margin with a text marker.

Respondents had to answer questions concerning the language use and the content of these sections. We used 7-point semantics differentials as in (15) and (16):

\[(15)\quad \text{The meaning of the words is} \]
\[
\begin{array}{ccccccc}
\text{very clear} & ) & ) & ) & ) & ) & ) \\
\text{not at all clear} & ) & ) & ) & ) & ) & ) \\
\end{array}
\]

\[(16)\quad \text{There is} \]
\[
\begin{array}{ccccccc}
\text{too much} & ) & ) & ) & ) & ) & ) \\
\text{too little} & ) & ) & ) & ) & ) & ) \\
\end{array}
\]

\[\text{information on side effects and risks.}\]

We controlled for order effects by varying the order of positive and negative answers.

We carried out a reliability analysis over all the German and Dutch data. The results are presented in table 6; they allowed us aggregate some of the data concerning questions on language use and content. In the following we only discuss the aggregated data.

<table>
<thead>
<tr>
<th>Language use</th>
<th>.74</th>
</tr>
</thead>
<tbody>
<tr>
<td>Content</td>
<td>.75</td>
</tr>
</tbody>
</table>

Table 6. Reliability analysis scores on language use and content
In the following part of the questionnaire we tried to find out how effective the different versions of the PPLs were. The communicative function of the respective text passages is to enable the patient to find an adequate answer to the question of whether she could take the medicinal product or not. Respondents were asked to concentrate on the section of pregnancy and breastfeeding and decide on the basis of these text passages whether they would take the drug during their pregnancy. In a second question they were asked whether they would take the drug while breastfeeding. In their answers they had to use one of the following five categories: “yes, surely”, “yes”, “yes, but only on practitioner’s advise”, “no”, “not at all”.

We asked these questions to find out whether the information provided in the texts is given in a way that it enables the patient to make an adequate decision about the drug use. PPLs should present information of risks in way that patients can evaluate them properly without overestimating them. The latter would be an instance of miscommunication. The drug used in this experiment should not be taken during pregnancy or while breastfeeding except on the advise of a practitioner.

In the last part of the questionnaire respondents were asked to make a comparison for the sections ‘Therapeutic indications’, ‘Contra-indications’, ‘Use of the drug during pregnancy and while breastfeeding’, ‘Warnings’ and ‘Side effects’ between the PPL she answered questions about (for example D/D (see 5.1.1.) in the Netherlands) and the respective other PPL (for example D/G in the Netherlands). They had to indicate their preference for one of the leaflets.
5.1.4. Design

For the first part of the questionnaire we chose a between group design. Half of the Dutch respondents were presented with the original Dutch version the other half with Dutch translation of the German PPL. About half of the German respondents read the original German version and the other half the German translation of the Dutch PPL.

For the second part of the questionnaire, where respondents had to compare two different version of the PPL, we chose a within group design.

Procedure

Respondents were interviewed in a face-to-face situation. They were asked to imagine the following situation: Imagine that you need a painkiller during your pregnancy because you suffer from a severe headache. You would like to know whether you could take a particular painkiller and therefore read the PPL.

Processing the data

The data were coded in SPSS 11. In order to determine differences between groups chi-square tests and variance analysis were carried out.

5.2. Results

We first discuss the results of that part of the experiment with a within group design.

Respondents had to express a preference for one of the two PPLs.

<table>
<thead>
<tr>
<th>Country</th>
<th>Preference for Dutch version</th>
<th>Preference for German version</th>
</tr>
</thead>
<tbody>
<tr>
<td>Netherlands</td>
<td>42 (87%)</td>
<td>6 (12%)</td>
</tr>
<tr>
<td>Germany</td>
<td>34 (71%)</td>
<td>14 (28%)</td>
</tr>
<tr>
<td>total</td>
<td>76 (89%)</td>
<td>20 (20%)</td>
</tr>
</tbody>
</table>

Table 7. Preference for either the Dutch or the German version
Table 7 shows that respondents from both countries have a clear preference for the Dutch PPL. 89% of all respondents prefer the Dutch version to the German one. However, there is a significant differences between Dutch and German respondents ($\chi^2=4.04, df=1, p=.044$); there are more Dutch respondents (87%), who prefer the Dutch leaflet, than German respondents (71%). This difference seems to support research questions 1 and 2, but it is not very convincing given that 71% of the German respondents express a preference for the Dutch PPL.

Looking at that part of the experiment in which respondents had to evaluate the language use and the content of the PPLs (between group design) we found similar results. Table 8 and 9 give an overview of the difference between Dutch and German respondents concerning the language use and the content in the PPLs.

