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CHAPTER 5

Differences between Germany and the Netherlands in patient package leaflets for Ibuprofen 400 tablets and consequences for adequate drug use

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The EU has issued three directives for patient package leaflets (PPLs) for drugs distributed within the EU: 92/27/EEC, 2001/83/EEC and 2004/27/EEC. These directives were to assist in the establishment of a domestic market with free movement of goods as well as 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. An additional non-mandatory guideline is concerned with the way in which the information has to be formulated, however, the detail of information to be included is left to the discretion of the manufacturer. With the goal of 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, Van den Brandt, Crijns, Domínguez, Hendriks, Planken, & Starren 2003). The question is whether they also have an impact on the disign of PPLs and whether the scope the EU directives leave for the design of PPL's is used differently in the Netherlands and Germany. Our study, based on five German and five 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 greater compliance with the recommended use of the drug in both countries.

Keywords: patient package leaflets, culture, Germany, Netherlands, EU Directives, communicative effectiveness, appreciation, adequate drug use

Background

The EU has issued three directives for patient package leaflets (PPLs) for drugs distributed within the EU: 92/27/EEC, 2001/83/EC and 2004/27/EC. (The latter is an amendment of the 2001 directive.) These directives were to assist in the establishment of a domestic market with free movement of goods as well as protect consumer interests. Although the 2001 and 2004 directives are much more detailed than the 1992 version, 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]

(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 pharmacotherapeutic 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 articles 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:
- the formulation of certain special warnings for certain categories of medicinal products,
- the particular information needs relating to self medication,

– 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 considerable scope for the design of PPLs. For example, if you look at article 59 of 2001/83/EEC.[2]

(9) "A list of information which is necessary before taking the medicinal product.

– contra-indication,
– appropriate precautions for use,
– 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,
– special warnings.

The list must:

– 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),
– mention, if appropriate, potential effects on the ability to drive vehicles or to operate machinery,
– 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 directives provide information with respect to the type of information needed, but does not specify the level of detail and the way it should be represented. For example, it is 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 acceptable 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

typeface, graphic layout, the physical format, the style and content of PPLs, The guideline also provides a model leaflet and a method for testing readability. However, this 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 required directives. The question is whether pharmaceutical companies 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 et al. 2003; Honold 1999; Fukuoka, Kojima, & Spyridakis 1999; Le Pair, Crijns, & Hoeken 2000) we would expect that the pharmaceutical companies in the member states make use of the scope of the directives and come up with different PPLs for use within their own borders. 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 where they operate in and save the costs for the design of several different PPL's.

In this chapter, we investigate whether differences in cultural values between member states in the EU have an impact on the design of PPLs considering the scope of 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), Hofstede (2001), Hampden-Turner and Trompenaars (2000) which examine cultural differences between the two countries. Their work is discussed in Section 1. In Section 2 we look at the legal aspects of PPLs in the two countries. In Section 3, the results of a corpus analysis of German and Dutch PPLs for Ibuprofen 400 tablets is presented. The results of this 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 4.

1. 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 six 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 document design or specifically in our study, 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 patients. The 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: 168). These studies have shown that the two cultures differ considerably in three of the fifteen 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: 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 risks 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.

2. The impact of culture on the legislation

Before we have a look at the corpus analysis to see whether the results match our predictions formulated in 1 to 4 above, we first look at the legislation concerning PPLs in Germany and the Netherlands, the integration of EU-regulation in particular.[3] Differences in national legislation could also reflect cultural differences between the two countries and consequently have an influence on the design of PPLs.

In 2004, 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 directive as well as the supplement became part of the Dutch *Bijsluiter 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]. The 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 it into the *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) [Fifth law to change the law governing the manufacture and prescription of drugs]. In 2002, Germany 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'. In 2004 the directive 2001/83/EEC was integrated in the AMG (*Zwölftess Gesetz zur Änderung des Arzneimittelgesetzes* (30.07.2004) [Twelfth law to change the law governing the manufacture and prescription of drugs]. But unlike the Netherlands, Germany had its 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 even specified the header and sub-header that are required 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 no. 2).[4]

3. The corpus analysis

The corpus

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

1. The composition of tablets 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.
2. 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: 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 content. In our study we only used PPLs of non-prescription tablets containing 400mg Ibuprofen.

3. 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 ingredient on the market. Consequently, there are a variety of PPLs available for analysis.

For each country we were able to find five different PPLs. All PPLs were available on the Internet at the moment of collection (see references).[5] Table 1 gives an overview of the PPLs we examined.

