



# Information of package inserts is frequently



# incomprehensible of patients

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### Background:

- Package inserts are very important for patient information
- Their suitability is still under discussion.
- Recommendations for testing the readability are given by the European Commission. <sup>2</sup>
- According to Sless and Wiseman: <sup>1</sup>
  1. Over 90 % of the patients find the relevant information.
  2. Over 90 % of those finding the information are able to understand it.
  3. Thus over 81 % of the patients in total are able to use the package inserts appropriately.

### Aims:

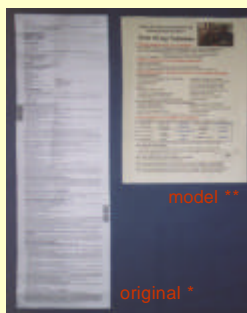
- The PAINT survey (package insert test) examined the comprehensibility and availability of information from five package inserts \* for different drugs and five model package inserts \*\* for the same drugs developed for this test.

### Methods:

- A questionnaire with 15 questions referring to the content of the package inserts was adapted using references by Sless and Wiseman <sup>1</sup>, the EMEA <sup>2</sup> and the EFPIA <sup>3</sup> for a written survey.
- 1,150 patients were asked to participate in the PAINT survey.
- Cross over testing
- Every person got an original \* and one model \*\* package insert within an interval of 4 weeks.
- Time: September 2002 to April 2003

### Results:

- 1,105 persons answered the questionnaire in the first trial and 1,051 in the second trial (return rate: 95.9 and 91.2 %).
- Participants:
  - 10 to 92 years old, average age: 38 years
  - 69.1 % living in or near Jena, 30.9% in other parts of Germany
  - 65.4 % woman, 34.6 % man
- Questions to the content of package inserts (Table 1)
  - original versions: 74.7 to 85.8 % of all questions were answered correctly  
3.8 to 6.9 % answers not found
  - model versions: 92.6 to 94.4 % of all questions were answered correctly  
2.2 to 2.5 % answers not found
- Time needed to answer the 15 questions (Table 2)
  - original versions: 14.3 to 19.6 minutes
  - model versions: 10.9 to 13.8 minutes
- The question: „What is the maximum dose for a day?“ (Table 3)
  - original versions: 9.4 to 90.2 % answered correctly  
0.9 to 9.9 % answers not found
  - model versions: 83.6 to 94.0 % answered correctly  
0 to 0.5 % answers not found



Frequently mistakes regarding the original package inserts were connected with dosage instructions in milligram instead of „tablet“ or volume. The maximal daily dosage was better found in those versions presenting this information in a table.

### Conclusions:

- It is possible to improve package inserts.
- All models but only 2 original package inserts are easy to understand.
- With regard to dosage instructions the following is recommended:
  1. Every dose should be given in a number of tablets or capsules and volume respectively.
  2. Dosage instructions should be given in a table.

<sup>1</sup> Sless, D., Wiseman, R.: Writing about medicines for people: usability guidelines for consumer medicine information. Department of Health and Family Services, Canberra (1997)

<sup>2</sup> European Commission: A guideline on the readability of the label and package leaflet of medicinal products for human use, Brussels, 29. September 1998. (1998)

<sup>3</sup> EFPIA: EFPIA general recommendations for readability user testing of package leaflets for medicinal products for human use submitted or approved under the European centralised procedure - final document - Version from March 2003.

## PAINT Package Insert Test

Table 1: Correctness of answers concerning the content of original vs model package inserts (15 questions)

package insert	correct answers (%)		answers not found (%)		n	
	original	model	original	model	original	model
Enalapril	78.5*	93.2	6.7*	2.5	218	214
Ibuprofen	85.8*	94.4	6.9*	2.3	215	213
Paracetamol	82.6*	93.3	3.8*	2.2	213	219
Repaglinide	79.0*	93.3	4.5*	2.3	214	216
Telmisartan	74.7*	92.6	6.2*	2.3	213	216

(\* significant differences between the results of the original and the model version of package inserts)

Table 2: Calculated median of the time needed to answer the 15 questions

package insert	time to answer the 15 questions (min)		n	
	original	model	original	model
Enalapril	19.6*	13.1	203	197
Ibuprofen	18.8*	12.4	200	200
Paracetamol	14.3*	12.0	197	203
Repaglinide	15.3*	13.8	204	199
Telmisartan	15.3*	10.9	195	198

(\* significant differences between the results of the original and the model version of package inserts)

Table 3: Calculated median for the answers to the question: „What is the maximum dose for one day?“

package insert	correct answers (%)		answers not found (%)		n	
	original	model	original	model	original	model
Enalapril	52.5*	83.6	0.9	0	217	213
Ibuprofen	90.2	90.0	1.4	0	215	210
Paracetamol	9.4*	84.9	7.0*	0	213	218
Repaglinide	36.0*	94.0	7.5*	0.5	214	216
Telmisartan	33.3*	92.1	9.9*	0.5	213	216

(\* significant differences between the results of the original and the model version of package inserts)