<table>
<thead>
<tr>
<th></th>
<th>Dutch version M (SD)</th>
<th>German version M (SD)</th>
<th>Significant differences</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Netherlands</td>
<td>2.63 (.63)</td>
<td>3.44 (.70)</td>
<td>$F = 18.658, df = 1, p = .001$</td>
</tr>
<tr>
<td>Germany</td>
<td>3.42 (1.06)</td>
<td>3.56 (1.13)</td>
<td>Not significant</td>
</tr>
</tbody>
</table>

Table 8. Significant differences in the appreciation of the language use (1 = positive, 7 = negative)

<table>
<thead>
<tr>
<th></th>
<th>Dutch version M (SD)</th>
<th>German version M (SD)</th>
<th>Significant differences</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Netherlands</td>
<td>3.43 (.73)</td>
<td>3.86 (.62)</td>
<td>$F = 4.935, df = 1, p = .031$</td>
</tr>
<tr>
<td>Germany</td>
<td>3.41 (1.04)</td>
<td>3.52 (.87)</td>
<td>Not significant</td>
</tr>
</tbody>
</table>

Table 9. Significant differences in the appreciation of the content (1 = positive, 7 = negative)

The Dutch respondents evaluated both the language use and the content of the Dutch version significantly better than the language use and content of the German version. Generally, Dutch respondents found that the German version lacked clarity, comprehensibility and contained too much specialist terminology and information.

In sum, when comparing the two versions of the PPL the Dutch respondents have a strong preference for the Dutch PPL. When they have to evaluate language use and
content it is also the Dutch version that is appreciated more. This means that the answer to research question 1 is according to our expectations. This is not true for research question 2 because we could not find any significant differences in the judgment of the two versions of the PPLs by German respondents.

We were not only looking at the appreciation of the two versions of the PPL, but we were also interested in the communicative effectiveness of the two versions. We asked respondents to concentrate on those aspects of the PPL that deal with pregnancy and breastfeeding, and imagine that they had a severe headache. We then asked them whether they would take the drug referred to in the PPL during pregnancy and while breastfeeding. Tables 10 and 11. show the results of these two questions. The categories ‘yes, surely’ (cf. 5.1.3) did not occur. The categories ‘no’ and ‘not at all’ were summed.

<table>
<thead>
<tr>
<th>Intention to use drug</th>
<th>G/D</th>
<th>D/D</th>
<th>Total Dutch content</th>
<th>G/G</th>
<th>D/G</th>
<th>Total German content</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Only on physicians advice</td>
<td>2</td>
<td>3</td>
<td>5 (10%)</td>
<td>8</td>
<td>10</td>
<td>18 (36%)</td>
</tr>
<tr>
<td>No</td>
<td>22</td>
<td>21</td>
<td>43</td>
<td>17</td>
<td>15</td>
<td>32</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>24</td>
<td>5</td>
<td>49</td>
<td>25</td>
<td>25</td>
<td>50</td>
</tr>
</tbody>
</table>

Table 10. Intention to take the drug during pregnancy (see 5.1.1 for abbreviation G/D and so on)

<table>
<thead>
<tr>
<th>Intention to use drug</th>
<th>G/D</th>
<th>D/D</th>
<th>Total Dutch content</th>
<th>G/G</th>
<th>D/G</th>
<th>Total German content</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Only on physicians advice</td>
<td>0</td>
<td>2</td>
<td>2 (4%)</td>
<td>6</td>
<td>5</td>
<td>11 (22%)</td>
</tr>
<tr>
<td>No</td>
<td>24</td>
<td>22</td>
<td>46</td>
<td>19</td>
<td>18</td>
<td>37</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>24</td>
<td>25</td>
<td>49</td>
<td>26</td>
<td>24</td>
<td>50</td>
</tr>
</tbody>
</table>

Table 11. Intention to take the drug while breastfeeding (see 5.1.1 for abbreviation G/D and so on)

Tables 10 and 11 show that the intention to use the drug is similar in the two situations (pregnancy and breastfeeding).

The intention to use the tablets without consulting a doctor first (answer “yes”) was expressed occasionally by both groups of respondents for both the Dutch and the
German content. That some respondents express this intention is a cause for concern because the product may not be used without consulting a doctor in either of the situation. For the statistical analysis we did not look at "yes"-answers because of their low frequency.

The Dutch version of the PPL leads to significant lower drug use than the German version (during pregnancy $\chi^2=8.92$, df=1, $p=.003$, while breastfeeding $\chi^2=7.21$, df=1, $p=.007$). This would mean that the German version of the PPL leads to a more adequate drug use because the drug may be used on physicians’ advice in these situations. The patient does not need to suffer unnecessary pain. However the German PPL does not have the desired effect either because the majority of the respondents say that they would not use the tablet.