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

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

Research methodology

We determine the elaborateness and the detail of the information in PPLs (expectations no. 1) by counting the total number of words used in the PPL. We assumed that the elaboration and detail of information increased 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 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 the text offers a wider scope for culture-specific interpretation than sections such as 'identification of the medicinal product', or '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 of pharmaceutical and/or medical terms.

The degree of structure (expectations no. 2) was determined by counting the number of headings and subheadings. We also looked for other means that provide structure, such as the use of bullets or separate paragraphs. We counted the numbers of specialist terms to determine the degree of specialist terminology usage (expectations no. 3). The amount of information on risks (expectations no. 4) was determined by counting the risks mentioned.

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

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.

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

Table 2. Number of words in Dutch and German PPLs

Dutch PPLs	Number of words	German PPLs	Number of words
Advil 400	761	Advel	2039
Ibuprofen 400 Kring	1050	Aktren Forte	1769
Ibuprofen 400 PCH	1019	Ibuhexal Akut 400	2350
MP Ibuprofen	972	Ibu-rathiopharm 400	2003
Ibuprofen 400 Huismerk	996	Vivimed Migräne	2370
Mean	**959**		**1706,5**

respectively, the shortest German PPL is still more than 1,5 times as long as the longest Dutch PPL.[6]

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 borstvoeding* [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 and considerably more complex than that of the Dutch PPLs. 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 sub-sections 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.

Table 3. Structure of Dutch and German PPLs

Dutch PPLs	Number of headings	Number of sub-headings	German PPLs	Number of headings	Number of sub-headings
Advil 400	4	0	Advel	2	7
Ibuprofen 400 Kring	4	0	Aktren Forte	1	8
Ibuprofen 400 PCH	3	3	Ibuhexal Akut 400	2	7
MP Ibuprofen	4	0	Ibu-rathiopharm 400	2	8
Ibuprofen 400 Huismerk	3	2	Vivimede Migrän	1	9
Total/mean	18/3,6	5/1,0		8/1,6	39/7,8

Use of specific terminology
We distinguished two types of terminology usage: 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 bleeding in the gastro-intestinal tract (gastro-intestinal bleeding)]

(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-steroidal anti-inflammatory group].

Table 4 shows that German PPLs make much more use of specific terminology than their Dutch equivalents.

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

Dutch PPLs	simple use	explanatory	German PPLs	simple use	explanatory
Advil 400	0	0	Advel	1	17
Ibuprofen 400 Kring	1	0	Aktren Forte	7	3
Ibuprofen 400 PCH	0	0	Ibuhexal Akut 400	17	2
MP Ibuprofen	1	1	Ibu-rathiopharm 400	14	2
Ibuprofen 400 Huismerk	1	1	Vivimed Migräne	7	5
Total/mean	**3/0,6**	**2/0,4**		**62/12,4**	**12/2,4**

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 liver – and kidney function tests and blood counts need to be taken regularly].

(14) Sie dürfen ibuhexal ® akut 400 nicht anwenden bei ungeklärten Blutbildstörungen
[Do not take ibuhexal ® akut 400 in case of unresolved blood count disorders].

As Table 5 shows German PPLs mention all three types of risks more often than their Dutch equivalents.

To summarize, our four expectations 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. 2).

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

Dutch PPLs	direct	indirect	circumstantial	German PPLs	direct	indirect	circumstantial
Advil 400	3	0	17	Advel	5	4	32
Ibuprofen 400 Kring	3	0	17	Aktren Forte	2	3	28
Ibuprofen 400 PCH	4	0	18	Ibuhexal Akut 400	5	2	29
MP Ibuprofen	3	0	17	Ibu-rathiopharm 400	2	2	28
Ibuprofen 400 Huismerk	3	0	18	Vivimed Migräne	4	0	29
Total/mean	16/3,2	0	87/17,4		18/3.6	11/2.2	146/29,2

4. 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 now is whether the two different PPL styles 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 produced for the Dutch culture more than those produced for the German culture?
2. Do German patients appreciate the PPLs that are produced for the German culture more than those produced for the Dutch culture?
3. Do PPLs produced for the Dutch culture communicate more effectively in the Netherlands than in Germany?
4. Do PPLs produced for the German culture communicate more effectively in Germany than in the Netherlands?

Research methodology

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 PPLs were clear for all versions. Consequently, we randomly took one version from each country and translated them into the respective other language. In order to ensure equivalence between the Dutch and the German versions, three native (or very proficient) speakers of Dutch and German reverse-translated the PPLs back into the respective source language, discussed differences in the translations and came up with a final version of each PPL. 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.

1. An original Dutch version (D/D).
2. A German translation of the Dutch version (G/D).
3. An original German version (G/G).
4. A Dutch translation of the German version (D/G).

Versions 1 and 4 were used in the Netherlands, 2 and 3 in Germany.[7]

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 this restriction, we were also able to ask direct questions with respect to the communication function of parts of the PPL, those that concerned pregnancy and breastfeeding. This restriction allowed for a closer approximation of a real life situation where pregnant women would have to make a choice.

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

Measuring instruments

The respondents were presented with one of the four versions of the PPL and had to fill in a questionnaire with questions concerning the text. After a section of more general questions concerning the PPL,[8] 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 these are most problematic sections. Each of the target sections were indicated by way of a marker in the margin of the PPL.

Respondents had to answer questions concerning the language use and the content of these sections. We used a 7-point semantic differential scale as in (15) and (16).

(15) The meaning of the words is
very clear O O O O O O O not at all clear

(16) There is
too much O O O O O O O too little
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 test over all the German and Dutch data. The results are presented in Table 6: they allowed us to aggregate some of the data concerning questions on language use and content. In the following we only discuss the aggregated data.

In the following part of the questionnaire we tried to determine the effectiveness of the different PPLs. The communicative function of the respective text passage is to enable the patient to find an adequate answer to the ques-

Table 6. Reliability analysis scores on language use and content

	Crombach's α for positive and recoded questions
Language use	.74
Content	.75

tion of whether she could take the medicine product or not. Respondents were asked to concentrate on the section on pregnancy and breastfeeding and decide on the basis of these text passage 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 enables the patient to make an adequate decision about taking the drug. PPLs should present information in a 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, therefore this information should be evident to the respondents.

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 4 under *Materials* in the Netherlands) and the respective other PPL (for example D/G in the Netherlands). In this part, respondents only had to indicate a preference for one of the PPLs.

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. The respondents were then asked to read the PPL to get that information.

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.

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 7 shows that respondents from both countries have a clear preference for the Dutch PPL. 89% off 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 PPL than German respondents (71%). This difference seems to support research questions 1 and 2, but not very convincingly given that 71% of the German respondents express a preference for the Dutch PPL.

Tables 8 and 9 show the results for the second part of the experiment (between group design), where respondents evaluated language usage and the content of the PPLs respectively.

The Dutch respondents evaluated both language usage and content of the Dutch PPL significantly better than the German PPL. 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 which confirms research

Table 7. Preference for either the Dutch or the German version

Country	Preference for Dutch version	Preference for German version
Netherlands	42 (87%)	6 (12%)
Germany	34 (71%)	14 (28 %)
Total	**76 (89%)**	**20 (20%)**

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

	Dutch version M (SD)	German version M (SD)	Significant differences
The Netherlands	2.63 (.63)	3.44 (.70)	F = 18,658, df = 1, p = .001
Germany	3.42 (1.06)	3.56 (1.13)	Not significant

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

	Dutch version M (SD)	German version M (SD)	Significant differences
The Netherlands	3.43 (.73)	3.86 (.62)	F = 4.935, df = 1, P = .031
Germany	3.41 (1.04)	3.52 (.87)	Not significant

question 1. However we could not find any significant differences in the judgment of the two versions of the PPLs by German respondents, which does not corroborate with research question 2.

We not only analyzed the appreciation of the two versions of the PPL, but also the effectiveness of the two versions to communicate needed information. 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' did not occur; the categories 'no' and 'not at all' were combined.

Tables 10 and 11 show that the intention to use the drug is similar for both 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 since the product may not be used without consulting a doctor in either 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[9] because the drug may be used on a physicians' advice in these situations. The patient does not need to suffer

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

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

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

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

unnecessary pain. However the German PPL is hardly more effective sinced a majority of the respondents say that they would not use the tablet at all.

Our expectation that the Dutch PPL would lead to greater compliance in the Netherlands was not borne out. On the contrary, the German PPL would result in more acceptable drug use than the Dutch one during pregnancy and while breastfeeding. However, our expectation that the German version of the PPL should lead to correct drug use in Germany was borne out in both situations.

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 predicted 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 language usage 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 correct use of the drug (cf. Maes, Ummelen, & Hoeken 1996: 148). Our research shows that the German PPLs lead to correct drug use more than the Dutch one by both the German and the Dutch respondents (Tables 10 and 11). On the other hand, we are cognizant 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 leads to safer drug use. We would choose the latter.

One problem of our research is that we did not test whether the German respondents do indeed have higher uncertainty avoidance and 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 Joossens, 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 layout 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.

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