Our expectation (3, in 5.) that the Dutch PPL would lead to a more adequate drug use in the Netherlands was not borne out. On the contrary, the German version leads to a more adequate drug use than the Dutch one during pregnancy and while breastfeeding. However, our expectation that the German version of the PPL should lead to a more adequate drug use in Germany (4, in 5.) was borne out in both situations.

6. Conclusion and discussion

In this study, we addressed the question whether culture has an influence on the design of PPLs and whether cultural differences in their design have an influence on their appreciation and communicative function.

We have shown that there are a number of differences between Dutch and German PPLs for tablets containing 400 mg Ibuprofen and that those differences are in
line with what we expected on the basis of differences between Dutch and German culture.

The experimental part of this study revealed that Dutch as well as German respondents prefer the Dutch version of the PPL (see table 7). In terms of content and language use the Dutch appreciated the Dutch version more than the German version (see tables 8 and 9). The German respondents did not appreciate the language use and the content of the German version more than that of the Dutch version. One of the conclusions that could be drawn from these results concerning the evaluation of the language use and the content of the PPLs is that if we had to choose just one PPL for the two countries it would probably be the Dutch one.

However, appreciation by patients is not the only aspect important to PPLs, it is also important that they lead to adequate drug use (cf. Maes, Ummelen & Hoeken, 1996, p.148). Our research shows that the German PPLs lead to more adequate drug use than the Dutch one by both the German and the Dutch respondents (tables 10 and 11). On the other hand, we need to keep in mind that we only asked for respondent’s intention to use the tables and not whether they actually use it, which could lead to different results.

If we had to choose just one PPL for the two countries we would have to decide whether to use the one with the higher appreciation for language use and content or the one which lead to a more adequate drug use. We would choose the latter.

One problem of our research is that we did not test whether our German respondents do indeed have a higher uncertainty avoidance and a lower context than our Dutch respondents, as suggested in the literature. Given the fact that individual differences within one culture may occur, this might not be the case. In addition,
respondents of both groups were from a region close to the border of the respective other country. It could be that cultural differences in border regions are less distinct. Future research will have to take these two aspects into account. In order to decide whether one version of a PPL for a particular drug within the EU is sufficient further research will have to be done in other EU countries with cultures that are more distinct than the Dutch and the German. Following our results, the German version of the PPL should be the one used in the Netherlands and Germany.

Notes

1 All citation are from the English language versions of the respective directives.
2 The 2004 amendment (2004/83/EEC) hardly made any changes to this article: is taken is replaced by taking, bullets are replaced by numbers, and what is mentioned under this list must now appears in a separate paragraph in article 2. There are not changes with respect to the content of this article.
3 For a more detailed history of PPL up to 1990 in the two countries see Joossen 1990.
4 Note, however, that registration of medicinal products is not restricted to the national level. Since 1995 is also possible to register them at the European Medicine Agency (EMEA). EMEA registrations are based on English documentation and patient package leaflets following the European directives.
5 PPLs used in this study can be obtained from the first two authors on request.
6 There is a slight difference between Dutch and German with respect to the compound nouns. German compound nouns tend to be longer and slightly more frequent than Dutch compounds (cf. Altman & Best, 1996 for German and Rheinländer, 2001 for Dutch) so in terms of the number of words of a text we would expect the German text to be shorter than the Dutch one. However, the differences between Dutch and German in our word count are so evident that this difference can be ignored here.
7 The original version and the translations used in the experiments can be obtained from the first two authors on request.
8 These questions were concerned of whether the length and the lay-out of the PPL differed from what respondents are used to. This was not the case for either of the versions: respondents did not signal any differences with PPL there are used to read.
9 Since the PPL’s we used in this study are PPLs for over-the-counter painkillers, we are only concerned with adequate drug use in terms of whether you are allowed to take the drug or not and the dosage, so we do not look at the adequate drug use in terms of compliance, concordance, adherence and persistence.
References


(Retrieved April 20th, 2005).


**Dutch PPLs**

http://www.advil.nl/images/advil-400.pdf

http://www.kring-apotheek.nl/Genesmiddelen/r_Pijn.asp

http://www.multipharma.nl/http://212.204.198.96/index.jsp

http://www.centrafarm.nl/apothekers_home.cfm


**German PPLs**

http://www.hexal.de/gi/advel.pdf

http://www.bayervital.de/pages/produkte/pdf/beipackzettel/aktren_forte

http://www.hexal.de/gi/ibu_akut_400

http://www2.ratiopharm.com/apps/c25_teratioproduct/de/display_v2/index.cfm?fuseacti
on=getbeilage&pID=1441&IID=2

http://www.mannpharma.de/kopfschmerzen/vivimed_family/ibu_vivimed_gebrauchsinfo.htm